



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-REXA-08-US Clinical Study Report Appendix 15.4 Statistical Output**

<b>Study Title:</b>	A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting
<b>Study Number:</b>	ZRHM-REXA-08-US
<b>Product Name:</b>	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
<b>Study Initiated (first subject screened):</b>	17 December 2013
<b>Study Completed (last subject last visit):</b>	12 October 2014
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<b>Version:</b>	1.0
<b>Date:</b>	25 May 2016

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

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This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.

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## **15.4 STATISTICAL OUTPUT**



### **15.4.1 Disposition and Background Data**

Not applicable.





## **15.4.2 Product Use**

Not applicable.



### **15.4.3 Primary Endpoints**



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	131
Number of Observations Used	131



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.91212775	4.58242555	67.55	<.0001
Error	125	8.47998723	0.06783990		
Corrected Total	130	31.39211498			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.729869	23.47272	0.260461	1.109633

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.04592888	0.04592888	0.68	0.4122
SEX	1	0.05176277	0.05176277	0.76	0.3841
UCPDGR1	1	0.04796506	0.04796506	0.71	0.4020
TRTP	2	22.76647104	11.38323552	167.80	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.68105323	0.68105323	10.04	0.0019
SEX	1	0.09073536	0.09073536	1.34	0.2497
UCPDGR1	1	0.04944525	0.04944525	0.73	0.3949
TRTP	2	22.76647104	11.38323552	167.80	<.0001



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.87323286	1
THSm2.2	0.84581552	2
mCC	1.80979157	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6601	<.0001
2	0.6601		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.873233	0.765201	0.981264
THSm2.2	0.845816	0.784692	0.906939
mCC	1.809792	1.720550	1.899033



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.027417	-0.095687	0.150521
1	3	-0.936559	-1.076085	-0.797033
2	3	-0.963976	-1.071562	-0.856390

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11.59187786	2.31837557	18.73	<.0001
Error	82	10.14787206	0.12375454		
Corrected Total	87	21.73974992			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.533211	28.00654	0.351788	1.256091

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.23172496	0.23172496	1.87	0.1749
SEX	1	0.06166442	0.06166442	0.50	0.4823
UCPDGR1	1	0.15235306	0.15235306	1.23	0.2704
TRTP	2	11.14613542	5.57306771	45.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.35316619	0.35316619	2.85	0.0950
SEX	1	0.02120036	0.02120036	0.17	0.6800
UCPDGR1	1	0.00061825	0.00061825	0.00	0.9438
TRTP	2	11.14613542	5.57306771	45.03	<.0001





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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	1.07328138	1
THSm2.2	0.97343281	2
mCC	1.73357875	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4444	<.0001
2	0.4444		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	1.073281	0.835134	1.311429
THSm2.2	0.973433	0.869315	1.077551
mCC	1.733579	1.608608	1.858549



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.099849	-0.158603	0.358301
1	3	-0.660297	-0.926434	-0.394161
2	3	-0.760146	-0.922337	-0.597954

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	112.9893847	22.5978769	48.63	<.0001
Error	110	51.1205738	0.4647325		
Corrected Total	115	164.1099586			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.688498	13.06975	0.681713	5.215961

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.13284100	12.13284100	26.11	<.0001
SEX	1	1.90998599	1.90998599	4.11	0.0451
UCPDGR1	1	2.56823945	2.56823945	5.53	0.0205
TRTP	2	96.37831830	48.18915915	103.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.80846720	23.80846720	51.23	<.0001
SEX	1	1.16283767	1.16283767	2.50	0.1166
UCPDGR1	1	1.69851620	1.69851620	3.65	0.0585
TRTP	2	96.37831830	48.18915915	103.69	<.0001



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.55351078	1
THSm2.2	4.70914093	2
mCC	6.78247628	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3670	<.0001
2	0.3670		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.553511	4.258080	4.848941
THSm2.2	4.709141	4.537912	4.880370
mCC	6.782476	6.532712	7.032240



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.155630	-0.496131	0.184871
1	3	-2.228965	-2.614885	-1.843046
2	3	-2.073335	-2.377583	-1.769088

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	64.6349616	12.9269923	23.62	<.0001
Error	75	41.0490062	0.5473201		
Corrected Total	80	105.6839678			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.611587	12.27299	0.739811	6.027958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	15.53142725	15.53142725	28.38	<.0001
SEX	1	0.01300962	0.01300962	0.02	0.8779
UCPDGR1	1	1.64005517	1.64005517	3.00	0.0876
TRTP	2	47.45046957	23.72523479	43.35	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.95872884	23.95872884	43.77	<.0001
SEX	1	0.10752546	0.10752546	0.20	0.6589
UCPDGR1	1	0.09978625	0.09978625	0.18	0.6706
TRTP	2	47.45046957	23.72523479	43.35	<.0001





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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.79927860	1
THSm2.2	5.36493288	2
mCC	7.05143994	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1285	<.0001
2	0.1285		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.799279	5.290236	6.308321
THSm2.2	5.364933	5.130650	5.599216
mCC	7.051440	6.774523	7.328357



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.434346	-0.128659	0.997350
1	3	-1.252161	-1.822335	-0.681988
2	3	-1.686507	-2.051058	-1.321956

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.45476502	7.29095300	58.45	<.0001
Error	112	13.97014046	0.12473340		
Corrected Total	117	50.42490549			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.722952	6.163521	0.353176	5.730104

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.07271952	11.07271952	88.77	<.0001
SEX	1	0.10376972	0.10376972	0.83	0.3637
UCPDGR1	1	0.46174225	0.46174225	3.70	0.0569
TRTP	2	24.81653354	12.40826677	99.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.87270161	8.87270161	71.13	<.0001
SEX	1	0.07538181	0.07538181	0.60	0.4386
UCPDGR1	1	0.19155267	0.19155267	1.54	0.2179
TRTP	2	24.81653354	12.40826677	99.48	<.0001



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.02420407	1
THSm2.2	5.62810439	2
mCC	6.40965327	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.024204	4.871209	5.177199
THSm2.2	5.628104	5.541071	5.715137
mCC	6.409653	6.281048	6.538259



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.603900	-0.779168	-0.428633
1	3	-1.385449	-1.585192	-1.185707
2	3	-0.781549	-0.935835	-0.627263

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.78307872	3.95661574	15.73	<.0001
Error	75	18.86831138	0.25157749		
Corrected Total	80	38.65139010			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.511834	8.469901	0.501575	5.921852

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.53692217	8.53692217	33.93	<.0001
SEX	1	0.15737334	0.15737334	0.63	0.4315
UCPDGR1	1	0.54502019	0.54502019	2.17	0.1452
TRTP	2	10.54376301	5.27188150	20.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.77474282	5.77474282	22.95	<.0001
SEX	1	0.11529427	0.11529427	0.46	0.5005
UCPDGR1	1	0.16415014	0.16415014	0.65	0.4218
TRTP	2	10.54376301	5.27188150	20.96	<.0001





**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.35157474	1
THSm2.2	5.73917849	2
mCC	6.39274157	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0431	<.0001
2	0.0431		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.351575	5.009002	5.694147
THSm2.2	5.739178	5.582537	5.895820
mCC	6.392742	6.205142	6.580341



***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.387604	-0.762890	-0.012318
1	3	-1.041167	-1.429609	-0.652724
2	3	-0.653563	-0.896448	-0.410678

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	143.4202832	28.6840566	72.49	<.0001
Error	110	43.5277843	0.3957071		
Corrected Total	115	186.9480674			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.767166	11.60413	0.629053	5.420935

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	44.14608354	44.14608354	111.56	<.0001
SEX	1	2.60491806	2.60491806	6.58	0.0116
UCPDGR1	1	1.04121559	1.04121559	2.63	0.1076
TRTP	2	95.62806597	47.81403299	120.83	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	41.49796040	41.49796040	104.87	<.0001
SEX	1	1.45429220	1.45429220	3.68	0.0578
UCPDGR1	1	0.62064509	0.62064509	1.57	0.2131
TRTP	2	95.62806597	47.81403299	120.83	<.0001



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.87560284	1
THSm2.2	4.89868861	2
mCC	6.97158076	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8841	<.0001
2	0.8841		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.875603	4.603008	5.148197
THSm2.2	4.898689	4.741771	5.055606
mCC	6.971581	6.743422	7.199739



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.023086	-0.336228	0.290056
1	3	-2.095978	-2.451111	-1.740845
2	3	-2.072892	-2.348759	-1.797025

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	71.9975415	14.3995083	14.04	<.0001
Error	75	76.8933220	1.0252443		
Corrected Total	80	148.8908635			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.483559	16.55601	1.012543	6.115867

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	27.34966115	27.34966115	26.68	<.0001
SEX	1	0.01047167	0.01047167	0.01	0.9198
UCPDGR1	1	1.17616196	1.17616196	1.15	0.2876
TRTP	2	43.46124674	21.73062337	21.20	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.42075798	24.42075798	23.82	<.0001
SEX	1	0.01794724	0.01794724	0.02	0.8951
UCPDGR1	1	0.07353092	0.07353092	0.07	0.7896
TRTP	2	43.46124674	21.73062337	21.20	<.0001





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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.42652345	1
THSm2.2	5.58785208	2
mCC	7.09830482	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6708	<.0001
2	0.6708		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.426523	4.738115	6.114932
THSm2.2	5.587852	5.271952	5.903753
mCC	7.098305	6.720295	7.476314



***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.161329	-0.914553	0.591896
1	3	-1.671781	-2.450835	-0.892728
2	3	-1.510453	-2.000837	-1.020069

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.6196501	20.9239300	136.52	<.0001
Error	112	17.1659445	0.1532674		
Corrected Total	117	121.7855946			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.859048	9.250820	0.391494	4.231990

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	89.37773334	89.37773334	583.15	<.0001
SEX	1	0.00635924	0.00635924	0.04	0.8390
UCPDGR1	1	0.06100082	0.06100082	0.40	0.5294
TRTP	2	15.17455674	7.58727837	49.50	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	82.80420233	82.80420233	540.26	<.0001
SEX	1	0.06706117	0.06706117	0.44	0.5097
UCPDGR1	1	0.03121796	0.03121796	0.20	0.6526
TRTP	2	15.17455674	7.58727837	49.50	<.0001



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.01538537	1
THSm2.2	4.01526627	2
mCC	4.84064260	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.9990	<.0001
2	0.9990		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.015385	3.845796	4.184974
THSm2.2	4.015266	3.918647	4.111885
mCC	4.840643	4.698658	4.982628



***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.000119	-0.194219	0.194457
1	3	-0.825257	-1.046220	-0.604294
2	3	-0.825376	-0.996217	-0.654536

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	52.6300602	10.5260120	13.98	<.0001
Error	75	56.4809148	0.7530789		
Corrected Total	80	109.1109750			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.482353	20.40270	0.867801	4.253363

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	21.37671767	21.37671767	28.39	<.0001
SEX	1	0.61155287	0.61155287	0.81	0.3704
UCPDGR1	1	0.19635274	0.19635274	0.26	0.6111
TRTP	2	30.44543692	15.22271846	20.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	25.70889262	25.70889262	34.14	<.0001
SEX	1	1.22595946	1.22595946	1.63	0.2059
UCPDGR1	1	0.07237004	0.07237004	0.10	0.7574
TRTP	2	30.44543692	15.22271846	20.21	<.0001





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**Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.98949422	1
THSm2.2	3.71477683	2
mCC	5.04635424	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3978	0.0022
2	0.3978		<.0001
3	0.0022	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.989494	3.401428	4.577561
THSm2.2	3.714777	3.443283	3.986271
mCC	5.046354	4.722631	5.370077



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***Listing 15.4.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.274717	-0.368840	0.918274
1	3	-1.056860	-1.721254	-0.392466
2	3	-1.331577	-1.753319	-0.909836

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



1

***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	111



2

***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	111
Number of Observations Used	111
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04679

Fit Statistics	
-2 Res Log Likelihood	-4.6
AIC (smaller is better)	-2.6
AICC (smaller is better)	-2.5
BIC (smaller is better)	0.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	105	5.69	0.0188
SEX	1	105	0.13	0.7141
UCPDGR1	1	105	1.01	0.3164
TRTP	2	105	224.93	<.0001



3

**Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8434	0.05026	105	16.78	<.0001	0.05	0.7437	0.9430
TRTP	THSm2.2	0.8523	0.02772	105	30.74	<.0001	0.05	0.7974	0.9073
TRTP	mCC	1.8450	0.04058	105	45.46	<.0001	0.05	1.7645	1.9254
TRTP	SA	0.8434	0.05026	105	16.78	<.0001	0.05	0.7437	0.9430
TRTP	THSm2.2	0.8523	0.02772	105	30.74	<.0001	0.05	0.7974	0.9073
TRTP	mCC	1.8450	0.04058	105	45.46	<.0001	0.05	1.7645	1.9254

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0016	0.06406	105	-15.63	<.0001	0.05	-1.1286	-0.8746
TRTP	THSm2.2	mCC	-0.9926	0.04869	105	-20.39	<.0001	0.05	-1.0892	-0.8961
TRTP	THSm2.2	SA	0.008968	0.05671	105	0.16	0.8747	0.05	-0.1035	0.1214
TRTP	mCC	SA	1.0016	0.06406	105	15.63	<.0001	0.05	0.8746	1.1286



4

***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	69



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	69
Number of Observations Used	69
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.09572

Fit Statistics	
-2 Res Log Likelihood	46.9
AIC (smaller is better)	48.9
AICC (smaller is better)	48.9
BIC (smaller is better)	51.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	63	7.39	0.0084
SEX	1	63	0.20	0.6535
UCPDGR1	1	63	0.00	0.9774
TRTP	2	63	55.05	<.0001



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.0304	0.1274	63	8.08	<.0001	0.05	0.7757	1.2850
TRTP	THSm2.2	0.9508	0.05059	63	18.79	<.0001	0.05	0.8497	1.0519
TRTP	mCC	1.7882	0.06335	63	28.23	<.0001	0.05	1.6616	1.9148
TRTP	SA	1.0304	0.1274	63	8.08	<.0001	0.05	0.7757	1.2850
TRTP	THSm2.2	0.9508	0.05059	63	18.79	<.0001	0.05	0.8497	1.0519
TRTP	mCC	1.7882	0.06335	63	28.23	<.0001	0.05	1.6616	1.9148

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7578	0.1420	63	-5.34	<.0001	0.05	-1.0416	-0.4741
TRTP	THSm2.2	mCC	-0.8374	0.08123	63	-10.31	<.0001	0.05	-0.9998	-0.6751
TRTP	THSm2.2	SA	-0.07959	0.1376	63	-0.58	0.5650	0.05	-0.3545	0.1954
TRTP	mCC	SA	0.7578	0.1420	63	5.34	<.0001	0.05	0.4741	1.0416





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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4688

Fit Statistics	
-2 Res Log Likelihood	246.4
AIC (smaller is better)	248.4
AICC (smaller is better)	248.5
BIC (smaller is better)	251.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	108	46.83	<.0001
SEX	1	108	2.73	0.1016
UCPDGR1	1	108	3.27	0.0732
TRTP	2	108	102.61	<.0001



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5602	0.1497	108	30.45	<.0001	0.05	4.2634	4.8570
TRTP	THSm2.2	4.7197	0.08751	108	53.93	<.0001	0.05	4.5462	4.8931
TRTP	mCC	6.8108	0.1285	108	52.99	<.0001	0.05	6.5561	7.0656
TRTP	SA	4.5602	0.1497	108	30.45	<.0001	0.05	4.2634	4.8570
TRTP	THSm2.2	4.7197	0.08751	108	53.93	<.0001	0.05	4.5462	4.8931
TRTP	mCC	6.8108	0.1285	108	52.99	<.0001	0.05	6.5561	7.0656

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2507	0.1967	108	-11.44	<.0001	0.05	-2.6406	-1.8607
TRTP	THSm2.2	mCC	-2.0912	0.1557	108	-13.43	<.0001	0.05	-2.3998	-1.7826
TRTP	THSm2.2	SA	0.1595	0.1729	108	0.92	0.3584	0.05	-0.1833	0.5022
TRTP	mCC	SA	2.2507	0.1967	108	11.44	<.0001	0.05	1.8607	2.6406



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5546

Fit Statistics	
-2 Res Log Likelihood	185.8
AIC (smaller is better)	187.8
AICC (smaller is better)	187.9
BIC (smaller is better)	190.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	74	42.58	<.0001
SEX	1	74	0.18	0.6690
UCPDGR1	1	74	0.17	0.6791
TRTP	2	74	41.55	<.0001



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.7950	0.2571	74	22.54	<.0001	0.05	5.2827	6.3073
TRTP	THSm2.2	5.3610	0.1185	74	45.22	<.0001	0.05	5.1247	5.5972
TRTP	mCC	7.0440	0.1422	74	49.54	<.0001	0.05	6.7607	7.3273
TRTP	SA	5.7950	0.2571	74	22.54	<.0001	0.05	5.2827	6.3073
TRTP	THSm2.2	5.3610	0.1185	74	45.22	<.0001	0.05	5.1247	5.5972
TRTP	mCC	7.0440	0.1422	74	49.54	<.0001	0.05	6.7607	7.3273

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2490	0.2893	74	-4.32	<.0001	0.05	-1.8254	-0.6725
TRTP	THSm2.2	mCC	-1.6830	0.1864	74	-9.03	<.0001	0.05	-2.0544	-1.3116
TRTP	THSm2.2	SA	-0.4341	0.2845	74	-1.53	0.1313	0.05	-1.0009	0.1328
TRTP	mCC	SA	1.2490	0.2893	74	4.32	<.0001	0.05	0.6725	1.8254



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1235

Fit Statistics	
-2 Res Log Likelihood	102.3
AIC (smaller is better)	104.3
AICC (smaller is better)	104.4
BIC (smaller is better)	107.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	110	66.47	<.0001
SEX	1	110	0.74	0.3906
UCPDGR1	1	110	1.69	0.1967
TRTP	2	110	95.61	<.0001





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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.0194	0.07684	110	65.33	<.0001	0.05	4.8671	5.1717
TRTP	THSm2.2	5.6220	0.04414	110	127.36	<.0001	0.05	5.5345	5.7095
TRTP	mCC	6.3852	0.06569	110	97.20	<.0001	0.05	6.2550	6.5154
TRTP	SA	5.0194	0.07684	110	65.33	<.0001	0.05	4.8671	5.1717
TRTP	THSm2.2	5.6220	0.04414	110	127.36	<.0001	0.05	5.5345	5.7095
TRTP	mCC	6.3852	0.06569	110	97.20	<.0001	0.05	6.2550	6.5154

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.3658	0.1009	110	-13.53	<.0001	0.05	-1.5658	-1.1657
TRTP	THSm2.2	mCC	-0.7632	0.07850	110	-9.72	<.0001	0.05	-0.9188	-0.6076
TRTP	THSm2.2	SA	0.6026	0.08819	110	6.83	<.0001	0.05	0.4278	0.7773
TRTP	mCC	SA	1.3658	0.1009	110	13.53	<.0001	0.05	1.1657	1.5658



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2545

Fit Statistics	
-2 Res Log Likelihood	126.5
AIC (smaller is better)	128.5
AICC (smaller is better)	128.6
BIC (smaller is better)	130.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	74	22.36	<.0001
SEX	1	74	0.49	0.4859
UCPDGR1	1	74	0.60	0.4414
TRTP	2	74	20.00	<.0001



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**Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.3514	0.1730	74	30.94	<.0001	0.05	5.0068	5.6960
TRTP	THSm2.2	5.7385	0.07911	74	72.53	<.0001	0.05	5.5809	5.8962
TRTP	mCC	6.3860	0.09607	74	66.47	<.0001	0.05	6.1945	6.5774
TRTP	SA	5.3514	0.1730	74	30.94	<.0001	0.05	5.0068	5.6960
TRTP	THSm2.2	5.7385	0.07911	74	72.53	<.0001	0.05	5.5809	5.8962
TRTP	mCC	6.3860	0.09607	74	66.47	<.0001	0.05	6.1945	6.5774

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0346	0.1970	74	-5.25	<.0001	0.05	-1.4270	-0.6421
TRTP	THSm2.2	mCC	-0.6474	0.1238	74	-5.23	<.0001	0.05	-0.8941	-0.4008
TRTP	THSm2.2	SA	0.3872	0.1895	74	2.04	0.0446	0.05	0.009590	0.7647
TRTP	mCC	SA	1.0346	0.1970	74	5.25	<.0001	0.05	0.6421	1.4270



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4018

Fit Statistics	
-2 Res Log Likelihood	229.5
AIC (smaller is better)	231.5
AICC (smaller is better)	231.5
BIC (smaller is better)	234.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	108	102.79	<.0001
SEX	1	108	3.18	0.0773
UCPDGR1	1	108	1.42	0.2362
TRTP	2	108	115.48	<.0001



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.8740	0.1386	108	35.16	<.0001	0.05	4.5992	5.1487
TRTP	THSm2.2	4.8921	0.08052	108	60.76	<.0001	0.05	4.7325	5.0517
TRTP	mCC	6.9639	0.1182	108	58.92	<.0001	0.05	6.7296	7.1982
TRTP	SA	4.8740	0.1386	108	35.16	<.0001	0.05	4.5992	5.1487
TRTP	THSm2.2	4.8921	0.08052	108	60.76	<.0001	0.05	4.7325	5.0517
TRTP	mCC	6.9639	0.1182	108	58.92	<.0001	0.05	6.7296	7.1982

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.0900	0.1819	108	-11.49	<.0001	0.05	-2.4504	-1.7295
TRTP	THSm2.2	mCC	-2.0719	0.1422	108	-14.57	<.0001	0.05	-2.3538	-1.7900
TRTP	THSm2.2	SA	0.01808	0.1595	108	0.11	0.9100	0.05	-0.2981	0.3343
TRTP	mCC	SA	2.0900	0.1819	108	11.49	<.0001	0.05	1.7295	2.4504



***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80





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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0369

Fit Statistics	
-2 Res Log Likelihood	231.8
AIC (smaller is better)	233.8
AICC (smaller is better)	233.9
BIC (smaller is better)	236.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	74	22.23	<.0001
SEX	1	74	0.01	0.9273
UCPDGR1	1	74	0.05	0.8179
TRTP	2	74	20.15	<.0001



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**Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.4190	0.3474	74	15.60	<.0001	0.05	4.7268	6.1111
TRTP	THSm2.2	5.5807	0.1597	74	34.96	<.0001	0.05	5.2626	5.8988
TRTP	mCC	7.0771	0.1936	74	36.56	<.0001	0.05	6.6915	7.4628
TRTP	SA	5.4190	0.3474	74	15.60	<.0001	0.05	4.7268	6.1111
TRTP	THSm2.2	5.5807	0.1597	74	34.96	<.0001	0.05	5.2626	5.8988
TRTP	mCC	7.0771	0.1936	74	36.56	<.0001	0.05	6.6915	7.4628

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6582	0.3948	74	-4.20	<.0001	0.05	-2.4447	-0.8716
TRTP	THSm2.2	mCC	-1.4964	0.2500	74	-5.98	<.0001	0.05	-1.9946	-0.9982
TRTP	THSm2.2	SA	0.1618	0.3802	74	0.43	0.6717	0.05	-0.5959	0.9194
TRTP	mCC	SA	1.6582	0.3948	74	4.20	<.0001	0.05	0.8716	2.4447



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1538

Fit Statistics	
-2 Res Log Likelihood	127.8
AIC (smaller is better)	129.8
AICC (smaller is better)	129.8
BIC (smaller is better)	132.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	110	508.50	<.0001
SEX	1	110	0.25	0.6185
UCPDGR1	1	110	0.36	0.5505
TRTP	2	110	46.12	<.0001



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**Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0032	0.08574	110	46.69	<.0001	0.05	3.8333	4.1731
TRTP	THSm2.2	4.0098	0.04936	110	81.24	<.0001	0.05	3.9120	4.1076
TRTP	mCC	4.8183	0.07312	110	65.90	<.0001	0.05	4.6734	4.9632
TRTP	SA	4.0032	0.08574	110	46.69	<.0001	0.05	3.8333	4.1731
TRTP	THSm2.2	4.0098	0.04936	110	81.24	<.0001	0.05	3.9120	4.1076
TRTP	mCC	4.8183	0.07312	110	65.90	<.0001	0.05	4.6734	4.9632

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.8151	0.1125	110	-7.25	<.0001	0.05	-1.0381	-0.5922
TRTP	THSm2.2	mCC	-0.8085	0.08770	110	-9.22	<.0001	0.05	-0.9823	-0.6347
TRTP	THSm2.2	SA	0.006622	0.09844	110	0.07	0.9465	0.05	-0.1885	0.2017
TRTP	mCC	SA	0.8151	0.1125	110	7.25	<.0001	0.05	0.5922	1.0381



***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Model Information	
Data Set	WORK.ADBX1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set***

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7512

Fit Statistics	
-2 Res Log Likelihood	207.9
AIC (smaller is better)	209.9
AICC (smaller is better)	210.0
BIC (smaller is better)	212.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	74	32.85	<.0001
SEX	1	74	1.40	0.2406
UCPDGR1	1	74	0.15	0.6962
TRTP	2	74	18.81	<.0001



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**Listing 15.4.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model- PP Set**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9923	0.2948	74	13.54	<.0001	0.05	3.4048	4.5798
TRTP	THSm2.2	3.7142	0.1362	74	27.27	<.0001	0.05	3.4429	3.9856
TRTP	mCC	5.0124	0.1648	74	30.42	<.0001	0.05	4.6841	5.3407
TRTP	SA	3.9923	0.2948	74	13.54	<.0001	0.05	3.4048	4.5798
TRTP	THSm2.2	3.7142	0.1362	74	27.27	<.0001	0.05	3.4429	3.9856
TRTP	mCC	5.0124	0.1648	74	30.42	<.0001	0.05	4.6841	5.3407

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0201	0.3348	74	-3.05	0.0032	0.05	-1.6872	-0.3530
TRTP	THSm2.2	mCC	-1.2982	0.2136	74	-6.08	<.0001	0.05	-1.7239	-0.8725
TRTP	THSm2.2	SA	-0.2781	0.3227	74	-0.86	0.3916	0.05	-0.9210	0.3648
TRTP	mCC	SA	1.0201	0.3348	74	3.05	0.0032	0.05	0.3530	1.6872





1

***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	131
Number of Observations Used	131



2

***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.91212775	4.58242555	67.55	<.0001
Error	125	8.47998723	0.06783990		
Corrected Total	130	31.39211498			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.729869	23.47272	0.260461	1.109633

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.04592888	0.04592888	0.68	0.4122
SEX	1	0.05176277	0.05176277	0.76	0.3841
UCPDGR1	1	0.04796506	0.04796506	0.71	0.4020
TRTP	2	22.76647104	11.38323552	167.80	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.68105323	0.68105323	10.04	0.0019
SEX	1	0.09073536	0.09073536	1.34	0.2497
UCPDGR1	1	0.04944525	0.04944525	0.73	0.3949
TRTP	2	22.76647104	11.38323552	167.80	<.0001



3

***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.87323286	1
THSm2.2	0.84581552	2
mCC	1.80979157	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6601	<.0001
2	0.6601		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.873233	0.765201	0.981264
THSm2.2	0.845816	0.784692	0.906939
mCC	1.809792	1.720550	1.899033



4

***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.027417	-0.095687	0.150521
1	3	-0.936559	-1.076085	-0.797033
2	3	-0.963976	-1.071562	-0.856390

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



5

***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	79
Number of Observations Used	79



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13.11003293	2.62200659	27.53	<.0001
Error	73	6.95311981	0.09524822		
Corrected Total	78	20.06315274			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.653438	24.59765	0.308623	1.254685

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.55202126	0.55202126	5.80	0.0186
SEX	1	0.05394163	0.05394163	0.57	0.4541
UCPDGR1	1	0.36400746	0.36400746	3.82	0.0544
TRTP	2	12.14006257	6.07003129	63.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.86287467	0.86287467	9.06	0.0036
SEX	1	0.17293424	0.17293424	1.82	0.1820
UCPDGR1	1	0.05136640	0.05136640	0.54	0.4651
TRTP	2	12.14006257	6.07003129	63.73	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.83450616	1
THSm2.2	0.96639367	2
mCC	1.75282482	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3080	<.0001
2	0.3080		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.834506	0.598969	1.070043
THSm2.2	0.966394	0.868511	1.064276
mCC	1.752825	1.640979	1.864670



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.131888	-0.387920	0.124145
1	3	-0.918319	-1.176649	-0.659988
2	3	-0.786431	-0.935336	-0.637526

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	112.9893847	22.5978769	48.63	<.0001
Error	110	51.1205738	0.4647325		
Corrected Total	115	164.1099586			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.688498	13.06975	0.681713	5.215961

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.13284100	12.13284100	26.11	<.0001
SEX	1	1.90998599	1.90998599	4.11	0.0451
UCPDGR1	1	2.56823945	2.56823945	5.53	0.0205
TRTP	2	96.37831830	48.18915915	103.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.80846720	23.80846720	51.23	<.0001
SEX	1	1.16283767	1.16283767	2.50	0.1166
UCPDGR1	1	1.69851620	1.69851620	3.65	0.0585
TRTP	2	96.37831830	48.18915915	103.69	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.55351078	1
THSm2.2	4.70914093	2
mCC	6.78247628	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3670	<.0001
2	0.3670		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.553511	4.258080	4.848941
THSm2.2	4.709141	4.537912	4.880370
mCC	6.782476	6.532712	7.032240



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.155630	-0.496131	0.184871
1	3	-2.228965	-2.614885	-1.843046
2	3	-2.073335	-2.377583	-1.769088

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	64.65612242	12.93122448	26.04	<.0001
Error	67	33.26741564	0.49652859		
Corrected Total	72	97.92353806			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.660272	11.64032	0.704648	6.053510

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	16.56239262	16.56239262	33.36	<.0001
SEX	1	0.18105014	0.18105014	0.36	0.5480
UCPDGR1	1	2.38175441	2.38175441	4.80	0.0320
TRTP	2	45.53092524	22.76546262	45.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.16811425	23.16811425	46.66	<.0001
SEX	1	0.05166970	0.05166970	0.10	0.7480
UCPDGR1	1	0.23756354	0.23756354	0.48	0.4915
TRTP	2	45.53092524	22.76546262	45.85	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.44694470	1
THSm2.2	5.38741965	2
mCC	7.04090776	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8431	<.0001
2	0.8431		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.446945	4.905047	5.988842
THSm2.2	5.387420	5.148436	5.626404
mCC	7.040908	6.776638	7.305178



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.059525	-0.538474	0.657524
1	3	-1.593963	-2.189818	-0.998108
2	3	-1.653488	-2.013273	-1.293703

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.45476502	7.29095300	58.45	<.0001
Error	112	13.97014046	0.12473340		
Corrected Total	117	50.42490549			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.722952	6.163521	0.353176	5.730104

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.07271952	11.07271952	88.77	<.0001
SEX	1	0.10376972	0.10376972	0.83	0.3637
UCPDGR1	1	0.46174225	0.46174225	3.70	0.0569
TRTP	2	24.81653354	12.40826677	99.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.87270161	8.87270161	71.13	<.0001
SEX	1	0.07538181	0.07538181	0.60	0.4386
UCPDGR1	1	0.19155267	0.19155267	1.54	0.2179
TRTP	2	24.81653354	12.40826677	99.48	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.02420407	1
THSm2.2	5.62810439	2
mCC	6.40965327	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.024204	4.871209	5.177199
THSm2.2	5.628104	5.541071	5.715137
mCC	6.409653	6.281048	6.538259



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.603900	-0.779168	-0.428633
1	3	-1.385449	-1.585192	-1.185707
2	3	-0.781549	-0.935835	-0.627263

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.65524541	3.73104908	14.19	<.0001
Error	67	17.61936989	0.26297567		
Corrected Total	72	36.27461530			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.514278	8.613432	0.512812	5.953626

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.29091275	8.29091275	31.53	<.0001
SEX	1	0.03022288	0.03022288	0.11	0.7357
UCPDGR1	1	0.37886690	0.37886690	1.44	0.2343
TRTP	2	9.95524289	4.97762144	18.93	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.54007359	5.54007359	21.07	<.0001
SEX	1	0.08291924	0.08291924	0.32	0.5763
UCPDGR1	1	0.05847055	0.05847055	0.22	0.6388
TRTP	2	9.95524289	4.97762144	18.93	<.0001



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.33504172	1
THSm2.2	5.73446067	2
mCC	6.39789668	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0714	<.0001
2	0.0714		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.335042	4.938714	5.731369
THSm2.2	5.734461	5.561986	5.906935
mCC	6.397897	6.205529	6.590264



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.399419	-0.834661	0.035824
1	3	-1.062855	-1.501504	-0.624206
2	3	-0.663436	-0.922587	-0.404285

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	143.4202832	28.6840566	72.49	<.0001
Error	110	43.5277843	0.3957071		
Corrected Total	115	186.9480674			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.767166	11.60413	0.629053	5.420935

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	44.14608354	44.14608354	111.56	<.0001
SEX	1	2.60491806	2.60491806	6.58	0.0116
UCPDGR1	1	1.04121559	1.04121559	2.63	0.1076
TRTP	2	95.62806597	47.81403299	120.83	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	41.49796040	41.49796040	104.87	<.0001
SEX	1	1.45429220	1.45429220	3.68	0.0578
UCPDGR1	1	0.62064509	0.62064509	1.57	0.2131
TRTP	2	95.62806597	47.81403299	120.83	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.87560284	1
THSm2.2	4.89868861	2
mCC	6.97158076	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8841	<.0001
2	0.8841		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.875603	4.603008	5.148197
THSm2.2	4.898689	4.741771	5.055606
mCC	6.971581	6.743422	7.199739



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.023086	-0.336228	0.290056
1	3	-2.095978	-2.451111	-1.740845
2	3	-2.072892	-2.348759	-1.797025

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	75.5712378	15.1142476	15.50	<.0001
Error	67	65.3156860	0.9748610		
Corrected Total	72	140.8869238			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.536396	16.11811	0.987350	6.125719

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	27.63994495	27.63994495	28.35	<.0001
SEX	1	0.00651411	0.00651411	0.01	0.9351
UCPDGR1	1	2.32106722	2.32106722	2.38	0.1275
TRTP	2	45.60371154	22.80185577	23.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.21200365	23.21200365	23.81	<.0001
SEX	1	0.03774556	0.03774556	0.04	0.8446
UCPDGR1	1	0.45705177	0.45705177	0.47	0.4959
TRTP	2	45.60371154	22.80185577	23.39	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.00342537	1
THSm2.2	5.59155780	2
mCC	7.09070216	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1619	<.0001
2	0.1619		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.003425	4.247020	5.759830
THSm2.2	5.591558	5.259781	5.923335
mCC	7.090702	6.720809	7.460595



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.588132	-1.418215	0.241950
1	3	-2.087277	-2.923025	-1.251529
2	3	-1.499144	-1.998115	-1.000174

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.6196501	20.9239300	136.52	<.0001
Error	112	17.1659445	0.1532674		
Corrected Total	117	121.7855946			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.859048	9.250820	0.391494	4.231990

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	89.37773334	89.37773334	583.15	<.0001
SEX	1	0.00635924	0.00635924	0.04	0.8390
UCPDGR1	1	0.06100082	0.06100082	0.40	0.5294
TRTP	2	15.17455674	7.58727837	49.50	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	82.80420233	82.80420233	540.26	<.0001
SEX	1	0.06706117	0.06706117	0.44	0.5097
UCPDGR1	1	0.03121796	0.03121796	0.20	0.6526
TRTP	2	15.17455674	7.58727837	49.50	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.01538537	1
THSm2.2	4.01526627	2
mCC	4.84064260	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.9990	<.0001
2	0.9990		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.015385	3.845796	4.184974
THSm2.2	4.015266	3.918647	4.111885
mCC	4.840643	4.698658	4.982628



***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.000119	-0.194219	0.194457
1	3	-0.825257	-1.046220	-0.604294
2	3	-0.825376	-0.996217	-0.654536

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	50.1239747	10.0247949	12.58	<.0001
Error	67	53.3862805	0.7968102		
Corrected Total	72	103.5102552			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.484242	20.79738	0.892642	4.292090

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	21.11421592	21.11421592	26.50	<.0001
SEX	1	1.50247118	1.50247118	1.89	0.1743
UCPDGR1	1	0.64472034	0.64472034	0.81	0.3716
TRTP	2	26.86256731	13.43128365	16.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.51726431	24.51726431	30.77	<.0001
SEX	1	1.29168421	1.29168421	1.62	0.2073
UCPDGR1	1	0.00008900	0.00008900	0.00	0.9916
TRTP	2	26.86256731	13.43128365	16.86	<.0001



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.84270894	1
THSm2.2	3.75746832	2
mCC	5.02687137	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8212	0.0025
2	0.8212		<.0001
3	0.0025	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.842709	3.159723	4.525694
THSm2.2	3.757468	3.457115	4.057821
mCC	5.026871	4.692968	5.360775



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***Listing 15.4.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.085241	-0.664663	0.835144
1	3	-1.184162	-1.937750	-0.430575
2	3	-1.269403	-1.720721	-0.818085

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





1

***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	131
Number of Observations Used	131



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.91212775	4.58242555	67.55	<.0001
Error	125	8.47998723	0.06783990		
Corrected Total	130	31.39211498			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.729869	23.47272	0.260461	1.109633

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.04592888	0.04592888	0.68	0.4122
SEX	1	0.05176277	0.05176277	0.76	0.3841
UCPDGR1	1	0.04796506	0.04796506	0.71	0.4020
TRTP	2	22.76647104	11.38323552	167.80	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.68105323	0.68105323	10.04	0.0019
SEX	1	0.09073536	0.09073536	1.34	0.2497
UCPDGR1	1	0.04944525	0.04944525	0.73	0.3949
TRTP	2	22.76647104	11.38323552	167.80	<.0001



3

***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.87323286	1
THSm2.2	0.84581552	2
mCC	1.80979157	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6601	<.0001
2	0.6601		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.873233	0.765201	0.981264
THSm2.2	0.845816	0.784692	0.906939
mCC	1.809792	1.720550	1.899033



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.027417	-0.095687	0.150521
1	3	-0.936559	-1.076085	-0.797033
2	3	-0.963976	-1.071562	-0.856390

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11.59187786	2.31837557	18.73	<.0001
Error	82	10.14787206	0.12375454		
Corrected Total	87	21.73974992			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.533211	28.00654	0.351788	1.256091

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.23172496	0.23172496	1.87	0.1749
SEX	1	0.06166442	0.06166442	0.50	0.4823
UCPDGR1	1	0.15235306	0.15235306	1.23	0.2704
TRTP	2	11.14613542	5.57306771	45.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.35316619	0.35316619	2.85	0.0950
SEX	1	0.02120036	0.02120036	0.17	0.6800
UCPDGR1	1	0.00061825	0.00061825	0.00	0.9438
TRTP	2	11.14613542	5.57306771	45.03	<.0001



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	1.07328138	1
THSm2.2	0.97343281	2
mCC	1.73357875	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4444	<.0001
2	0.4444		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	1.073281	0.835134	1.311429
THSm2.2	0.973433	0.869315	1.077551
mCC	1.733579	1.608608	1.858549



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.099849	-0.158603	0.358301
1	3	-0.660297	-0.926434	-0.394161
2	3	-0.760146	-0.922337	-0.597954

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	112.9893847	22.5978769	48.63	<.0001
Error	110	51.1205738	0.4647325		
Corrected Total	115	164.1099586			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.688498	13.06975	0.681713	5.215961

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.13284100	12.13284100	26.11	<.0001
SEX	1	1.90998599	1.90998599	4.11	0.0451
UCPDGR1	1	2.56823945	2.56823945	5.53	0.0205
TRTP	2	96.37831830	48.18915915	103.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.80846720	23.80846720	51.23	<.0001
SEX	1	1.16283767	1.16283767	2.50	0.1166
UCPDGR1	1	1.69851620	1.69851620	3.65	0.0585
TRTP	2	96.37831830	48.18915915	103.69	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.55351078	1
THSm2.2	4.70914093	2
mCC	6.78247628	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3670	<.0001
2	0.3670		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.553511	4.258080	4.848941
THSm2.2	4.709141	4.537912	4.880370
mCC	6.782476	6.532712	7.032240



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.155630	-0.496131	0.184871
1	3	-2.228965	-2.614885	-1.843046
2	3	-2.073335	-2.377583	-1.769088

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	64.6349616	12.9269923	23.62	<.0001
Error	75	41.0490062	0.5473201		
Corrected Total	80	105.6839678			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.611587	12.27299	0.739811	6.027958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	15.53142725	15.53142725	28.38	<.0001
SEX	1	0.01300962	0.01300962	0.02	0.8779
UCPDGR1	1	1.64005517	1.64005517	3.00	0.0876
TRTP	2	47.45046957	23.72523479	43.35	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	23.95872884	23.95872884	43.77	<.0001
SEX	1	0.10752546	0.10752546	0.20	0.6589
UCPDGR1	1	0.09978625	0.09978625	0.18	0.6706
TRTP	2	47.45046957	23.72523479	43.35	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.79927860	1
THSm2.2	5.36493288	2
mCC	7.05143994	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1285	<.0001
2	0.1285		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.799279	5.290236	6.308321
THSm2.2	5.364933	5.130650	5.599216
mCC	7.051440	6.774523	7.328357



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.434346	-0.128659	0.997350
1	3	-1.252161	-1.822335	-0.681988
2	3	-1.686507	-2.051058	-1.321956

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.45476502	7.29095300	58.45	<.0001
Error	112	13.97014046	0.12473340		
Corrected Total	117	50.42490549			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.722952	6.163521	0.353176	5.730104

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.07271952	11.07271952	88.77	<.0001
SEX	1	0.10376972	0.10376972	0.83	0.3637
UCPDGR1	1	0.46174225	0.46174225	3.70	0.0569
TRTP	2	24.81653354	12.40826677	99.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.87270161	8.87270161	71.13	<.0001
SEX	1	0.07538181	0.07538181	0.60	0.4386
UCPDGR1	1	0.19155267	0.19155267	1.54	0.2179
TRTP	2	24.81653354	12.40826677	99.48	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.02420407	1
THSm2.2	5.62810439	2
mCC	6.40965327	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.024204	4.871209	5.177199
THSm2.2	5.628104	5.541071	5.715137
mCC	6.409653	6.281048	6.538259



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.603900	-0.779168	-0.428633
1	3	-1.385449	-1.585192	-1.185707
2	3	-0.781549	-0.935835	-0.627263

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.78307872	3.95661574	15.73	<.0001
Error	75	18.86831138	0.25157749		
Corrected Total	80	38.65139010			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.511834	8.469901	0.501575	5.921852

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.53692217	8.53692217	33.93	<.0001
SEX	1	0.15737334	0.15737334	0.63	0.4315
UCPDGR1	1	0.54502019	0.54502019	2.17	0.1452
TRTP	2	10.54376301	5.27188150	20.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.77474282	5.77474282	22.95	<.0001
SEX	1	0.11529427	0.11529427	0.46	0.5005
UCPDGR1	1	0.16415014	0.16415014	0.65	0.4218
TRTP	2	10.54376301	5.27188150	20.96	<.0001



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.35157474	1
THSm2.2	5.73917849	2
mCC	6.39274157	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0431	<.0001
2	0.0431		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.351575	5.009002	5.694147
THSm2.2	5.739178	5.582537	5.895820
mCC	6.392742	6.205142	6.580341



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.387604	-0.762890	-0.012318
1	3	-1.041167	-1.429609	-0.652724
2	3	-0.653563	-0.896448	-0.410678

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	143.4202832	28.6840566	72.49	<.0001
Error	110	43.5277843	0.3957071		
Corrected Total	115	186.9480674			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.767166	11.60413	0.629053	5.420935

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	44.14608354	44.14608354	111.56	<.0001
SEX	1	2.60491806	2.60491806	6.58	0.0116
UCPDGR1	1	1.04121559	1.04121559	2.63	0.1076
TRTP	2	95.62806597	47.81403299	120.83	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	41.49796040	41.49796040	104.87	<.0001
SEX	1	1.45429220	1.45429220	3.68	0.0578
UCPDGR1	1	0.62064509	0.62064509	1.57	0.2131
TRTP	2	95.62806597	47.81403299	120.83	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.87560284	1
THSm2.2	4.89868861	2
mCC	6.97158076	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8841	<.0001
2	0.8841		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.875603	4.603008	5.148197
THSm2.2	4.898689	4.741771	5.055606
mCC	6.971581	6.743422	7.199739



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.023086	-0.336228	0.290056
1	3	-2.095978	-2.451111	-1.740845
2	3	-2.072892	-2.348759	-1.797025

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	71.9975415	14.3995083	14.04	<.0001
Error	75	76.8933220	1.0252443		
Corrected Total	80	148.8908635			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.483559	16.55601	1.012543	6.115867

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	27.34966115	27.34966115	26.68	<.0001
SEX	1	0.01047167	0.01047167	0.01	0.9198
UCPDGR1	1	1.17616196	1.17616196	1.15	0.2876
TRTP	2	43.46124674	21.73062337	21.20	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.42075798	24.42075798	23.82	<.0001
SEX	1	0.01794724	0.01794724	0.02	0.8951
UCPDGR1	1	0.07353092	0.07353092	0.07	0.7896
TRTP	2	43.46124674	21.73062337	21.20	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.42652345	1
THSm2.2	5.58785208	2
mCC	7.09830482	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6708	<.0001
2	0.6708		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.426523	4.738115	6.114932
THSm2.2	5.587852	5.271952	5.903753
mCC	7.098305	6.720295	7.476314



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.161329	-0.914553	0.591896
1	3	-1.671781	-2.450835	-0.892728
2	3	-1.510453	-2.000837	-1.020069

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.6196501	20.9239300	136.52	<.0001
Error	112	17.1659445	0.1532674		
Corrected Total	117	121.7855946			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.859048	9.250820	0.391494	4.231990

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	89.37773334	89.37773334	583.15	<.0001
SEX	1	0.00635924	0.00635924	0.04	0.8390
UCPDGR1	1	0.06100082	0.06100082	0.40	0.5294
TRTP	2	15.17455674	7.58727837	49.50	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	82.80420233	82.80420233	540.26	<.0001
SEX	1	0.06706117	0.06706117	0.44	0.5097
UCPDGR1	1	0.03121796	0.03121796	0.20	0.6526
TRTP	2	15.17455674	7.58727837	49.50	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.01538537	1
THSm2.2	4.01526627	2
mCC	4.84064260	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.9990	<.0001
2	0.9990		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.015385	3.845796	4.184974
THSm2.2	4.015266	3.918647	4.111885
mCC	4.840643	4.698658	4.982628



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.000119	-0.194219	0.194457
1	3	-0.825257	-1.046220	-0.604294
2	3	-0.825376	-0.996217	-0.654536

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	52.6300602	10.5260120	13.98	<.0001
Error	75	56.4809148	0.7530789		
Corrected Total	80	109.1109750			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.482353	20.40270	0.867801	4.253363

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	21.37671767	21.37671767	28.39	<.0001
SEX	1	0.61155287	0.61155287	0.81	0.3704
UCPDGR1	1	0.19635274	0.19635274	0.26	0.6111
TRTP	2	30.44543692	15.22271846	20.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	25.70889262	25.70889262	34.14	<.0001
SEX	1	1.22595946	1.22595946	1.63	0.2059
UCPDGR1	1	0.07237004	0.07237004	0.10	0.7574
TRTP	2	30.44543692	15.22271846	20.21	<.0001



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***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.98949422	1
THSm2.2	3.71477683	2
mCC	5.04635424	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3978	0.0022
2	0.3978		<.0001
3	0.0022	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.989494	3.401428	4.577561
THSm2.2	3.714777	3.443283	3.986271
mCC	5.046354	4.722631	5.370077



***Listing 15.4.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-PP Set***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.274717	-0.368840	0.918274
1	3	-1.056860	-1.721254	-0.392466
2	3	-1.331577	-1.753319	-0.909836

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	153
Number of Observations Used	153



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.05570088	5.61114018	67.44	<.0001
Error	147	12.23042804	0.08320019		
Corrected Total	152	40.28612892			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.696411	25.55463	0.288444	1.128737

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.47222361	0.47222361	5.68	0.0185
SEX	1	0.05854757	0.05854757	0.70	0.4029
UCPDGR1	1	0.00025820	0.00025820	0.00	0.9557
TRTP	2	27.52467149	13.76233575	165.41	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.96124270	0.96124270	11.55	0.0009
SEX	1	0.06338638	0.06338638	0.76	0.3842
UCPDGR1	1	0.00361912	0.00361912	0.04	0.8351
TRTP	2	27.52467149	13.76233575	165.41	<.0001



3

***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.90922190	1
THSm2.2	0.85482601	2
mCC	1.83731517	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3562	<.0001
2	0.3562		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.909222	0.812329	1.006115
THSm2.2	0.854826	0.789464	0.920188
mCC	1.837315	1.746620	1.928010



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.054396	-0.061748	0.170540
1	3	-0.928093	-1.060126	-0.796061
2	3	-0.982489	-1.093584	-0.871395

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	153
Number of Observations Used	153



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Dependent Variable: LOGAVAL***

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13.62205212	2.72441042	19.10	<.0001
Error	147	20.96474893	0.14261734		
Corrected Total	152	34.58680106			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.393851	28.72361	0.377647	1.314762

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.69248913	1.69248913	11.87	0.0007
SEX	1	0.09528502	0.09528502	0.67	0.4150
UCPDGR1	1	0.00268904	0.00268904	0.02	0.8910
TRTP	2	11.83158893	5.91579446	41.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.04170471	2.04170471	14.32	0.0002
SEX	1	0.08100544	0.08100544	0.57	0.4523
UCPDGR1	1	0.00143862	0.00143862	0.01	0.9201
TRTP	2	11.83158893	5.91579446	41.48	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	1.30196091	1
THSm2.2	1.09766584	2
mCC	1.76760754	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0088	<.0001
2	0.0088		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	1.301961	1.175103	1.428819
THSm2.2	1.097666	1.012091	1.183241
mCC	1.767608	1.648864	1.886351



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.204295	0.052233	0.356357
1	3	-0.465647	-0.638511	-0.292783
2	3	-0.669942	-0.815393	-0.524491

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	142.2064638	28.4412928	42.19	<.0001
Error	135	90.9970054	0.6740519		
Corrected Total	140	233.2034692			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.609796	15.38326	0.821007	5.337013

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.6880057	24.6880057	36.63	<.0001
SEX	1	1.0145931	1.0145931	1.51	0.2220
UCPDGR1	1	0.1215167	0.1215167	0.18	0.6718
TRTP	2	116.3823483	58.1911742	86.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	37.5277799	37.5277799	55.67	<.0001
SEX	1	0.4183230	0.4183230	0.62	0.4322
UCPDGR1	1	0.2065729	0.2065729	0.31	0.5808
TRTP	2	116.3823483	58.1911742	86.33	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.99000522	1
THSm2.2	4.72183243	2
mCC	6.89887215	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1170	<.0001
2	0.1170		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.990005	4.717324	5.262687
THSm2.2	4.721832	4.523460	4.920205
mCC	6.898872	6.626675	7.171069



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.268173	-0.067979	0.604325
1	3	-1.908867	-2.292404	-1.525330
2	3	-2.177040	-2.514242	-1.839837

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	103.9872139	20.7974428	33.81	<.0001
Error	135	83.0396363	0.6151084		
Corrected Total	140	187.0268502			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.556002	12.69414	0.784288	6.178352

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	43.05972163	43.05972163	70.00	<.0001
SEX	1	0.03496526	0.03496526	0.06	0.8119
UCPDGR1	1	0.54097339	0.54097339	0.88	0.3500
TRTP	2	60.35155360	30.17577680	49.06	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	56.66717632	56.66717632	92.13	<.0001
SEX	1	0.40955278	0.40955278	0.67	0.4159
UCPDGR1	1	0.21198674	0.21198674	0.34	0.5581
TRTP	2	60.35155360	30.17577680	49.06	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	6.28117906	1
THSm2.2	5.58017706	2
mCC	7.18667613	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	6.281179	6.020693	6.541665
THSm2.2	5.580177	5.390676	5.769678
mCC	7.186676	6.926653	7.446699



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.701002	0.379884	1.022120
1	3	-0.905497	-1.271881	-0.539113
2	3	-1.606499	-1.928621	-1.284378

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	41.03966588	8.20793318	40.82	<.0001
Error	137	27.54947311	0.20109104		
Corrected Total	142	68.58913899			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.598341	7.768861	0.448432	5.772169

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.79073226	12.79073226	63.61	<.0001
SEX	1	0.17918153	0.17918153	0.89	0.3469
UCPDGR1	1	0.02923330	0.02923330	0.15	0.7036
TRTP	2	28.04051879	14.02025940	69.72	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.44568631	10.44568631	51.95	<.0001
SEX	1	0.24964654	0.24964654	1.24	0.2671
UCPDGR1	1	0.00069190	0.00069190	0.00	0.9533
TRTP	2	28.04051879	14.02025940	69.72	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.27511699	1
THSm2.2	5.64803022	2
mCC	6.48255317	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.275117	5.126215	5.424019
THSm2.2	5.648030	5.541555	5.754505
mCC	6.482553	6.334074	6.631032



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.372913	-0.555077	-0.190750
1	3	-1.207436	-1.416837	-0.998035
2	3	-0.834523	-1.016565	-0.652481

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.68534649	5.73706930	20.15	<.0001
Error	137	39.00683763	0.28472144		
Corrected Total	142	67.69218411			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.423762	8.978640	0.533593	5.942915

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.19374320	14.19374320	49.85	<.0001
SEX	1	0.00339542	0.00339542	0.01	0.9132
UCPDGR1	1	0.01129417	0.01129417	0.04	0.8424
TRTP	2	14.47691370	7.23845685	25.42	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.49033257	10.49033257	36.84	<.0001
SEX	1	0.00235092	0.00235092	0.01	0.9277
UCPDGR1	1	0.03170550	0.03170550	0.11	0.7391
TRTP	2	14.47691370	7.23845685	25.42	<.0001



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.70889196	1
THSm2.2	5.78342970	2
mCC	6.48973673	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4977	<.0001
2	0.4977		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.708892	5.531713	5.886071
THSm2.2	5.783430	5.656734	5.910125
mCC	6.489737	6.313060	6.666413



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.074538	-0.291296	0.142220
1	3	-0.780845	-1.030013	-0.531677
2	3	-0.706307	-0.922921	-0.489694

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	192.0598601	38.4119720	63.00	<.0001
Error	135	82.3152530	0.6097426		
Corrected Total	140	274.3751131			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.699990	14.08137	0.780860	5.545342

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	67.3218093	67.3218093	110.41	<.0001
SEX	1	1.5057679	1.5057679	2.47	0.1184
UCPDGR1	1	0.0013450	0.0013450	0.00	0.9626
TRTP	2	123.2309380	61.6154690	101.05	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	56.8646581	56.8646581	93.26	<.0001
SEX	1	0.8181516	0.8181516	1.34	0.2488
UCPDGR1	1	0.0036990	0.0036990	0.01	0.9380
TRTP	2	123.2309380	61.6154690	101.05	<.0001



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Least Squares Means**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.19064119	1
THSm2.2	4.92280860	2
mCC	7.14518889	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0985	<.0001
2	0.0985		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.190641	4.931412	5.449870
THSm2.2	4.922809	4.735208	5.110409
mCC	7.145189	6.887249	7.403129



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.267833	-0.050599	0.586264
1	3	-1.954548	-2.319050	-1.590045
2	3	-2.222380	-2.540160	-1.904601

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	114.4885246	22.8977049	20.07	<.0001
Error	135	153.9893325	1.1406617		
Corrected Total	140	268.4778571			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.426436	16.68955	1.068018	6.399319

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	74.07086533	74.07086533	64.94	<.0001
SEX	1	0.01970471	0.01970471	0.02	0.8956
UCPDGR1	1	0.08710654	0.08710654	0.08	0.7827
TRTP	2	40.31084801	20.15542400	17.67	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	69.20565087	69.20565087	60.67	<.0001
SEX	1	0.04490151	0.04490151	0.04	0.8430
UCPDGR1	1	0.14308025	0.14308025	0.13	0.7238
TRTP	2	40.31084801	20.15542400	17.67	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	6.31898647	1
THSm2.2	5.97605884	2
mCC	7.27776028	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1218	0.0002
2	0.1218		<.0001
3	0.0002	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	6.318986	5.964427	6.673546
THSm2.2	5.976059	5.719469	6.232648
mCC	7.277760	6.924964	7.630556



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.342928	-0.092606	0.778461
1	3	-0.958774	-1.457321	-0.460227
2	3	-1.301701	-1.736343	-0.867060

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	135.3016264	27.0603253	148.59	<.0001
Error	137	24.9490608	0.1821099		
Corrected Total	142	160.2506871			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.844312	9.953185	0.426743	4.287506

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	115.7614647	115.7614647	635.67	<.0001
SEX	1	0.1284651	0.1284651	0.71	0.4024
UCPDGR1	1	0.0222343	0.0222343	0.12	0.7273
TRTP	2	19.3894622	9.6947311	53.24	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	102.0092854	102.0092854	560.15	<.0001
SEX	1	0.2713923	0.2713923	1.49	0.2243
UCPDGR1	1	0.0201270	0.0201270	0.11	0.7401
TRTP	2	19.3894622	9.6947311	53.24	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.10052530	1
THSm2.2	4.04870031	2
mCC	4.91395723	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5559	<.0001
2	0.5559		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.100525	3.958808	4.242243
THSm2.2	4.048700	3.947257	4.150144
mCC	4.913957	4.772965	5.054949



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.051825	-0.121733	0.225383
1	3	-0.813432	-1.012845	-0.614019
2	3	-0.865257	-1.038139	-0.692375

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS**

**Dependent Variable: LOGAVAL**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	114.4566663	22.8913333	29.09	<.0001
Error	137	107.7917531	0.7868011		
Corrected Total	142	222.2484194			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.514994	19.91010	0.887018	4.455116

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	81.78474313	81.78474313	103.95	<.0001
SEX	1	0.65036178	0.65036178	0.83	0.3649
UCPDGR1	1	0.00530713	0.00530713	0.01	0.9347
TRTP	2	32.01625422	16.00812711	20.35	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	75.35698835	75.35698835	95.78	<.0001
SEX	1	0.94369357	0.94369357	1.20	0.2754
UCPDGR1	1	0.00921157	0.00921157	0.01	0.9140
TRTP	2	32.01625422	16.00812711	20.35	<.0001



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***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.45603716	1
THSm2.2	4.04416896	2
mCC	5.20320967	3

Least Squares Means for effect TRTP Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0256	0.0005
2	0.0256		<.0001
3	0.0005	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.456037	4.161467	4.750607
THSm2.2	4.044169	3.833311	4.255027
mCC	5.203210	4.910147	5.496272



***Listing 15.4.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA for the Secondary Objective-FAS***

***Least Squares Means***

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.411868	0.051114	0.772623
1	3	-0.747173	-1.161668	-0.332677
2	3	-1.159041	-1.518388	-0.799693

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	249.3463328	49.8692666	182.88	<.0001
Error	117	31.9037236	0.2726814		
Corrected Total	122	281.2500564			

R-Square	Coeff Var	Root MSE	logaval Mean
0.886565	23.25412	0.522189	2.245577

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.7023630	3.7023630	13.58	0.0003
SEXC	1	1.6177120	1.6177120	5.93	0.0164
UCPDGR1	1	0.8913218	0.8913218	3.27	0.0732
TRTPN	2	243.1349360	121.5674680	445.82	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.9167040	2.9167040	10.70	0.0014
SEXC	1	0.4604910	0.4604910	1.69	0.1963
UCPDGR1	1	0.6537721	0.6537721	2.40	0.1242
TRTPN	2	243.1349360	121.5674680	445.82	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.47082761	1
2	4.67206631	2
3	1.30579657	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1998
2	<.0001		<.0001
3	0.1998	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.470828	1.345030	1.596625
2	4.672066	4.485906	4.858227
3	1.305797	1.084192	1.527401

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.201239	-3.424703	-2.977774
1	3	0.165031	-0.088464	0.418526
2	3	3.366270	3.077235	3.655305

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	247.7681852	49.5536370	172.61	<.0001
Error	112	32.1542165	0.2870912		
Corrected Total	117	279.9224018			

R-Square	Coeff Var	Root MSE	logaval Mean
0.885132	30.80357	0.535809	1.739438

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.5973892	7.5973892	26.46	<.0001
SEXC	1	7.4891964	7.4891964	26.09	<.0001
UCPDGR1	1	1.3930881	1.3930881	4.85	0.0297
TRTPN	2	231.2885115	115.6442558	402.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.6271627	2.6271627	9.15	0.0031
SEXC	1	4.3550573	4.3550573	15.17	0.0002
UCPDGR1	1	0.5859653	0.5859653	2.04	0.1559
TRTPN	2	231.2885115	115.6442558	402.81	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.98381812	1
2	4.16636820	2
3	0.82711602	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2466
2	<.0001		<.0001
3	0.2466	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.983818	0.851392	1.116244
2	4.166368	3.971754	4.360983
3	0.827116	0.594840	1.059392

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.182550	-3.416305	-2.948795
1	3	0.156702	-0.109884	0.423288
2	3	3.339252	3.036194	3.642311

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	29.66307625	5.93261525	44.86	<.0001
Error	112	14.81240126	0.13225358		
Corrected Total	117	44.47547752			

R-Square	Coeff Var	Root MSE	logaval Mean
0.666954	7.576507	0.363667	4.799928

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.71467362	15.71467362	118.82	<.0001
SEXC	1	0.00467306	0.00467306	0.04	0.8512
UCPDGR1	1	1.50701001	1.50701001	11.39	0.0010
TRTPN	2	12.43671956	6.21835978	47.02	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.00346865	15.00346865	113.44	<.0001
SEXC	1	0.00948206	0.00948206	0.07	0.7894
UCPDGR1	1	1.24099342	1.24099342	9.38	0.0027
TRTPN	2	12.43671956	6.21835978	47.02	<.0001



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*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U1OHP24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.61739062	1
2	5.34395400	2
3	4.54466181	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4319
2	<.0001		<.0001
3	0.4319	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.617391	4.526651	4.708130
2	5.343954	5.212085	5.475823
3	4.544662	4.387356	4.701967

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U1OHP24U Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.726563	-0.886005	-0.567122
1	3	0.072729	-0.109974	0.255432
2	3	0.799292	0.594278	1.004306

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	117
Number of Observations Used	117



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	39.28627256	7.85725451	85.61	<.0001
Error	111	10.18806648	0.09178438		
Corrected Total	116	49.47433904			

R-Square	Coeff Var	Root MSE	logaval Mean
0.794074	7.073578	0.302959	4.282972

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	24.97235918	24.97235918	272.08	<.0001
SEXC	1	0.28659091	0.28659091	3.12	0.0800
UCPDGR1	1	1.69337690	1.69337690	18.45	<.0001
TRTPN	2	12.33394556	6.16697278	67.19	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	19.12968900	19.12968900	208.42	<.0001
SEXC	1	0.50138775	0.50138775	5.46	0.0212
UCPDGR1	1	1.46453641	1.46453641	15.96	0.0001
TRTPN	2	12.33394556	6.16697278	67.19	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.10119030	1
2	4.83290096	2
3	4.05282878	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5290
2	<.0001		<.0001
3	0.5290	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.101190	4.024786	4.177594
2	4.832901	4.722943	4.942859
3	4.052829	3.922725	4.182933

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.731711	-0.864675	-0.598746
1	3	0.048362	-0.103391	0.200114
2	3	0.780072	0.609470	0.950675

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.1040980	20.8208196	89.63	<.0001
Error	117	27.1786085	0.2322958		
Corrected Total	122	131.2827065			

R-Square	Coeff Var	Root MSE	logaval Mean
0.792976	26.81087	0.481971	1.797669

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.39122108	4.39122108	18.90	<.0001
SEXC	1	0.02120516	0.02120516	0.09	0.7631
UCPDGR1	1	0.08624515	0.08624515	0.37	0.5435
TRTPN	2	99.60542663	49.80271331	214.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.42802328	2.42802328	10.45	0.0016
SEXC	1	0.09696701	0.09696701	0.42	0.5195
UCPDGR1	1	0.02190511	0.02190511	0.09	0.7593
TRTPN	2	99.60542663	49.80271331	214.39	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.28709305	1
2	3.34401289	2
3	1.20194538	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4724
2	<.0001		<.0001
3	0.4724	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.287093	1.171030	1.403156
2	3.344013	3.172006	3.516020
3	1.201945	0.997363	1.406527

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.056920	-2.263273	-1.850566
1	3	0.085148	-0.148769	0.319064
2	3	2.142068	1.874905	2.409230

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	103.7237099	20.7447420	79.40	<.0001
Error	112	29.2636532	0.2612826		
Corrected Total	117	132.9873631			

R-Square	Coeff Var	Root MSE	logaval Mean
0.779952	39.65218	0.511158	1.289105

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	6.71941025	6.71941025	25.72	<.0001
SEXC	1	3.02649457	3.02649457	11.58	0.0009
UCPDGR1	1	0.26086136	0.26086136	1.00	0.3199
TRTPN	2	93.71694371	46.85847185	179.34	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.31140465	2.31140465	8.85	0.0036
SEXC	1	1.73335774	1.73335774	6.63	0.0113
UCPDGR1	1	0.04037185	0.04037185	0.15	0.6950
TRTPN	2	93.71694371	46.85847185	179.34	<.0001

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.80811185	1
2	2.83944813	2
3	0.72163375	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5017
2	<.0001		<.0001
3	0.5017	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.808112	0.681960	0.934264
2	2.839448	2.653536	3.025360
3	0.721634	0.500021	0.943246

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.031336	-2.254408	-1.808264
1	3	0.086478	-0.167715	0.340671
2	3	2.117814	1.828382	2.407246

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	39.78529752	7.95705950	54.56	<.0001
Error	117	17.06302709	0.14583784		
Corrected Total	122	56.84832461			

R-Square	Coeff Var	Root MSE	logaval Mean
0.699850	6.101988	0.381887	6.258406

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.23610025	12.23610025	83.90	<.0001
SEXC	1	1.39406963	1.39406963	9.56	0.0025
UCPDGR1	1	0.35260695	0.35260695	2.42	0.1227
TRTPN	2	25.80252070	12.90126035	88.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.15385810	9.15385810	62.77	<.0001
SEXC	1	1.39181308	1.39181308	9.54	0.0025
UCPDGR1	1	0.21501530	0.21501530	1.47	0.2271
TRTPN	2	25.80252070	12.90126035	88.46	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.13535124	1
2	6.93069658	2
3	5.55103474	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.135351	6.043417	6.227285
2	6.930697	6.794443	7.066951
3	5.551035	5.388992	5.713077

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.795345	-0.958916	-0.631775
1	3	0.584317	0.399178	0.769455
2	3	1.379662	1.168106	1.591218

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	74.7063010	14.9412602	44.20	<.0001
Error	117	39.5503854	0.3380375		
Corrected Total	122	114.2566864			

R-Square	Coeff Var	Root MSE	logaval Mean
0.653846	38.54154	0.581410	1.508528

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.03421315	7.03421315	20.81	<.0001
SEXC	1	0.53793007	0.53793007	1.59	0.2096
UCPDGR1	1	0.42541304	0.42541304	1.26	0.2642
TRTPN	2	66.70874478	33.35437239	98.67	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	4.73253681	4.73253681	14.00	0.0003
SEXC	1	0.21030770	0.21030770	0.62	0.4318
UCPDGR1	1	0.25233679	0.25233679	0.75	0.3894
TRTPN	2	66.70874478	33.35437239	98.67	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.13966579	1
2	2.77550059	2
3	0.90965941	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1093
2	<.0001		<.0001
3	0.1093	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.139666	0.999660	1.279672
2	2.775501	2.567948	2.983054
3	0.909659	0.662757	1.156562

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.635835	-1.884800	-1.386869
1	3	0.230006	-0.052281	0.512294
2	3	1.865841	1.543323	2.188359

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	79.7389053	15.9477811	45.43	<.0001
Error	112	39.3186655	0.3510595		
Corrected Total	117	119.0575708			

R-Square	Coeff Var	Root MSE	logaval Mean
0.669751	60.31354	0.592503	0.982371

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.58241573	11.58241573	32.99	<.0001
SEXC	1	3.65713153	3.65713153	10.42	0.0016
UCPDGR1	1	0.55244902	0.55244902	1.57	0.2123
TRTPN	2	63.94690905	31.97345452	91.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.25382637	5.25382637	14.97	0.0002
SEXC	1	2.74214157	2.74214157	7.81	0.0061
UCPDGR1	1	0.20762155	0.20762155	0.59	0.4435
TRTPN	2	63.94690905	31.97345452	91.08	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.61998276	1
2	2.26470515	2
3	0.43249847	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2101
2	<.0001		<.0001
3	0.2101	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.619983	0.473779	0.766186
2	2.264705	2.049137	2.480273
3	0.432498	0.175562	0.689435

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.644722	-1.903328	-1.386116
1	3	0.187484	-0.107229	0.482198
2	3	1.832207	1.496529	2.167884

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	55.53601937	11.10720387	43.95	<.0001
Error	114	28.81313689	0.25274681		
Corrected Total	119	84.34915626			

R-Square	Coeff Var	Root MSE	logaval Mean
0.658406	11.91013	0.502739	4.221108

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.94116327	10.94116327	43.29	<.0001
SEXC	1	0.14295552	0.14295552	0.57	0.4536
UCPDGR1	1	1.76009850	1.76009850	6.96	0.0095
TRTPN	2	42.69180209	21.34590104	84.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.34734746	6.34734746	25.11	<.0001
SEXC	1	0.23364064	0.23364064	0.92	0.3384
UCPDGR1	1	1.13438771	1.13438771	4.49	0.0363
TRTPN	2	42.69180209	21.34590104	84.46	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.99338963	1
2	5.21150456	2
3	3.52041313	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0005
2	<.0001		<.0001
3	0.0005	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.993390	3.869909	4.116870
2	5.211505	5.029100	5.393909
3	3.520413	3.295758	3.745068

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.218115	-1.436728	-0.999502
1	3	0.472977	0.213400	0.732553
2	3	1.691091	1.400598	1.981585

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	66.46732385	13.29346477	50.67	<.0001
Error	112	29.38241170	0.26234296		
Corrected Total	117	95.84973555			

R-Square	Coeff Var	Root MSE	logaval Mean
0.693453	13.85339	0.512194	3.697247

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	20.69174064	20.69174064	78.87	<.0001
SEXC	1	1.57579548	1.57579548	6.01	0.0158
UCPDGR1	1	1.77357487	1.77357487	6.76	0.0106
TRTPN	2	42.42621287	21.21310643	80.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.06674769	9.06674769	34.56	<.0001
SEXC	1	2.08454066	2.08454066	7.95	0.0057
UCPDGR1	1	1.14118917	1.14118917	4.35	0.0393
TRTPN	2	42.42621287	21.21310643	80.86	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.46859916	1
2	4.70850894	2
3	3.04779587	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0021
2	<.0001		<.0001
3	0.0021	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.468599	3.340281	3.596917
2	4.708509	4.522276	4.894742
3	3.047796	2.820620	3.274972

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.239910	-1.463586	-1.016234
1	3	0.420803	0.156573	0.685033
2	3	1.660713	1.364969	1.956457

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	110.0738092	22.0147618	116.16	<.0001
Error	117	22.1732973	0.1895154		
Corrected Total	122	132.2471064			

R-Square	Coeff Var	Root MSE	logaval Mean
0.832334	12.03664	0.435334	3.616736

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.72330881	36.72330881	193.77	<.0001
SEXC	1	0.85359983	0.85359983	4.50	0.0359
UCPDGR1	1	0.00910099	0.00910099	0.05	0.8269
TRTPN	2	72.48779954	36.24389977	191.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.67520856	28.67520856	151.31	<.0001
SEXC	1	1.77731826	1.77731826	9.38	0.0027
UCPDGR1	1	0.00140717	0.00140717	0.01	0.9315
TRTPN	2	72.48779954	36.24389977	191.25	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.15940756	1
2	4.91903476	2
3	3.10393016	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6034
2	<.0001		<.0001
3	0.6034	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.159408	3.054607	3.264209
2	4.919035	4.763683	5.074386
3	3.103930	2.919392	3.288468

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.759627	-1.946118	-1.573136
1	3	0.055477	-0.155414	0.266369
2	3	1.815105	1.574164	2.056045

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	106.5246649	21.3049330	131.09	<.0001
Error	112	18.2020848	0.1625186		
Corrected Total	117	124.7267497			

R-Square	Coeff Var	Root MSE	logaval Mean
0.854064	13.04101	0.403136	3.091294

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.22032356	36.22032356	222.87	<.0001
SEXC	1	0.47434529	0.47434529	2.92	0.0903
UCPDGR1	1	0.03985073	0.03985073	0.25	0.6214
TRTPN	2	69.79014537	34.89507268	214.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.90465575	28.90465575	177.85	<.0001
SEXC	1	1.04460575	1.04460575	6.43	0.0126
UCPDGR1	1	0.00611497	0.00611497	0.04	0.8465
TRTPN	2	69.79014537	34.89507268	214.71	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.63771454	1
2	4.39630650	2
3	2.58098385	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5752
2	<.0001		<.0001
3	0.5752	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.637715	2.538418	2.737011
2	4.396306	4.249593	4.543020
3	2.580984	2.406344	2.755623

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.758592	-1.934721	-1.582463
1	3	0.056731	-0.143250	0.256712
2	3	1.815323	1.587557	2.043088

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	54.27225702	10.85445140	40.83	<.0001
Error	117	31.10440568	0.26584962		
Corrected Total	122	85.37666270			

R-Square	Coeff Var	Root MSE	logaval Mean
0.635680	6.612153	0.515606	7.797855

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	32.65795538	32.65795538	122.84	<.0001
SEXC	1	0.03477997	0.03477997	0.13	0.7182
UCPDGR1	1	0.29714158	0.29714158	1.12	0.2926
TRTPN	2	21.28238010	10.64119005	40.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	32.15351292	32.15351292	120.95	<.0001
SEXC	1	0.08554324	0.08554324	0.32	0.5716
UCPDGR1	1	0.27766986	0.27766986	1.04	0.3089
TRTPN	2	21.28238010	10.64119005	40.03	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.55391047	1
2	8.50399294	2
3	7.51397344	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7528
2	<.0001		<.0001
3	0.7528	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.553910	7.429165	7.678656
2	8.503993	8.320237	8.687748
3	7.513973	7.295404	7.732543

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.950082	-1.171215	-0.728950
1	3	0.039937	-0.210594	0.290468
2	3	0.990020	0.705159	1.274880

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.63380425	12.72676085	47.10	<.0001
Error	112	30.26175066	0.27019420		
Corrected Total	117	93.89555491			

R-Square	Coeff Var	Root MSE	logaval Mean
0.677708	7.134142	0.519802	7.286119

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	42.90034824	42.90034824	158.78	<.0001
SEXC	1	0.30551150	0.30551150	1.13	0.2899
UCPDGR1	1	0.43334609	0.43334609	1.60	0.2080
TRTPN	2	19.99459843	9.99729921	37.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	31.33108480	31.33108480	115.96	<.0001
SEXC	1	0.15191418	0.15191418	0.56	0.4549
UCPDGR1	1	0.29826441	0.29826441	1.10	0.2957
TRTPN	2	19.99459843	9.99729921	37.00	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.05620010	1
2	7.99286568	2
3	7.01090990	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7292
2	<.0001		<.0001
3	0.7292	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.056200	6.927238	7.185162
2	7.992866	7.804381	8.181350
3	7.010910	6.785716	7.236104

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.936666	-1.163947	-0.709384
1	3	0.045290	-0.213281	0.303861
2	3	0.981956	0.688579	1.275332

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	40.69819350	8.13963870	30.68	<.0001
Error	117	31.04326466	0.26532705		
Corrected Total	122	71.74145817			

R-Square	Coeff Var	Root MSE	logaval Mean
0.567290	9.713234	0.515099	5.303065

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.22031644	15.22031644	57.36	<.0001
SEXC	1	0.06899082	0.06899082	0.26	0.6111
UCPDGR1	1	0.68188158	0.68188158	2.57	0.1116
TRTPN	2	24.72700466	12.36350233	46.60	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	14.37574812	14.37574812	54.18	<.0001
SEXC	1	0.05369063	0.05369063	0.20	0.6537
UCPDGR1	1	0.59372063	0.59372063	2.24	0.1374
TRTPN	2	24.72700466	12.36350233	46.60	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.06756640	1
2	6.05689491	2
3	4.91384583	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2249
2	<.0001		<.0001
3	0.2249	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.067566	4.943562	5.191571
2	6.056895	5.873295	6.240495
3	4.913846	4.695561	5.132131

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.989329	-1.209780	-0.768877
1	3	0.153721	-0.095786	0.403227
2	3	1.143049	0.858353	1.427745

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	42.39958219	8.47991644	33.62	<.0001
Error	112	28.24598847	0.25219633		
Corrected Total	117	70.64557065			

R-Square	Coeff Var	Root MSE	logaval Mean
0.600173	10.52574	0.502192	4.771081

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	18.43184284	18.43184284	73.09	<.0001
SEXC	1	0.15609048	0.15609048	0.62	0.4331
UCPDGR1	1	0.68647982	0.68647982	2.72	0.1018
TRTPN	2	23.12516905	11.56258453	45.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.51829177	15.51829177	61.53	<.0001
SEXC	1	0.11827517	0.11827517	0.47	0.4949
UCPDGR1	1	0.46039203	0.46039203	1.83	0.1794
TRTPN	2	23.12516905	11.56258453	45.85	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.55726407	1
2	5.51797742	2
3	4.36702153	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1331
2	<.0001		<.0001
3	0.1331	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.557264	4.433492	4.681036
2	5.517977	5.335560	5.700395
3	4.367022	4.149417	4.584626

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.960713	-1.179860	-0.741567
1	3	0.190243	-0.058871	0.439356
2	3	1.150956	0.867493	1.434419

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	109.5410261	21.9082052	47.19	<.0001
Error	112	51.9986956	0.4642741		
Corrected Total	117	161.5397216			

R-Square	Coeff Var	Root MSE	logaval Mean
0.678106	11.91897	0.681377	5.716742

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.80181189	9.80181189	21.11	<.0001
SEXC	1	0.00274767	0.00274767	0.01	0.9388
UCPDGR1	1	2.96337163	2.96337163	6.38	0.0129
TRTPN	2	96.77309487	48.38654743	104.22	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.41460987	22.41460987	48.28	<.0001
SEXC	1	0.00288350	0.00288350	0.01	0.9373
UCPDGR1	1	2.11764071	2.11764071	4.56	0.0349
TRTPN	2	96.77309487	48.38654743	104.22	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.20020969	1
2	7.27446686	2
3	5.04926625	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3798
2	<.0001		<.0001
3	0.3798	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.200210	5.032103	5.368316
2	7.274467	7.024237	7.524697
3	5.049266	4.753892	5.344641

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.074257	-2.377058	-1.771456
1	3	0.150943	-0.188250	0.490137
2	3	2.225201	1.839652	2.610749

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	122
Number of Observations Used	122

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	257.7085919	51.5417184	166.95	<.0001
Error	116	35.8127165	0.3087303		
Corrected Total	121	293.5213084			

R-Square	Coeff Var	Root MSE	logaval Mean
0.877989	29.71049	0.555635	1.870165

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	35.5438936	35.5438936	115.13	<.0001
SEXC	1	0.3414123	0.3414123	1.11	0.2952
UCPDGR1	1	0.9493592	0.9493592	3.08	0.0821
TRTPN	2	220.8739267	110.4369634	357.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.4498987	28.4498987	92.15	<.0001
SEXC	1	0.0810033	0.0810033	0.26	0.6095
UCPDGR1	1	0.5152899	0.5152899	1.67	0.1990
TRTPN	2	220.8739267	110.4369634	357.71	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.43440027	1
2	2.60592114	2
3	-1.01104612	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.1577	<.0001
2	0.1577		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.434400	2.299430	2.569370
2	2.605921	2.407502	2.804340
3	-1.011046	-1.246588	-0.775504

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.171521	-0.410415	0.067373
1	3	3.445446	3.175833	3.715060
2	3	3.616967	3.309312	3.924623

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	236.4214436	47.2842887	197.17	<.0001
Error	112	26.8598080	0.2398197		
Corrected Total	117	263.2812516			

R-Square	Coeff Var	Root MSE	logaval Mean
0.897981	35.33841	0.489714	1.385784

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	25.1596338	25.1596338	104.91	<.0001
SEXC	1	0.4201557	0.4201557	1.75	0.1883
UCPDGR1	1	0.9002020	0.9002020	3.75	0.0552
TRTPN	2	209.9414521	104.9707261	437.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.1832345	22.1832345	92.50	<.0001
SEXC	1	0.1099693	0.1099693	0.46	0.4997
UCPDGR1	1	0.1102320	0.1102320	0.46	0.4992
TRTPN	2	209.9414521	104.9707261	437.71	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.95427441	1
2	2.08976185	2
3	-1.49170145	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.2125	<.0001
2	0.2125		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.954274	1.833667	2.074882
2	2.089762	1.911365	2.268159
3	-1.491701	-1.703861	-1.279542

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.135487	-0.349588	0.078613
1	3	3.445976	3.203052	3.688899
2	3	3.581463	3.304746	3.858180

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	97.1170901	19.4234180	113.94	<.0001
Error	114	19.4334756	0.1704691		
Corrected Total	119	116.5505657			

R-Square	Coeff Var	Root MSE	logaval Mean
0.833261	8.735498	0.412879	4.726451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	81.19089527	81.19089527	476.28	<.0001
SEXC	1	0.09705496	0.09705496	0.57	0.4521
UCPDGR1	1	0.08699398	0.08699398	0.51	0.4765
TRTPN	2	15.74214585	7.87107292	46.17	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	80.07922286	80.07922286	469.76	<.0001
SEXC	1	0.20091244	0.20091244	1.18	0.2799
UCPDGR1	1	0.05117204	0.05117204	0.30	0.5848
TRTPN	2	15.74214585	7.87107292	46.17	<.0001

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.50326264	1
2	5.34466156	2
3	4.51780387	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8880
2	<.0001		<.0001
3	0.8880	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.503263	4.403097	4.603428
2	5.344662	5.194979	5.494344
3	4.517804	4.338967	4.696640

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.841399	-1.020669	-0.662129
1	3	-0.014541	-0.218695	0.189612
2	3	0.826858	0.593878	1.059837

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	232.3105538	46.4621108	89.79	<.0001
Error	114	58.9871966	0.5174315		
Corrected Total	119	291.2977504			

R-Square	Coeff Var	Root MSE	logaval Mean
0.797502	129.2799	0.719327	0.556410

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	41.6823842	41.6823842	80.56	<.0001
SEXC	1	0.2001803	0.2001803	0.39	0.5352
UCPDGR1	1	1.6660491	1.6660491	3.22	0.0754
TRTPN	2	188.7619403	94.3809701	182.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	31.1151834	31.1151834	60.13	<.0001
SEXC	1	0.3142361	0.3142361	0.61	0.4374
UCPDGR1	1	0.4798071	0.4798071	0.93	0.3376
TRTPN	2	188.7619403	94.3809701	182.40	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.37922790	1
2	2.35124005	2
3	-1.52949478	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.379228	0.204446	0.554009
2	2.351240	2.090390	2.612090
3	-1.529495	-1.842195	-1.216794

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.972012	-2.284345	-1.659679
1	3	1.908723	1.551126	2.266320
2	3	3.880735	3.473525	4.287944

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	238.1247797	47.6249559	98.36	<.0001
Error	112	54.2287762	0.4841855		
Corrected Total	117	292.3535559			

R-Square	Coeff Var	Root MSE	logaval Mean
0.814510	1099.526	0.695834	0.063285

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	49.0190639	49.0190639	101.24	<.0001
SEXC	1	0.0044931	0.0044931	0.01	0.9234
UCPDGR1	1	0.9832054	0.9832054	2.03	0.1569
TRTPN	2	188.1180173	94.0590087	194.26	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	32.7519209	32.7519209	67.64	<.0001
SEXC	1	0.0005554	0.0005554	0.00	0.9730
UCPDGR1	1	0.1586144	0.1586144	0.33	0.5682
TRTPN	2	188.1180173	94.0590087	194.26	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.09965301	1
2	1.86185743	2
3	-2.01410631	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.099653	-0.271974	0.072668
2	1.861857	1.609407	2.114308
3	-2.014106	-2.316465	-1.711748

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.961510	-2.265253	-1.657768
1	3	1.914453	1.566691	2.262216
2	3	3.875964	3.481963	4.269964

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17.67448416	3.53489683	16.97	<.0001
Error	117	24.37831929	0.20836170		
Corrected Total	122	42.05280345			

R-Square	Coeff Var	Root MSE	logaval Mean
0.420293	10.30246	0.456467	4.430657

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	1.82574867	1.82574867	8.76	0.0037
SEXC	1	0.06901280	0.06901280	0.33	0.5660
UCPDGR1	1	0.03007294	0.03007294	0.14	0.7047
TRTPN	2	15.74964975	7.87482488	37.79	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.70957121	0.70957121	3.41	0.0675
SEXC	1	0.18996734	0.18996734	0.91	0.3416
UCPDGR1	1	0.00080694	0.00080694	0.00	0.9505
TRTPN	2	15.74964975	7.87482488	37.79	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.27689523	1
2	5.02511234	2
3	4.03607726	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0332
2	<.0001		<.0001
3	0.0332	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.276895	4.166995	4.386795
2	5.025112	4.861588	5.188637
3	4.036077	3.842225	4.229929

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.748217	-0.944419	-0.552015
1	3	0.240818	0.019463	0.462173
2	3	0.989035	0.735054	1.243016

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.58445447	3.91689089	18.00	<.0001
Error	112	24.37839655	0.21766425		
Corrected Total	117	43.96285102			

R-Square	Coeff Var	Root MSE	logaval Mean
0.445477	11.90997	0.466545	3.917264

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	2.93181061	2.93181061	13.47	0.0004
SEXC	1	2.23590055	2.23590055	10.27	0.0018
UCPDGR1	1	0.08606345	0.08606345	0.40	0.5308
TRTPN	2	14.33067987	7.16533994	32.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.56255950	0.56255950	2.58	0.1107
SEXC	1	1.96520201	1.96520201	9.03	0.0033
UCPDGR1	1	0.00544433	0.00544433	0.03	0.8746
TRTPN	2	14.33067987	7.16533994	32.92	<.0001

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.80254342	1
2	4.52159904	2
3	3.55008689	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0330
2	<.0001		<.0001
3	0.0330	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.802543	3.687647	3.917439
2	4.521599	4.350787	4.692411
3	3.550087	3.347864	3.752310

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.719056	-0.923654	-0.514457
1	3	0.252457	0.020815	0.484098
2	3	0.971512	0.706436	1.236588

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	21.27474590	4.25494918	12.65	<.0001
Error	112	37.66486122	0.33629340		
Corrected Total	117	58.93960712			

R-Square	Coeff Var	Root MSE	logaval Mean
0.360958	6.632629	0.579908	8.743262

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	19.26150433	19.26150433	57.28	<.0001
SEXC	1	0.27103023	0.27103023	0.81	0.3713
UCPDGR1	1	0.15125432	0.15125432	0.45	0.5038
TRTPN	2	1.59095701	0.79547851	2.37	0.0986

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	18.13696470	18.13696470	53.93	<.0001
SEXC	1	0.42661705	0.42661705	1.27	0.2624
UCPDGR1	1	0.19604049	0.19604049	0.58	0.4468
TRTPN	2	1.59095701	0.79547851	2.37	0.0986

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.75248836	1
2	8.59373223	2
3	8.95360890	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.2185	0.1685
2	0.2185		0.0319
3	0.1685	0.0319	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.752488	8.610249	8.894728
2	8.593732	8.382359	8.805105
3	8.953609	8.702400	9.204817

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.158756	-0.095457	0.412969
1	3	-0.201121	-0.488658	0.086417
2	3	-0.359877	-0.687947	-0.031806

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	25.92928654	5.18585731	15.92	<.0001
Error	110	35.83159283	0.32574175		
Corrected Total	115	61.76087937			

R-Square	Coeff Var	Root MSE	logaval Mean
0.419834	6.948486	0.570738	8.213845

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.32028614	23.32028614	71.59	<.0001
SEXC	1	0.99015607	0.99015607	3.04	0.0840
UCPDGR1	1	0.03447420	0.03447420	0.11	0.7456
TRTPN	2	1.58437014	0.79218507	2.43	0.0926

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	18.60863070	18.60863070	57.13	<.0001
SEXC	1	1.12868572	1.12868572	3.46	0.0654
UCPDGR1	1	0.05969410	0.05969410	0.18	0.6694
TRTPN	2	1.58437014	0.79218507	2.43	0.0926

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.22829054	1
2	8.07946416	2
3	8.43893411	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.2423	0.1446
2	0.2423		0.0295
3	0.1446	0.0295	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.228291	8.085965	8.370616
2	8.079464	7.872103	8.286825
3	8.438934	8.191387	8.686481

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.148826	-0.102046	0.399698
1	3	-0.210644	-0.494752	0.073465
2	3	-0.359470	-0.682486	-0.036454

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	130.3986503	26.0797301	63.00	<.0001
Error	112	46.3672139	0.4139930		
Corrected Total	117	176.7658643			

R-Square	Coeff Var	Root MSE	logaval Mean
0.737691	10.84572	0.643423	5.932504

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	32.75014226	32.75014226	79.11	<.0001
SEXC	1	0.73563705	0.73563705	1.78	0.1852
UCPDGR1	1	0.94129064	0.94129064	2.27	0.1344
TRTPN	2	95.97158038	47.98579019	115.91	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	38.27611707	38.27611707	92.46	<.0001
SEXC	1	0.31361719	0.31361719	0.76	0.3860
UCPDGR1	1	0.57920751	0.57920751	1.40	0.2394
TRTPN	2	95.97158038	47.98579019	115.91	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.41065580	1
2	7.48058721	2
3	5.38324580	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8652
2	<.0001		<.0001
3	0.8652	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.410656	5.252795	5.568517
2	7.480587	7.247156	7.714019
3	5.383246	5.104526	5.661965



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.069931	-2.350802	-1.789061
1	3	0.027410	-0.291704	0.346524
2	3	2.097341	1.734198	2.460485

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	77.5301691	15.5060338	20.83	<.0001
Error	77	57.3313585	0.7445631		
Corrected Total	82	134.8615276			

R-Square	Coeff Var	Root MSE	logaval Mean
0.574887	25.87035	0.862881	3.335404

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	2.34251029	2.34251029	3.15	0.0801
SEXC	1	0.44561949	0.44561949	0.60	0.4415
UCPDGR1	1	2.53772998	2.53772998	3.41	0.0687
TRTPN	2	72.20430936	36.10215468	48.49	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.92224524	1.92224524	2.58	0.1122
SEXC	1	0.76281228	0.76281228	1.02	0.3146
UCPDGR1	1	0.31239238	0.31239238	0.42	0.5191
TRTPN	2	72.20430936	36.10215468	48.49	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.68606003	1
2	4.58457158	2
3	2.31323978	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2508
2	<.0001		<.0001
3	0.2508	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.686060	2.424272	2.947849
2	4.584572	4.262574	4.906569
3	2.313240	1.723736	2.902744

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.898512	-2.311966	-1.485057
1	3	0.372820	-0.268764	1.014405
2	3	2.271332	1.604387	2.938276

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.2715785	16.0543157	22.28	<.0001
Error	75	54.0509001	0.7206787		
Corrected Total	80	134.3224786			

R-Square	Coeff Var	Root MSE	logaval Mean
0.597603	30.02349	0.848928	2.827546

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.10885694	4.10885694	5.70	0.0195
SEXC	1	0.07850557	0.07850557	0.11	0.7423
UCPDGR1	1	2.57138612	2.57138612	3.57	0.0628
TRTPN	2	73.51282986	36.75641493	51.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.37963235	3.37963235	4.69	0.0335
SEXC	1	0.00035440	0.00035440	0.00	0.9824
UCPDGR1	1	0.31686929	0.31686929	0.44	0.5093
TRTPN	2	73.51282986	36.75641493	51.00	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.16026619	1
2	4.10598675	2
3	1.86797043	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3608
2	<.0001		<.0001
3	0.3608	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.160266	1.894580	2.425952
2	4.105987	3.788786	4.423187
3	1.867970	1.290312	2.445628

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.945721	-2.356938	-1.534503
1	3	0.292296	-0.340996	0.925588
2	3	2.238016	1.583706	2.892326

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	82
Number of Observations Used	82

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10.71436905	2.14287381	9.51	<.0001
Error	76	17.11938169	0.22525502		
Corrected Total	81	27.83375074			

R-Square	Coeff Var	Root MSE	logaval Mean
0.384942	8.932639	0.474610	5.313216

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	6.94423841	6.94423841	30.83	<.0001
SEXC	1	0.01186224	0.01186224	0.05	0.8191
UCPDGR1	1	0.35286561	0.35286561	1.57	0.2146
TRTPN	2	3.40540280	1.70270140	7.56	0.0010

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.57225403	6.57225403	29.18	<.0001
SEXC	1	0.01124411	0.01124411	0.05	0.8238
UCPDGR1	1	0.15974419	0.15974419	0.71	0.4024
TRTPN	2	3.40540280	1.70270140	7.56	0.0010

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.18870826	1
2	5.57881265	2
3	5.02660783	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.0013	0.3853
2	0.0013		0.0041
3	0.3853	0.0041	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.188708	5.039170	5.338247
2	5.578813	5.401328	5.756298
3	5.026608	4.693010	5.360205

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.390104	-0.623223	-0.156986
1	3	0.162100	-0.207628	0.531829
2	3	0.552205	0.181101	0.923309

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	15.70357882	3.14071576	14.12	<.0001
Error	75	16.68517061	0.22246894		
Corrected Total	80	32.38874942			

R-Square	Coeff Var	Root MSE	logaval Mean
0.484847	9.817395	0.471666	4.804392

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.32184596	11.32184596	50.89	<.0001
SEXC	1	0.37680041	0.37680041	1.69	0.1971
UCPDGR1	1	0.44839075	0.44839075	2.02	0.1598
TRTPN	2	3.55654170	1.77827085	7.99	0.0007

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	8.76465240	8.76465240	39.40	<.0001
SEXC	1	0.32909963	0.32909963	1.48	0.2277
UCPDGR1	1	0.23087583	0.23087583	1.04	0.3116
TRTPN	2	3.55654170	1.77827085	7.99	0.0007

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.68855096	1
2	5.09719591	2
3	4.55115987	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.0008	0.4528
2	0.0008		0.0039
3	0.4528	0.0039	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.688551	4.537686	4.839416
2	5.097196	4.921120	5.273271
3	4.551160	4.225259	4.877061

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means***Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.408645	-0.641008	-0.176282
1	3	0.137391	-0.225248	0.500030
2	3	0.546036	0.180498	0.911574

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.62339440	12.72467888	29.01	<.0001
Error	77	33.76885812	0.43855660		
Corrected Total	82	97.39225252			

R-Square	Coeff Var	Root MSE	logaval Mean
0.653270	29.64909	0.662236	2.233580

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.91125085	3.91125085	8.92	0.0038
SEXC	1	0.93794281	0.93794281	2.14	0.1477
UCPDGR1	1	1.86516109	1.86516109	4.25	0.0426
TRTPN	2	56.90903965	28.45451982	64.88	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.64096915	3.64096915	8.30	0.0051
SEXC	1	1.12584802	1.12584802	2.57	0.1132
UCPDGR1	1	0.13523045	0.13523045	0.31	0.5803
TRTPN	2	56.90903965	28.45451982	64.88	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.57431721	1
2	3.34293426	2
3	1.67194443	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6943
2	<.0001		<.0001
3	0.6943	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.574317	1.373427	1.775208
2	3.342934	3.095791	3.590078
3	1.671944	1.219138	2.124751

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.768617	-2.085941	-1.451294
1	3	-0.097627	-0.590331	0.395076
2	3	1.670990	1.158673	2.183307

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	65.76987614	13.15397523	34.07	<.0001
Error	75	28.95333398	0.38604445		
Corrected Total	80	94.72321012			

R-Square	Coeff Var	Root MSE	logaval Mean
0.694337	36.09023	0.621325	1.721587

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.88752840	4.88752840	12.66	0.0007
SEXC	1	0.00451797	0.00451797	0.01	0.9141
UCPDGR1	1	1.55196582	1.55196582	4.02	0.0486
TRTPN	2	59.32586395	29.66293198	76.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	4.76306610	4.76306610	12.34	0.0008
SEXC	1	0.09806658	0.09806658	0.25	0.6157
UCPDGR1	1	0.04313036	0.04313036	0.11	0.7391
TRTPN	2	59.32586395	29.66293198	76.84	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.03616613	1
2	2.86637973	2
3	1.21516532	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4445
2	<.0001		<.0001
3	0.4445	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.036166	0.841935	1.230398
2	2.866380	2.634261	3.098499
3	1.215165	0.791847	1.638484

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.830214	-2.131148	-1.529280
1	3	-0.178999	-0.642907	0.284909
2	3	1.651214	1.171795	2.130634

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.54091005	3.70818201	15.72	<.0001
Error	77	18.16693897	0.23593427		
Corrected Total	82	36.70784902			

R-Square	Coeff Var	Root MSE	logaval Mean
0.505094	7.566099	0.485731	6.419829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.27676745	7.27676745	30.84	<.0001
SEXC	1	0.07567089	0.07567089	0.32	0.5728
UCPDGR1	1	0.52044230	0.52044230	2.21	0.1416
TRTPN	2	10.66802941	5.33401470	22.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.45088873	5.45088873	23.10	<.0001
SEXC	1	0.13890622	0.13890622	0.59	0.4452
UCPDGR1	1	0.14174015	0.14174015	0.60	0.4407
TRTPN	2	10.66802941	5.33401470	22.61	<.0001

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.22116915	1
2	6.87709589	2
3	5.82971928	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0351
2	<.0001		<.0001
3	0.0351	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.221169	6.073896	6.368442
2	6.877096	6.695854	7.058338
3	5.829719	5.495287	6.164152

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.655927	-0.888696	-0.423157
1	3	0.391450	0.028138	0.754762
2	3	1.047377	0.669386	1.425368

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	33.13407647	6.62681529	10.48	<.0001
Error	77	48.66764790	0.63204738		
Corrected Total	82	81.80172437			

R-Square	Coeff Var	Root MSE	logaval Mean
0.405054	36.59237	0.795014	2.172623

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	2.63146159	2.63146159	4.16	0.0447
SEXC	1	1.87283108	1.87283108	2.96	0.0892
UCPDGR1	1	0.81662741	0.81662741	1.29	0.2592
TRTPN	2	27.81315638	13.90657819	22.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.72250718	2.72250718	4.31	0.0413
SEXC	1	2.08061061	2.08061061	3.29	0.0735
UCPDGR1	1	0.07305734	0.07305734	0.12	0.7348
TRTPN	2	27.81315638	13.90657819	22.00	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.72361490	1
2	2.92709363	2
3	1.61058794	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7043
2	<.0001		<.0001
3	0.7043	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.723615	1.482335	1.964894
2	2.927094	2.630604	3.223583
3	1.610588	1.067951	2.153225

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.203479	-1.584429	-0.822528
1	3	0.113027	-0.477816	0.703870
2	3	1.316506	0.703237	1.929775

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	35.44429140	7.08885828	11.65	<.0001
Error	75	45.64785615	0.60863808		
Corrected Total	80	81.09214755			

R-Square	Coeff Var	Root MSE	logaval Mean
0.437087	47.09817	0.780153	1.656439

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.02161656	5.02161656	8.25	0.0053
SEXC	1	0.13418840	0.13418840	0.22	0.6400
UCPDGR1	1	1.33045228	1.33045228	2.19	0.1435
TRTPN	2	28.95803416	14.47901708	23.79	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.65661930	5.65661930	9.29	0.0032
SEXC	1	0.22232546	0.22232546	0.37	0.5474
UCPDGR1	1	0.22393180	0.22393180	0.37	0.5460
TRTPN	2	28.95803416	14.47901708	23.79	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.19246923	1
2	2.44828553	2
3	1.17604889	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9553
2	<.0001		<.0001
3	0.9553	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.192469	0.948365	1.436573
2	2.448286	2.157108	2.739463
3	1.176049	0.645259	1.706839

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.255816	-1.633920	-0.877713
1	3	0.016420	-0.565399	0.598239
2	3	1.272237	0.671764	1.872710

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.48586868	4.09717374	9.83	<.0001
Error	77	32.08961657	0.41674827		
Corrected Total	82	52.57548525			

R-Square	Coeff Var	Root MSE	logaval Mean
0.389647	13.40128	0.645560	4.817156

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.78727514	7.78727514	18.69	<.0001
SEXC	1	0.19913757	0.19913757	0.48	0.4915
UCPDGR1	1	1.16356980	1.16356980	2.79	0.0988
TRTPN	2	11.33588618	5.66794309	13.60	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.74893610	10.74893610	25.79	<.0001
SEXC	1	0.15367489	0.15367489	0.37	0.5455
UCPDGR1	1	0.49743497	0.49743497	1.19	0.2780
TRTPN	2	11.33588618	5.66794309	13.60	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.52080935	1
2	5.31693198	2
3	4.56112173	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8703
2	<.0001		0.0034
3	0.8703	0.0034	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.520809	4.321394	4.720224
2	5.316932	5.075048	5.558816
3	4.561122	4.116756	5.005488

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.796123	-1.111724	-0.480521
1	3	-0.040312	-0.530246	0.449621
2	3	0.755810	0.258714	1.252906

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.99034592	4.59806918	11.17	<.0001
Error	75	30.87496140	0.41166615		
Corrected Total	80	53.86530732			

R-Square	Coeff Var	Root MSE	logaval Mean
0.426812	14.90355	0.641612	4.305096

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.76740730	9.76740730	23.73	<.0001
SEXC	1	0.14178106	0.14178106	0.34	0.5591
UCPDGR1	1	1.00940336	1.00940336	2.45	0.1216
TRTPN	2	12.07175420	6.03587710	14.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	11.14898676	11.14898676	27.08	<.0001
SEXC	1	0.03920340	0.03920340	0.10	0.7585
UCPDGR1	1	0.34260470	0.34260470	0.83	0.3645
TRTPN	2	12.07175420	6.03587710	14.66	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.00094220	1
2	4.83722268	2
3	4.07423002	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7651
2	<.0001		0.0029
3	0.7651	0.0029	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.000942	3.795406	4.206479
2	4.837223	4.597160	5.077286
3	4.074230	3.635512	4.512949

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.836280	-1.154405	-0.518156
1	3	-0.073288	-0.560118	0.413542
2	3	0.762993	0.270150	1.255835

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.2826712	16.0565342	16.74	<.0001
Error	77	73.8481166	0.9590664		
Corrected Total	82	154.1307878			

R-Square	Coeff Var	Root MSE	logaval Mean
0.520874	26.16460	0.979319	3.742917

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	13.87041317	13.87041317	14.46	0.0003
SEXC	1	2.10124900	2.10124900	2.19	0.1429
UCPDGR1	1	0.30252586	0.30252586	0.32	0.5760
TRTPN	2	64.00848316	32.00424158	33.37	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.84050371	10.84050371	11.30	0.0012
SEXC	1	3.30423128	3.30423128	3.45	0.0673
UCPDGR1	1	0.27410187	0.27410187	0.29	0.5945
TRTPN	2	64.00848316	32.00424158	33.37	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.02231512	1
2	4.90411211	2
3	3.16298853	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6992
2	<.0001		<.0001
3	0.6992	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.022315	2.725454	3.319176
2	4.904112	4.538769	5.269455
3	3.162989	2.498212	3.827765

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.881797	-2.351343	-1.412251
1	3	-0.140673	-0.862871	0.581525
2	3	1.741124	0.989019	2.493228

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	81.3294935	16.2658987	17.94	<.0001
Error	75	67.9872019	0.9064960		
Corrected Total	80	149.3166954			

R-Square	Coeff Var	Root MSE	logaval Mean
0.544678	29.45320	0.952101	3.232589

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	13.27823331	13.27823331	14.65	0.0003
SEXC	1	0.97325382	0.97325382	1.07	0.3035
UCPDGR1	1	0.13991046	0.13991046	0.15	0.6955
TRTPN	2	66.93809593	33.46904796	36.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	12.55106266	12.55106266	13.85	0.0004
SEXC	1	2.15620293	2.15620293	2.38	0.1272
UCPDGR1	1	0.55012561	0.55012561	0.61	0.4384
TRTPN	2	66.93809593	33.46904796	36.92	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.47450212	1
2	4.42006760	2
3	2.67073530	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5805
2	<.0001		<.0001
3	0.5805	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.474502	2.178086	2.770918
2	4.420068	4.064402	4.775733
3	2.670735	2.025753	3.315717

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.945565	-2.406670	-1.484461
1	3	-0.196233	-0.900576	0.508110
2	3	1.749332	1.019324	2.479341

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	27.93892465	5.58778493	13.88	<.0001
Error	77	31.00297922	0.40263609		
Corrected Total	82	58.94190387			

R-Square	Coeff Var	Root MSE	logaval Mean
0.474008	7.830637	0.634536	8.103251

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.12528872	12.12528872	30.11	<.0001
SEXC	1	0.00002071	0.00002071	0.00	0.9943
UCPDGR1	1	0.88061592	0.88061592	2.19	0.1432
TRTPN	2	14.93299931	7.46649965	18.54	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	13.40643872	13.40643872	33.30	<.0001
SEXC	1	0.00350918	0.00350918	0.01	0.9259
UCPDGR1	1	0.15099270	0.15099270	0.38	0.5421
TRTPN	2	14.93299931	7.46649965	18.54	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.74927075	1
2	8.67895160	2
3	7.98723034	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3152
2	<.0001		0.0058
3	0.3152	0.0058	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.749271	7.555230	7.943312
2	8.678952	8.442305	8.915599
3	7.987230	7.557658	8.416803

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.929681	-1.235414	-0.623947
1	3	-0.237960	-0.706642	0.230722
2	3	0.691721	0.206337	1.177106

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	31.48905035	6.29781007	15.77	<.0001
Error	75	29.95540759	0.39940543		
Corrected Total	80	61.44445794			

R-Square	Coeff Var	Root MSE	logaval Mean
0.512480	8.323963	0.631985	7.592361

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	14.68412628	14.68412628	36.76	<.0001
SEXC	1	0.66586752	0.66586752	1.67	0.2006
UCPDGR1	1	0.74170543	0.74170543	1.86	0.1770
TRTPN	2	15.39735111	7.69867555	19.28	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	11.55573129	11.55573129	28.93	<.0001
SEXC	1	0.34450134	0.34450134	0.86	0.3560
UCPDGR1	1	0.06676813	0.06676813	0.17	0.6838
TRTPN	2	15.39735111	7.69867555	19.28	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.24038466	1
2	8.19516328	2
3	7.49218356	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2872
2	<.0001		0.0050
3	0.2872	0.0050	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.240385	7.040844	7.439925
2	8.195163	7.959451	8.430876
3	7.492184	7.064406	7.919961

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.954779	-1.262904	-0.646653
1	3	-0.251799	-0.719769	0.216172
2	3	0.702980	0.219376	1.186583

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.93174761	3.78634952	11.79	<.0001
Error	77	24.72610770	0.32111828		
Corrected Total	82	43.65785531			

R-Square	Coeff Var	Root MSE	logaval Mean
0.433639	10.48417	0.566673	5.405034

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.31144444	8.31144444	25.88	<.0001
SEXC	1	0.00543778	0.00543778	0.02	0.8968
UCPDGR1	1	1.23492770	1.23492770	3.85	0.0535
TRTPN	2	9.37993769	4.68996884	14.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.43657448	9.43657448	29.39	<.0001
SEXC	1	0.00304851	0.00304851	0.01	0.9226
UCPDGR1	1	0.55800971	0.55800971	1.74	0.1913
TRTPN	2	9.37993769	4.68996884	14.61	<.0001

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.15442462	1
2	5.86580961	2
3	5.15719299	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9895
2	<.0001		0.0017
3	0.9895	0.0017	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.154425	4.982563	5.326286
2	5.865810	5.654542	6.077077
3	5.157193	4.772476	5.541910

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.711385	-0.983015	-0.439755
1	3	-0.002768	-0.421357	0.415820
2	3	0.708617	0.274161	1.143072

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.58346161	4.11669232	11.76	<.0001
Error	75	26.24674851	0.34995665		
Corrected Total	80	46.83021012			

R-Square	Coeff Var	Root MSE	logaval Mean
0.439534	12.02772	0.591571	4.918400

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.41322573	10.41322573	29.76	<.0001
SEXC	1	0.23921584	0.23921584	0.68	0.4110
UCPDGR1	1	0.85967475	0.85967475	2.46	0.1212
TRTPN	2	9.07134528	4.53567264	12.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.43229582	9.43229582	26.95	<.0001
SEXC	1	0.19528997	0.19528997	0.56	0.4574
UCPDGR1	1	0.31863682	0.31863682	0.91	0.3430
TRTPN	2	9.07134528	4.53567264	12.96	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.68095031	1
2	5.38152318	2
3	4.65717362	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9142
2	<.0001		0.0021
3	0.9142	0.0021	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.680950	4.495934	4.865966
2	5.381523	5.160854	5.602193
3	4.657174	4.256618	5.057730

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.700573	-0.987454	-0.413691
1	3	0.023777	-0.414199	0.461752
2	3	0.724350	0.271452	1.177247

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.9640124	12.7928025	22.67	<.0001
Error	77	43.4523559	0.5643163		
Corrected Total	82	107.4163683			

R-Square	Coeff Var	Root MSE	logaval Mean
0.595477	11.49237	0.751210	6.536599

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	14.94266838	14.94266838	26.48	<.0001
SEXC	1	0.81598018	0.81598018	1.45	0.2329
UCPDGR1	1	2.38038521	2.38038521	4.22	0.0434
TRTPN	2	45.82497859	22.91248929	40.60	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.96453860	22.96453860	40.69	<.0001
SEXC	1	0.59228606	0.59228606	1.05	0.3088
UCPDGR1	1	0.46105576	0.46105576	0.82	0.3689
TRTPN	2	45.82497859	22.91248929	40.60	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.89749652	1
2	7.53539898	2
3	6.29199405	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1733
2	<.0001		<.0001
3	0.1733	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.897497	5.666801	6.128192
2	7.535399	7.253857	7.816941
3	6.291994	5.772289	6.811699

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.637902	-2.003837	-1.271968
1	3	-0.394498	-0.966014	0.177019
2	3	1.243405	0.663359	1.823451

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	82
Number of Observations Used	82

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	49.20455543	9.84091109	16.87	<.0001
Error	76	44.33029396	0.58329334		
Corrected Total	81	93.53484939			

R-Square	Coeff Var	Root MSE	logaval Mean
0.526056	34.83654	0.763736	2.192343

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	21.34531952	21.34531952	36.59	<.0001
SEXC	1	0.00084305	0.00084305	0.00	0.9698
UCPDGR1	1	0.12416717	0.12416717	0.21	0.6458
TRTPN	2	27.73422567	13.86711284	23.77	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	13.50875842	13.50875842	23.16	<.0001
SEXC	1	0.36901252	0.36901252	0.63	0.4289
UCPDGR1	1	0.01451787	0.01451787	0.02	0.8751
TRTPN	2	27.73422567	13.86711284	23.77	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.36211099	1
2	2.41379677	2
3	0.48701656	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.7814	<.0001
2	0.7814		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.362111	2.126067	2.598155
2	2.413797	2.128061	2.699532
3	0.487017	-0.034573	1.008606

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.051686	-0.421422	0.318050
1	3	1.875094	1.307922	2.442267
2	3	1.926780	1.335055	2.518506

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	52.23836739	10.44767348	17.84	<.0001
Error	75	43.92263581	0.58563514		
Corrected Total	80	96.16100320			

R-Square	Coeff Var	Root MSE	logaval Mean
0.543239	45.14707	0.765268	1.695056

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.34197888	23.34197888	39.86	<.0001
SEXC	1	0.02334443	0.02334443	0.04	0.8423
UCPDGR1	1	0.23841566	0.23841566	0.41	0.5254
TRTPN	2	28.63462842	14.31731421	24.45	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	14.28358674	14.28358674	24.39	<.0001
SEXC	1	0.09149988	0.09149988	0.16	0.6938
UCPDGR1	1	0.05295732	0.05295732	0.09	0.7645
TRTPN	2	28.63462842	14.31731421	24.45	<.0001



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*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.88528664	1
2	1.92297651	2
3	-0.02006354	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.8402	<.0001
2	0.8402		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.885287	1.647039	2.123534
2	1.922977	1.635816	2.210137
3	-0.020064	-0.539777	0.499650

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.037690	-0.408876	0.333496
1	3	1.905350	1.337648	2.473052
2	3	1.943040	1.352816	2.533264

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	53.4115208	10.6823042	13.05	<.0001
Error	77	63.0342605	0.8186268		
Corrected Total	82	116.4457813			

R-Square	Coeff Var	Root MSE	logaval Mean
0.458681	19.10675	0.904780	4.735394

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	20.75192228	20.75192228	25.35	<.0001
SEXC	1	2.25302353	2.25302353	2.75	0.1012
UCPDGR1	1	0.27273123	0.27273123	0.33	0.5655
TRTPN	2	30.13384375	15.06692188	18.41	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.51625547	23.51625547	28.73	<.0001
SEXC	1	2.65514977	2.65514977	3.24	0.0756
UCPDGR1	1	0.02744272	0.02744272	0.03	0.8552
TRTPN	2	30.13384375	15.06692188	18.41	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.20489027	1
2	5.51473002	2
3	4.47068009	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4308
2	<.0001		0.0036
3	0.4308	0.0036	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.204890	3.930221	4.479560
2	5.514730	5.177353	5.852107
3	4.470680	3.856936	5.084424

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.309840	-1.743926	-0.875754
1	3	-0.265790	-0.934082	0.402503
2	3	1.044050	0.351022	1.737078

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	87.5162255	17.5032451	29.22	<.0001
Error	77	46.1234747	0.5990062		
Corrected Total	82	133.6397002			

R-Square	Coeff Var	Root MSE	logaval Mean
0.654867	89.73280	0.773955	0.862511

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	13.83830517	13.83830517	23.10	<.0001
SEXC	1	0.35673261	0.35673261	0.60	0.4426
UCPDGR1	1	0.96136845	0.96136845	1.60	0.2090
TRTPN	2	72.35981930	36.17990965	60.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.21189147	15.21189147	25.40	<.0001
SEXC	1	0.00157433	0.00157433	0.00	0.9592
UCPDGR1	1	0.11336282	0.11336282	0.19	0.6648
TRTPN	2	72.35981930	36.17990965	60.40	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.38298081	1
2	2.07311086	2
3	-0.64400564	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0006
2	<.0001		<.0001
3	0.0006	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.382981	0.147283	0.618678
2	2.073111	1.784186	2.362036
3	-0.644006	-1.170584	-0.117427



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.690130	-2.062892	-1.317369
1	3	1.026986	0.452216	1.601757
2	3	2.717117	2.123777	3.310456

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	93.3512896	18.6702579	33.03	<.0001
Error	75	42.3939571	0.5652528		
Corrected Total	80	135.7452467			

R-Square	Coeff Var	Root MSE	logaval Mean
0.687695	196.4724	0.751833	0.382666

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	17.64896638	17.64896638	31.22	<.0001
SEXC	1	1.95564003	1.95564003	3.46	0.0668
UCPDGR1	1	0.87373467	0.87373467	1.55	0.2176
TRTPN	2	72.87294856	36.43647428	64.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	18.18055617	18.18055617	32.16	<.0001
SEXC	1	0.37459562	0.37459562	0.66	0.4182
UCPDGR1	1	0.06939995	0.06939995	0.12	0.7270
TRTPN	2	72.87294856	36.43647428	64.46	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.10852910	1
2	1.61725261	2
3	-1.09641295	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0008
2	<.0001		<.0001
3	0.0008	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.108529	-0.345838	0.128780
2	1.617253	1.336278	1.898227
3	-1.096413	-1.607302	-0.585524

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.725782	-2.094483	-1.357080
1	3	0.987884	0.426010	1.549758
2	3	2.713666	2.137720	3.289611

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17.33232544	3.46646509	9.55	<.0001
Error	77	27.95898181	0.36310366		
Corrected Total	82	45.29130725			

R-Square	Coeff Var	Root MSE	logaval Mean
0.382685	13.05326	0.602581	4.616325

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.58246619	3.58246619	9.87	0.0024
SEXC	1	0.11308553	0.11308553	0.31	0.5784
UCPDGR1	1	0.07113074	0.07113074	0.20	0.6593
TRTPN	2	13.56564298	6.78282149	18.68	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.79658554	1.79658554	4.95	0.0291
SEXC	1	0.29608497	0.29608497	0.82	0.3693
UCPDGR1	1	0.06690326	0.06690326	0.18	0.6689
TRTPN	2	13.56564298	6.78282149	18.68	<.0001



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.32267206	1
2	5.16252964	2
3	4.19723253	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5765
2	<.0001		<.0001
3	0.5765	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.322672	4.139930	4.505414
2	5.162530	4.936209	5.388850
3	4.197233	3.786723	4.607742

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means***Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.839858	-1.130505	-0.549210
1	3	0.125440	-0.319844	0.570724
2	3	0.965297	0.498222	1.432372

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



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**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.75579640	3.75115928	9.76	<.0001
Error	75	28.83813861	0.38450851		
Corrected Total	80	47.59393501			

R-Square	Coeff Var	Root MSE	logaval Mean
0.394080	15.06137	0.620088	4.117072

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.63778521	4.63778521	12.06	0.0009
SEXC	1	0.66408625	0.66408625	1.73	0.1928
UCPDGR1	1	0.16182049	0.16182049	0.42	0.5185
TRTPN	2	13.29210445	6.64605222	17.28	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.57888036	1.57888036	4.11	0.0463
SEXC	1	0.48619045	0.48619045	1.26	0.2644
UCPDGR1	1	0.01296506	0.01296506	0.03	0.8548
TRTPN	2	13.29210445	6.64605222	17.28	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.85141487	1
2	4.68870679	2
3	3.73762497	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6230
2	<.0001		0.0002
3	0.6230	0.0002	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.851415	3.658514	4.044316
2	4.688707	4.454783	4.922631
3	3.737625	3.316855	4.158395

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.837292	-1.139220	-0.535364
1	3	0.113790	-0.345438	0.573018
2	3	0.951082	0.472184	1.429979

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.09942638	2.41988528	4.21	0.0020
Error	77	44.27448452	0.57499331		
Corrected Total	82	56.37391090			

R-Square	Coeff Var	Root MSE	logaval Mean
0.214628	8.707378	0.758283	8.708513

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.07231507	11.07231507	19.26	<.0001
SEXC	1	0.03843142	0.03843142	0.07	0.7967
UCPDGR1	1	0.54810367	0.54810367	0.95	0.3320
TRTPN	2	0.44057623	0.22028811	0.38	0.6830

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.63199259	10.63199259	18.49	<.0001
SEXC	1	0.01549404	0.01549404	0.03	0.8700
UCPDGR1	1	0.52351027	0.52351027	0.91	0.3430
TRTPN	2	0.44057623	0.22028811	0.38	0.6830

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.71209091	1
2	8.64446108	2
3	8.90003290	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.7130	0.5096
2	0.7130		0.3851
3	0.5096	0.3851	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.712091	8.481465	8.942717
2	8.644461	8.361446	8.927476
3	8.900033	8.382346	9.417720

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.067630	-0.297152	0.432411
1	3	-0.187942	-0.752741	0.376857
2	3	-0.255572	-0.838214	0.327070

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	9.34025361	1.86805072	3.08	0.0139
Error	75	45.50069485	0.60667593		
Corrected Total	80	54.84094846			

R-Square	Coeff Var	Root MSE	logaval Mean
0.170315	9.496988	0.778894	8.201485

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.30694122	8.30694122	13.69	0.0004
SEXC	1	0.23801425	0.23801425	0.39	0.5330
UCPDGR1	1	0.43094868	0.43094868	0.71	0.4020
TRTPN	2	0.36434945	0.18217473	0.30	0.7415

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.40817233	6.40817233	10.56	0.0017
SEXC	1	0.57710911	0.57710911	0.95	0.3325
UCPDGR1	1	0.44932379	0.44932379	0.74	0.3922
TRTPN	2	0.36434945	0.18217473	0.30	0.7415

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.24095412	1
2	8.14690541	2
3	8.36731212	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.6219	0.6650
2	0.6219		0.4643
3	0.6650	0.4643	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.240954	7.996860	8.485049
2	8.146905	7.856406	8.437405
3	8.367312	7.838964	8.895661

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.094049	-0.284330	0.472428
1	3	-0.126358	-0.705282	0.452566
2	3	-0.220407	-0.817402	0.376588

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	83
Number of Observations Used	83

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	67.8365792	13.5673158	12.77	<.0001
Error	77	81.8100217	1.0624678		
Corrected Total	82	149.6466009			

R-Square	Coeff Var	Root MSE	logaval Mean
0.453312	15.51727	1.030761	6.642668

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	24.97153135	24.97153135	23.50	<.0001
SEXC	1	0.17435806	0.17435806	0.16	0.6865
UCPDGR1	1	1.65032859	1.65032859	1.55	0.2164
TRTPN	2	41.04036118	20.52018059	19.31	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.87378211	23.87378211	22.47	<.0001
SEXC	1	0.28182568	0.28182568	0.27	0.6080
UCPDGR1	1	0.28731139	0.28731139	0.27	0.6045
TRTPN	2	41.04036118	20.52018059	19.31	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.14272140	1
2	7.58944779	2
3	5.93594919	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5925
2	<.0001		<.0001
3	0.5925	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.142721	5.829871	6.455571
2	7.589448	7.205092	7.973804
3	5.935949	5.232450	6.639448

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.446726	-1.940678	-0.952775
1	3	0.206772	-0.559290	0.972834
2	3	1.653499	0.858708	2.448289

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

**Dependent Variable: AVAL**    **Analysis Value**

**Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10756.15391	2151.23078	129.95	<.0001
Error	128	2118.92818	16.55413		
Corrected Total	133	12875.08209			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.835424	55.23836	4.068676	7.365672

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	398.12057	398.12057	24.05	<.0001
SEXC	1	6.33881	6.33881	0.38	0.5371
UCPDGR1	1	25.14655	25.14655	1.52	0.2200
TRTPN	2	10326.54798	5163.27399	311.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	299.83991	299.83991	18.11	<.0001
SEXC	1	12.51419	12.51419	0.76	0.3862
UCPDGR1	1	48.83937	48.83937	2.95	0.0883
TRTPN	2	10326.54798	5163.27399	311.90	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.2010190	1
2	22.1634650	2
3	2.0282839	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.8569
2	<.0001		<.0001
3	0.8569	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.201019	1.255223	3.146815
2	22.163465	20.796630	23.530300
3	2.028284	0.373016	3.683552

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set******Least Squares Means*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-19.962446	-21.612352	-18.312540
1	3	0.172735	-1.719521	2.064991
2	3	20.135181	17.998235	22.272128

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set*****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

**Dependent Variable: AVAL**    **Analysis Value**

**Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4347.053884	869.410777	19.98	<.0001
Error	82	3568.662025	43.520269		
Corrected Total	87	7915.715909			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.549167	63.17030	6.596989	10.44318

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	51.910464	51.910464	1.19	0.2780
SEXC	1	2.600438	2.600438	0.06	0.8075
UCPDGR1	1	20.160864	20.160864	0.46	0.4980
TRTPN	2	4272.382118	2136.191059	49.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	40.888896	40.888896	0.94	0.3352
SEXC	1	54.477641	54.477641	1.25	0.2665
UCPDGR1	1	149.783002	149.783002	3.44	0.0672
TRTPN	2	4272.382118	2136.191059	49.08	<.0001

**Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set****Least Squares Means****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.9858920	1
2	19.6066469	2
3	5.0876247	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.9670
2	<.0001		<.0001
3	0.9670	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.985892	3.032516	6.939268
2	19.606647	17.262969	21.950325
3	5.087625	0.594269	9.580980

*Listing 15.4.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**Least Squares Means*

Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-14.620755	-17.663714	-11.577795
1	3	-0.101733	-4.981201	4.777735
2	3	14.519022	9.506278	19.531766

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	282.7152947	56.5430589	89.66	<.0001
Error	142	89.5464439	0.6306088		
Corrected Total	147	372.2617386			

R-Square	Coeff Var	Root MSE	logaval Mean
0.759453	33.41240	0.794109	2.376689

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.7434418	12.7434418	20.21	<.0001
SEXC	1	0.9137072	0.9137072	1.45	0.2307
UCPDGR1	1	0.0007145	0.0007145	0.00	0.9732
TRTPN	2	269.0574310	134.5287155	213.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	7.7417854	7.7417854	12.28	0.0006
SEXC	1	0.1761882	0.1761882	0.28	0.5979
UCPDGR1	1	0.0186854	0.0186854	0.03	0.8636
TRTPN	2	269.0574310	134.5287155	213.33	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.49312462	1
2	4.70971188	2
3	1.83783782	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0332
2	<.0001		<.0001
3	0.0332	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.493125	1.308355	1.677894
2	4.709712	4.450803	4.968620
3	1.837838	1.577888	2.097788

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.216587	-3.533254	-2.899921
1	3	-0.344713	-0.661498	-0.027928
2	3	2.871874	2.506466	3.237282

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	281.0862010	56.2172402	86.23	<.0001
Error	137	89.3191055	0.6519643		
Corrected Total	142	370.4053066			

R-Square	Coeff Var	Root MSE	logaval Mean
0.758861	43.19963	0.807443	1.869097

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	18.0186696	18.0186696	27.64	<.0001
SEXC	1	4.2188119	4.2188119	6.47	0.0121
UCPDGR1	1	0.0029659	0.0029659	0.00	0.9463
TRTPN	2	258.8457537	129.4228768	198.51	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.6911680	6.6911680	10.26	0.0017
SEXC	1	2.6981278	2.6981278	4.14	0.0438
UCPDGR1	1	0.0004372	0.0004372	0.00	0.9794
TRTPN	2	258.8457537	129.4228768	198.51	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.00054393	1
2	4.20601256	2
3	1.34894670	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0375
2	<.0001		<.0001
3	0.0375	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.000544	0.808782	1.192306
2	4.206013	3.938873	4.473152
3	1.348947	1.080944	1.616949

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.205469	-3.532844	-2.878093
1	3	-0.348403	-0.676316	-0.020489
2	3	2.857066	2.479864	3.234267

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	37.22727469	7.44545494	47.47	<.0001
Error	137	21.49007214	0.15686184		
Corrected Total	142	58.71734683			

R-Square	Coeff Var	Root MSE	logaval Mean
0.634008	8.243673	0.396058	4.804386

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	22.24913736	22.24913736	141.84	<.0001
SEXC	1	0.00444879	0.00444879	0.03	0.8665
UCPDGR1	1	0.65688265	0.65688265	4.19	0.0426
TRTPN	2	14.31680589	7.15840295	45.64	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.41189264	23.41189264	149.25	<.0001
SEXC	1	0.00008033	0.00008033	0.00	0.9820
UCPDGR1	1	0.64441051	0.64441051	4.11	0.0446
TRTPN	2	14.31680589	7.15840295	45.64	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1OHP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.61467787	1
2	5.35028584	2
3	4.63078149	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8447
2	<.0001		<.0001
3	0.8447	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.614678	4.519345	4.710011
2	5.350286	5.219470	5.481102
3	4.630781	4.499889	4.761674



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*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U1OHP24U Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.735608	-0.897168	-0.574048
1	3	-0.016104	-0.178335	0.146127
2	3	0.719504	0.535439	0.903570

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	142
Number of Observations Used	142



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	49.42398452	9.88479690	78.17	<.0001
Error	136	17.19715998	0.12644971		
Corrected Total	141	66.62114450			

R-Square	Coeff Var	Root MSE	logaval Mean
0.741866	8.301983	0.355598	4.283286

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	34.22635020	34.22635020	270.67	<.0001
SEXC	1	0.23300002	0.23300002	1.84	0.1769
UCPDGR1	1	0.61131950	0.61131950	4.83	0.0296
TRTPN	2	14.35331481	7.17665741	56.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.65439555	28.65439555	226.61	<.0001
SEXC	1	0.25854527	0.25854527	2.04	0.1550
UCPDGR1	1	0.62060553	0.62060553	4.91	0.0284
TRTPN	2	14.35331481	7.17665741	56.76	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.09667962	1
2	4.83621837	2
3	4.12061977	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7458
2	<.0001		<.0001
3	0.7458	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.096680	4.010246	4.183113
2	4.836218	4.718801	4.953636
3	4.120620	4.003580	4.237660



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.739539	-0.884701	-0.594377
1	3	-0.023940	-0.169678	0.121798
2	3	0.715599	0.550261	0.880936

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	120.8649792	24.1729958	60.17	<.0001
Error	142	57.0433032	0.4017134		
Corrected Total	147	177.9082824			

R-Square	Coeff Var	Root MSE	logaval Mean
0.679367	33.59116	0.633809	1.886832

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.1441172	10.1441172	25.25	<.0001
SEXC	1	0.0089437	0.0089437	0.02	0.8816
UCPDGR1	1	0.1559259	0.1559259	0.39	0.5343
TRTPN	2	110.5559923	55.2779961	137.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.5889067	5.5889067	13.91	0.0003
SEXC	1	0.2695192	0.2695192	0.67	0.4141
UCPDGR1	1	0.1067930	0.1067930	0.27	0.6069
TRTPN	2	110.5559923	55.2779961	137.61	<.0001



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*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.30941011	1
2	3.37152120	2
3	1.52436401	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0950
2	<.0001		<.0001
3	0.0950	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.309410	1.161923	1.456897
2	3.371521	3.164754	3.578288
3	1.524364	1.316870	1.731858

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.062111	-2.315034	-1.809189
1	3	-0.214954	-0.467793	0.037885
2	3	1.847157	1.555327	2.138987

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	120.2915099	24.0583020	55.93	<.0001
Error	137	58.9327595	0.4301661		
Corrected Total	142	179.2242694			

R-Square	Coeff Var	Root MSE	logaval Mean
0.671179	47.67293	0.655871	1.375771

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.7632101	12.7632101	29.67	<.0001
SEXC	1	1.8305966	1.8305966	4.26	0.0410
UCPDGR1	1	0.0845994	0.0845994	0.20	0.6581
TRTPN	2	105.6131037	52.8065519	122.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.1715765	5.1715765	12.02	0.0007
SEXC	1	1.0777088	1.0777088	2.51	0.1158
UCPDGR1	1	0.1124151	0.1124151	0.26	0.6100
TRTPN	2	105.6131037	52.8065519	122.76	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.82612242	1
2	2.87110009	2
3	1.03254231	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1277
2	<.0001		<.0001
3	0.1277	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.826122	0.670380	0.981865
2	2.871100	2.653959	3.088241
3	1.032542	0.814850	1.250235

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.044978	-2.311055	-1.778901
1	3	-0.206420	-0.472774	0.059934
2	3	1.838558	1.532020	2.145095

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	45.22567185	9.04513437	42.42	<.0001
Error	142	30.27791692	0.21322477		
Corrected Total	147	75.50358877			

R-Square	Coeff Var	Root MSE	logaval Mean
0.598987	7.328241	0.461763	6.301139

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	14.47011811	14.47011811	67.86	<.0001
SEXC	1	1.95547081	1.95547081	9.17	0.0029
UCPDGR1	1	0.03416799	0.03416799	0.16	0.6895
TRTPN	2	28.76591494	14.38295747	67.45	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	11.12608653	11.12608653	52.18	<.0001
SEXC	1	2.14584634	2.14584634	10.06	0.0019
UCPDGR1	1	0.00799630	0.00799630	0.04	0.8467
TRTPN	2	28.76591494	14.38295747	67.45	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.15550379	1
2	6.99808027	2
3	5.79750671	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0002
2	<.0001		<.0001
3	0.0002	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.155504	6.047982	6.263026
2	6.998080	6.847530	7.148631
3	5.797507	5.646367	5.948647

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.842576	-1.026809	-0.658344
1	3	0.357997	0.173789	0.542205
2	3	1.200574	0.988122	1.413026

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	84.1459574	16.8291915	37.35	<.0001
Error	142	63.9767114	0.4505402		
Corrected Total	147	148.1226688			

R-Square	Coeff Var	Root MSE	logaval Mean
0.568083	42.09357	0.671223	1.594597

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.61622966	11.61622966	25.78	<.0001
SEXC	1	0.12608398	0.12608398	0.28	0.5976
UCPDGR1	1	0.01563323	0.01563323	0.03	0.8525
TRTPN	2	72.38801058	36.19400529	80.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	8.12903668	8.12903668	18.04	<.0001
SEXC	1	0.01116587	0.01116587	0.02	0.8751
UCPDGR1	1	0.02709524	0.02709524	0.06	0.8066
TRTPN	2	72.38801058	36.19400529	80.33	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.15690518	1
2	2.80795286	2
3	1.26280949	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4358
2	<.0001		<.0001
3	0.4358	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.156905	1.000746	1.313065
2	2.807953	2.588992	3.026913
3	1.262809	1.042910	1.482709

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.651048	-1.918818	-1.383277
1	3	-0.105904	-0.373767	0.161958
2	3	1.545143	1.235868	1.854418

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	89.5523781	17.9104756	38.54	<.0001
Error	137	63.6735937	0.4647708		
Corrected Total	142	153.2259719			

R-Square	Coeff Var	Root MSE	logaval Mean
0.584446	63.77897	0.681741	1.068912

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	16.71321497	16.71321497	35.96	<.0001
SEXC	1	2.22281834	2.22281834	4.78	0.0304
UCPDGR1	1	0.01619698	0.01619698	0.03	0.8522
TRTPN	2	70.60014785	35.30007392	75.95	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.00408219	9.00408219	19.37	<.0001
SEXC	1	1.65642359	1.65642359	3.56	0.0612
UCPDGR1	1	0.00724833	0.00724833	0.02	0.9008
TRTPN	2	70.60014785	35.30007392	75.95	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.63651667	1
2	2.29967710	2
3	0.77119694	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3379
2	<.0001		<.0001
3	0.3379	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.636517	0.474608	0.798425
2	2.299677	2.074013	2.525341
3	0.771197	0.544880	0.997514

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.663160	-1.939641	-1.386679
1	3	-0.134680	-0.411634	0.142274
2	3	1.528480	1.209658	1.847303

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	57.9825029	11.5965006	33.56	<.0001
Error	139	48.0270497	0.3455183		
Corrected Total	144	106.0095526			

R-Square	Coeff Var	Root MSE	logaval Mean
0.546955	13.74027	0.587808	4.277994

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	13.61270957	13.61270957	39.40	<.0001
SEXC	1	0.14079269	0.14079269	0.41	0.5243
UCPDGR1	1	0.21769946	0.21769946	0.63	0.4287
TRTPN	2	44.01130119	22.00565060	63.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	13.19991622	13.19991622	38.20	<.0001
SEXC	1	0.06271299	0.06271299	0.18	0.6707
UCPDGR1	1	0.18294627	0.18294627	0.53	0.4680
TRTPN	2	44.01130119	22.00565060	63.69	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.01418114	1
2	5.23466563	2
3	3.86842452	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2353
2	<.0001		<.0001
3	0.2353	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.014181	3.875426	4.152936
2	5.234666	5.040611	5.428721
3	3.868425	3.671547	4.065302

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.220484	-1.458409	-0.982560
1	3	0.145757	-0.096024	0.387537
2	3	1.366241	1.090925	1.641558

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	70.6653178	14.1330636	39.67	<.0001
Error	137	48.8116385	0.3562893		
Corrected Total	142	119.4769563			

R-Square	Coeff Var	Root MSE	logaval Mean
0.591456	15.90888	0.596900	3.751990

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.91731833	23.91731833	67.13	<.0001
SEXC	1	1.91002015	1.91002015	5.36	0.0221
UCPDGR1	1	0.17329207	0.17329207	0.49	0.4867
TRTPN	2	44.66468724	22.33234362	62.68	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.80400829	15.80400829	44.36	<.0001
SEXC	1	1.47986457	1.47986457	4.15	0.0435
UCPDGR1	1	0.13589446	0.13589446	0.38	0.5379
TRTPN	2	44.66468724	22.33234362	62.68	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.49154775	1
2	4.73116320	2
3	3.36308496	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3042
2	<.0001		<.0001
3	0.3042	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.491548	3.348086	3.635009
2	4.731163	4.534051	4.928275
3	3.363085	3.163792	3.562378

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.239615	-1.482096	-0.997135
1	3	0.128463	-0.117867	0.374792
2	3	1.368078	1.088306	1.647851

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	133.1409780	26.6281956	85.22	<.0001
Error	142	44.3697236	0.3124628		
Corrected Total	147	177.5107016			

R-Square	Coeff Var	Root MSE	logaval Mean
0.750045	15.10780	0.558984	3.699969

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	47.74817595	47.74817595	152.81	<.0001
SEXC	1	1.34982588	1.34982588	4.32	0.0395
UCPDGR1	1	0.15598504	0.15598504	0.50	0.4810
TRTPN	2	83.88699113	41.94349556	134.24	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	35.37191374	35.37191374	113.20	<.0001
SEXC	1	2.33311797	2.33311797	7.47	0.0071
UCPDGR1	1	0.12176578	0.12176578	0.39	0.5335
TRTPN	2	83.88699113	41.94349556	134.24	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.19522625	1
2	4.97820240	2
3	3.33169785	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2284
2	<.0001		<.0001
3	0.2284	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.195226	3.065067	3.325386
2	4.978202	4.795924	5.160481
3	3.331698	3.148761	3.514635

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.782976	-2.006049	-1.559903
1	3	-0.136472	-0.359480	0.086537
2	3	1.646505	1.389332	1.903677

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	131.8061761	26.3612352	91.39	<.0001
Error	137	39.5185370	0.2884565		
Corrected Total	142	171.3247131			

R-Square	Coeff Var	Root MSE	logaval Mean
0.769335	16.91715	0.537081	3.174774

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	49.56817630	49.56817630	171.84	<.0001
SEXC	1	1.09251897	1.09251897	3.79	0.0537
UCPDGR1	1	0.13084179	0.13084179	0.45	0.5018
TRTPN	2	81.01463908	40.50731954	140.43	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	38.35740859	38.35740859	132.97	<.0001
SEXC	1	1.68931910	1.68931910	5.86	0.0168
UCPDGR1	1	0.18601885	0.18601885	0.64	0.4233
TRTPN	2	81.01463908	40.50731954	140.43	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.67479060	1
2	4.45286167	2
3	2.80430614	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2426
2	<.0001		<.0001
3	0.2426	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.674791	2.547255	2.802326
2	4.452862	4.275085	4.630638
3	2.804306	2.625947	2.982666

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.778071	-1.996136	-1.560006
1	3	-0.129516	-0.347750	0.088719
2	3	1.648556	1.397803	1.899308

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	68.3891663	13.6778333	47.26	<.0001
Error	142	41.1014133	0.2894466		
Corrected Total	147	109.4905796			

R-Square	Coeff Var	Root MSE	logaval Mean
0.624612	6.804504	0.538002	7.906563

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	43.38881785	43.38881785	149.90	<.0001
SEXC	1	0.10773172	0.10773172	0.37	0.5428
UCPDGR1	1	0.01514101	0.01514101	0.05	0.8194
TRTPN	2	24.87747574	12.43873787	42.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	43.29030556	43.29030556	149.56	<.0001
SEXC	1	0.25137642	0.25137642	0.87	0.3530
UCPDGR1	1	0.00067766	0.00067766	0.00	0.9615
TRTPN	2	24.87747574	12.43873787	42.97	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.60027057	1
2	8.59555380	2
3	7.79628955	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0736
2	<.0001		<.0001
3	0.0736	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.600271	7.474786	7.725755
2	8.595554	8.420200	8.770908
3	7.796290	7.620200	7.972379

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.995283	-1.209832	-0.780735
1	3	-0.196019	-0.411015	0.018977
2	3	0.799264	0.551825	1.046704

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.1901830	16.0380366	54.14	<.0001
Error	137	40.5868557	0.2962544		
Corrected Total	142	120.7770387			

R-Square	Coeff Var	Root MSE	logaval Mean
0.663952	7.361702	0.544293	7.393570

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	56.34925612	56.34925612	190.21	<.0001
SEXC	1	0.13520023	0.13520023	0.46	0.5005
UCPDGR1	1	0.01581103	0.01581103	0.05	0.8176
TRTPN	2	23.68991566	11.84495783	39.98	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	44.14754030	44.14754030	149.02	<.0001
SEXC	1	0.01707219	0.01707219	0.06	0.8106
UCPDGR1	1	0.00142897	0.00142897	0.00	0.9447
TRTPN	2	23.68991566	11.84495783	39.98	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.10074497	1
2	8.08595034	2
3	7.28786660	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0969
2	<.0001		<.0001
3	0.0969	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.100745	6.970896	7.230594
2	8.085950	7.906155	8.265745
3	7.287867	7.107208	7.468525

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.985205	-1.205808	-0.764602
1	3	-0.187122	-0.408485	0.034242
2	3	0.798084	0.544005	1.052163

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	48.68803582	9.73760716	30.25	<.0001
Error	142	45.70888485	0.32189356		
Corrected Total	147	94.39692067			

R-Square	Coeff Var	Root MSE	logaval Mean
0.515780	10.50655	0.567357	5.400029

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	19.66398667	19.66398667	61.09	<.0001
SEXC	1	0.27976945	0.27976945	0.87	0.3528
UCPDGR1	1	0.01113043	0.01113043	0.03	0.8527
TRTPN	2	28.73314927	14.36657463	44.63	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	16.63593785	16.63593785	51.68	<.0001
SEXC	1	0.39915349	0.39915349	1.24	0.2673
UCPDGR1	1	0.02753333	0.02753333	0.09	0.7704
TRTPN	2	28.73314927	14.36657463	44.63	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.11817753	1
2	6.15235839	2
3	5.16858078	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6605
2	<.0001		<.0001
3	0.6605	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.118178	4.986101	5.250254
2	6.152358	5.967442	6.337275
3	5.168581	4.982921	5.354241

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.034181	-1.260358	-0.808004
1	3	-0.050403	-0.276775	0.175969
2	3	0.983778	0.722888	1.244668

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	49.96045612	9.99209122	31.02	<.0001
Error	137	44.13618377	0.32216193		
Corrected Total	142	94.09663988			

R-Square	Coeff Var	Root MSE	logaval Mean
0.530948	11.65509	0.567593	4.869916

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	22.87874029	22.87874029	71.02	<.0001
SEXC	1	0.01221937	0.01221937	0.04	0.8459
UCPDGR1	1	0.00003195	0.00003195	0.00	0.9921
TRTPN	2	27.06946451	13.53473226	42.01	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	17.61652630	17.61652630	54.68	<.0001
SEXC	1	0.00087155	0.00087155	0.00	0.9586
UCPDGR1	1	0.00039715	0.00039715	0.00	0.9720
TRTPN	2	27.06946451	13.53473226	42.01	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.61095825	1
2	5.62036940	2
3	4.62845915	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8810
2	<.0001		<.0001
3	0.8810	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.610958	4.476190	4.745726
2	5.620369	5.432720	5.808019
3	4.628459	4.439780	4.817139



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.009411	-1.239577	-0.779245
1	3	-0.017501	-0.248244	0.213242
2	3	0.991910	0.727014	1.256806

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	139.9520592	27.9904118	41.83	<.0001
Error	137	91.6684557	0.6691128		
Corrected Total	142	231.6205150			

R-Square	Coeff Var	Root MSE	logaval Mean
0.604230	13.99936	0.817993	5.843075

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	22.4025378	22.4025378	33.48	<.0001
SEXC	1	0.1244634	0.1244634	0.19	0.6669
UCPDGR1	1	0.2422734	0.2422734	0.36	0.5483
TRTPN	2	117.1827846	58.5913923	87.57	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	36.4964309	36.4964309	54.54	<.0001
SEXC	1	0.1236045	0.1236045	0.18	0.6680
UCPDGR1	1	0.4158488	0.4158488	0.62	0.4319
TRTPN	2	117.1827846	58.5913923	87.57	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.21631401	1
2	7.39938533	2
3	5.50147715	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0930
2	<.0001		<.0001
3	0.0930	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.216314	5.021910	5.410718
2	7.399385	7.127635	7.671136
3	5.501477	5.229710	5.773244

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.183071	-2.517673	-1.848470
1	3	-0.285163	-0.618493	0.048166
2	3	1.897908	1.515797	2.280019

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	147
Number of Observations Used	147

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	307.3599599	61.4719920	88.62	<.0001
Error	141	97.8078210	0.6936725		
Corrected Total	146	405.1677809			

R-Square	Coeff Var	Root MSE	logaval Mean
0.758599	47.81203	0.832870	1.741968

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.5962728	36.5962728	52.76	<.0001
SEXC	1	0.7904825	0.7904825	1.14	0.2876
UCPDGR1	1	0.9027750	0.9027750	1.30	0.2559
TRTPN	2	269.0704297	134.5352148	193.95	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	35.5023097	35.5023097	51.18	<.0001
SEXC	1	0.5994737	0.5994737	0.86	0.3542
UCPDGR1	1	0.0152787	0.0152787	0.02	0.8822
TRTPN	2	269.0704297	134.5352148	193.95	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.45490791	1
2	2.62782401	2
3	-0.60407144	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.3072	<.0001
2	0.3072		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.454908	2.259238	2.650577
2	2.627824	2.356005	2.899643
3	-0.604071	-0.876690	-0.331452

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.172916	-0.506460	0.160628
1	3	3.058979	2.725999	3.391959
2	3	3.231895	2.848530	3.615260

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	289.8095749	57.9619150	89.97	<.0001
Error	137	88.2626237	0.6442527		
Corrected Total	142	378.0721985			

R-Square	Coeff Var	Root MSE	logaval Mean
0.766546	64.51374	0.802654	1.244159

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	27.5158804	27.5158804	42.71	<.0001
SEXC	1	0.7044572	0.7044572	1.09	0.2975
UCPDGR1	1	0.8356645	0.8356645	1.30	0.2567
TRTPN	2	260.7535727	130.3767864	202.37	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	29.2654056	29.2654056	45.43	<.0001
SEXC	1	0.8862692	0.8862692	1.38	0.2429
UCPDGR1	1	0.0920804	0.0920804	0.14	0.7060
TRTPN	2	260.7535727	130.3767864	202.37	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.96916740	1
2	2.10386251	2
3	-1.10366626	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.4157	<.0001
2	0.4157		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.969167	1.778576	2.159759
2	2.103863	1.837741	2.369984
3	-1.103666	-1.370276	-0.837056

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.134695	-0.460946	0.191556
1	3	3.072834	2.746649	3.399019
2	3	3.207529	2.832662	3.582395

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	124.3045209	24.8609042	124.23	<.0001
Error	139	27.8164722	0.2001185		
Corrected Total	144	152.1209930			

R-Square	Coeff Var	Root MSE	logaval Mean
0.817142	9.340787	0.447346	4.789169

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	103.9597090	103.9597090	519.49	<.0001
SEXC	1	0.2674125	0.2674125	1.34	0.2497
UCPDGR1	1	0.0005029	0.0005029	0.00	0.9601
TRTPN	2	20.0768964	10.0384482	50.16	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	95.41556546	95.41556546	476.80	<.0001
SEXC	1	0.42970414	0.42970414	2.15	0.1451
UCPDGR1	1	0.00005032	0.00005032	0.00	0.9874
TRTPN	2	20.07689644	10.03844822	50.16	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.54291189	1
2	5.42546771	2
3	4.61237267	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4492
2	<.0001		<.0001
3	0.4492	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.542912	4.438202	4.647621
2	5.425468	5.277775	5.573161
3	4.612373	4.463798	4.760947

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.882556	-1.062909	-0.702203
1	3	-0.069461	-0.250440	0.111519
2	3	0.813095	0.604134	1.022056

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	249.3361255	49.8672251	52.75	<.0001
Error	139	131.3918385	0.9452650		
Corrected Total	144	380.7279640			

R-Square	Coeff Var	Root MSE	logaval Mean
0.654893	168.4171	0.972247	0.577285

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.4467929	36.4467929	38.56	<.0001
SEXC	1	0.7917886	0.7917886	0.84	0.3617
UCPDGR1	1	0.1689779	0.1689779	0.18	0.6731
TRTPN	2	211.9285660	105.9642830	112.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	26.9321261	26.9321261	28.49	<.0001
SEXC	1	1.4246171	1.4246171	1.51	0.2217
UCPDGR1	1	0.0731114	0.0731114	0.08	0.7813
TRTPN	2	211.9285660	105.9642830	112.10	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.39394044	1
2	2.43159554	2
3	-0.97596511	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.393940	0.165920	0.621960
2	2.431596	2.110619	2.752572
3	-0.975965	-1.299604	-0.652327

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.037655	-2.429731	-1.645579
1	3	1.369906	0.974869	1.764942
2	3	3.407561	2.952787	3.862334

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	255.3401863	51.0680373	55.07	<.0001
Error	137	127.0503294	0.9273747		
Corrected Total	142	382.3905158			

R-Square	Coeff Var	Root MSE	logaval Mean
0.667747	1264.792	0.963003	0.076139

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	42.9929539	42.9929539	46.36	<.0001
SEXC	1	0.0017487	0.0017487	0.00	0.9654
UCPDGR1	1	0.0172981	0.0172981	0.02	0.8916
TRTPN	2	212.3281856	106.1640928	114.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	27.2172661	27.2172661	29.35	<.0001
SEXC	1	0.0637322	0.0637322	0.07	0.7936
UCPDGR1	1	0.3160871	0.3160871	0.34	0.5603
TRTPN	2	212.3281856	106.1640928	114.48	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.08556646	1
2	1.93754490	2
3	-1.47832841	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.085566	-0.315525	0.144392
2	1.937545	1.619436	2.255654
3	-1.478328	-1.798820	-1.157837

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.023111	-2.413488	-1.632735
1	3	1.392762	0.998772	1.786752
2	3	3.415873	2.965156	3.866590

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.10481658	4.02096332	16.65	<.0001
Error	142	34.28884325	0.24147073		
Corrected Total	147	54.39365983			

R-Square	Coeff Var	Root MSE	logaval Mean
0.369617	10.95777	0.491397	4.484460

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.15844255	3.15844255	13.08	0.0004
SEXC	1	0.28267037	0.28267037	1.17	0.2811
UCPDGR1	1	0.03693117	0.03693117	0.15	0.6963
TRTPN	2	16.62677249	8.31338625	34.43	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.36814122	1.36814122	5.67	0.0186
SEXC	1	0.53916167	0.53916167	2.23	0.1373
UCPDGR1	1	0.06740584	0.06740584	0.28	0.5981
TRTPN	2	16.62677249	8.31338625	34.43	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.29205460	1
2	5.05625724	2
3	4.25005972	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6727
2	<.0001		<.0001
3	0.6727	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.292055	4.177638	4.406471
2	5.056257	4.895558	5.216956
3	4.250060	4.088899	4.411220

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.764203	-0.960885	-0.567521
1	3	0.041995	-0.154108	0.238098
2	3	0.806198	0.578978	1.033417

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	21.67851057	4.33570211	16.95	<.0001
Error	137	35.03542578	0.25573303		
Corrected Total	142	56.71393635			

R-Square	Coeff Var	Root MSE	logaval Mean
0.382243	12.74390	0.505701	3.968178

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.69743177	4.69743177	18.37	<.0001
SEXC	1	1.53326949	1.53326949	6.00	0.0156
UCPDGR1	1	0.00974110	0.00974110	0.04	0.8455
TRTPN	2	15.43806821	7.71903411	30.18	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.44527196	1.44527196	5.65	0.0188
SEXC	1	1.30433746	1.30433746	5.10	0.0255
UCPDGR1	1	0.04867333	0.04867333	0.19	0.6633
TRTPN	2	15.43806821	7.71903411	30.18	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.81498827	1
2	4.55607805	2
3	3.75596344	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5708
2	<.0001		<.0001
3	0.5708	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.814988	3.694913	3.935064
2	4.556078	4.387826	4.724330
3	3.755963	3.588055	3.923872



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.741090	-0.947108	-0.535072
1	3	0.059025	-0.146367	0.264417
2	3	0.800115	0.562751	1.037479

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	24.63218653	4.92643731	16.21	<.0001
Error	137	41.64209820	0.30395692		
Corrected Total	142	66.27428473			

R-Square	Coeff Var	Root MSE	logaval Mean
0.371670	6.310281	0.551323	8.736899

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.41034522	23.41034522	77.02	<.0001
SEXC	1	0.10971781	0.10971781	0.36	0.5490
UCPDGR1	1	0.21747740	0.21747740	0.72	0.3991
TRTPN	2	0.89464610	0.44732305	1.47	0.2331

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.42238348	22.42238348	73.77	<.0001
SEXC	1	0.21831561	0.21831561	0.72	0.3982
UCPDGR1	1	0.26489694	0.26489694	0.87	0.3522
TRTPN	2	0.89464610	0.44732305	1.47	0.2331

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.73886462	1
2	8.63584560	2
3	8.85906724	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.3659	0.2903
2	0.3659		0.0890
3	0.2903	0.0890	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.738865	8.608123	8.869606
2	8.635846	8.453092	8.818599
3	8.859067	8.676115	9.042019

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.103019	-0.121518	0.327556
1	3	-0.120203	-0.344109	0.103704
2	3	-0.223222	-0.480927	0.034484

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.91910033	5.78382007	19.40	<.0001
Error	135	40.24942844	0.29814391		
Corrected Total	140	69.16852877			

R-Square	Coeff Var	Root MSE	logaval Mean
0.418096	6.654469	0.546026	8.205396

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	27.37716882	27.37716882	91.83	<.0001
SEXC	1	0.66148802	0.66148802	2.22	0.1387
UCPDGR1	1	0.03690667	0.03690667	0.12	0.7255
TRTPN	2	0.84353682	0.42176841	1.41	0.2466

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	21.87707005	21.87707005	73.38	<.0001
SEXC	1	0.76227743	0.76227743	2.56	0.1122
UCPDGR1	1	0.05924018	0.05924018	0.20	0.6565
TRTPN	2	0.84353682	0.42176841	1.41	0.2466

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.21249409	1
2	8.11614324	2
3	8.33254280	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.3942	0.2883
2	0.3942		0.0958
3	0.2883	0.0958	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.212494	8.080879	8.344110
2	8.116143	7.935705	8.296581
3	8.332543	8.151192	8.513893

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.096351	-0.126564	0.319265
1	3	-0.120049	-0.342772	0.102675
2	3	-0.216400	-0.471595	0.038796

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	179.4390291	35.8878058	58.30	<.0001
Error	137	84.3298626	0.6155464		
Corrected Total	142	263.7688916			

R-Square	Coeff Var	Root MSE	logaval Mean
0.680289	12.94611	0.784568	6.060260

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	55.1155712	55.1155712	89.54	<.0001
SEXC	1	0.3356123	0.3356123	0.55	0.4615
UCPDGR1	1	0.0062086	0.0062086	0.01	0.9201
TRTPN	2	123.9816369	61.9908185	100.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	53.3844761	53.3844761	86.73	<.0001
SEXC	1	0.0740615	0.0740615	0.12	0.7292
UCPDGR1	1	0.0168119	0.0168119	0.03	0.8690
TRTPN	2	123.9816369	61.9908185	100.71	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.43599049	1
2	7.65857277	2
3	5.70811400	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0932
2	<.0001		<.0001
3	0.0932	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.435990	5.250277	5.621704
2	7.658573	7.399559	7.917587
3	5.708114	5.447762	5.968466

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.222582	-2.540227	-1.904938
1	3	-0.272124	-0.590461	0.046214
2	3	1.950459	1.584308	2.316610

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	91.8467831	18.3693566	23.10	<.0001
Error	142	112.9287667	0.7952730		
Corrected Total	147	204.7755497			

R-Square	Coeff Var	Root MSE	logaval Mean
0.448524	25.93203	0.891781	3.438917

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.80629715	10.80629715	13.59	0.0003
SEXC	1	0.01759021	0.01759021	0.02	0.8820
UCPDGR1	1	0.08094696	0.08094696	0.10	0.7502
TRTPN	2	80.94194875	40.47097438	50.89	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	8.37830651	8.37830651	10.54	0.0015
SEXC	1	0.00199066	0.00199066	0.00	0.9602
UCPDGR1	1	0.21750112	0.21750112	0.27	0.6018
TRTPN	2	80.94194875	40.47097438	50.89	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.86495967	1
2	4.67497169	2
3	3.34558255	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0085
2	<.0001		<.0001
3	0.0085	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.864960	2.657464	3.072455
2	4.674972	4.384219	4.965725
3	3.345583	3.053660	3.637505

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.810012	-2.165627	-1.454397
1	3	-0.480623	-0.836371	-0.124875
2	3	1.329389	0.919037	1.739741

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.4140113	20.8828023	26.60	<.0001
Error	137	107.5394859	0.7849598		
Corrected Total	142	211.9534972			

R-Square	Coeff Var	Root MSE	logaval Mean
0.492627	29.89262	0.885980	2.963874

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.37972155	23.37972155	29.78	<.0001
SEXC	1	0.71368865	0.71368865	0.91	0.3420
UCPDGR1	1	0.10327065	0.10327065	0.13	0.7174
TRTPN	2	80.21733046	40.10866523	51.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.24400615	15.24400615	19.42	<.0001
SEXC	1	0.48524064	0.48524064	0.62	0.4331
UCPDGR1	1	0.18924968	0.18924968	0.24	0.6242
TRTPN	2	80.21733046	40.10866523	51.10	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.38358370	1
2	4.21651508	2
3	2.89648033	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0055
2	<.0001		<.0001
3	0.0055	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.383584	2.173170	2.593997
2	4.216515	3.923392	4.509638
3	2.896480	2.602411	3.190550



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.832931	-2.192150	-1.473713
1	3	-0.512897	-0.872705	-0.153088
2	3	1.320035	0.906144	1.733925

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.58419795	4.11683959	19.01	<.0001
Error	137	29.66772747	0.21655276		
Corrected Total	142	50.25192541			

R-Square	Coeff Var	Root MSE	logaval Mean
0.409620	8.828345	0.465352	5.271116

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	16.03746623	16.03746623	74.06	<.0001
SEXC	1	0.16721523	0.16721523	0.77	0.3811
UCPDGR1	1	0.10080359	0.10080359	0.47	0.4962
TRTPN	2	4.27871289	2.13935645	9.88	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.58296972	15.58296972	71.96	<.0001
SEXC	1	0.15085150	0.15085150	0.70	0.4054
UCPDGR1	1	0.07501025	0.07501025	0.35	0.5571
TRTPN	2	4.27871289	2.13935645	9.88	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.20202820	1
2	5.55483797	2
3	5.10190323	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.0003	0.3008
2	0.0003		<.0001
3	0.3008	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.202028	5.090015	5.314041
2	5.554838	5.401134	5.708542
3	5.101903	4.948110	5.255696

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.352810	-0.542636	-0.162984
1	3	0.100125	-0.090490	0.290740
2	3	0.452935	0.236665	0.669205

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	142
Number of Observations Used	142



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U10HPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	31.48588410	6.29717682	27.21	<.0001
Error	136	31.47296233	0.23141884		
Corrected Total	141	62.95884643			

R-Square	Coeff Var	Root MSE	logaval Mean
0.500103	10.05197	0.481060	4.785728

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	26.57936833	26.57936833	114.85	<.0001
SEXC	1	0.13035111	0.13035111	0.56	0.4542
UCPDGR1	1	0.06632164	0.06632164	0.29	0.5933
TRTPN	2	4.70984302	2.35492151	10.18	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	21.29674162	21.29674162	92.03	<.0001
SEXC	1	0.11719135	0.11719135	0.51	0.4779
UCPDGR1	1	0.05347159	0.05347159	0.23	0.6315
TRTPN	2	4.70984302	2.35492151	10.18	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.70936659	1
2	5.09997844	2
3	4.64219301	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.0001	0.5016
2	0.0001		<.0001
3	0.5016	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.709367	4.592438	4.826295
2	5.099978	4.941133	5.258824
3	4.642193	4.483859	4.800527

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=U10HPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.390612	-0.586990	-0.194234
1	3	0.067174	-0.129984	0.264331
2	3	0.457785	0.234113	0.681458

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.7025785	16.1405157	31.77	<.0001
Error	142	72.1414915	0.5080387		
Corrected Total	147	152.8440699			

R-Square	Coeff Var	Root MSE	logaval Mean
0.528006	30.62380	0.712768	2.327498

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	14.20325273	14.20325273	27.96	<.0001
SEXC	1	0.59239809	0.59239809	1.17	0.2820
UCPDGR1	1	0.01336325	0.01336325	0.03	0.8714
TRTPN	2	65.89356441	32.94678220	64.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.37451178	10.37451178	20.42	<.0001
SEXC	1	0.87567842	0.87567842	1.72	0.1913
UCPDGR1	1	0.07460410	0.07460410	0.15	0.7021
TRTPN	2	65.89356441	32.94678220	64.85	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.77902541	1
2	3.41668315	2
3	2.27232944	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0008
2	<.0001		<.0001
3	0.0008	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.779025	1.613165	1.944886
2	3.416683	3.184157	3.649209
3	2.272329	2.038986	2.505673

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.637658	-1.922089	-1.353226
1	3	-0.493304	-0.777641	-0.208967
2	3	1.144354	0.816168	1.472540

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	89.2330112	17.8466022	37.71	<.0001
Error	137	64.8341766	0.4732422		
Corrected Total	142	154.0671878			

R-Square	Coeff Var	Root MSE	logaval Mean
0.579182	37.27652	0.687926	1.845467

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	22.10436528	22.10436528	46.71	<.0001
SEXC	1	0.00173400	0.00173400	0.00	0.9518
UCPDGR1	1	0.00721069	0.00721069	0.02	0.9019
TRTPN	2	67.11970125	33.55985063	70.91	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.53145087	15.53145087	32.82	<.0001
SEXC	1	0.00928887	0.00928887	0.02	0.8888
UCPDGR1	1	0.04610992	0.04610992	0.10	0.7554
TRTPN	2	67.11970125	33.55985063	70.91	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.27954198	1
2	2.96030984	2
3	1.83905559	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0001
2	<.0001		<.0001
3	0.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.279542	1.116187	1.442897
2	2.960310	2.732557	3.188063
3	1.839056	1.610723	2.067388

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.680768	-1.959849	-1.401686
1	3	-0.559514	-0.838886	-0.280142
2	3	1.121254	0.799735	1.442774

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	26.73728135	5.34745627	19.23	<.0001
Error	142	39.49349283	0.27812319		
Corrected Total	147	66.23077418			

R-Square	Coeff Var	Root MSE	logaval Mean
0.403699	8.195703	0.527374	6.434761

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.99294709	11.99294709	43.12	<.0001
SEXC	1	0.90363093	0.90363093	3.25	0.0736
UCPDGR1	1	0.02283038	0.02283038	0.08	0.7749
TRTPN	2	13.81787294	6.90893647	24.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.09690383	9.09690383	32.71	<.0001
SEXC	1	1.16955446	1.16955446	4.21	0.0421
UCPDGR1	1	0.02914704	0.02914704	0.10	0.7466
TRTPN	2	13.81787294	6.90893647	24.84	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.27409054	1
2	6.94255705	2
3	6.17711336	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3637
2	<.0001		<.0001
3	0.3637	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.274091	6.151291	6.396890
2	6.942557	6.770615	7.114499
3	6.177113	6.004498	6.349728



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.668467	-0.878876	-0.458057
1	3	0.096977	-0.113405	0.307359
2	3	0.765444	0.522805	1.008083

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	42.5652582	8.5130516	13.47	<.0001
Error	142	89.7314430	0.6319116		
Corrected Total	147	132.2967012			

R-Square	Coeff Var	Root MSE	logaval Mean
0.321741	35.24397	0.794929	2.255502

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.90229680	10.90229680	17.25	<.0001
SEXC	1	1.12172059	1.12172059	1.78	0.1849
UCPDGR1	1	0.08122719	0.08122719	0.13	0.7205
TRTPN	2	30.46001363	15.23000681	24.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	7.87635361	7.87635361	12.46	0.0006
SEXC	1	1.57968968	1.57968968	2.50	0.1161
UCPDGR1	1	0.03478173	0.03478173	0.06	0.8148
TRTPN	2	30.46001363	15.23000681	24.10	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.88905404	1
2	2.99824826	2
3	2.16365220	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0892
2	<.0001		<.0001
3	0.0892	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.889054	1.704114	2.073994
2	2.998248	2.738933	3.257563
3	2.163652	1.903226	2.424078

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.109194	-1.426314	-0.792074
1	3	-0.274598	-0.591827	0.042631
2	3	0.834596	0.468322	1.200870

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	54.3556008	10.8711202	17.38	<.0001
Error	137	85.6850877	0.6254386		
Corrected Total	142	140.0406885			

R-Square	Coeff Var	Root MSE	logaval Mean
0.388141	44.59504	0.790847	1.773396

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	22.24491961	22.24491961	35.57	<.0001
SEXC	1	0.01699747	0.01699747	0.03	0.8693
UCPDGR1	1	0.00414327	0.00414327	0.01	0.9352
TRTPN	2	32.08954047	16.04477023	25.65	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	17.65321992	17.65321992	28.23	<.0001
SEXC	1	0.05511913	0.05511913	0.09	0.7670
UCPDGR1	1	0.02481680	0.02481680	0.04	0.8424
TRTPN	2	32.08954047	16.04477023	25.65	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.38460272	1
2	2.54610332	2
3	1.75153498	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0255
2	<.0001		<.0001
3	0.0255	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.384603	1.196782	1.572423
2	2.546103	2.284324	2.807883
3	1.751535	1.488999	2.014071

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.161501	-1.482230	-0.840772
1	3	-0.366932	-0.688210	-0.045655
2	3	0.794568	0.424722	1.164415

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	35.91574837	7.18314967	15.59	<.0001
Error	139	64.03709690	0.46069854		
Corrected Total	144	99.95284527			

R-Square	Coeff Var	Root MSE	logaval Mean
0.359327	14.25072	0.678748	4.762903

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	21.34772229	21.34772229	46.34	<.0001
SEXC	1	1.49588868	1.49588868	3.25	0.0737
UCPDGR1	1	0.26243410	0.26243410	0.57	0.4517
TRTPN	2	12.80970331	6.40485165	13.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.53807497	22.53807497	48.92	<.0001
SEXC	1	1.38927412	1.38927412	3.02	0.0847
UCPDGR1	1	0.27084984	0.27084984	0.59	0.4445
TRTPN	2	12.80970331	6.40485165	13.90	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.58035516	1
2	5.26151531	2
3	4.55874898	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8786
2	<.0001		<.0001
3	0.8786	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.580355	4.420133	4.740577
2	5.261515	5.037438	5.485592
3	4.558749	4.331412	4.786086

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.681160	-0.955894	-0.406427
1	3	0.021606	-0.257580	0.300793
2	3	0.702766	0.384856	1.020677

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	43.2450262	8.6490052	17.79	<.0001
Error	137	66.6016073	0.4861431		
Corrected Total	142	109.8466335			

R-Square	Coeff Var	Root MSE	logaval Mean
0.393685	16.32611	0.697240	4.270704

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	28.96968359	28.96968359	59.59	<.0001
SEXC	1	0.11411377	0.11411377	0.23	0.6288
UCPDGR1	1	0.10956851	0.10956851	0.23	0.6357
TRTPN	2	14.05166032	7.02583016	14.45	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	26.04216119	26.04216119	53.57	<.0001
SEXC	1	0.15897798	0.15897798	0.33	0.5684
UCPDGR1	1	0.11964914	0.11964914	0.25	0.6206
TRTPN	2	14.05166032	7.02583016	14.45	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.07861755	1
2	4.80435922	2
3	4.08732464	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9524
2	<.0001		<.0001
3	0.9524	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.078618	3.911040	4.246195
2	4.804359	4.574113	5.034606
3	4.087325	3.854530	4.320119

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.725742	-1.008984	-0.442500
1	3	-0.008707	-0.296445	0.279031
2	3	0.717035	0.390232	1.043838

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	100.9984301	20.1996860	20.27	<.0001
Error	142	141.5153943	0.9965873		
Corrected Total	147	242.5138244			

R-Square	Coeff Var	Root MSE	logaval Mean
0.416465	25.26710	0.998292	3.950957

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	37.58633089	37.58633089	37.72	<.0001
SEXC	1	2.51864472	2.51864472	2.53	0.1141
UCPDGR1	1	0.00038917	0.00038917	0.00	0.9843
TRTPN	2	60.89306531	30.44653265	30.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.57894893	28.57894893	28.68	<.0001
SEXC	1	3.11940283	3.11940283	3.13	0.0790
UCPDGR1	1	0.01364856	0.01364856	0.01	0.9070
TRTPN	2	60.89306531	30.44653265	30.55	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.41455185	1
2	4.98797159	2
3	3.86917323	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0256
2	<.0001		<.0001
3	0.0256	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.414552	3.182100	3.647004
2	4.987972	4.662440	5.313503
3	3.869173	3.542465	4.195882

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.573420	-1.971807	-1.175032
1	3	-0.454621	-0.852893	-0.056349
2	3	1.118798	0.659512	1.578084

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	108.1036081	21.6207216	22.09	<.0001
Error	137	134.0607712	0.9785458		
Corrected Total	142	242.1643794			

R-Square	Coeff Var	Root MSE	logaval Mean
0.446406	28.67931	0.989215	3.449228

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	42.52706893	42.52706893	43.46	<.0001
SEXC	1	1.74402077	1.74402077	1.78	0.1841
UCPDGR1	1	0.00706719	0.00706719	0.01	0.9324
TRTPN	2	63.82545124	31.91272562	32.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	34.89334564	34.89334564	35.66	<.0001
SEXC	1	1.98933020	1.98933020	2.03	0.1562
UCPDGR1	1	0.02933589	0.02933589	0.03	0.8628
TRTPN	2	63.82545124	31.91272562	32.61	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.88201670	1
2	4.52199234	2
3	3.40517500	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0111
2	<.0001		<.0001
3	0.0111	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.882017	2.647118	3.116915
2	4.521992	4.194557	4.849427
3	3.405175	3.076667	3.733683

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.639976	-2.041615	-1.238336
1	3	-0.523158	-0.925111	-0.121206
2	3	1.116817	0.654972	1.578662

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	49.6623836	9.9324767	23.77	<.0001
Error	142	59.3448786	0.4179217		
Corrected Total	147	109.0072622			

R-Square	Coeff Var	Root MSE	logaval Mean
0.455588	7.916945	0.646469	8.165633

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	33.02680982	33.02680982	79.03	<.0001
SEXC	1	0.02947342	0.02947342	0.07	0.7910
UCPDGR1	1	0.11849080	0.11849080	0.28	0.5952
TRTPN	2	16.48760954	8.24380477	19.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	32.85897219	32.85897219	78.62	<.0001
SEXC	1	0.13860945	0.13860945	0.33	0.5656
UCPDGR1	1	0.02967577	0.02967577	0.07	0.7903
TRTPN	2	16.48760954	8.24380477	19.73	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.87573062	1
2	8.69367073	2
3	8.19313539	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0164
2	<.0001		0.0011
3	0.0164	0.0011	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.875731	7.724947	8.026514
2	8.693671	8.482964	8.904378
3	8.193135	7.981544	8.404726

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.817940	-1.075744	-0.560136
1	3	-0.317405	-0.575746	-0.059063
2	3	0.500535	0.203209	0.797861

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.2779525	12.6555905	27.54	<.0001
Error	137	62.9676498	0.4596179		
Corrected Total	142	126.2456023			

R-Square	Coeff Var	Root MSE	logaval Mean
0.501229	8.831847	0.677951	7.676212

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	44.50545696	44.50545696	96.83	<.0001
SEXC	1	0.42456391	0.42456391	0.92	0.3382
UCPDGR1	1	0.26126553	0.26126553	0.57	0.4522
TRTPN	2	18.08666607	9.04333304	19.68	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	33.53139144	33.53139144	72.95	<.0001
SEXC	1	0.10960375	0.10960375	0.24	0.6261
UCPDGR1	1	0.12493830	0.12493830	0.27	0.6029
TRTPN	2	18.08666607	9.04333304	19.68	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.37443651	1
2	8.24390627	2
3	7.72878398	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0122
2	<.0001		0.0016
3	0.0122	0.0016	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.374437	7.212701	7.536172
2	8.243906	8.019960	8.467853
3	7.728784	7.503762	7.953806

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.869470	-1.144245	-0.594694
1	3	-0.354347	-0.630070	-0.078625
2	3	0.515122	0.198650	0.831594

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	34.08790017	6.81758003	17.76	<.0001
Error	142	54.51769548	0.38392743		
Corrected Total	147	88.60559565			

R-Square	Coeff Var	Root MSE	logaval Mean
0.384715	11.41186	0.619619	5.429601

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	18.18386583	18.18386583	47.36	<.0001
SEXC	1	0.36411651	0.36411651	0.95	0.3318
UCPDGR1	1	0.17860818	0.17860818	0.47	0.4963
TRTPN	2	15.36130966	7.68065483	20.01	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	16.28848140	16.28848140	42.43	<.0001
SEXC	1	0.32044907	0.32044907	0.83	0.3625
UCPDGR1	1	0.23243510	0.23243510	0.61	0.4378
TRTPN	2	15.36130966	7.68065483	20.01	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.20309236	1
2	5.97415817	2
3	5.29807533	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4488
2	<.0001		<.0001
3	0.4488	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.203092	5.058850	5.347335
2	5.974158	5.772208	6.176109
3	5.298075	5.095313	5.500837

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.771066	-1.018077	-0.524054
1	3	-0.094983	-0.342207	0.152241
2	3	0.676083	0.391161	0.961005

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.85010519	7.37002104	17.58	<.0001
Error	137	57.43630633	0.41924311		
Corrected Total	142	94.28641152			

R-Square	Coeff Var	Root MSE	logaval Mean
0.390832	13.11161	0.647490	4.938293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	21.47286205	21.47286205	51.22	<.0001
SEXC	1	0.01702851	0.01702851	0.04	0.8406
UCPDGR1	1	0.07983663	0.07983663	0.19	0.6632
TRTPN	2	15.28037799	7.64018900	18.22	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	17.19727356	17.19727356	41.02	<.0001
SEXC	1	0.00791089	0.00791089	0.02	0.8909
UCPDGR1	1	0.08243898	0.08243898	0.20	0.6581
TRTPN	2	15.28037799	7.64018900	18.22	<.0001



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.72189647	1
2	5.50038659	2
3	4.80647808	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5262
2	<.0001		<.0001
3	0.5262	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.721896	4.568158	4.875635
2	5.500387	5.286323	5.714450
3	4.806478	4.591239	5.021717



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.778490	-1.041055	-0.515925
1	3	-0.084582	-0.347805	0.178642
2	3	0.693909	0.391724	0.996093

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	98.7205055	19.7441011	32.71	<.0001
Error	137	82.7070936	0.6037014		
Corrected Total	142	181.4275991			

R-Square	Coeff Var	Root MSE	logaval Mean
0.544132	11.66512	0.776982	6.660733

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	40.21792591	40.21792591	66.62	<.0001
SEXC	1	1.41619570	1.41619570	2.35	0.1279
UCPDGR1	1	0.15653022	0.15653022	0.26	0.6114
TRTPN	2	56.92985368	28.46492684	47.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	51.78824981	51.78824981	85.78	<.0001
SEXC	1	1.65742828	1.65742828	2.75	0.0998
UCPDGR1	1	0.01057298	0.01057298	0.02	0.8949
TRTPN	2	56.92985368	28.46492684	47.15	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.08192755	1
2	7.63570541	2
3	6.75488769	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.081928	5.897270	6.266585
2	7.635705	7.377580	7.893831
3	6.754888	6.496746	7.013030

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.553778	-1.871604	-1.235952
1	3	-0.672960	-0.989578	-0.356342
2	3	0.880818	0.517864	1.243771

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	147
Number of Observations Used	147

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	43.3879701	8.6775940	15.52	<.0001
Error	141	78.8304203	0.5590810		
Corrected Total	146	122.2183904			

R-Square	Coeff Var	Root MSE	logaval Mean
0.355004	32.65798	0.747717	2.289539

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	29.03988866	29.03988866	51.94	<.0001
SEXC	1	0.04093477	0.04093477	0.07	0.7871
UCPDGR1	1	0.01592650	0.01592650	0.03	0.8662
TRTPN	2	14.29122018	7.14561009	12.78	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	27.38274453	27.38274453	48.98	<.0001
SEXC	1	0.07070918	0.07070918	0.13	0.7226
UCPDGR1	1	0.10192382	0.10192382	0.18	0.6701
TRTPN	2	14.29122018	7.14561009	12.78	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.46514285	1
2	2.46828029	2
3	1.74679059	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.9835	<.0001
2	0.9835		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.465143	2.289479	2.640807
2	2.468280	2.224252	2.712308
3	1.746791	1.502044	1.991537

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.003137	-0.302580	0.296305
1	3	0.718352	0.419416	1.017288
2	3	0.721490	0.377320	1.065659

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	43.1102470	8.6220494	15.84	<.0001
Error	137	74.5681186	0.5442928		
Corrected Total	142	117.6783656			

R-Square	Coeff Var	Root MSE	logaval Mean
0.366340	40.47459	0.737762	1.822778

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	30.98615252	30.98615252	56.93	<.0001
SEXC	1	0.01113952	0.01113952	0.02	0.8865
UCPDGR1	1	0.03634614	0.03634614	0.07	0.7965
TRTPN	2	12.07660883	6.03830441	11.09	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	27.09801792	27.09801792	49.79	<.0001
SEXC	1	0.04753237	0.04753237	0.09	0.7680
UCPDGR1	1	0.20435898	0.20435898	0.38	0.5411
TRTPN	2	12.07660883	6.03830441	11.09	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.98126079	1
2	2.00450840	2
3	1.31781682	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: logaval			
i/j	1	2	3
1		0.8784	<.0001
2	0.8784		0.0001
3	<.0001	0.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.981261	1.806078	2.156444
2	2.004508	1.759902	2.249115
3	1.317817	1.072761	1.562872

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.023248	-0.323122	0.276627
1	3	0.663444	0.363630	0.963258
2	3	0.686692	0.342131	1.031252

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	101.3061070	20.2612214	24.10	<.0001
Error	139	116.8734689	0.8408163		
Corrected Total	144	218.1795759			

R-Square	Coeff Var	Root MSE	logaval Mean
0.464324	18.61462	0.916960	4.926022

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	68.71591752	68.71591752	81.73	<.0001
SEXC	1	1.68559316	1.68559316	2.00	0.1590
UCPDGR1	1	0.00105630	0.00105630	0.00	0.9718
TRTPN	2	30.90354007	15.45177003	18.38	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	64.38640801	64.38640801	76.58	<.0001
SEXC	1	1.97247466	1.97247466	2.35	0.1279
UCPDGR1	1	0.03679887	0.03679887	0.04	0.8346
TRTPN	2	30.90354007	15.45177003	18.38	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.52494330	1
2	5.65831742	2
3	4.92009635	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0370
2	<.0001		0.0009
3	0.0370	0.0009	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.524943	4.310312	4.739574
2	5.658317	5.355579	5.961056
3	4.920096	4.615552	5.224641

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.133374	-1.503058	-0.763690
1	3	-0.395153	-0.766121	-0.024185
2	3	0.738221	0.309897	1.166545

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	145
Number of Observations Used	145

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	132.7018994	26.5403799	28.16	<.0001
Error	139	130.9866933	0.9423503		
Corrected Total	144	263.6885927			

R-Square	Coeff Var	Root MSE	logaval Mean
0.503252	112.1283	0.970747	0.865747

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	48.22724633	48.22724633	51.18	<.0001
SEXC	1	1.25426052	1.25426052	1.33	0.2506
UCPDGR1	1	0.50949573	0.50949573	0.54	0.4634
TRTPN	2	82.71089681	41.35544841	43.89	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	43.54944127	43.54944127	46.21	<.0001
SEXC	1	0.92540133	0.92540133	0.98	0.3234
UCPDGR1	1	0.43837947	0.43837947	0.47	0.4963
TRTPN	2	82.71089681	41.35544841	43.89	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.47764474	1
2	2.19243650	2
3	0.37977240	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6245
2	<.0001		<.0001
3	0.6245	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.477645	0.249977	0.705313
2	2.192437	1.871955	2.512918
3	0.379772	0.056633	0.702912



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.714792	-2.106262	-1.323321
1	3	0.097872	-0.296555	0.492300
2	3	1.812664	1.358593	2.266736

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	157.4376275	31.4875255	33.41	<.0001
Error	137	129.1198379	0.9424806		
Corrected Total	142	286.5574654			

R-Square	Coeff Var	Root MSE	logaval Mean
0.549410	246.7387	0.970814	0.393459

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	69.09842381	69.09842381	73.32	<.0001
SEXC	1	2.94591104	2.94591104	3.13	0.0793
UCPDGR1	1	0.35796287	0.35796287	0.38	0.5387
TRTPN	2	85.03532976	42.51766488	45.11	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	51.51803015	51.51803015	54.66	<.0001
SEXC	1	2.28996650	2.28996650	2.43	0.1214
UCPDGR1	1	0.32340817	0.32340817	0.34	0.5590
TRTPN	2	85.03532976	42.51766488	45.11	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.01045686	1
2	1.74652831	2
3	-0.07038673	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7659
2	<.0001		<.0001
3	0.7659	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.010457	-0.242280	0.221367
2	1.746528	1.425839	2.067217
3	-0.070387	-0.393478	0.252705

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.756985	-2.150528	-1.363442
1	3	0.059930	-0.337256	0.457116
2	3	1.816915	1.362542	2.271288

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	25.91487195	5.18297439	16.74	<.0001
Error	142	43.95903025	0.30957064		
Corrected Total	147	69.87390219			

R-Square	Coeff Var	Root MSE	logaval Mean
0.370881	12.17224	0.556391	4.570981

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.85369254	5.85369254	18.91	<.0001
SEXC	1	0.61907790	0.61907790	2.00	0.1595
UCPDGR1	1	0.30794974	0.30794974	0.99	0.3203
TRTPN	2	19.13415176	9.56707588	30.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.73076971	2.73076971	8.82	0.0035
SEXC	1	1.18811093	1.18811093	3.84	0.0521
UCPDGR1	1	0.35916243	0.35916243	1.16	0.2833
TRTPN	2	19.13415176	9.56707588	30.90	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.33405603	1
2	5.18005542	2
3	4.36639503	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7738
2	<.0001		<.0001
3	0.7738	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.334056	4.204506	4.463606
2	5.180055	4.998102	5.362009
3	4.366395	4.183919	4.548871

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means***Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.845999	-1.068695	-0.623304
1	3	-0.032339	-0.254379	0.189701
2	3	0.813660	0.556388	1.070933

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143



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**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.86326270	5.77265254	18.38	<.0001
Error	137	43.01721917	0.31399430		
Corrected Total	142	71.88048188			

R-Square	Coeff Var	Root MSE	logaval Mean
0.401545	13.70772	0.560352	4.087858

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.42555312	8.42555312	26.83	<.0001
SEXC	1	0.52832760	0.52832760	1.68	0.1968
UCPDGR1	1	0.25206898	0.25206898	0.80	0.3718
TRTPN	2	19.65731300	9.82865650	31.30	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.54485443	3.54485443	11.29	0.0010
SEXC	1	0.30087305	0.30087305	0.96	0.3294
UCPDGR1	1	0.34497067	0.34497067	1.10	0.2964
TRTPN	2	19.65731300	9.82865650	31.30	<.0001

*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.86277498	1
2	4.74058694	2
3	3.91797914	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6322
2	<.0001		<.0001
3	0.6322	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.862775	3.729723	3.995827
2	4.740587	4.554152	4.927022
3	3.917979	3.731925	4.104034

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.877812	-1.106094	-0.649529
1	3	-0.055204	-0.282793	0.172384
2	3	0.822608	0.559592	1.085624

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10.68718530	2.13743706	3.88	0.0026
Error	137	75.50830403	0.55115550		
Corrected Total	142	86.19548933			

R-Square	Coeff Var	Root MSE	logaval Mean
0.123988	8.510715	0.742398	8.723103

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.19312670	10.19312670	18.49	<.0001
SEXC	1	0.01429405	0.01429405	0.03	0.8723
UCPDGR1	1	0.08454068	0.08454068	0.15	0.6959
TRTPN	2	0.39522387	0.19761194	0.36	0.6993

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.56634998	9.56634998	17.36	<.0001
SEXC	1	0.00202600	0.00202600	0.00	0.9517
UCPDGR1	1	0.06160473	0.06160473	0.11	0.7386
TRTPN	2	0.39522387	0.19761194	0.36	0.6993



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*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.77284899	1
2	8.69581739	2
3	8.64915293	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.6152	0.4186
2	0.6152		0.7907
3	0.4186	0.7907	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.772849	8.596796	8.948902
2	8.695817	8.449726	8.941909
3	8.649153	8.402794	8.895512



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*Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**Least Squares Means*

Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.077032	-0.225324	0.379387
1	3	0.123696	-0.177811	0.425203
2	3	0.046664	-0.300356	0.393684

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	141
Number of Observations Used	141

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11.04508628	2.20901726	4.03	0.0019
Error	135	74.00001972	0.54814829		
Corrected Total	140	85.04510600			

R-Square	Coeff Var	Root MSE	logaval Mean
0.129873	8.984973	0.740370	8.240096

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.20127910	9.20127910	16.79	<.0001
SEXC	1	1.43263159	1.43263159	2.61	0.1083
UCPDGR1	1	0.02214014	0.02214014	0.04	0.8410
TRTPN	2	0.38903544	0.19451772	0.35	0.7019

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.27437674	6.27437674	11.45	0.0009
SEXC	1	1.41252514	1.41252514	2.58	0.1108
UCPDGR1	1	0.01113672	0.01113672	0.02	0.8869
TRTPN	2	0.38903544	0.19451772	0.35	0.7019

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.30746420	1
2	8.24043501	2
3	8.18128941	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.6617	0.4101
2	0.6617		0.7359
3	0.4101	0.7359	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.307464	8.129003	8.485925
2	8.240435	7.995775	8.485095
3	8.181289	7.935391	8.427187

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.067029	-0.235226	0.369285
1	3	0.126175	-0.175822	0.428171
2	3	0.059146	-0.286881	0.405172

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	143
Number of Observations Used	143

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	99.3714262	19.8742852	17.64	<.0001
Error	137	154.3520256	1.1266571		
Corrected Total	142	253.7234518			

R-Square	Coeff Var	Root MSE	logaval Mean
0.391653	15.40468	1.061441	6.890379

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	60.80890950	60.80890950	53.97	<.0001
SEXC	1	0.33099317	0.33099317	0.29	0.5887
UCPDGR1	1	0.27485336	0.27485336	0.24	0.6222
TRTPN	2	37.95667015	18.97833507	16.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	60.24395213	60.24395213	53.47	<.0001
SEXC	1	0.32566263	0.32566263	0.29	0.5917
UCPDGR1	1	0.37315150	0.37315150	0.33	0.5659
TRTPN	2	37.95667015	18.97833507	16.84	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.48717424	1
2	7.74298115	2
3	6.79943919	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1539
2	<.0001		0.0002
3	0.1539	0.0002	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.487174	6.235923	6.738426
2	7.742981	7.392561	8.093401
3	6.799439	6.447209	7.151670

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.255807	-1.685548	-0.826066
1	3	-0.312265	-0.742943	0.118413
2	3	0.943542	0.448176	1.438908

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

**Dependent Variable: AVAL**    **Analysis Value**

**Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13607.59594	2721.51919	73.83	<.0001
Error	153	5640.00155	36.86276		
Corrected Total	158	19247.59748			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.706976	72.42039	6.071471	8.383648

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1418.92990	1418.92990	38.49	<.0001
SEXC	1	14.15518	14.15518	0.38	0.5364
UCPDGR1	1	71.88550	71.88550	1.95	0.1646
TRTPN	2	12102.62536	6051.31268	164.16	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	790.79659	790.79659	21.45	<.0001
SEXC	1	1.15543	1.15543	0.03	0.8597
UCPDGR1	1	83.85856	83.85856	2.27	0.1335
TRTPN	2	12102.62536	6051.31268	164.16	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.4302858	1
2	23.1187560	2
3	4.9744656	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.0348
2	<.0001		<.0001
3	0.0348	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.430286	1.060918	3.799654
2	23.118756	21.236407	25.001105
3	4.974466	3.034706	6.914226

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-20.688470	-23.004734	-18.372206
1	3	-2.544180	-4.903678	-0.184681
2	3	18.144290	15.458270	20.830311

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set*****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

**Dependent Variable: AVAL    Analysis Value**

**Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6338.57778	1267.71556	23.33	<.0001
Error	153	8312.81845	54.33215		
Corrected Total	158	14651.39623			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.432626	64.35994	7.371034	11.45283

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1027.576021	1027.576021	18.91	<.0001
SEXC	1	2.641514	2.641514	0.05	0.8258
UCPDGR1	1	62.027154	62.027154	1.14	0.2870
TRTPN	2	5246.333087	2623.166544	48.28	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	754.557929	754.557929	13.89	0.0003
SEXC	1	2.572823	2.572823	0.05	0.8280
UCPDGR1	1	45.345387	45.345387	0.83	0.3624
TRTPN	2	5246.333087	2623.166544	48.28	<.0001

**Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set****Least Squares Means****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	6.7327997	1
2	20.6808621	2
3	11.2718174	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.0020
2	<.0001		<.0001
3	0.0020	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	6.732800	5.074179	8.391420
2	20.680862	18.397376	22.964348
3	11.271817	8.917788	13.625847

***Listing 15.4.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set******Least Squares Means*****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-13.948062	-16.752719	-11.143405
1	3	-4.539018	-7.396398	-1.681637
2	3	9.409045	6.146681	12.671409

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





1

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	111



2

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	111
Number of Observations Used	111
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04679

Fit Statistics	
-2 Res Log Likelihood	-4.6
AIC (smaller is better)	-2.6
AICC (smaller is better)	-2.5
BIC (smaller is better)	0.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	105	5.69	0.0188
SEX	1	105	0.13	0.7141
UCPDGR1	1	105	1.01	0.3164
TRTP	2	105	224.93	<.0001



3

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8434	0.05026	105	16.78	<.0001	0.05	0.7437	0.9430
TRTP	THSm2.2	0.8523	0.02772	105	30.74	<.0001	0.05	0.7974	0.9073
TRTP	mCC	1.8450	0.04058	105	45.46	<.0001	0.05	1.7645	1.9254
TRTP	SA	0.8434	0.05026	105	16.78	<.0001	0.05	0.7437	0.9430
TRTP	THSm2.2	0.8523	0.02772	105	30.74	<.0001	0.05	0.7974	0.9073
TRTP	mCC	1.8450	0.04058	105	45.46	<.0001	0.05	1.7645	1.9254

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0016	0.06406	105	-15.63	<.0001	0.05	-1.1286	-0.8746
TRTP	THSm2.2	mCC	-0.9926	0.04869	105	-20.39	<.0001	0.05	-1.0892	-0.8961
TRTP	THSm2.2	SA	0.008968	0.05671	105	0.16	0.8747	0.05	-0.1035	0.1214
TRTP	mCC	SA	1.0016	0.06406	105	15.63	<.0001	0.05	0.8746	1.1286



4

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	69



5

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	69
Number of Observations Used	69
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.09572

Fit Statistics	
-2 Res Log Likelihood	46.9
AIC (smaller is better)	48.9
AICC (smaller is better)	48.9
BIC (smaller is better)	51.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	63	7.39	0.0084
SEX	1	63	0.20	0.6535
UCPDGR1	1	63	0.00	0.9774
TRTP	2	63	55.05	<.0001



6

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=2 Parameter Code=CARBXHGB Parameter=COHb (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.0304	0.1274	63	8.08	<.0001	0.05	0.7757	1.2850
TRTP	THSm2.2	0.9508	0.05059	63	18.79	<.0001	0.05	0.8497	1.0519
TRTP	mCC	1.7882	0.06335	63	28.23	<.0001	0.05	1.6616	1.9148
TRTP	SA	1.0304	0.1274	63	8.08	<.0001	0.05	0.7757	1.2850
TRTP	THSm2.2	0.9508	0.05059	63	18.79	<.0001	0.05	0.8497	1.0519
TRTP	mCC	1.7882	0.06335	63	28.23	<.0001	0.05	1.6616	1.9148

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7578	0.1420	63	-5.34	<.0001	0.05	-1.0416	-0.4741
TRTP	THSm2.2	mCC	-0.8374	0.08123	63	-10.31	<.0001	0.05	-0.9998	-0.6751
TRTP	THSm2.2	SA	-0.07959	0.1376	63	-0.58	0.5650	0.05	-0.3545	0.1954
TRTP	mCC	SA	0.7578	0.1420	63	5.34	<.0001	0.05	0.4741	1.0416



7

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



8

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2867

Fit Statistics	
-2 Res Log Likelihood	195.5
AIC (smaller is better)	197.5
AICC (smaller is better)	197.5
BIC (smaller is better)	200.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	7.61	0.0068
SEX	1	110	14.34	0.0002
UCPDGR1	1	110	2.11	0.1495
TRTP	2	110	386.47	<.0001





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8217	0.1171	110	7.02	<.0001	0.05	0.5896	1.0539
TRTP	THSm2.2	0.9785	0.06747	110	14.50	<.0001	0.05	0.8447	1.1122
TRTP	mCC	4.1365	0.09991	110	41.40	<.0001	0.05	3.9385	4.3345
TRTP	SA	0.8217	0.1171	110	7.02	<.0001	0.05	0.5896	1.0539
TRTP	THSm2.2	0.9785	0.06747	110	14.50	<.0001	0.05	0.8447	1.1122
TRTP	mCC	4.1365	0.09991	110	41.40	<.0001	0.05	3.9385	4.3345

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.3147	0.1538	110	-21.55	<.0001	0.05	-3.6195	-3.0099
TRTP	THSm2.2	mCC	-3.1580	0.1196	110	-26.41	<.0001	0.05	-3.3950	-2.9210
TRTP	THSm2.2	SA	0.1567	0.1347	110	1.16	0.2471	0.05	-0.1102	0.4236
TRTP	mCC	SA	3.3147	0.1538	110	21.55	<.0001	0.05	3.0099	3.6195



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



11

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7291

Fit Statistics	
-2 Res Log Likelihood	204.9
AIC (smaller is better)	206.9
AICC (smaller is better)	207.0
BIC (smaller is better)	209.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	4.44	0.0385
SEX	1	74	0.00	0.9909
UCPDGR1	1	74	0.39	0.5328
TRTP	2	74	48.83	<.0001



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=10 Parameter Code=U1NACRE Parameter=1-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.8681	0.2916	74	6.41	<.0001	0.05	1.2870	2.4492
TRTP	THSm2.2	2.1600	0.1342	74	16.09	<.0001	0.05	1.8926	2.4275
TRTP	mCC	4.0953	0.1624	74	25.21	<.0001	0.05	3.7716	4.4189
TRTP	SA	1.8681	0.2916	74	6.41	<.0001	0.05	1.2870	2.4492
TRTP	THSm2.2	2.1600	0.1342	74	16.09	<.0001	0.05	1.8926	2.4275
TRTP	mCC	4.0953	0.1624	74	25.21	<.0001	0.05	3.7716	4.4189

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2271	0.3318	74	-6.71	<.0001	0.05	-2.8882	-1.5661
TRTP	THSm2.2	mCC	-1.9352	0.2097	74	-9.23	<.0001	0.05	-2.3530	-1.5175
TRTP	THSm2.2	SA	0.2919	0.3198	74	0.91	0.3643	0.05	-0.3453	0.9290
TRTP	mCC	SA	2.2271	0.3318	74	6.71	<.0001	0.05	1.5661	2.8882



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2761

Fit Statistics	
-2 Res Log Likelihood	199.5
AIC (smaller is better)	201.5
AICC (smaller is better)	201.5
BIC (smaller is better)	204.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	10.18	0.0018
SEX	1	115	1.43	0.2349
UCPDGR1	1	115	2.39	0.1246
TRTP	2	115	426.04	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.3036	0.1126	115	11.58	<.0001	0.05	1.0806	1.5266
TRTP	THSm2.2	1.4677	0.06450	115	22.75	<.0001	0.05	1.3399	1.5955
TRTP	mCC	4.6582	0.09629	115	48.38	<.0001	0.05	4.4674	4.8489
TRTP	SA	1.3036	0.1126	115	11.58	<.0001	0.05	1.0806	1.5266
TRTP	THSm2.2	1.4677	0.06450	115	22.75	<.0001	0.05	1.3399	1.5955
TRTP	mCC	4.6582	0.09629	115	48.38	<.0001	0.05	4.4674	4.8489

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.3546	0.1478	115	-22.70	<.0001	0.05	-3.6473	-3.0618
TRTP	THSm2.2	mCC	-3.1904	0.1151	115	-27.73	<.0001	0.05	-3.4184	-2.9625
TRTP	THSm2.2	SA	0.1641	0.1290	115	1.27	0.2060	0.05	-0.09147	0.4197
TRTP	mCC	SA	3.3546	0.1478	115	22.70	<.0001	0.05	3.0618	3.6473



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7543

Fit Statistics	
-2 Res Log Likelihood	212.8
AIC (smaller is better)	214.8
AICC (smaller is better)	214.9
BIC (smaller is better)	217.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	2.55	0.1145
SEX	1	76	1.01	0.3175
UCPDGR1	1	76	0.42	0.5208
TRTP	2	76	46.92	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=11 Parameter Code=U1NA24U Parameter=1-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.3126	0.2980	76	7.76	<.0001	0.05	1.7192	2.9061
TRTP	THSm2.2	2.6856	0.1323	76	20.29	<.0001	0.05	2.4220	2.9492
TRTP	mCC	4.5854	0.1652	76	27.76	<.0001	0.05	4.2565	4.9144
TRTP	SA	2.3126	0.2980	76	7.76	<.0001	0.05	1.7192	2.9061
TRTP	THSm2.2	2.6856	0.1323	76	20.29	<.0001	0.05	2.4220	2.9492
TRTP	mCC	4.5854	0.1652	76	27.76	<.0001	0.05	4.2565	4.9144

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2728	0.3387	76	-6.71	<.0001	0.05	-2.9473	-1.5983
TRTP	THSm2.2	mCC	-1.8998	0.2110	76	-9.00	<.0001	0.05	-2.3200	-1.4796
TRTP	THSm2.2	SA	0.3730	0.3243	76	1.15	0.2538	0.05	-0.2730	1.0189
TRTP	mCC	SA	2.2728	0.3387	76	6.71	<.0001	0.05	1.5983	2.9473



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	115



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	115
Number of Observations Used	115
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.09283

Fit Statistics	
-2 Res Log Likelihood	70.9
AIC (smaller is better)	72.9
AICC (smaller is better)	72.9
BIC (smaller is better)	75.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	109	198.12	<.0001
SEX	1	109	5.43	0.0216
UCPDGR1	1	109	16.37	<.0001
TRTP	2	109	63.06	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0537	0.06607	109	61.35	<.0001	0.05	3.9227	4.1846
TRTP	THSm2.2	4.1058	0.03926	109	104.58	<.0001	0.05	4.0280	4.1837
TRTP	mCC	4.8274	0.05685	109	84.92	<.0001	0.05	4.7147	4.9400
TRTP	SA	4.0537	0.06607	109	61.35	<.0001	0.05	3.9227	4.1846
TRTP	THSm2.2	4.1058	0.03926	109	104.58	<.0001	0.05	4.0280	4.1837
TRTP	mCC	4.8274	0.05685	109	84.92	<.0001	0.05	4.7147	4.9400

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7737	0.08719	109	-8.87	<.0001	0.05	-0.9465	-0.6009
TRTP	THSm2.2	mCC	-0.7215	0.06851	109	-10.53	<.0001	0.05	-0.8573	-0.5857
TRTP	THSm2.2	SA	0.05217	0.07738	109	0.67	0.5016	0.05	-0.1012	0.2055
TRTP	mCC	SA	0.7737	0.08719	109	8.87	<.0001	0.05	0.6009	0.9465



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2255

Fit Statistics	
-2 Res Log Likelihood	117.9
AIC (smaller is better)	119.9
AICC (smaller is better)	119.9
BIC (smaller is better)	122.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	38.78	<.0001
SEX	1	74	1.45	0.2319
UCPDGR1	1	74	1.02	0.3165
TRTP	2	74	7.70	0.0009



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=13 Parameter Code=U1OHPCRE Parameter=Total 1-OHP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5516	0.1647	74	27.63	<.0001	0.05	4.2234	4.8798
TRTP	THSm2.2	4.6890	0.07624	74	61.51	<.0001	0.05	4.5370	4.8409
TRTP	mCC	5.0974	0.09035	74	56.42	<.0001	0.05	4.9173	5.2774
TRTP	SA	4.5516	0.1647	74	27.63	<.0001	0.05	4.2234	4.8798
TRTP	THSm2.2	4.6890	0.07624	74	61.51	<.0001	0.05	4.5370	4.8409
TRTP	mCC	5.0974	0.09035	74	56.42	<.0001	0.05	4.9173	5.2774

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.5458	0.1856	74	-2.94	0.0044	0.05	-0.9155	-0.1761
TRTP	THSm2.2	mCC	-0.4084	0.1186	74	-3.44	0.0010	0.05	-0.6448	-0.1720
TRTP	THSm2.2	SA	0.1374	0.1833	74	0.75	0.4559	0.05	-0.2278	0.5025
TRTP	mCC	SA	0.5458	0.1856	74	2.94	0.0044	0.05	0.1761	0.9155





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1344

Fit Statistics	
-2 Res Log Likelihood	111.9
AIC (smaller is better)	113.9
AICC (smaller is better)	114.0
BIC (smaller is better)	116.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	105.50	<.0001
SEX	1	110	0.10	0.7508
UCPDGR1	1	110	9.42	0.0027
TRTP	2	110	44.54	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5517	0.08024	110	56.73	<.0001	0.05	4.3927	4.7107
TRTP	THSm2.2	4.6284	0.04669	110	99.12	<.0001	0.05	4.5359	4.7209
TRTP	mCC	5.3499	0.06836	110	78.26	<.0001	0.05	5.2144	5.4853
TRTP	SA	4.5517	0.08024	110	56.73	<.0001	0.05	4.3927	4.7107
TRTP	THSm2.2	4.6284	0.04669	110	99.12	<.0001	0.05	4.5359	4.7209
TRTP	mCC	5.3499	0.06836	110	78.26	<.0001	0.05	5.2144	5.4853

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7982	0.1052	110	-7.58	<.0001	0.05	-1.0068	-0.5896
TRTP	THSm2.2	mCC	-0.7215	0.08232	110	-8.76	<.0001	0.05	-0.8846	-0.5583
TRTP	THSm2.2	SA	0.07673	0.09353	110	0.82	0.4137	0.05	-0.1086	0.2621
TRTP	mCC	SA	0.7982	0.1052	110	7.58	<.0001	0.05	0.5896	1.0068



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	81



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	81
Number of Observations Used	81
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2270

Fit Statistics	
-2 Res Log Likelihood	119.7
AIC (smaller is better)	121.7
AICC (smaller is better)	121.7
BIC (smaller is better)	124.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	75	28.91	<.0001
SEX	1	75	0.07	0.7915
UCPDGR1	1	75	0.77	0.3828
TRTP	2	75	7.70	0.0009



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=14 Parameter Code=U1OHP24U Parameter=Total 1-OHP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.0254	0.1683	75	29.87	<.0001	0.05	4.6902	5.3606
TRTP	THSm2.2	5.1897	0.07534	75	68.89	<.0001	0.05	5.0396	5.3398
TRTP	mCC	5.5898	0.09081	75	61.56	<.0001	0.05	5.4089	5.7707
TRTP	SA	5.0254	0.1683	75	29.87	<.0001	0.05	4.6902	5.3606
TRTP	THSm2.2	5.1897	0.07534	75	68.89	<.0001	0.05	5.0396	5.3398
TRTP	mCC	5.5898	0.09081	75	61.56	<.0001	0.05	5.4089	5.7707

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.5644	0.1880	75	-3.00	0.0037	0.05	-0.9390	-0.1898
TRTP	THSm2.2	mCC	-0.4001	0.1186	75	-3.37	0.0012	0.05	-0.6363	-0.1639
TRTP	THSm2.2	SA	0.1643	0.1864	75	0.88	0.3810	0.05	-0.2071	0.5356
TRTP	mCC	SA	0.5644	0.1880	75	3.00	0.0037	0.05	0.1898	0.9390



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2550

Fit Statistics	
-2 Res Log Likelihood	182.8
AIC (smaller is better)	184.8
AICC (smaller is better)	184.8
BIC (smaller is better)	187.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	7.35	0.0078
SEX	1	110	5.59	0.0198
UCPDGR1	1	110	0.14	0.7106
TRTP	2	110	174.53	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.7161	0.1105	110	6.48	<.0001	0.05	0.4971	0.9350
TRTP	THSm2.2	0.7964	0.06354	110	12.53	<.0001	0.05	0.6705	0.9223
TRTP	mCC	2.8035	0.09431	110	29.73	<.0001	0.05	2.6166	2.9904
TRTP	SA	0.7161	0.1105	110	6.48	<.0001	0.05	0.4971	0.9350
TRTP	THSm2.2	0.7964	0.06354	110	12.53	<.0001	0.05	0.6705	0.9223
TRTP	mCC	2.8035	0.09431	110	29.73	<.0001	0.05	2.6166	2.9904

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.0875	0.1452	110	-14.38	<.0001	0.05	-2.3752	-1.7998
TRTP	THSm2.2	mCC	-2.0071	0.1127	110	-17.80	<.0001	0.05	-2.2306	-1.7837
TRTP	THSm2.2	SA	0.08034	0.1270	110	0.63	0.5282	0.05	-0.1713	0.3320
TRTP	mCC	SA	2.0875	0.1452	110	14.38	<.0001	0.05	1.7998	2.3752



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3893

Fit Statistics	
-2 Res Log Likelihood	158.7
AIC (smaller is better)	160.7
AICC (smaller is better)	160.8
BIC (smaller is better)	163.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	11.46	0.0011
SEX	1	74	0.19	0.6615
UCPDGR1	1	74	0.08	0.7803
TRTP	2	74	73.54	<.0001



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=16 Parameter Code=U2NACRE Parameter=2-NA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.2135	0.2133	74	5.69	<.0001	0.05	0.7884	1.6385
TRTP	THSm2.2	1.0348	0.09801	74	10.56	<.0001	0.05	0.8395	1.2301
TRTP	mCC	2.8521	0.1187	74	24.03	<.0001	0.05	2.6156	3.0885
TRTP	SA	1.2135	0.2133	74	5.69	<.0001	0.05	0.7884	1.6385
TRTP	THSm2.2	1.0348	0.09801	74	10.56	<.0001	0.05	0.8395	1.2301
TRTP	mCC	2.8521	0.1187	74	24.03	<.0001	0.05	2.6156	3.0885

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6386	0.2426	74	-6.75	<.0001	0.05	-2.1219	-1.1552
TRTP	THSm2.2	mCC	-1.8172	0.1532	74	-11.86	<.0001	0.05	-2.1225	-1.5120
TRTP	THSm2.2	SA	-0.1787	0.2339	74	-0.76	0.4473	0.05	-0.6446	0.2873
TRTP	mCC	SA	1.6386	0.2426	74	6.75	<.0001	0.05	1.1552	2.1219



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2314

Fit Statistics	
-2 Res Log Likelihood	179.3
AIC (smaller is better)	181.3
AICC (smaller is better)	181.3
BIC (smaller is better)	184.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	10.12	0.0019
SEX	1	115	0.77	0.3818
UCPDGR1	1	115	0.07	0.7930
TRTP	2	115	207.38	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.1993	0.1031	115	11.63	<.0001	0.05	0.9951	1.4035
TRTP	THSm2.2	1.2773	0.05903	115	21.64	<.0001	0.05	1.1603	1.3942
TRTP	mCC	3.3237	0.08820	115	37.68	<.0001	0.05	3.1490	3.4984
TRTP	SA	1.1993	0.1031	115	11.63	<.0001	0.05	0.9951	1.4035
TRTP	THSm2.2	1.2773	0.05903	115	21.64	<.0001	0.05	1.1603	1.3942
TRTP	mCC	3.3237	0.08820	115	37.68	<.0001	0.05	3.1490	3.4984

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.1244	0.1355	115	-15.68	<.0001	0.05	-2.3927	-1.8561
TRTP	THSm2.2	mCC	-2.0464	0.1053	115	-19.43	<.0001	0.05	-2.2551	-1.8378
TRTP	THSm2.2	SA	0.07800	0.1181	115	0.66	0.5103	0.05	-0.1559	0.3119
TRTP	mCC	SA	2.1244	0.1355	115	15.68	<.0001	0.05	1.8561	2.3927



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4443

Fit Statistics	
-2 Res Log Likelihood	172.8
AIC (smaller is better)	174.8
AICC (smaller is better)	174.9
BIC (smaller is better)	177.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	8.10	0.0057
SEX	1	76	2.51	0.1175
UCPDGR1	1	76	0.30	0.5877
TRTP	2	76	62.64	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=17 Parameter Code=U2NA24U Parameter=2-NA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.6704	0.2288	76	7.30	<.0001	0.05	1.2147	2.1261
TRTP	THSm2.2	1.5727	0.1016	76	15.48	<.0001	0.05	1.3704	1.7750
TRTP	mCC	3.3399	0.1267	76	26.35	<.0001	0.05	3.0875	3.5924
TRTP	SA	1.6704	0.2288	76	7.30	<.0001	0.05	1.2147	2.1261
TRTP	THSm2.2	1.5727	0.1016	76	15.48	<.0001	0.05	1.3704	1.7750
TRTP	mCC	3.3399	0.1267	76	26.35	<.0001	0.05	3.0875	3.5924

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6695	0.2600	76	-6.42	<.0001	0.05	-2.1873	-1.1517
TRTP	THSm2.2	mCC	-1.7672	0.1619	76	-10.91	<.0001	0.05	-2.0897	-1.4447
TRTP	THSm2.2	SA	-0.09770	0.2491	76	-0.39	0.6960	0.05	-0.5937	0.3983
TRTP	mCC	SA	1.6695	0.2600	76	6.42	<.0001	0.05	1.1517	2.1873



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1235

Fit Statistics	
-2 Res Log Likelihood	102.3
AIC (smaller is better)	104.3
AICC (smaller is better)	104.4
BIC (smaller is better)	107.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	66.47	<.0001
SEX	1	110	0.74	0.3906
UCPDGR1	1	110	1.69	0.1967
TRTP	2	110	95.61	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.0194	0.07684	110	65.33	<.0001	0.05	4.8671	5.1717
TRTP	THSm2.2	5.6220	0.04414	110	127.36	<.0001	0.05	5.5345	5.7095
TRTP	mCC	6.3852	0.06569	110	97.20	<.0001	0.05	6.2550	6.5154
TRTP	SA	5.0194	0.07684	110	65.33	<.0001	0.05	4.8671	5.1717
TRTP	THSm2.2	5.6220	0.04414	110	127.36	<.0001	0.05	5.5345	5.7095
TRTP	mCC	6.3852	0.06569	110	97.20	<.0001	0.05	6.2550	6.5154

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.3658	0.1009	110	-13.53	<.0001	0.05	-1.5658	-1.1657
TRTP	THSm2.2	mCC	-0.7632	0.07850	110	-9.72	<.0001	0.05	-0.9188	-0.6076
TRTP	THSm2.2	SA	0.6026	0.08819	110	6.83	<.0001	0.05	0.4278	0.7773
TRTP	mCC	SA	1.3658	0.1009	110	13.53	<.0001	0.05	1.1657	1.5658



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2545

Fit Statistics	
-2 Res Log Likelihood	126.5
AIC (smaller is better)	128.5
AICC (smaller is better)	128.6
BIC (smaller is better)	130.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	22.36	<.0001
SEX	1	74	0.49	0.4859
UCPDGR1	1	74	0.60	0.4414
TRTP	2	74	20.00	<.0001



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=19 Parameter Code=U3HPMCRE Parameter=3-HPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.3514	0.1730	74	30.94	<.0001	0.05	5.0068	5.6960
TRTP	THSm2.2	5.7385	0.07911	74	72.53	<.0001	0.05	5.5809	5.8962
TRTP	mCC	6.3860	0.09607	74	66.47	<.0001	0.05	6.1945	6.5774
TRTP	SA	5.3514	0.1730	74	30.94	<.0001	0.05	5.0068	5.6960
TRTP	THSm2.2	5.7385	0.07911	74	72.53	<.0001	0.05	5.5809	5.8962
TRTP	mCC	6.3860	0.09607	74	66.47	<.0001	0.05	6.1945	6.5774

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0346	0.1970	74	-5.25	<.0001	0.05	-1.4270	-0.6421
TRTP	THSm2.2	mCC	-0.6474	0.1238	74	-5.23	<.0001	0.05	-0.8941	-0.4008
TRTP	THSm2.2	SA	0.3872	0.1895	74	2.04	0.0446	0.05	0.009590	0.7647
TRTP	mCC	SA	1.0346	0.1970	74	5.25	<.0001	0.05	0.6421	1.4270





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1468

Fit Statistics	
-2 Res Log Likelihood	126.3
AIC (smaller is better)	128.3
AICC (smaller is better)	128.3
BIC (smaller is better)	131.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	61.81	<.0001
SEX	1	115	9.98	0.0020
UCPDGR1	1	115	1.56	0.2147
TRTP	2	115	84.48	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.5517	0.08211	115	67.61	<.0001	0.05	5.3891	5.7144
TRTP	THSm2.2	6.1344	0.04700	115	130.52	<.0001	0.05	6.0413	6.2275
TRTP	mCC	6.9182	0.07026	115	98.47	<.0001	0.05	6.7790	7.0574
TRTP	SA	5.5517	0.08211	115	67.61	<.0001	0.05	5.3891	5.7144
TRTP	THSm2.2	6.1344	0.04700	115	130.52	<.0001	0.05	6.0413	6.2275
TRTP	mCC	6.9182	0.07026	115	98.47	<.0001	0.05	6.7790	7.0574

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.3665	0.1079	115	-12.67	<.0001	0.05	-1.5802	-1.1528
TRTP	THSm2.2	mCC	-0.7838	0.08395	115	-9.34	<.0001	0.05	-0.9501	-0.6175
TRTP	THSm2.2	SA	0.5827	0.09399	115	6.20	<.0001	0.05	0.3965	0.7689
TRTP	mCC	SA	1.3665	0.1079	115	12.67	<.0001	0.05	1.1528	1.5802



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2388

Fit Statistics	
-2 Res Log Likelihood	124.9
AIC (smaller is better)	126.9
AICC (smaller is better)	127.0
BIC (smaller is better)	129.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	22.84	<.0001
SEX	1	76	0.61	0.4383
UCPDGR1	1	76	0.62	0.4340
TRTP	2	76	22.13	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=20 Parameter Code=U3HPM24U Parameter=3-HPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.8287	0.1690	76	34.49	<.0001	0.05	5.4921	6.1653
TRTP	THSm2.2	6.2210	0.07441	76	83.60	<.0001	0.05	6.0727	6.3692
TRTP	mCC	6.8812	0.09294	76	74.04	<.0001	0.05	6.6961	7.0664
TRTP	SA	5.8287	0.1690	76	34.49	<.0001	0.05	5.4921	6.1653
TRTP	THSm2.2	6.2210	0.07441	76	83.60	<.0001	0.05	6.0727	6.3692
TRTP	mCC	6.8812	0.09294	76	74.04	<.0001	0.05	6.6961	7.0664

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0525	0.1919	76	-5.48	<.0001	0.05	-1.4348	-0.6702
TRTP	THSm2.2	mCC	-0.6603	0.1187	76	-5.56	<.0001	0.05	-0.8968	-0.4238
TRTP	THSm2.2	SA	0.3922	0.1836	76	2.14	0.0359	0.05	0.02660	0.7579
TRTP	mCC	SA	1.0525	0.1919	76	5.48	<.0001	0.05	0.6702	1.4348



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3476

Fit Statistics	
-2 Res Log Likelihood	216.9
AIC (smaller is better)	218.9
AICC (smaller is better)	218.9
BIC (smaller is better)	221.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	12.76	0.0005
SEX	1	110	7.02	0.0093
UCPDGR1	1	110	0.64	0.4263
TRTP	2	110	86.64	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.4266	0.1290	110	3.31	0.0013	0.05	0.1709	0.6823
TRTP	THSm2.2	0.6120	0.07420	110	8.25	<.0001	0.05	0.4649	0.7590
TRTP	mCC	2.2278	0.1101	110	20.23	<.0001	0.05	2.0096	2.4460
TRTP	SA	0.4266	0.1290	110	3.31	0.0013	0.05	0.1709	0.6823
TRTP	THSm2.2	0.6120	0.07420	110	8.25	<.0001	0.05	0.4649	0.7590
TRTP	mCC	2.2278	0.1101	110	20.23	<.0001	0.05	2.0096	2.4460

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8012	0.1695	110	-10.62	<.0001	0.05	-2.1372	-1.4652
TRTP	THSm2.2	mCC	-1.6158	0.1316	110	-12.27	<.0001	0.05	-1.8767	-1.3550
TRTP	THSm2.2	SA	0.1853	0.1483	110	1.25	0.2142	0.05	-0.1086	0.4793
TRTP	mCC	SA	1.8012	0.1695	110	10.62	<.0001	0.05	1.4652	2.1372



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	78



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6152

Fit Statistics	
-2 Res Log Likelihood	187.7
AIC (smaller is better)	189.7
AICC (smaller is better)	189.8
BIC (smaller is better)	192.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	72	6.16	0.0154
SEX	1	72	0.17	0.6848
UCPDGR1	1	72	0.14	0.7116
TRTP	2	72	23.13	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=22 Parameter Code=U4ABPCRE Parameter=4-ABP (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.1636	0.2677	72	4.35	<.0001	0.05	0.6300	1.6972
TRTP	THSm2.2	1.1568	0.1262	72	9.17	<.0001	0.05	0.9053	1.4083
TRTP	mCC	2.4291	0.1493	72	16.27	<.0001	0.05	2.1316	2.7267
TRTP	SA	1.1636	0.2677	72	4.35	<.0001	0.05	0.6300	1.6972
TRTP	THSm2.2	1.1568	0.1262	72	9.17	<.0001	0.05	0.9053	1.4083
TRTP	mCC	2.4291	0.1493	72	16.27	<.0001	0.05	2.1316	2.7267

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2655	0.3044	72	-4.16	<.0001	0.05	-1.8724	-0.6586
TRTP	THSm2.2	mCC	-1.2723	0.1945	72	-6.54	<.0001	0.05	-1.6600	-0.8846
TRTP	THSm2.2	SA	-0.00677	0.2942	72	-0.02	0.9817	0.05	-0.5933	0.5797
TRTP	mCC	SA	1.2655	0.3044	72	4.16	<.0001	0.05	0.6586	1.8724



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3399

Fit Statistics	
-2 Res Log Likelihood	223.5
AIC (smaller is better)	225.5
AICC (smaller is better)	225.6
BIC (smaller is better)	228.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	13.20	0.0004
SEX	1	115	0.42	0.5202
UCPDGR1	1	115	0.79	0.3762
TRTP	2	115	93.75	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.9076	0.1250	115	7.26	<.0001	0.05	0.6599	1.1553
TRTP	THSm2.2	1.1354	0.07155	115	15.87	<.0001	0.05	0.9937	1.2771
TRTP	mCC	2.7532	0.1069	115	25.75	<.0001	0.05	2.5415	2.9650
TRTP	SA	0.9076	0.1250	115	7.26	<.0001	0.05	0.6599	1.1553
TRTP	THSm2.2	1.1354	0.07155	115	15.87	<.0001	0.05	0.9937	1.2771
TRTP	mCC	2.7532	0.1069	115	25.75	<.0001	0.05	2.5415	2.9650

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8456	0.1643	115	-11.24	<.0001	0.05	-2.1710	-1.5203
TRTP	THSm2.2	mCC	-1.6179	0.1277	115	-12.67	<.0001	0.05	-1.8708	-1.3649
TRTP	THSm2.2	SA	0.2278	0.1432	115	1.59	0.1146	0.05	-0.05596	0.5115
TRTP	mCC	SA	1.8456	0.1643	115	11.24	<.0001	0.05	1.5203	2.1710



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6450

Fit Statistics	
-2 Res Log Likelihood	196.2
AIC (smaller is better)	198.2
AICC (smaller is better)	198.2
BIC (smaller is better)	200.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	2.70	0.1045
SEX	1	74	2.97	0.0891
UCPDGR1	1	74	0.03	0.8738
TRTP	2	74	21.52	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=23 Parameter Code=U4ABP24U Parameter=4-ABP (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.5988	0.2750	74	5.81	<.0001	0.05	1.0508	2.1468
TRTP	THSm2.2	1.6931	0.1253	74	13.52	<.0001	0.05	1.4435	1.9427
TRTP	mCC	2.9215	0.1528	74	19.12	<.0001	0.05	2.6171	3.2260
TRTP	SA	1.5988	0.2750	74	5.81	<.0001	0.05	1.0508	2.1468
TRTP	THSm2.2	1.6931	0.1253	74	13.52	<.0001	0.05	1.4435	1.9427
TRTP	mCC	2.9215	0.1528	74	19.12	<.0001	0.05	2.6171	3.2260

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.3227	0.3127	74	-4.23	<.0001	0.05	-1.9457	-0.6998
TRTP	THSm2.2	mCC	-1.2284	0.1969	74	-6.24	<.0001	0.05	-1.6208	-0.8360
TRTP	THSm2.2	SA	0.09434	0.3003	74	0.31	0.7543	0.05	-0.5039	0.6926
TRTP	mCC	SA	1.3227	0.3127	74	4.23	<.0001	0.05	0.6998	1.9457



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1643

Fit Statistics	
-2 Res Log Likelihood	134.2
AIC (smaller is better)	136.2
AICC (smaller is better)	136.2
BIC (smaller is better)	138.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	167.98	<.0001
SEX	1	110	6.39	0.0129
UCPDGR1	1	110	0.03	0.8740
TRTP	2	110	204.38	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.5711	0.08865	110	29.00	<.0001	0.05	2.3954	2.7468
TRTP	THSm2.2	2.6271	0.05088	110	51.63	<.0001	0.05	2.5263	2.7280
TRTP	mCC	4.3750	0.07574	110	57.76	<.0001	0.05	4.2249	4.5251
TRTP	SA	2.5711	0.08865	110	29.00	<.0001	0.05	2.3954	2.7468
TRTP	THSm2.2	2.6271	0.05088	110	51.63	<.0001	0.05	2.5263	2.7280
TRTP	mCC	4.3750	0.07574	110	57.76	<.0001	0.05	4.2249	4.5251

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8039	0.1164	110	-15.50	<.0001	0.05	-2.0345	-1.5733
TRTP	THSm2.2	mCC	-1.7478	0.09056	110	-19.30	<.0001	0.05	-1.9273	-1.5684
TRTP	THSm2.2	SA	0.05603	0.1017	110	0.55	0.5827	0.05	-0.1455	0.2575
TRTP	mCC	SA	1.8039	0.1164	110	15.50	<.0001	0.05	1.5733	2.0345



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.9172

Fit Statistics	
-2 Res Log Likelihood	221.9
AIC (smaller is better)	223.9
AICC (smaller is better)	224.0
BIC (smaller is better)	226.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	13.43	0.0005
SEX	1	74	2.25	0.1377
UCPDGR1	1	74	0.64	0.4269
TRTP	2	74	35.33	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=25 Parameter Code=UCEMACRE Parameter=CEMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.6712	0.3257	74	8.20	<.0001	0.05	2.0222	3.3202
TRTP	THSm2.2	2.4733	0.1497	74	16.52	<.0001	0.05	2.1750	2.7716
TRTP	mCC	4.4078	0.1822	74	24.19	<.0001	0.05	4.0448	4.7708
TRTP	SA	2.6712	0.3257	74	8.20	<.0001	0.05	2.0222	3.3202
TRTP	THSm2.2	2.4733	0.1497	74	16.52	<.0001	0.05	2.1750	2.7716
TRTP	mCC	4.4078	0.1822	74	24.19	<.0001	0.05	4.0448	4.7708

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.7366	0.3704	74	-4.69	<.0001	0.05	-2.4747	-0.9985
TRTP	THSm2.2	mCC	-1.9345	0.2350	74	-8.23	<.0001	0.05	-2.4028	-1.4663
TRTP	THSm2.2	SA	-0.1979	0.3557	74	-0.56	0.5797	0.05	-0.9066	0.5108
TRTP	mCC	SA	1.7366	0.3704	74	4.69	<.0001	0.05	0.9985	2.4747





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1919

Fit Statistics	
-2 Res Log Likelihood	157.6
AIC (smaller is better)	159.6
AICC (smaller is better)	159.6
BIC (smaller is better)	162.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	147.59	<.0001
SEX	1	115	9.44	0.0026
UCPDGR1	1	115	0.00	0.9579
TRTP	2	115	182.15	<.0001



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.1016	0.09378	115	33.08	<.0001	0.05	2.9159	3.2874
TRTP	THSm2.2	3.1566	0.05374	115	58.74	<.0001	0.05	3.0501	3.2630
TRTP	mCC	4.9068	0.08033	115	61.08	<.0001	0.05	4.7477	5.0660
TRTP	SA	3.1016	0.09378	115	33.08	<.0001	0.05	2.9159	3.2874
TRTP	THSm2.2	3.1566	0.05374	115	58.74	<.0001	0.05	3.0501	3.2630
TRTP	mCC	4.9068	0.08033	115	61.08	<.0001	0.05	4.7477	5.0660

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8052	0.1232	115	-14.65	<.0001	0.05	-2.0492	-1.5612
TRTP	THSm2.2	mCC	-1.7503	0.09599	115	-18.23	<.0001	0.05	-1.9404	-1.5601
TRTP	THSm2.2	SA	0.05492	0.1074	115	0.51	0.6099	0.05	-0.1577	0.2676
TRTP	mCC	SA	1.8052	0.1232	115	14.65	<.0001	0.05	1.5612	2.0492



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.9717

Fit Statistics	
-2 Res Log Likelihood	232.1
AIC (smaller is better)	234.1
AICC (smaller is better)	234.2
BIC (smaller is better)	236.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	11.14	0.0013
SEX	1	76	3.37	0.0702
UCPDGR1	1	76	0.28	0.5953
TRTP	2	76	32.19	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=26 Parameter Code=UCEMA24U Parameter=CEMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.1627	0.3361	76	9.41	<.0001	0.05	2.4933	3.8321
TRTP	THSm2.2	3.0217	0.1501	76	20.14	<.0001	0.05	2.7229	3.3206
TRTP	mCC	4.9018	0.1874	76	26.15	<.0001	0.05	4.5286	5.2751
TRTP	SA	3.1627	0.3361	76	9.41	<.0001	0.05	2.4933	3.8321
TRTP	THSm2.2	3.0217	0.1501	76	20.14	<.0001	0.05	2.7229	3.3206
TRTP	mCC	4.9018	0.1874	76	26.15	<.0001	0.05	4.5286	5.2751

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.7391	0.3821	76	-4.55	<.0001	0.05	-2.5002	-0.9781
TRTP	THSm2.2	mCC	-1.8801	0.2396	76	-7.85	<.0001	0.05	-2.3573	-1.4029
TRTP	THSm2.2	SA	-0.1410	0.3651	76	-0.39	0.7005	0.05	-0.8681	0.5862
TRTP	mCC	SA	1.7391	0.3821	76	4.55	<.0001	0.05	0.9781	2.5002



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2740

Fit Statistics	
-2 Res Log Likelihood	191.0
AIC (smaller is better)	193.0
AICC (smaller is better)	193.1
BIC (smaller is better)	195.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	114.25	<.0001
SEX	1	110	0.40	0.5301
UCPDGR1	1	110	0.97	0.3271
TRTP	2	110	35.38	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	7.0069	0.1145	110	61.22	<.0001	0.05	6.7801	7.2337
TRTP	THSm2.2	7.0472	0.06618	110	106.48	<.0001	0.05	6.9161	7.1784
TRTP	mCC	7.9835	0.09762	110	81.78	<.0001	0.05	7.7901	8.1770
TRTP	SA	7.0069	0.1145	110	61.22	<.0001	0.05	6.7801	7.2337
TRTP	THSm2.2	7.0472	0.06618	110	106.48	<.0001	0.05	6.9161	7.1784
TRTP	mCC	7.9835	0.09762	110	81.78	<.0001	0.05	7.7901	8.1770

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9766	0.1502	110	-6.50	<.0001	0.05	-1.2743	-0.6789
TRTP	THSm2.2	mCC	-0.9363	0.1171	110	-8.00	<.0001	0.05	-1.1683	-0.7043
TRTP	THSm2.2	SA	0.04032	0.1317	110	0.31	0.7600	0.05	-0.2206	0.3012
TRTP	mCC	SA	0.9766	0.1502	110	6.50	<.0001	0.05	0.6789	1.2743



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4046

Fit Statistics	
-2 Res Log Likelihood	161.9
AIC (smaller is better)	163.9
AICC (smaller is better)	163.9
BIC (smaller is better)	166.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	28.57	<.0001
SEX	1	74	0.83	0.3664
UCPDGR1	1	74	0.17	0.6772
TRTP	2	74	18.82	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=38 Parameter Code=UHEMACRE Parameter=HEMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	7.4933	0.2162	74	34.66	<.0001	0.05	7.0626	7.9241
TRTP	THSm2.2	7.2423	0.1008	74	71.88	<.0001	0.05	7.0416	7.4431
TRTP	mCC	8.2012	0.1209	74	67.85	<.0001	0.05	7.9604	8.4421
TRTP	SA	7.4933	0.2162	74	34.66	<.0001	0.05	7.0626	7.9241
TRTP	THSm2.2	7.2423	0.1008	74	71.88	<.0001	0.05	7.0416	7.4431
TRTP	mCC	8.2012	0.1209	74	67.85	<.0001	0.05	7.9604	8.4421

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7079	0.2456	74	-2.88	0.0052	0.05	-1.1973	-0.2184
TRTP	THSm2.2	mCC	-0.9589	0.1571	74	-6.10	<.0001	0.05	-1.2720	-0.6458
TRTP	THSm2.2	SA	-0.2510	0.2365	74	-1.06	0.2919	0.05	-0.7222	0.2202
TRTP	mCC	SA	0.7079	0.2456	74	2.88	0.0052	0.05	0.2184	1.1973



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



86

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2694

Fit Statistics	
-2 Res Log Likelihood	197.0
AIC (smaller is better)	199.0
AICC (smaller is better)	199.1
BIC (smaller is better)	201.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	117.52	<.0001
SEX	1	115	0.42	0.5160
UCPDGR1	1	115	0.86	0.3560
TRTP	2	115	38.82	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	7.5162	0.1111	115	67.65	<.0001	0.05	7.2961	7.7363
TRTP	THSm2.2	7.5509	0.06398	115	118.03	<.0001	0.05	7.4241	7.6776
TRTP	mCC	8.5062	0.09509	115	89.45	<.0001	0.05	8.3178	8.6945
TRTP	SA	7.5162	0.1111	115	67.65	<.0001	0.05	7.2961	7.7363
TRTP	THSm2.2	7.5509	0.06398	115	118.03	<.0001	0.05	7.4241	7.6776
TRTP	mCC	8.5062	0.09509	115	89.45	<.0001	0.05	8.3178	8.6945

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9900	0.1458	115	-6.79	<.0001	0.05	-1.2789	-0.7011
TRTP	THSm2.2	mCC	-0.9553	0.1138	115	-8.40	<.0001	0.05	-1.1807	-0.7299
TRTP	THSm2.2	SA	0.03470	0.1276	115	0.27	0.7861	0.05	-0.2180	0.2874
TRTP	mCC	SA	0.9900	0.1458	115	6.79	<.0001	0.05	0.7011	1.2789



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





89

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4052

Fit Statistics	
-2 Res Log Likelihood	166.0
AIC (smaller is better)	168.0
AICC (smaller is better)	168.1
BIC (smaller is better)	170.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	32.79	<.0001
SEX	1	76	0.02	0.8937
UCPDGR1	1	76	0.43	0.5128
TRTP	2	76	18.67	<.0001



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=39 Parameter Code=UHEMA24U Parameter=HEMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	7.9866	0.2165	76	36.89	<.0001	0.05	7.5554	8.4178
TRTP	THSm2.2	7.7521	0.09770	76	79.35	<.0001	0.05	7.5575	7.9467
TRTP	mCC	8.6965	0.1210	76	71.87	<.0001	0.05	8.4555	8.9375
TRTP	SA	7.9866	0.2165	76	36.89	<.0001	0.05	7.5554	8.4178
TRTP	THSm2.2	7.7521	0.09770	76	79.35	<.0001	0.05	7.5575	7.9467
TRTP	mCC	8.6965	0.1210	76	71.87	<.0001	0.05	8.4555	8.9375

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7099	0.2459	76	-2.89	0.0051	0.05	-1.1996	-0.2202
TRTP	THSm2.2	mCC	-0.9444	0.1554	76	-6.08	<.0001	0.05	-1.2540	-0.6349
TRTP	THSm2.2	SA	-0.2345	0.2362	76	-0.99	0.3238	0.05	-0.7049	0.2358
TRTP	mCC	SA	0.7099	0.2459	76	2.89	0.0051	0.05	0.2202	1.1996



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2542

Fit Statistics	
-2 Res Log Likelihood	181.9
AIC (smaller is better)	183.9
AICC (smaller is better)	183.9
BIC (smaller is better)	186.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	56.53	<.0001
SEX	1	110	0.44	0.5090
UCPDGR1	1	110	1.93	0.1671
TRTP	2	110	42.76	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3601	0.1103	110	39.54	<.0001	0.05	4.1416	4.5787
TRTP	THSm2.2	4.5507	0.06333	110	71.86	<.0001	0.05	4.4252	4.6763
TRTP	mCC	5.4929	0.09406	110	58.40	<.0001	0.05	5.3065	5.6793
TRTP	SA	4.3601	0.1103	110	39.54	<.0001	0.05	4.1416	4.5787
TRTP	THSm2.2	4.5507	0.06333	110	71.86	<.0001	0.05	4.4252	4.6763
TRTP	mCC	5.4929	0.09406	110	58.40	<.0001	0.05	5.3065	5.6793

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.1328	0.1446	110	-7.83	<.0001	0.05	-1.4194	-0.8462
TRTP	THSm2.2	mCC	-0.9422	0.1126	110	-8.37	<.0001	0.05	-1.1653	-0.7191
TRTP	THSm2.2	SA	0.1906	0.1264	110	1.51	0.1346	0.05	-0.05998	0.4412
TRTP	mCC	SA	1.1328	0.1446	110	7.83	<.0001	0.05	0.8462	1.4194



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



95

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3539

Fit Statistics	
-2 Res Log Likelihood	151.2
AIC (smaller is better)	153.2
AICC (smaller is better)	153.3
BIC (smaller is better)	155.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	25.99	<.0001
SEX	1	74	0.61	0.4392
UCPDGR1	1	74	0.83	0.3641
TRTP	2	74	12.22	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=41 Parameter Code=UHMPMCRE Parameter=HMPMA (ng/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6571	0.2022	74	23.03	<.0001	0.05	4.2541	5.0600
TRTP	THSm2.2	4.6799	0.09344	74	50.08	<.0001	0.05	4.4937	4.8660
TRTP	mCC	5.3719	0.1130	74	47.52	<.0001	0.05	5.1466	5.5971
TRTP	SA	4.6571	0.2022	74	23.03	<.0001	0.05	4.2541	5.0600
TRTP	THSm2.2	4.6799	0.09344	74	50.08	<.0001	0.05	4.4937	4.8660
TRTP	mCC	5.3719	0.1130	74	47.52	<.0001	0.05	5.1466	5.5971

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7148	0.2298	74	-3.11	0.0026	0.05	-1.1726	-0.2570
TRTP	THSm2.2	mCC	-0.6920	0.1463	74	-4.73	<.0001	0.05	-0.9835	-0.4005
TRTP	THSm2.2	SA	0.02279	0.2211	74	0.10	0.9182	0.05	-0.4177	0.4633
TRTP	mCC	SA	0.7148	0.2298	74	3.11	0.0026	0.05	0.2570	1.1726





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2685

Fit Statistics	
-2 Res Log Likelihood	195.9
AIC (smaller is better)	197.9
AICC (smaller is better)	198.0
BIC (smaller is better)	200.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	52.49	<.0001
SEX	1	115	0.24	0.6246
UCPDGR1	1	115	2.34	0.1286
TRTP	2	115	43.75	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.9128	0.1109	115	44.31	<.0001	0.05	4.6931	5.1324
TRTP	THSm2.2	5.0674	0.06356	115	79.73	<.0001	0.05	4.9415	5.1933
TRTP	mCC	6.0429	0.09493	115	63.65	<.0001	0.05	5.8548	6.2309
TRTP	SA	4.9128	0.1109	115	44.31	<.0001	0.05	4.6931	5.1324
TRTP	THSm2.2	5.0674	0.06356	115	79.73	<.0001	0.05	4.9415	5.1933
TRTP	mCC	6.0429	0.09493	115	63.65	<.0001	0.05	5.8548	6.2309

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.1301	0.1455	115	-7.76	<.0001	0.05	-1.4184	-0.8418
TRTP	THSm2.2	mCC	-0.9755	0.1135	115	-8.60	<.0001	0.05	-1.2002	-0.7507
TRTP	THSm2.2	SA	0.1546	0.1270	115	1.22	0.2257	0.05	-0.09686	0.4061
TRTP	mCC	SA	1.1301	0.1455	115	7.76	<.0001	0.05	0.8418	1.4184



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



101

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3253

Fit Statistics	
-2 Res Log Likelihood	148.7
AIC (smaller is better)	150.7
AICC (smaller is better)	150.7
BIC (smaller is better)	153.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	28.99	<.0001
SEX	1	76	0.01	0.9274
UCPDGR1	1	76	1.72	0.1935
TRTP	2	76	14.17	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=42 Parameter Code=UHMPM24U Parameter=HMPMA (ug) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.1562	0.1945	76	26.51	<.0001	0.05	4.7689	5.5436
TRTP	THSm2.2	5.1537	0.08688	76	59.32	<.0001	0.05	4.9807	5.3267
TRTP	mCC	5.8666	0.1084	76	54.12	<.0001	0.05	5.6507	6.0825
TRTP	SA	5.1562	0.1945	76	26.51	<.0001	0.05	4.7689	5.5436
TRTP	THSm2.2	5.1537	0.08688	76	59.32	<.0001	0.05	4.9807	5.3267
TRTP	mCC	5.8666	0.1084	76	54.12	<.0001	0.05	5.6507	6.0825

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7104	0.2207	76	-3.22	0.0019	0.05	-1.1499	-0.2708
TRTP	THSm2.2	mCC	-0.7129	0.1386	76	-5.14	<.0001	0.05	-0.9890	-0.4368
TRTP	THSm2.2	SA	-0.00254	0.2116	76	-0.01	0.9905	0.05	-0.4240	0.4189
TRTP	mCC	SA	0.7104	0.2207	76	3.22	0.0019	0.05	0.2708	1.1499



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



104

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4688

Fit Statistics	
-2 Res Log Likelihood	246.4
AIC (smaller is better)	248.4
AICC (smaller is better)	248.5
BIC (smaller is better)	251.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	108	46.83	<.0001
SEX	1	108	2.73	0.1016
UCPDGR1	1	108	3.27	0.0732
TRTP	2	108	102.61	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5602	0.1497	108	30.45	<.0001	0.05	4.2634	4.8570
TRTP	THSm2.2	4.7197	0.08751	108	53.93	<.0001	0.05	4.5462	4.8931
TRTP	mCC	6.8108	0.1285	108	52.99	<.0001	0.05	6.5561	7.0656
TRTP	SA	4.5602	0.1497	108	30.45	<.0001	0.05	4.2634	4.8570
TRTP	THSm2.2	4.7197	0.08751	108	53.93	<.0001	0.05	4.5462	4.8931
TRTP	mCC	6.8108	0.1285	108	52.99	<.0001	0.05	6.5561	7.0656

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2507	0.1967	108	-11.44	<.0001	0.05	-2.6406	-1.8607
TRTP	THSm2.2	mCC	-2.0912	0.1557	108	-13.43	<.0001	0.05	-2.3998	-1.7826
TRTP	THSm2.2	SA	0.1595	0.1729	108	0.92	0.3584	0.05	-0.1833	0.5022
TRTP	mCC	SA	2.2507	0.1967	108	11.44	<.0001	0.05	1.8607	2.6406



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5546

Fit Statistics	
-2 Res Log Likelihood	185.8
AIC (smaller is better)	187.8
AICC (smaller is better)	187.9
BIC (smaller is better)	190.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	42.58	<.0001
SEX	1	74	0.18	0.6690
UCPDGR1	1	74	0.17	0.6791
TRTP	2	74	41.55	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=45 Parameter Code=UMHBMCRE Parameter=MHBMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.7950	0.2571	74	22.54	<.0001	0.05	5.2827	6.3073
TRTP	THSm2.2	5.3610	0.1185	74	45.22	<.0001	0.05	5.1247	5.5972
TRTP	mCC	7.0440	0.1422	74	49.54	<.0001	0.05	6.7607	7.3273
TRTP	SA	5.7950	0.2571	74	22.54	<.0001	0.05	5.2827	6.3073
TRTP	THSm2.2	5.3610	0.1185	74	45.22	<.0001	0.05	5.1247	5.5972
TRTP	mCC	7.0440	0.1422	74	49.54	<.0001	0.05	6.7607	7.3273

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2490	0.2893	74	-4.32	<.0001	0.05	-1.8254	-0.6725
TRTP	THSm2.2	mCC	-1.6830	0.1864	74	-9.03	<.0001	0.05	-2.0544	-1.3116
TRTP	THSm2.2	SA	-0.4341	0.2845	74	-1.53	0.1313	0.05	-1.0009	0.1328
TRTP	mCC	SA	1.2490	0.2893	74	4.32	<.0001	0.05	0.6725	1.8254



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



110

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4628

Fit Statistics	
-2 Res Log Likelihood	249.3
AIC (smaller is better)	251.3
AICC (smaller is better)	251.3
BIC (smaller is better)	254.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	41.75	<.0001
SEX	1	110	0.03	0.8604
UCPDGR1	1	110	3.99	0.0483
TRTP	2	110	105.32	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.0581	0.1489	110	33.97	<.0001	0.05	4.7631	5.3532
TRTP	THSm2.2	5.2160	0.08537	110	61.10	<.0001	0.05	5.0468	5.3852
TRTP	mCC	7.3152	0.1279	110	57.19	<.0001	0.05	7.0617	7.5687
TRTP	SA	5.0581	0.1489	110	33.97	<.0001	0.05	4.7631	5.3532
TRTP	THSm2.2	5.2160	0.08537	110	61.10	<.0001	0.05	5.0468	5.3852
TRTP	mCC	7.3152	0.1279	110	57.19	<.0001	0.05	7.0617	7.5687

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2570	0.1954	110	-11.55	<.0001	0.05	-2.6442	-1.8698
TRTP	THSm2.2	mCC	-2.0992	0.1539	110	-13.64	<.0001	0.05	-2.4042	-1.7942
TRTP	THSm2.2	SA	0.1578	0.1713	110	0.92	0.3588	0.05	-0.1816	0.4972
TRTP	mCC	SA	2.2570	0.1954	110	11.55	<.0001	0.05	1.8698	2.6442



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5711

Fit Statistics	
-2 Res Log Likelihood	192.7
AIC (smaller is better)	194.7
AICC (smaller is better)	194.8
BIC (smaller is better)	197.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	40.27	<.0001
SEX	1	76	1.07	0.3035
UCPDGR1	1	76	0.84	0.3619
TRTP	2	76	39.59	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=46 Parameter Code=UMHBM24U Parameter=MHBMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	6.2883	0.2624	76	23.96	<.0001	0.05	5.7656	6.8110
TRTP	THSm2.2	5.8936	0.1166	76	50.52	<.0001	0.05	5.6612	6.1259
TRTP	mCC	7.5398	0.1445	76	52.18	<.0001	0.05	7.2521	7.8276
TRTP	SA	6.2883	0.2624	76	23.96	<.0001	0.05	5.7656	6.8110
TRTP	THSm2.2	5.8936	0.1166	76	50.52	<.0001	0.05	5.6612	6.1259
TRTP	mCC	7.5398	0.1445	76	52.18	<.0001	0.05	7.2521	7.8276

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2516	0.2943	76	-4.25	<.0001	0.05	-1.8377	-0.6655
TRTP	THSm2.2	mCC	-1.6463	0.1869	76	-8.81	<.0001	0.05	-2.0186	-1.2739
TRTP	THSm2.2	SA	-0.3947	0.2887	76	-1.37	0.1756	0.05	-0.9698	0.1803
TRTP	mCC	SA	1.2516	0.2943	76	4.25	<.0001	0.05	0.6655	1.8377



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2439

Fit Statistics	
-2 Res Log Likelihood	177.3
AIC (smaller is better)	179.3
AICC (smaller is better)	179.4
BIC (smaller is better)	182.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	90.23	<.0001
SEX	1	110	0.39	0.5355
UCPDGR1	1	110	0.51	0.4750
TRTP	2	110	428.76	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.4973	0.1080	110	-13.86	<.0001	0.05	-1.7113	-1.2833
TRTP	THSm2.2	1.9510	0.06196	110	31.49	<.0001	0.05	1.8282	2.0738
TRTP	mCC	2.0813	0.09243	110	22.52	<.0001	0.05	1.8981	2.2645
TRTP	SA	-1.4973	0.1080	110	-13.86	<.0001	0.05	-1.7113	-1.2833
TRTP	THSm2.2	1.9510	0.06196	110	31.49	<.0001	0.05	1.8282	2.0738
TRTP	mCC	2.0813	0.09243	110	22.52	<.0001	0.05	1.8981	2.2645

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.5786	0.1418	110	-25.24	<.0001	0.05	-3.8596	-3.2976
TRTP	THSm2.2	mCC	-0.1303	0.1104	110	-1.18	0.2407	0.05	-0.3491	0.08859
TRTP	THSm2.2	SA	3.4483	0.1239	110	27.84	<.0001	0.05	3.2029	3.6938
TRTP	mCC	SA	3.5786	0.1418	110	25.24	<.0001	0.05	3.2976	3.8596



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



119

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5933

Fit Statistics	
-2 Res Log Likelihood	189.4
AIC (smaller is better)	191.4
AICC (smaller is better)	191.5
BIC (smaller is better)	193.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	23.46	<.0001
SEX	1	74	0.14	0.7092
UCPDGR1	1	74	0.10	0.7562
TRTP	2	74	24.03	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=47 Parameter Code=UNEQCRE Parameter=NEQ (mg/g creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.02421	0.2625	74	-0.09	0.9268	0.05	-0.5473	0.4989
TRTP	THSm2.2	1.8809	0.1204	74	15.62	<.0001	0.05	1.6409	2.1208
TRTP	mCC	1.9144	0.1470	74	13.02	<.0001	0.05	1.6215	2.2074
TRTP	SA	-0.02421	0.2625	74	-0.09	0.9268	0.05	-0.5473	0.4989
TRTP	THSm2.2	1.8809	0.1204	74	15.62	<.0001	0.05	1.6409	2.1208
TRTP	mCC	1.9144	0.1470	74	13.02	<.0001	0.05	1.6215	2.2074

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.9386	0.2994	74	-6.48	<.0001	0.05	-2.5351	-1.3422
TRTP	THSm2.2	mCC	-0.03355	0.1891	74	-0.18	0.8597	0.05	-0.4104	0.3433
TRTP	THSm2.2	SA	1.9051	0.2868	74	6.64	<.0001	0.05	1.3335	2.4766
TRTP	mCC	SA	1.9386	0.2994	74	6.48	<.0001	0.05	1.3422	2.5351





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	120



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	120
Number of Observations Used	120
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3140

Fit Statistics	
-2 Res Log Likelihood	212.1
AIC (smaller is better)	214.1
AICC (smaller is better)	214.1
BIC (smaller is better)	216.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	114	90.43	<.0001
SEX	1	114	0.22	0.6381
UCPDGR1	1	114	1.69	0.1962
TRTP	2	114	350.32	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.0085	0.1199	114	-8.41	<.0001	0.05	-1.2461	-0.7709
TRTP	THSm2.2	2.4389	0.06939	114	35.15	<.0001	0.05	2.3014	2.5764
TRTP	mCC	2.6073	0.1029	114	25.34	<.0001	0.05	2.4035	2.8111
TRTP	SA	-1.0085	0.1199	114	-8.41	<.0001	0.05	-1.2461	-0.7709
TRTP	THSm2.2	2.4389	0.06939	114	35.15	<.0001	0.05	2.3014	2.5764
TRTP	mCC	2.6073	0.1029	114	25.34	<.0001	0.05	2.4035	2.8111

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.6158	0.1577	114	-22.92	<.0001	0.05	-3.9282	-3.3033
TRTP	THSm2.2	mCC	-0.1684	0.1233	114	-1.37	0.1748	0.05	-0.4126	0.07589
TRTP	THSm2.2	SA	3.4474	0.1376	114	25.06	<.0001	0.05	3.1749	3.7199
TRTP	mCC	SA	3.6158	0.1577	114	22.92	<.0001	0.05	3.3033	3.9282



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	81



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	81
Number of Observations Used	81
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5909

Fit Statistics	
-2 Res Log Likelihood	191.5
AIC (smaller is better)	193.5
AICC (smaller is better)	193.6
BIC (smaller is better)	195.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	75	22.84	<.0001
SEX	1	75	0.64	0.4272
UCPDGR1	1	75	0.02	0.8853
TRTP	2	75	23.46	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=48 Parameter Code=UNEQ24U Parameter=NEQ (mg) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.4833	0.2635	75	1.83	0.0706	0.05	-0.04162	1.0083
TRTP	THSm2.2	2.3588	0.1193	75	19.78	<.0001	0.05	2.1212	2.5964
TRTP	mCC	2.4142	0.1465	75	16.48	<.0001	0.05	2.1224	2.7059
TRTP	SA	0.4833	0.2635	75	1.83	0.0706	0.05	-0.04162	1.0083
TRTP	THSm2.2	2.3588	0.1193	75	19.78	<.0001	0.05	2.1212	2.5964
TRTP	mCC	2.4142	0.1465	75	16.48	<.0001	0.05	2.1224	2.7059

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.9309	0.3003	75	-6.43	<.0001	0.05	-2.5290	-1.3327
TRTP	THSm2.2	mCC	-0.05539	0.1885	75	-0.29	0.7697	0.05	-0.4309	0.3201
TRTP	THSm2.2	SA	1.8755	0.2866	75	6.54	<.0001	0.05	1.3045	2.4465
TRTP	mCC	SA	1.9309	0.3003	75	6.43	<.0001	0.05	1.3327	2.5290



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



128

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1538

Fit Statistics	
-2 Res Log Likelihood	127.8
AIC (smaller is better)	129.8
AICC (smaller is better)	129.8
BIC (smaller is better)	132.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	508.50	<.0001
SEX	1	110	0.25	0.6185
UCPDGR1	1	110	0.36	0.5505
TRTP	2	110	46.12	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0032	0.08574	110	46.69	<.0001	0.05	3.8333	4.1731
TRTP	THSm2.2	4.0098	0.04936	110	81.24	<.0001	0.05	3.9120	4.1076
TRTP	mCC	4.8183	0.07312	110	65.90	<.0001	0.05	4.6734	4.9632
TRTP	SA	4.0032	0.08574	110	46.69	<.0001	0.05	3.8333	4.1731
TRTP	THSm2.2	4.0098	0.04936	110	81.24	<.0001	0.05	3.9120	4.1076
TRTP	mCC	4.8183	0.07312	110	65.90	<.0001	0.05	4.6734	4.9632

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.8151	0.1125	110	-7.25	<.0001	0.05	-1.0381	-0.5922
TRTP	THSm2.2	mCC	-0.8085	0.08770	110	-9.22	<.0001	0.05	-0.9823	-0.6347
TRTP	THSm2.2	SA	0.006622	0.09844	110	0.07	0.9465	0.05	-0.1885	0.2017
TRTP	mCC	SA	0.8151	0.1125	110	7.25	<.0001	0.05	0.5922	1.0381



130

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



131

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7512

Fit Statistics	
-2 Res Log Likelihood	207.9
AIC (smaller is better)	209.9
AICC (smaller is better)	210.0
BIC (smaller is better)	212.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	32.85	<.0001
SEX	1	74	1.40	0.2406
UCPDGR1	1	74	0.15	0.6962
TRTP	2	74	18.81	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=52 Parameter Code=UNNALCRE Parameter=Total NNAL (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9923	0.2948	74	13.54	<.0001	0.05	3.4048	4.5798
TRTP	THSm2.2	3.7142	0.1362	74	27.27	<.0001	0.05	3.4429	3.9856
TRTP	mCC	5.0124	0.1648	74	30.42	<.0001	0.05	4.6841	5.3407
TRTP	SA	3.9923	0.2948	74	13.54	<.0001	0.05	3.4048	4.5798
TRTP	THSm2.2	3.7142	0.1362	74	27.27	<.0001	0.05	3.4429	3.9856
TRTP	mCC	5.0124	0.1648	74	30.42	<.0001	0.05	4.6841	5.3407

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0201	0.3348	74	-3.05	0.0032	0.05	-1.6872	-0.3530
TRTP	THSm2.2	mCC	-1.2982	0.2136	74	-6.08	<.0001	0.05	-1.7239	-0.8725
TRTP	THSm2.2	SA	-0.2781	0.3227	74	-0.86	0.3916	0.05	-0.9210	0.3648
TRTP	mCC	SA	1.0201	0.3348	74	3.05	0.0032	0.05	0.3530	1.6872



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1716

Fit Statistics	
-2 Res Log Likelihood	142.1
AIC (smaller is better)	144.1
AICC (smaller is better)	144.2
BIC (smaller is better)	146.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	112	449.27	<.0001
SEX	1	112	0.96	0.3298
UCPDGR1	1	112	0.45	0.5027
TRTP	2	112	43.06	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5135	0.09059	112	49.82	<.0001	0.05	4.3341	4.6930
TRTP	THSm2.2	4.5047	0.05121	112	87.96	<.0001	0.05	4.4032	4.6062
TRTP	mCC	5.3309	0.07726	112	69.00	<.0001	0.05	5.1778	5.4840
TRTP	SA	4.5135	0.09059	112	49.82	<.0001	0.05	4.3341	4.6930
TRTP	THSm2.2	4.5047	0.05121	112	87.96	<.0001	0.05	4.4032	4.6062
TRTP	mCC	5.3309	0.07726	112	69.00	<.0001	0.05	5.1778	5.4840

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.8174	0.1189	112	-6.88	<.0001	0.05	-1.0528	-0.5819
TRTP	THSm2.2	mCC	-0.8262	0.09215	112	-8.97	<.0001	0.05	-1.0088	-0.6436
TRTP	THSm2.2	SA	-0.00884	0.1036	112	-0.09	0.9322	0.05	-0.2141	0.1964
TRTP	mCC	SA	0.8174	0.1189	112	6.88	<.0001	0.05	0.5819	1.0528



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.8236

Fit Statistics	
-2 Res Log Likelihood	220.2
AIC (smaller is better)	222.2
AICC (smaller is better)	222.2
BIC (smaller is better)	224.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	28.04	<.0001
SEX	1	76	3.03	0.0858
UCPDGR1	1	76	0.06	0.8137
TRTP	2	76	17.28	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=53 Parameter Code=UNNAL24U Parameter=Total NNAL (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.4727	0.3092	76	14.47	<.0001	0.05	3.8569	5.0885
TRTP	THSm2.2	4.2039	0.1384	76	30.38	<.0001	0.05	3.9283	4.4795
TRTP	mCC	5.4912	0.1725	76	31.83	<.0001	0.05	5.1476	5.8348
TRTP	SA	4.4727	0.3092	76	14.47	<.0001	0.05	3.8569	5.0885
TRTP	THSm2.2	4.2039	0.1384	76	30.38	<.0001	0.05	3.9283	4.4795
TRTP	mCC	5.4912	0.1725	76	31.83	<.0001	0.05	5.1476	5.8348

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0184	0.3509	76	-2.90	0.0048	0.05	-1.7172	-0.3196
TRTP	THSm2.2	mCC	-1.2873	0.2208	76	-5.83	<.0001	0.05	-1.7271	-0.8475
TRTP	THSm2.2	SA	-0.2689	0.3367	76	-0.80	0.4270	0.05	-0.9394	0.4017
TRTP	mCC	SA	1.0184	0.3509	76	2.90	0.0048	0.05	0.3196	1.7172



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4830

Fit Statistics	
-2 Res Log Likelihood	253.7
AIC (smaller is better)	255.7
AICC (smaller is better)	255.7
BIC (smaller is better)	258.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	59.11	<.0001
SEX	1	110	0.00	0.9970
UCPDGR1	1	110	0.41	0.5238
TRTP	2	110	188.40	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-2.0297	0.1524	110	-13.32	<.0001	0.05	-2.3316	-1.7277
TRTP	THSm2.2	-0.1109	0.08790	110	-1.26	0.2099	0.05	-0.2851	0.06333
TRTP	mCC	1.8151	0.1296	110	14.01	<.0001	0.05	1.5583	2.0719
TRTP	SA	-2.0297	0.1524	110	-13.32	<.0001	0.05	-2.3316	-1.7277
TRTP	THSm2.2	-0.1109	0.08790	110	-1.26	0.2099	0.05	-0.2851	0.06333
TRTP	mCC	1.8151	0.1296	110	14.01	<.0001	0.05	1.5583	2.0719

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.8447	0.1997	110	-19.25	<.0001	0.05	-4.2405	-3.4490
TRTP	THSm2.2	mCC	-1.9259	0.1556	110	-12.38	<.0001	0.05	-2.2343	-1.6176
TRTP	THSm2.2	SA	1.9188	0.1758	110	10.92	<.0001	0.05	1.5705	2.2671
TRTP	mCC	SA	3.8447	0.1997	110	19.25	<.0001	0.05	3.4490	4.2405



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



143

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5654

Fit Statistics	
-2 Res Log Likelihood	186.9
AIC (smaller is better)	188.9
AICC (smaller is better)	189.0
BIC (smaller is better)	191.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	31.71	<.0001
SEX	1	74	0.78	0.3792
UCPDGR1	1	74	0.08	0.7788
TRTP	2	74	61.47	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=55 Parameter Code=UNNNCRE Parameter=NNN (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.0909	0.2566	74	-4.25	<.0001	0.05	-1.6021	-0.5797
TRTP	THSm2.2	-0.1063	0.1191	74	-0.89	0.3750	0.05	-0.3437	0.1311
TRTP	mCC	1.5936	0.1432	74	11.13	<.0001	0.05	1.3082	1.8790
TRTP	SA	-1.0909	0.2566	74	-4.25	<.0001	0.05	-1.6021	-0.5797
TRTP	THSm2.2	-0.1063	0.1191	74	-0.89	0.3750	0.05	-0.3437	0.1311
TRTP	mCC	1.5936	0.1432	74	11.13	<.0001	0.05	1.3082	1.8790

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.6846	0.2907	74	-9.24	<.0001	0.05	-3.2637	-2.1054
TRTP	THSm2.2	mCC	-1.6999	0.1870	74	-9.09	<.0001	0.05	-2.0725	-1.3274
TRTP	THSm2.2	SA	0.9846	0.2821	74	3.49	0.0008	0.05	0.4225	1.5468
TRTP	mCC	SA	2.6846	0.2907	74	9.24	<.0001	0.05	2.1054	3.2637





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5198

Fit Statistics	
-2 Res Log Likelihood	266.3
AIC (smaller is better)	268.3
AICC (smaller is better)	268.3
BIC (smaller is better)	271.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	112	55.01	<.0001
SEX	1	112	0.72	0.3980
UCPDGR1	1	112	1.04	0.3101
TRTP	2	112	176.01	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.5384	0.1582	112	-9.72	<.0001	0.05	-1.8518	-1.2250
TRTP	THSm2.2	0.3725	0.08931	112	4.17	<.0001	0.05	0.1956	0.5495
TRTP	mCC	2.3153	0.1344	112	17.22	<.0001	0.05	2.0489	2.5816
TRTP	SA	-1.5384	0.1582	112	-9.72	<.0001	0.05	-1.8518	-1.2250
TRTP	THSm2.2	0.3725	0.08931	112	4.17	<.0001	0.05	0.1956	0.5495
TRTP	mCC	2.3153	0.1344	112	17.22	<.0001	0.05	2.0489	2.5816

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.8537	0.2072	112	-18.60	<.0001	0.05	-4.2643	-3.4431
TRTP	THSm2.2	mCC	-1.9428	0.1604	112	-12.11	<.0001	0.05	-2.2606	-1.6249
TRTP	THSm2.2	SA	1.9109	0.1813	112	10.54	<.0001	0.05	1.5516	2.2702
TRTP	mCC	SA	3.8537	0.2072	112	18.60	<.0001	0.05	3.4431	4.2643



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



149

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6046

Fit Statistics	
-2 Res Log Likelihood	196.8
AIC (smaller is better)	198.8
AICC (smaller is better)	198.9
BIC (smaller is better)	201.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	25.14	<.0001
SEX	1	76	0.01	0.9300
UCPDGR1	1	76	0.16	0.6930
TRTP	2	76	57.76	<.0001



150

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=56 Parameter Code=UNNN24U Parameter=NNN (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.6398	0.2658	76	-2.41	0.0185	0.05	-1.1691	-0.1105
TRTP	THSm2.2	0.3845	0.1189	76	3.23	0.0018	0.05	0.1477	0.6213
TRTP	mCC	2.0607	0.1480	76	13.93	<.0001	0.05	1.7660	2.3554
TRTP	SA	-0.6398	0.2658	76	-2.41	0.0185	0.05	-1.1691	-0.1105
TRTP	THSm2.2	0.3845	0.1189	76	3.23	0.0018	0.05	0.1477	0.6213
TRTP	mCC	2.0607	0.1480	76	13.93	<.0001	0.05	1.7660	2.3554

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.7005	0.3009	76	-8.97	<.0001	0.05	-3.2999	-2.1012
TRTP	THSm2.2	mCC	-1.6762	0.1899	76	-8.83	<.0001	0.05	-2.0543	-1.2980
TRTP	THSm2.2	SA	1.0244	0.2900	76	3.53	0.0007	0.05	0.4467	1.6020
TRTP	mCC	SA	2.7005	0.3009	76	8.97	<.0001	0.05	2.1012	3.2999



151

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



152

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2123

Fit Statistics	
-2 Res Log Likelihood	162.4
AIC (smaller is better)	164.4
AICC (smaller is better)	164.4
BIC (smaller is better)	167.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	2.35	0.1280
SEX	1	110	7.37	0.0077
UCPDGR1	1	110	0.02	0.8881
TRTP	2	110	31.31	<.0001





153

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.5474	0.1008	110	35.19	<.0001	0.05	3.3476	3.7471
TRTP	THSm2.2	3.7910	0.05783	110	65.56	<.0001	0.05	3.6764	3.9056
TRTP	mCC	4.4916	0.08655	110	51.90	<.0001	0.05	4.3201	4.6631
TRTP	SA	3.5474	0.1008	110	35.19	<.0001	0.05	3.3476	3.7471
TRTP	THSm2.2	3.7910	0.05783	110	65.56	<.0001	0.05	3.6764	3.9056
TRTP	mCC	4.4916	0.08655	110	51.90	<.0001	0.05	4.3201	4.6631

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9442	0.1329	110	-7.10	<.0001	0.05	-1.2076	-0.6808
TRTP	THSm2.2	mCC	-0.7006	0.1032	110	-6.79	<.0001	0.05	-0.9051	-0.4961
TRTP	THSm2.2	SA	0.2436	0.1157	110	2.11	0.0375	0.05	0.01433	0.4729
TRTP	mCC	SA	0.9442	0.1329	110	7.10	<.0001	0.05	0.6808	1.2076



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



155

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3841

Fit Statistics	
-2 Res Log Likelihood	157.4
AIC (smaller is better)	159.4
AICC (smaller is better)	159.5
BIC (smaller is better)	161.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	3.27	0.0747
SEX	1	74	1.53	0.2199
UCPDGR1	1	74	0.08	0.7762
TRTP	2	74	16.29	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=58 Parameter Code=UOTOLCRE Parameter=o-tol (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.7375	0.2110	74	17.71	<.0001	0.05	3.3170	4.1580
TRTP	THSm2.2	3.8502	0.09682	74	39.77	<.0001	0.05	3.6573	4.0431
TRTP	mCC	4.6687	0.1188	74	39.31	<.0001	0.05	4.4320	4.9054
TRTP	SA	3.7375	0.2110	74	17.71	<.0001	0.05	3.3170	4.1580
TRTP	THSm2.2	3.8502	0.09682	74	39.77	<.0001	0.05	3.6573	4.0431
TRTP	mCC	4.6687	0.1188	74	39.31	<.0001	0.05	4.4320	4.9054

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9312	0.2410	74	-3.86	0.0002	0.05	-1.4115	-0.4509
TRTP	THSm2.2	mCC	-0.8185	0.1526	74	-5.36	<.0001	0.05	-1.1225	-0.5145
TRTP	THSm2.2	SA	0.1127	0.2304	74	0.49	0.6260	0.05	-0.3464	0.5718
TRTP	mCC	SA	0.9312	0.2410	74	3.86	0.0002	0.05	0.4509	1.4115



157

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	121



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	121
Number of Observations Used	121
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2080

Fit Statistics	
-2 Res Log Likelihood	166.8
AIC (smaller is better)	168.8
AICC (smaller is better)	168.8
BIC (smaller is better)	171.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	115	3.82	0.0532
SEX	1	115	1.37	0.2443
UCPDGR1	1	115	0.00	0.9888
TRTP	2	115	36.26	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0360	0.09782	115	41.26	<.0001	0.05	3.8422	4.2298
TRTP	THSm2.2	4.2676	0.05594	115	76.30	<.0001	0.05	4.1568	4.3784
TRTP	mCC	5.0110	0.08392	115	59.71	<.0001	0.05	4.8448	5.1772
TRTP	SA	4.0360	0.09782	115	41.26	<.0001	0.05	3.8422	4.2298
TRTP	THSm2.2	4.2676	0.05594	115	76.30	<.0001	0.05	4.1568	4.3784
TRTP	mCC	5.0110	0.08392	115	59.71	<.0001	0.05	4.8448	5.1772

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9750	0.1289	115	-7.56	<.0001	0.05	-1.2304	-0.7196
TRTP	THSm2.2	mCC	-0.7434	0.1002	115	-7.42	<.0001	0.05	-0.9418	-0.5449
TRTP	THSm2.2	SA	0.2317	0.1119	115	2.07	0.0407	0.05	0.009989	0.4533
TRTP	mCC	SA	0.9750	0.1289	115	7.56	<.0001	0.05	0.7196	1.2304



160

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





161

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3672

Fit Statistics	
-2 Res Log Likelihood	158.0
AIC (smaller is better)	160.0
AICC (smaller is better)	160.0
BIC (smaller is better)	162.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	4.61	0.0350
SEX	1	76	0.76	0.3875
UCPDGR1	1	76	0.21	0.6461
TRTP	2	76	17.87	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=59 Parameter Code=UOTOL24U Parameter=o-tol (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.1959	0.2072	76	20.25	<.0001	0.05	3.7832	4.6086
TRTP	THSm2.2	4.3208	0.09226	76	46.83	<.0001	0.05	4.1371	4.5046
TRTP	mCC	5.1537	0.1158	76	44.50	<.0001	0.05	4.9231	5.3844
TRTP	SA	4.1959	0.2072	76	20.25	<.0001	0.05	3.7832	4.6086
TRTP	THSm2.2	4.3208	0.09226	76	46.83	<.0001	0.05	4.1371	4.5046
TRTP	mCC	5.1537	0.1158	76	44.50	<.0001	0.05	4.9231	5.3844

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.9578	0.2367	76	-4.05	0.0001	0.05	-1.4292	-0.4865
TRTP	THSm2.2	mCC	-0.8329	0.1479	76	-5.63	<.0001	0.05	-1.1275	-0.5383
TRTP	THSm2.2	SA	0.1250	0.2249	76	0.56	0.5800	0.05	-0.3229	0.5728
TRTP	mCC	SA	0.9578	0.2367	76	4.05	0.0001	0.05	0.4865	1.4292



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



164

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3312

Fit Statistics	
-2 Res Log Likelihood	207.8
AIC (smaller is better)	209.8
AICC (smaller is better)	209.8
BIC (smaller is better)	212.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	108	54.93	<.0001
SEX	1	108	3.21	0.0760
UCPDGR1	1	108	0.20	0.6557
TRTP	2	108	2.47	0.0896



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	8.4356	0.1260	108	66.96	<.0001	0.05	8.1859	8.6853
TRTP	THSm2.2	8.2240	0.07314	108	112.43	<.0001	0.05	8.0790	8.3690
TRTP	mCC	8.0675	0.1076	108	74.98	<.0001	0.05	7.8542	8.2808
TRTP	SA	8.4356	0.1260	108	66.96	<.0001	0.05	8.1859	8.6853
TRTP	THSm2.2	8.2240	0.07314	108	112.43	<.0001	0.05	8.0790	8.3690
TRTP	mCC	8.0675	0.1076	108	74.98	<.0001	0.05	7.8542	8.2808

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3681	0.1657	108	2.22	0.0284	0.05	0.03962	0.6965
TRTP	THSm2.2	mCC	0.1565	0.1297	108	1.21	0.2302	0.05	-0.1006	0.4136
TRTP	THSm2.2	SA	-0.2116	0.1448	108	-1.46	0.1470	0.05	-0.4987	0.07550
TRTP	mCC	SA	-0.3681	0.1657	108	-2.22	0.0284	0.05	-0.6965	-0.03962



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6146

Fit Statistics	
-2 Res Log Likelihood	192.2
AIC (smaller is better)	194.2
AICC (smaller is better)	194.2
BIC (smaller is better)	196.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	10.43	0.0018
SEX	1	74	0.91	0.3427
UCPDGR1	1	74	0.75	0.3901
TRTP	2	74	0.27	0.7610



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=62 Parameter Code=USBMACRE Parameter=S-BMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	8.3666	0.2670	74	31.33	<.0001	0.05	7.8346	8.8987
TRTP	THSm2.2	8.2411	0.1233	74	66.83	<.0001	0.05	7.9954	8.4868
TRTP	mCC	8.1517	0.1490	74	54.72	<.0001	0.05	7.8549	8.4486
TRTP	SA	8.3666	0.2670	74	31.33	<.0001	0.05	7.8346	8.8987
TRTP	THSm2.2	8.2411	0.1233	74	66.83	<.0001	0.05	7.9954	8.4868
TRTP	mCC	8.1517	0.1490	74	54.72	<.0001	0.05	7.8549	8.4486

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2149	0.3032	74	0.71	0.4808	0.05	-0.3893	0.8191
TRTP	THSm2.2	mCC	0.08938	0.1930	74	0.46	0.6446	0.05	-0.2951	0.4739
TRTP	THSm2.2	SA	-0.1255	0.2925	74	-0.43	0.6692	0.05	-0.7084	0.4574
TRTP	mCC	SA	-0.2149	0.3032	74	-0.71	0.4808	0.05	-0.8191	0.3893





***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3423

Fit Statistics	
-2 Res Log Likelihood	215.0
AIC (smaller is better)	217.0
AICC (smaller is better)	217.0
BIC (smaller is better)	219.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	52.70	<.0001
SEX	1	110	1.18	0.2794
UCPDGR1	1	110	0.57	0.4514
TRTP	2	110	2.33	0.1025



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	8.9567	0.1279	110	70.02	<.0001	0.05	8.7032	9.2102
TRTP	THSm2.2	8.7552	0.07309	110	119.79	<.0001	0.05	8.6104	8.9001
TRTP	mCC	8.5939	0.1097	110	78.33	<.0001	0.05	8.3765	8.8113
TRTP	SA	8.9567	0.1279	110	70.02	<.0001	0.05	8.7032	9.2102
TRTP	THSm2.2	8.7552	0.07309	110	119.79	<.0001	0.05	8.6104	8.9001
TRTP	mCC	8.5939	0.1097	110	78.33	<.0001	0.05	8.3765	8.8113

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3628	0.1683	110	2.16	0.0333	0.05	0.02931	0.6963
TRTP	THSm2.2	mCC	0.1613	0.1314	110	1.23	0.2222	0.05	-0.09907	0.4217
TRTP	THSm2.2	SA	-0.2015	0.1467	110	-1.37	0.1723	0.05	-0.4922	0.08920
TRTP	mCC	SA	-0.3628	0.1683	110	-2.16	0.0333	0.05	-0.6963	-0.02931



172

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5800

Fit Statistics	
-2 Res Log Likelihood	192.6
AIC (smaller is better)	194.6
AICC (smaller is better)	194.6
BIC (smaller is better)	196.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	18.07	<.0001
SEX	1	76	0.01	0.9033
UCPDGR1	1	76	0.98	0.3259
TRTP	2	76	0.32	0.7256



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=63 Parameter Code=USBMA24U Parameter=S-BMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	8.8974	0.2613	76	34.06	<.0001	0.05	8.3770	9.4177
TRTP	THSm2.2	8.7134	0.1163	76	74.93	<.0001	0.05	8.4818	8.9451
TRTP	mCC	8.6601	0.1448	76	59.79	<.0001	0.05	8.3717	8.9486
TRTP	SA	8.8974	0.2613	76	34.06	<.0001	0.05	8.3770	9.4177
TRTP	THSm2.2	8.7134	0.1163	76	74.93	<.0001	0.05	8.4818	8.9451
TRTP	mCC	8.6601	0.1448	76	59.79	<.0001	0.05	8.3717	8.9486

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2372	0.2956	76	0.80	0.4247	0.05	-0.3514	0.8259
TRTP	THSm2.2	mCC	0.05331	0.1856	76	0.29	0.7748	0.05	-0.3164	0.4230
TRTP	THSm2.2	SA	-0.1839	0.2850	76	-0.65	0.5206	0.05	-0.7515	0.3836
TRTP	mCC	SA	-0.2372	0.2956	76	-0.80	0.4247	0.05	-0.8259	0.3514



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4018

Fit Statistics	
-2 Res Log Likelihood	229.5
AIC (smaller is better)	231.5
AICC (smaller is better)	231.5
BIC (smaller is better)	234.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	108	102.79	<.0001
SEX	1	108	3.18	0.0773
UCPDGR1	1	108	1.42	0.2362
TRTP	2	108	115.48	<.0001





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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.8740	0.1386	108	35.16	<.0001	0.05	4.5992	5.1487
TRTP	THSm2.2	4.8921	0.08052	108	60.76	<.0001	0.05	4.7325	5.0517
TRTP	mCC	6.9639	0.1182	108	58.92	<.0001	0.05	6.7296	7.1982
TRTP	SA	4.8740	0.1386	108	35.16	<.0001	0.05	4.5992	5.1487
TRTP	THSm2.2	4.8921	0.08052	108	60.76	<.0001	0.05	4.7325	5.0517
TRTP	mCC	6.9639	0.1182	108	58.92	<.0001	0.05	6.7296	7.1982

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.0900	0.1819	108	-11.49	<.0001	0.05	-2.4504	-1.7295
TRTP	THSm2.2	mCC	-2.0719	0.1422	108	-14.57	<.0001	0.05	-2.3538	-1.7900
TRTP	THSm2.2	SA	0.01808	0.1595	108	0.11	0.9100	0.05	-0.2981	0.3343
TRTP	mCC	SA	2.0900	0.1819	108	11.49	<.0001	0.05	1.7295	2.4504



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0369

Fit Statistics	
-2 Res Log Likelihood	231.8
AIC (smaller is better)	233.8
AICC (smaller is better)	233.9
BIC (smaller is better)	236.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	22.23	<.0001
SEX	1	74	0.01	0.9273
UCPDGR1	1	74	0.05	0.8179
TRTP	2	74	20.15	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=66 Parameter Code=USPMACRE Parameter=S-PMA (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.4190	0.3474	74	15.60	<.0001	0.05	4.7268	6.1111
TRTP	THSm2.2	5.5807	0.1597	74	34.96	<.0001	0.05	5.2626	5.8988
TRTP	mCC	7.0771	0.1936	74	36.56	<.0001	0.05	6.6915	7.4628
TRTP	SA	5.4190	0.3474	74	15.60	<.0001	0.05	4.7268	6.1111
TRTP	THSm2.2	5.5807	0.1597	74	34.96	<.0001	0.05	5.2626	5.8988
TRTP	mCC	7.0771	0.1936	74	36.56	<.0001	0.05	6.6915	7.4628

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6582	0.3948	74	-4.20	<.0001	0.05	-2.4447	-0.8716
TRTP	THSm2.2	mCC	-1.4964	0.2500	74	-5.98	<.0001	0.05	-1.9946	-0.9982
TRTP	THSm2.2	SA	0.1618	0.3802	74	0.43	0.6717	0.05	-0.5959	0.9194
TRTP	mCC	SA	1.6582	0.3948	74	4.20	<.0001	0.05	0.8716	2.4447



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4204

Fit Statistics	
-2 Res Log Likelihood	238.4
AIC (smaller is better)	240.4
AICC (smaller is better)	240.5
BIC (smaller is better)	243.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	89.34	<.0001
SEX	1	110	0.60	0.4400
UCPDGR1	1	110	1.20	0.2763
TRTP	2	110	111.55	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.3879	0.1418	110	38.00	<.0001	0.05	5.1069	5.6688
TRTP	THSm2.2	5.4101	0.08099	110	66.80	<.0001	0.05	5.2497	5.5706
TRTP	mCC	7.4858	0.1209	110	61.91	<.0001	0.05	7.2462	7.7254
TRTP	SA	5.3879	0.1418	110	38.00	<.0001	0.05	5.1069	5.6688
TRTP	THSm2.2	5.4101	0.08099	110	66.80	<.0001	0.05	5.2497	5.5706
TRTP	mCC	7.4858	0.1209	110	61.91	<.0001	0.05	7.2462	7.7254

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.0979	0.1860	110	-11.28	<.0001	0.05	-2.4666	-1.7293
TRTP	THSm2.2	mCC	-2.0756	0.1448	110	-14.34	<.0001	0.05	-2.3625	-1.7887
TRTP	THSm2.2	SA	0.02230	0.1626	110	0.14	0.8912	0.05	-0.2999	0.3445
TRTP	mCC	SA	2.0979	0.1860	110	11.28	<.0001	0.05	1.7293	2.4666



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82





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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0763

Fit Statistics	
-2 Res Log Likelihood	240.5
AIC (smaller is better)	242.5
AICC (smaller is better)	242.6
BIC (smaller is better)	244.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	76	21.62	<.0001
SEX	1	76	0.25	0.6161
UCPDGR1	1	76	0.26	0.6145
TRTP	2	76	18.58	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=67 Parameter Code=USPMA24U Parameter=S-PMA (ng) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.9289	0.3554	76	16.68	<.0001	0.05	5.2211	6.6367
TRTP	THSm2.2	6.1358	0.1582	76	38.78	<.0001	0.05	5.8206	6.4509
TRTP	mCC	7.5789	0.1971	76	38.44	<.0001	0.05	7.1863	7.9716
TRTP	SA	5.9289	0.3554	76	16.68	<.0001	0.05	5.2211	6.6367
TRTP	THSm2.2	6.1358	0.1582	76	38.78	<.0001	0.05	5.8206	6.4509
TRTP	mCC	7.5789	0.1971	76	38.44	<.0001	0.05	7.1863	7.9716

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6500	0.4032	76	-4.09	0.0001	0.05	-2.4531	-0.8470
TRTP	THSm2.2	mCC	-1.4432	0.2522	76	-5.72	<.0001	0.05	-1.9454	-0.9409
TRTP	THSm2.2	SA	0.2069	0.3872	76	0.53	0.5947	0.05	-0.5643	0.9781
TRTP	mCC	SA	1.6500	0.4032	76	4.09	0.0001	0.05	0.8470	2.4531



***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2569

Fit Statistics	
-2 Res Log Likelihood	186.6
AIC (smaller is better)	188.6
AICC (smaller is better)	188.6
BIC (smaller is better)	191.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	112	24.64	<.0001
SEX	1	112	0.75	0.3878
UCPDGR1	1	112	4.28	0.0408
TRTP	2	112	80.68	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.5249	0.1146	112	30.77	<.0001	0.05	3.2979	3.7519
TRTP	THSm2.2	3.9930	0.06353	112	62.85	<.0001	0.05	3.8671	4.1188
TRTP	mCC	5.2102	0.09458	112	55.09	<.0001	0.05	5.0228	5.3977
TRTP	SA	3.5249	0.1146	112	30.77	<.0001	0.05	3.2979	3.7519
TRTP	THSm2.2	3.9930	0.06353	112	62.85	<.0001	0.05	3.8671	4.1188
TRTP	mCC	5.2102	0.09458	112	55.09	<.0001	0.05	5.0228	5.3977

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6854	0.1491	112	-11.30	<.0001	0.05	-1.9808	-1.3900
TRTP	THSm2.2	mCC	-1.2173	0.1129	112	-10.79	<.0001	0.05	-1.4409	-0.9937
TRTP	THSm2.2	SA	0.4681	0.1328	112	3.52	0.0006	0.05	0.2049	0.7313
TRTP	mCC	SA	1.6854	0.1491	112	11.30	<.0001	0.05	1.3900	1.9808



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4146

Fit Statistics	
-2 Res Log Likelihood	163.3
AIC (smaller is better)	165.3
AICC (smaller is better)	165.4
BIC (smaller is better)	167.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	74	26.25	<.0001
SEX	1	74	0.55	0.4614
UCPDGR1	1	74	1.70	0.1969
TRTP	2	74	12.61	<.0001



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**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=84 Parameter Code=UBAP24U Parameter=B[a]P (pg) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5583	0.2231	74	20.43	<.0001	0.05	4.1138	5.0028
TRTP	THSm2.2	4.5500	0.1023	74	44.47	<.0001	0.05	4.3462	4.7539
TRTP	mCC	5.3242	0.1232	74	43.23	<.0001	0.05	5.0788	5.5696
TRTP	SA	4.5583	0.2231	74	20.43	<.0001	0.05	4.1138	5.0028
TRTP	THSm2.2	4.5500	0.1023	74	44.47	<.0001	0.05	4.3462	4.7539
TRTP	mCC	5.3242	0.1232	74	43.23	<.0001	0.05	5.0788	5.5696

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7659	0.2504	74	-3.06	0.0031	0.05	-1.2648	-0.2671
TRTP	THSm2.2	mCC	-0.7742	0.1618	74	-4.78	<.0001	0.05	-1.0967	-0.4517
TRTP	THSm2.2	SA	-0.00828	0.2478	74	-0.03	0.9734	0.05	-0.5020	0.4855
TRTP	mCC	SA	0.7659	0.2504	74	3.06	0.0031	0.05	0.2671	1.2648





193

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	116



194

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	116
Number of Observations Used	116
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2649

Fit Statistics	
-2 Res Log Likelihood	187.0
AIC (smaller is better)	189.0
AICC (smaller is better)	189.0
BIC (smaller is better)	191.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	110	33.98	<.0001
SEX	1	110	6.83	0.0102
UCPDGR1	1	110	4.27	0.0412
TRTP	2	110	76.91	<.0001



195

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.0476	0.1153	110	26.44	<.0001	0.05	2.8192	3.2760
TRTP	THSm2.2	3.4626	0.06591	110	52.53	<.0001	0.05	3.3319	3.5932
TRTP	mCC	4.6930	0.09618	110	48.79	<.0001	0.05	4.5024	4.8836
TRTP	SA	3.0476	0.1153	110	26.44	<.0001	0.05	2.8192	3.2760
TRTP	THSm2.2	3.4626	0.06591	110	52.53	<.0001	0.05	3.3319	3.5932
TRTP	mCC	4.6930	0.09618	110	48.79	<.0001	0.05	4.5024	4.8836

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6454	0.1509	110	-10.90	<.0001	0.05	-1.9445	-1.3462
TRTP	THSm2.2	mCC	-1.2304	0.1151	110	-10.69	<.0001	0.05	-1.4586	-1.0023
TRTP	THSm2.2	SA	0.4149	0.1346	110	3.08	0.0026	0.05	0.1481	0.6818
TRTP	mCC	SA	1.6454	0.1509	110	10.90	<.0001	0.05	1.3462	1.9445



196

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	78



197

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4136

Fit Statistics	
-2 Res Log Likelihood	159.0
AIC (smaller is better)	161.0
AICC (smaller is better)	161.1
BIC (smaller is better)	163.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	72	26.75	<.0001
SEX	1	72	0.05	0.8241
UCPDGR1	1	72	1.10	0.2982
TRTP	2	72	13.15	<.0001



**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=85 Parameter Code=UBAPCRE Parameter=B[a]P (fg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0747	0.2212	72	18.42	<.0001	0.05	3.6338	4.5155
TRTP	THSm2.2	4.0286	0.1061	72	37.97	<.0001	0.05	3.8171	4.2400
TRTP	mCC	4.8360	0.1229	72	39.36	<.0001	0.05	4.5910	5.0809
TRTP	SA	4.0747	0.2212	72	18.42	<.0001	0.05	3.6338	4.5155
TRTP	THSm2.2	4.0286	0.1061	72	37.97	<.0001	0.05	3.8171	4.2400
TRTP	mCC	4.8360	0.1229	72	39.36	<.0001	0.05	4.5910	5.0809

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7613	0.2492	72	-3.05	0.0032	0.05	-1.2582	-0.2645
TRTP	THSm2.2	mCC	-0.8074	0.1643	72	-4.91	<.0001	0.05	-1.1350	-0.4799
TRTP	THSm2.2	SA	-0.04611	0.2474	72	-0.19	0.8527	0.05	-0.5394	0.4472
TRTP	mCC	SA	0.7613	0.2492	72	3.05	0.0032	0.05	0.2645	1.2582



199

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=105 Analysis Visit=DAY 5 - 20:00 - 21:30**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



200

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=105 Analysis Visit=DAY 5 - 20:00 - 21:30

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	15.2063

Fit Statistics	
-2 Res Log Likelihood	733.4
AIC (smaller is better)	735.4
AICC (smaller is better)	735.4
BIC (smaller is better)	738.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	15.97	0.0001
SEX	1	127	1.46	0.2290
UCPDGR1	1	127	2.57	0.1117
TRTP	2	127	319.68	<.0001





201

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=105 Analysis Visit=DAY 5 - 20:00 - 21:30

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.9982	0.8020	127	2.49	0.0140	0.05	0.4112	3.5851
TRTP	THSm2.2	2.1441	0.4582	127	4.68	<.0001	0.05	1.2374	3.0507
TRTP	mCC	21.7220	0.6731	127	32.27	<.0001	0.05	20.3901	23.0539
TRTP	SA	1.9982	0.8020	127	2.49	0.0140	0.05	0.4112	3.5851
TRTP	THSm2.2	2.1441	0.4582	127	4.68	<.0001	0.05	1.2374	3.0507
TRTP	mCC	21.7220	0.6731	127	32.27	<.0001	0.05	20.3901	23.0539

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-19.7239	1.0417	127	-18.93	<.0001	0.05	-21.7852	-17.6626
TRTP	THSm2.2	mCC	-19.5779	0.8066	127	-24.27	<.0001	0.05	-21.1741	-17.9818
TRTP	THSm2.2	SA	0.1459	0.9166	127	0.16	0.8738	0.05	-1.6679	1.9597
TRTP	mCC	SA	19.7239	1.0417	127	18.93	<.0001	0.05	17.6626	21.7852



202

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

**Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=190 Analysis Visit=DAY 90**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



203

***Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set***

Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=190 Analysis Visit=DAY 90

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	35.7356

Fit Statistics	
-2 Res Log Likelihood	498.6
AIC (smaller is better)	500.6
AICC (smaller is better)	500.7
BIC (smaller is better)	502.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	74	2.22	0.1400
SEX	1	74	1.65	0.2026
UCPDGR1	1	74	3.02	0.0863
TRTP	2	74	66.16	<.0001



204

**Listing 15.4.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Parameter (N)=1 Parameter Code=CO Parameter=Exhaled CO (ppm) Analysis Visit (N)=190 Analysis Visit=DAY 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.7019	2.1538	74	2.18	0.0322	0.05	0.4104	8.9935
TRTP	THSm2.2	4.5361	0.9270	74	4.89	<.0001	0.05	2.6890	6.3832
TRTP	mCC	20.6848	1.1150	74	18.55	<.0001	0.05	18.4632	22.9065
TRTP	SA	4.7019	2.1538	74	2.18	0.0322	0.05	0.4104	8.9935
TRTP	THSm2.2	4.5361	0.9270	74	4.89	<.0001	0.05	2.6890	6.3832
TRTP	mCC	20.6848	1.1150	74	18.55	<.0001	0.05	18.4632	22.9065

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-15.9829	2.4085	74	-6.64	<.0001	0.05	-20.7819	-11.1839
TRTP	THSm2.2	mCC	-16.1487	1.4533	74	-11.11	<.0001	0.05	-19.0445	-13.2530
TRTP	THSm2.2	SA	-0.1658	2.3432	74	-0.07	0.9438	0.05	-4.8348	4.5031
TRTP	mCC	SA	15.9829	2.4085	74	6.64	<.0001	0.05	11.1839	20.7819



1

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=CARBXHGB Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	131
Number of Observations Used	131



2

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=CARBXHGB Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.91212775	4.58242555	67.55	<.0001
Error	125	8.47998723	0.06783990		
Corrected Total	130	31.39211498			

R-Square	Coeff Var	Root MSE	logaval Mean
0.729869	23.47272	0.260461	1.109633

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	0.04592888	0.04592888	0.68	0.4122
SEXC	1	0.05176277	0.05176277	0.76	0.3841
UCPDGR1	1	0.04796506	0.04796506	0.71	0.4020
TRTPN	2	22.76647104	11.38323552	167.80	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.68105323	0.68105323	10.04	0.0019
SEXC	1	0.09073536	0.09073536	1.34	0.2497
UCPDGR1	1	0.04944525	0.04944525	0.73	0.3949
TRTPN	2	22.76647104	11.38323552	167.80	<.0001



3

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=CARBXHGB Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.84581552	1
2	1.80979157	2
3	0.87323286	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6601
2	<.0001		<.0001
3	0.6601	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.845816	0.784692	0.906939
2	1.809792	1.720550	1.899033
3	0.873233	0.765201	0.981264



4

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=CARBXHGB Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.963976	-1.071562	-0.856390
1	3	-0.027417	-0.150521	0.095687
2	3	0.936559	0.797033	1.076085

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





5

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



6

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	249.3463328	49.8692666	182.88	<.0001
Error	117	31.9037236	0.2726814		
Corrected Total	122	281.2500564			

R-Square	Coeff Var	Root MSE	logaval Mean
0.886565	23.25412	0.522189	2.245577

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.7023630	3.7023630	13.58	0.0003
SEXC	1	1.6177120	1.6177120	5.93	0.0164
UCPDGR1	1	0.8913218	0.8913218	3.27	0.0732
TRTPN	2	243.1349360	121.5674680	445.82	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.9167040	2.9167040	10.70	0.0014
SEXC	1	0.4604910	0.4604910	1.69	0.1963
UCPDGR1	1	0.6537721	0.6537721	2.40	0.1242
TRTPN	2	243.1349360	121.5674680	445.82	<.0001



7

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.47082761	1
2	4.67206631	2
3	1.30579657	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1998
2	<.0001		<.0001
3	0.1998	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.470828	1.345030	1.596625
2	4.672066	4.485906	4.858227
3	1.305797	1.084192	1.527401

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.201239	-3.424703	-2.977774
1	3	0.165031	-0.088464	0.418526
2	3	3.366270	3.077235	3.655305

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



10

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	247.7681852	49.5536370	172.61	<.0001
Error	112	32.1542165	0.2870912		
Corrected Total	117	279.9224018			

R-Square	Coeff Var	Root MSE	logaval Mean
0.885132	30.80357	0.535809	1.739438

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.5973892	7.5973892	26.46	<.0001
SEXC	1	7.4891964	7.4891964	26.09	<.0001
UCPDGR1	1	1.3930881	1.3930881	4.85	0.0297
TRTPN	2	231.2885115	115.6442558	402.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.6271627	2.6271627	9.15	0.0031
SEXC	1	4.3550573	4.3550573	15.17	0.0002
UCPDGR1	1	0.5859653	0.5859653	2.04	0.1559
TRTPN	2	231.2885115	115.6442558	402.81	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.98381812	1
2	4.16636820	2
3	0.82711602	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2466
2	<.0001		<.0001
3	0.2466	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.983818	0.851392	1.116244
2	4.166368	3.971754	4.360983
3	0.827116	0.594840	1.059392



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.182550	-3.416305	-2.948795
1	3	0.156702	-0.109884	0.423288
2	3	3.339252	3.036194	3.642311

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	29.66307625	5.93261525	44.86	<.0001
Error	112	14.81240126	0.13225358		
Corrected Total	117	44.47547752			

R-Square	Coeff Var	Root MSE	logaval Mean
0.666954	7.576507	0.363667	4.799928

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.71467362	15.71467362	118.82	<.0001
SEXC	1	0.00467306	0.00467306	0.04	0.8512
UCPDGR1	1	1.50701001	1.50701001	11.39	0.0010
TRTPN	2	12.43671956	6.21835978	47.02	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.00346865	15.00346865	113.44	<.0001
SEXC	1	0.00948206	0.00948206	0.07	0.7894
UCPDGR1	1	1.24099342	1.24099342	9.38	0.0027
TRTPN	2	12.43671956	6.21835978	47.02	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U10HP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.61739062	1
2	5.34395400	2
3	4.54466181	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4319
2	<.0001		<.0001
3	0.4319	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.617391	4.526651	4.708130
2	5.343954	5.212085	5.475823
3	4.544662	4.387356	4.701967



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1OHP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.726563	-0.886005	-0.567122
1	3	0.072729	-0.109974	0.255432
2	3	0.799292	0.594278	1.004306

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	117
Number of Observations Used	117



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	39.28627256	7.85725451	85.61	<.0001
Error	111	10.18806648	0.09178438		
Corrected Total	116	49.47433904			

R-Square	Coeff Var	Root MSE	logaval Mean
0.794074	7.073578	0.302959	4.282972

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	24.97235918	24.97235918	272.08	<.0001
SEXC	1	0.28659091	0.28659091	3.12	0.0800
UCPDGR1	1	1.69337690	1.69337690	18.45	<.0001
TRTPN	2	12.33394556	6.16697278	67.19	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	19.12968900	19.12968900	208.42	<.0001
SEXC	1	0.50138775	0.50138775	5.46	0.0212
UCPDGR1	1	1.46453641	1.46453641	15.96	0.0001
TRTPN	2	12.33394556	6.16697278	67.19	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.10119030	1
2	4.83290096	2
3	4.05282878	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5290
2	<.0001		<.0001
3	0.5290	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.101190	4.024786	4.177594
2	4.832901	4.722943	4.942859
3	4.052829	3.922725	4.182933

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U10HPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.731711	-0.864675	-0.598746
1	3	0.048362	-0.103391	0.200114
2	3	0.780072	0.609470	0.950675

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.1040980	20.8208196	89.63	<.0001
Error	117	27.1786085	0.2322958		
Corrected Total	122	131.2827065			

R-Square	Coeff Var	Root MSE	logaval Mean
0.792976	26.81087	0.481971	1.797669

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.39122108	4.39122108	18.90	<.0001
SEXC	1	0.02120516	0.02120516	0.09	0.7631
UCPDGR1	1	0.08624515	0.08624515	0.37	0.5435
TRTPN	2	99.60542663	49.80271331	214.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.42802328	2.42802328	10.45	0.0016
SEXC	1	0.09696701	0.09696701	0.42	0.5195
UCPDGR1	1	0.02190511	0.02190511	0.09	0.7593
TRTPN	2	99.60542663	49.80271331	214.39	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.28709305	1
2	3.34401289	2
3	1.20194538	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4724
2	<.0001		<.0001
3	0.4724	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.287093	1.171030	1.403156
2	3.344013	3.172006	3.516020
3	1.201945	0.997363	1.406527

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U2NA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.056920	-2.263273	-1.850566
1	3	0.085148	-0.148769	0.319064
2	3	2.142068	1.874905	2.409230

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	103.7237099	20.7447420	79.40	<.0001
Error	112	29.2636532	0.2612826		
Corrected Total	117	132.9873631			

R-Square	Coeff Var	Root MSE	logaval Mean
0.779952	39.65218	0.511158	1.289105

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	6.71941025	6.71941025	25.72	<.0001
SEXC	1	3.02649457	3.02649457	11.58	0.0009
UCPDGR1	1	0.26086136	0.26086136	1.00	0.3199
TRTPN	2	93.71694371	46.85847185	179.34	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	2.31140465	2.31140465	8.85	0.0036
SEXC	1	1.73335774	1.73335774	6.63	0.0113
UCPDGR1	1	0.04037185	0.04037185	0.15	0.6950
TRTPN	2	93.71694371	46.85847185	179.34	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.80811185	1
2	2.83944813	2
3	0.72163375	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5017
2	<.0001		<.0001
3	0.5017	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.808112	0.681960	0.934264
2	2.839448	2.653536	3.025360
3	0.721634	0.500021	0.943246

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U2NACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.031336	-2.254408	-1.808264
1	3	0.086478	-0.167715	0.340671
2	3	2.117814	1.828382	2.407246

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	39.78529752	7.95705950	54.56	<.0001
Error	117	17.06302709	0.14583784		
Corrected Total	122	56.84832461			

R-Square	Coeff Var	Root MSE	logaval Mean
0.699850	6.101988	0.381887	6.258406

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.23610025	12.23610025	83.90	<.0001
SEXC	1	1.39406963	1.39406963	9.56	0.0025
UCPDGR1	1	0.35260695	0.35260695	2.42	0.1227
TRTPN	2	25.80252070	12.90126035	88.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.15385810	9.15385810	62.77	<.0001
SEXC	1	1.39181308	1.39181308	9.54	0.0025
UCPDGR1	1	0.21501530	0.21501530	1.47	0.2271
TRTPN	2	25.80252070	12.90126035	88.46	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.13535124	1
2	6.93069658	2
3	5.55103474	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.135351	6.043417	6.227285
2	6.930697	6.794443	7.066951
3	5.551035	5.388992	5.713077

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.795345	-0.958916	-0.631775
1	3	0.584317	0.399178	0.769455
2	3	1.379662	1.168106	1.591218

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U3HPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U3HPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.45476502	7.29095300	58.45	<.0001
Error	112	13.97014046	0.12473340		
Corrected Total	117	50.42490549			

R-Square	Coeff Var	Root MSE	logaval Mean
0.722952	6.163521	0.353176	5.730104

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.07271952	11.07271952	88.77	<.0001
SEXC	1	0.10376972	0.10376972	0.83	0.3637
UCPDGR1	1	0.46174225	0.46174225	3.70	0.0569
TRTPN	2	24.81653354	12.40826677	99.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	8.87270161	8.87270161	71.13	<.0001
SEXC	1	0.07538181	0.07538181	0.60	0.4386
UCPDGR1	1	0.19155267	0.19155267	1.54	0.2179
TRTPN	2	24.81653354	12.40826677	99.48	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U3HPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.62810439	1
2	6.40965327	2
3	5.02420407	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.628104	5.541071	5.715137
2	6.409653	6.281048	6.538259
3	5.024204	4.871209	5.177199

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U3HPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.781549	-0.935835	-0.627263
1	3	0.603900	0.428633	0.779168
2	3	1.385449	1.185707	1.585192

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	74.7063010	14.9412602	44.20	<.0001
Error	117	39.5503854	0.3380375		
Corrected Total	122	114.2566864			

R-Square	Coeff Var	Root MSE	logaval Mean
0.653846	38.54154	0.581410	1.508528

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.03421315	7.03421315	20.81	<.0001
SEXC	1	0.53793007	0.53793007	1.59	0.2096
UCPDGR1	1	0.42541304	0.42541304	1.26	0.2642
TRTPN	2	66.70874478	33.35437239	98.67	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	4.73253681	4.73253681	14.00	0.0003
SEXC	1	0.21030770	0.21030770	0.62	0.4318
UCPDGR1	1	0.25233679	0.25233679	0.75	0.3894
TRTPN	2	66.70874478	33.35437239	98.67	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.13966579	1
2	2.77550059	2
3	0.90965941	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1093
2	<.0001		<.0001
3	0.1093	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.139666	0.999660	1.279672
2	2.775501	2.567948	2.983054
3	0.909659	0.662757	1.156562

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U4ABP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.635835	-1.884800	-1.386869
1	3	0.230006	-0.052281	0.512294
2	3	1.865841	1.543323	2.188359

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	79.7389053	15.9477811	45.43	<.0001
Error	112	39.3186655	0.3510595		
Corrected Total	117	119.0575708			

R-Square	Coeff Var	Root MSE	logaval Mean
0.669751	60.31354	0.592503	0.982371

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.58241573	11.58241573	32.99	<.0001
SEXC	1	3.65713153	3.65713153	10.42	0.0016
UCPDGR1	1	0.55244902	0.55244902	1.57	0.2123
TRTPN	2	63.94690905	31.97345452	91.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.25382637	5.25382637	14.97	0.0002
SEXC	1	2.74214157	2.74214157	7.81	0.0061
UCPDGR1	1	0.20762155	0.20762155	0.59	0.4435
TRTPN	2	63.94690905	31.97345452	91.08	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.61998276	1
2	2.26470515	2
3	0.43249847	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2101
2	<.0001		<.0001
3	0.2101	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.619983	0.473779	0.766186
2	2.264705	2.049137	2.480273
3	0.432498	0.175562	0.689435

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U4ABPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.644722	-1.903328	-1.386116
1	3	0.187484	-0.107229	0.482198
2	3	1.832207	1.496529	2.167884

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	55.53601937	11.10720387	43.95	<.0001
Error	114	28.81313689	0.25274681		
Corrected Total	119	84.34915626			

R-Square	Coeff Var	Root MSE	logaval Mean
0.658406	11.91013	0.502739	4.221108

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.94116327	10.94116327	43.29	<.0001
SEXC	1	0.14295552	0.14295552	0.57	0.4536
UCPDGR1	1	1.76009850	1.76009850	6.96	0.0095
TRTPN	2	42.69180209	21.34590104	84.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	6.34734746	6.34734746	25.11	<.0001
SEXC	1	0.23364064	0.23364064	0.92	0.3384
UCPDGR1	1	1.13438771	1.13438771	4.49	0.0363
TRTPN	2	42.69180209	21.34590104	84.46	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.99338963	1
2	5.21150456	2
3	3.52041313	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0005
2	<.0001		<.0001
3	0.0005	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.993390	3.869909	4.116870
2	5.211505	5.029100	5.393909
3	3.520413	3.295758	3.745068

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.218115	-1.436728	-0.999502
1	3	0.472977	0.213400	0.732553
2	3	1.691091	1.400598	1.981585

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	66.46732385	13.29346477	50.67	<.0001
Error	112	29.38241170	0.26234296		
Corrected Total	117	95.84973555			

R-Square	Coeff Var	Root MSE	logaval Mean
0.693453	13.85339	0.512194	3.697247

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	20.69174064	20.69174064	78.87	<.0001
SEXC	1	1.57579548	1.57579548	6.01	0.0158
UCPDGR1	1	1.77357487	1.77357487	6.76	0.0106
TRTPN	2	42.42621287	21.21310643	80.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.06674769	9.06674769	34.56	<.0001
SEXC	1	2.08454066	2.08454066	7.95	0.0057
UCPDGR1	1	1.14118917	1.14118917	4.35	0.0393
TRTPN	2	42.42621287	21.21310643	80.86	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.46859916	1
2	4.70850894	2
3	3.04779587	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0021
2	<.0001		<.0001
3	0.0021	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.468599	3.340281	3.596917
2	4.708509	4.522276	4.894742
3	3.047796	2.820620	3.274972

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UBAPCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.239910	-1.463586	-1.016234
1	3	0.420803	0.156573	0.685033
2	3	1.660713	1.364969	1.956457

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	110.0738092	22.0147618	116.16	<.0001
Error	117	22.1732973	0.1895154		
Corrected Total	122	132.2471064			

R-Square	Coeff Var	Root MSE	logaval Mean
0.832334	12.03664	0.435334	3.616736

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.72330881	36.72330881	193.77	<.0001
SEXC	1	0.85359983	0.85359983	4.50	0.0359
UCPDGR1	1	0.00910099	0.00910099	0.05	0.8269
TRTPN	2	72.48779954	36.24389977	191.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.67520856	28.67520856	151.31	<.0001
SEXC	1	1.77731826	1.77731826	9.38	0.0027
UCPDGR1	1	0.00140717	0.00140717	0.01	0.9315
TRTPN	2	72.48779954	36.24389977	191.25	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.15940756	1
2	4.91903476	2
3	3.10393016	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6034
2	<.0001		<.0001
3	0.6034	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.159408	3.054607	3.264209
2	4.919035	4.763683	5.074386
3	3.103930	2.919392	3.288468

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.759627	-1.946118	-1.573136
1	3	0.055477	-0.155414	0.266369
2	3	1.815105	1.574164	2.056045

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	106.5246649	21.3049330	131.09	<.0001
Error	112	18.2020848	0.1625186		
Corrected Total	117	124.7267497			

R-Square	Coeff Var	Root MSE	logaval Mean
0.854064	13.04101	0.403136	3.091294

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	36.22032356	36.22032356	222.87	<.0001
SEXC	1	0.47434529	0.47434529	2.92	0.0903
UCPDGR1	1	0.03985073	0.03985073	0.25	0.6214
TRTPN	2	69.79014537	34.89507268	214.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.90465575	28.90465575	177.85	<.0001
SEXC	1	1.04460575	1.04460575	6.43	0.0126
UCPDGR1	1	0.00611497	0.00611497	0.04	0.8465
TRTPN	2	69.79014537	34.89507268	214.71	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.63771454	1
2	4.39630650	2
3	2.58098385	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5752
2	<.0001		<.0001
3	0.5752	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.637715	2.538418	2.737011
2	4.396306	4.249593	4.543020
3	2.580984	2.406344	2.755623

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UCEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.758592	-1.934721	-1.582463
1	3	0.056731	-0.143250	0.256712
2	3	1.815323	1.587557	2.043088

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	54.27225702	10.85445140	40.83	<.0001
Error	117	31.10440568	0.26584962		
Corrected Total	122	85.37666270			

R-Square	Coeff Var	Root MSE	logaval Mean
0.635680	6.612153	0.515606	7.797855

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	32.65795538	32.65795538	122.84	<.0001
SEXC	1	0.03477997	0.03477997	0.13	0.7182
UCPDGR1	1	0.29714158	0.29714158	1.12	0.2926
TRTPN	2	21.28238010	10.64119005	40.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	32.15351292	32.15351292	120.95	<.0001
SEXC	1	0.08554324	0.08554324	0.32	0.5716
UCPDGR1	1	0.27766986	0.27766986	1.04	0.3089
TRTPN	2	21.28238010	10.64119005	40.03	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.55391047	1
2	8.50399294	2
3	7.51397344	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7528
2	<.0001		<.0001
3	0.7528	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.553910	7.429165	7.678656
2	8.503993	8.320237	8.687748
3	7.513973	7.295404	7.732543

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHEMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.950082	-1.171215	-0.728950
1	3	0.039937	-0.210594	0.290468
2	3	0.990020	0.705159	1.274880

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.63380425	12.72676085	47.10	<.0001
Error	112	30.26175066	0.27019420		
Corrected Total	117	93.89555491			

R-Square	Coeff Var	Root MSE	logaval Mean
0.677708	7.134142	0.519802	7.286119

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	42.90034824	42.90034824	158.78	<.0001
SEXC	1	0.30551150	0.30551150	1.13	0.2899
UCPDGR1	1	0.43334609	0.43334609	1.60	0.2080
TRTPN	2	19.99459843	9.99729921	37.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	31.33108480	31.33108480	115.96	<.0001
SEXC	1	0.15191418	0.15191418	0.56	0.4549
UCPDGR1	1	0.29826441	0.29826441	1.10	0.2957
TRTPN	2	19.99459843	9.99729921	37.00	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.05620010	1
2	7.99286568	2
3	7.01090990	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7292
2	<.0001		<.0001
3	0.7292	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.056200	6.927238	7.185162
2	7.992866	7.804381	8.181350
3	7.010910	6.785716	7.236104

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.936666	-1.163947	-0.709384
1	3	0.045290	-0.213281	0.303861
2	3	0.981956	0.688579	1.275332

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	40.69819350	8.13963870	30.68	<.0001
Error	117	31.04326466	0.26532705		
Corrected Total	122	71.74145817			

R-Square	Coeff Var	Root MSE	logaval Mean
0.567290	9.713234	0.515099	5.303065

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.22031644	15.22031644	57.36	<.0001
SEXC	1	0.06899082	0.06899082	0.26	0.6111
UCPDGR1	1	0.68188158	0.68188158	2.57	0.1116
TRTPN	2	24.72700466	12.36350233	46.60	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	14.37574812	14.37574812	54.18	<.0001
SEXC	1	0.05369063	0.05369063	0.20	0.6537
UCPDGR1	1	0.59372063	0.59372063	2.24	0.1374
TRTPN	2	24.72700466	12.36350233	46.60	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.06756640	1
2	6.05689491	2
3	4.91384583	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2249
2	<.0001		<.0001
3	0.2249	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.067566	4.943562	5.191571
2	6.056895	5.873295	6.240495
3	4.913846	4.695561	5.132131

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.989329	-1.209780	-0.768877
1	3	0.153721	-0.095786	0.403227
2	3	1.143049	0.858353	1.427745

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	42.39958219	8.47991644	33.62	<.0001
Error	112	28.24598847	0.25219633		
Corrected Total	117	70.64557065			

R-Square	Coeff Var	Root MSE	logaval Mean
0.600173	10.52574	0.502192	4.771081

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	18.43184284	18.43184284	73.09	<.0001
SEXC	1	0.15609048	0.15609048	0.62	0.4331
UCPDGR1	1	0.68647982	0.68647982	2.72	0.1018
TRTPN	2	23.12516905	11.56258453	45.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.51829177	15.51829177	61.53	<.0001
SEXC	1	0.11827517	0.11827517	0.47	0.4949
UCPDGR1	1	0.46039203	0.46039203	1.83	0.1794
TRTPN	2	23.12516905	11.56258453	45.85	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.55726407	1
2	5.51797742	2
3	4.36702153	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1331
2	<.0001		<.0001
3	0.1331	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.557264	4.433492	4.681036
2	5.517977	5.335560	5.700395
3	4.367022	4.149417	4.584626

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHMPMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.960713	-1.179860	-0.741567
1	3	0.190243	-0.058871	0.439356
2	3	1.150956	0.867493	1.434419

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	109.5410261	21.9082052	47.19	<.0001
Error	112	51.9986956	0.4642741		
Corrected Total	117	161.5397216			

R-Square	Coeff Var	Root MSE	logaval Mean
0.678106	11.91897	0.681377	5.716742

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.80181189	9.80181189	21.11	<.0001
SEXC	1	0.00274767	0.00274767	0.01	0.9388
UCPDGR1	1	2.96337163	2.96337163	6.38	0.0129
TRTPN	2	96.77309487	48.38654743	104.22	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.41460987	22.41460987	48.28	<.0001
SEXC	1	0.00288350	0.00288350	0.01	0.9373
UCPDGR1	1	2.11764071	2.11764071	4.56	0.0349
TRTPN	2	96.77309487	48.38654743	104.22	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.20020969	1
2	7.27446686	2
3	5.04926625	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3798
2	<.0001		<.0001
3	0.3798	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.200210	5.032103	5.368316
2	7.274467	7.024237	7.524697
3	5.049266	4.753892	5.344641

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UMHBM24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.074257	-2.377058	-1.771456
1	3	0.150943	-0.188250	0.490137
2	3	2.225201	1.839652	2.610749

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UMHBMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UMHBMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	112.9893847	22.5978769	48.63	<.0001
Error	110	51.1205738	0.4647325		
Corrected Total	115	164.1099586			

R-Square	Coeff Var	Root MSE	logaval Mean
0.688498	13.06975	0.681713	5.215961

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.13284100	12.13284100	26.11	<.0001
SEXC	1	1.90998599	1.90998599	4.11	0.0451
UCPDGR1	1	2.56823945	2.56823945	5.53	0.0205
TRTPN	2	96.37831830	48.18915915	103.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.80846720	23.80846720	51.23	<.0001
SEXC	1	1.16283767	1.16283767	2.50	0.1166
UCPDGR1	1	1.69851620	1.69851620	3.65	0.0585
TRTPN	2	96.37831830	48.18915915	103.69	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UMHBMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.70914093	1
2	6.78247628	2
3	4.55351078	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3670
2	<.0001		<.0001
3	0.3670	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.709141	4.537912	4.880370
2	6.782476	6.532712	7.032240
3	4.553511	4.258080	4.848941

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UMHBMCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.073335	-2.377583	-1.769088
1	3	0.155630	-0.184871	0.496131
2	3	2.228965	1.843046	2.614885

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	122
Number of Observations Used	122

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	257.7085919	51.5417184	166.95	<.0001
Error	116	35.8127165	0.3087303		
Corrected Total	121	293.5213084			

R-Square	Coeff Var	Root MSE	logaval Mean
0.877989	29.71049	0.555635	1.870165

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	35.5438936	35.5438936	115.13	<.0001
SEXC	1	0.3414123	0.3414123	1.11	0.2952
UCPDGR1	1	0.9493592	0.9493592	3.08	0.0821
TRTPN	2	220.8739267	110.4369634	357.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	28.4498987	28.4498987	92.15	<.0001
SEXC	1	0.0810033	0.0810033	0.26	0.6095
UCPDGR1	1	0.5152899	0.5152899	1.67	0.1990
TRTPN	2	220.8739267	110.4369634	357.71	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.43440027	1
2	2.60592114	2
3	-1.01104612	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.1577	<.0001
2	0.1577		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.434400	2.299430	2.569370
2	2.605921	2.407502	2.804340
3	-1.011046	-1.246588	-0.775504

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNEQ24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.171521	-0.410415	0.067373
1	3	3.445446	3.175833	3.715060
2	3	3.616967	3.309312	3.924623

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	236.4214436	47.2842887	197.17	<.0001
Error	112	26.8598080	0.2398197		
Corrected Total	117	263.2812516			

R-Square	Coeff Var	Root MSE	logaval Mean
0.897981	35.33841	0.489714	1.385784

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	25.1596338	25.1596338	104.91	<.0001
SEXC	1	0.4201557	0.4201557	1.75	0.1883
UCPDGR1	1	0.9002020	0.9002020	3.75	0.0552
TRTPN	2	209.9414521	104.9707261	437.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	22.1832345	22.1832345	92.50	<.0001
SEXC	1	0.1099693	0.1099693	0.46	0.4997
UCPDGR1	1	0.1102320	0.1102320	0.46	0.4992
TRTPN	2	209.9414521	104.9707261	437.71	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.95427441	1
2	2.08976185	2
3	-1.49170145	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.2125	<.0001
2	0.2125		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.954274	1.833667	2.074882
2	2.089762	1.911365	2.268159
3	-1.491701	-1.703861	-1.279542

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNEQCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.135487	-0.349588	0.078613
1	3	3.445976	3.203052	3.688899
2	3	3.581463	3.304746	3.858180

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	97.1170901	19.4234180	113.94	<.0001
Error	114	19.4334756	0.1704691		
Corrected Total	119	116.5505657			

R-Square	Coeff Var	Root MSE	logaval Mean
0.833261	8.735498	0.412879	4.726451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	81.19089527	81.19089527	476.28	<.0001
SEXC	1	0.09705496	0.09705496	0.57	0.4521
UCPDGR1	1	0.08699398	0.08699398	0.51	0.4765
TRTPN	2	15.74214585	7.87107292	46.17	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	80.07922286	80.07922286	469.76	<.0001
SEXC	1	0.20091244	0.20091244	1.18	0.2799
UCPDGR1	1	0.05117204	0.05117204	0.30	0.5848
TRTPN	2	15.74214585	7.87107292	46.17	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.50326264	1
2	5.34466156	2
3	4.51780387	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8880
2	<.0001		<.0001
3	0.8880	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.503263	4.403097	4.603428
2	5.344662	5.194979	5.494344
3	4.517804	4.338967	4.696640

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.841399	-1.020669	-0.662129
1	3	-0.014541	-0.218695	0.189612
2	3	0.826858	0.593878	1.059837

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNALCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNALCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.6196501	20.9239300	136.52	<.0001
Error	112	17.1659445	0.1532674		
Corrected Total	117	121.7855946			

R-Square	Coeff Var	Root MSE	logaval Mean
0.859048	9.250820	0.391494	4.231990

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	89.37773334	89.37773334	583.15	<.0001
SEXC	1	0.00635924	0.00635924	0.04	0.8390
UCPDGR1	1	0.06100082	0.06100082	0.40	0.5294
TRTPN	2	15.17455674	7.58727837	49.50	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	82.80420233	82.80420233	540.26	<.0001
SEXC	1	0.06706117	0.06706117	0.44	0.5097
UCPDGR1	1	0.03121796	0.03121796	0.20	0.6526
TRTPN	2	15.17455674	7.58727837	49.50	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNALCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.01526627	1
2	4.84064260	2
3	4.01538537	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9990
2	<.0001		<.0001
3	0.9990	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.015266	3.918647	4.111885
2	4.840643	4.698658	4.982628
3	4.015385	3.845796	4.184974



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNALCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.825376	-0.996217	-0.654536
1	3	-0.000119	-0.194457	0.194219
2	3	0.825257	0.604294	1.046220

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	120
Number of Observations Used	120



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	232.3105538	46.4621108	89.79	<.0001
Error	114	58.9871966	0.5174315		
Corrected Total	119	291.2977504			

R-Square	Coeff Var	Root MSE	logaval Mean
0.797502	129.2799	0.719327	0.556410

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	41.6823842	41.6823842	80.56	<.0001
SEXC	1	0.2001803	0.2001803	0.39	0.5352
UCPDGR1	1	1.6660491	1.6660491	3.22	0.0754
TRTPN	2	188.7619403	94.3809701	182.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	31.1151834	31.1151834	60.13	<.0001
SEXC	1	0.3142361	0.3142361	0.61	0.4374
UCPDGR1	1	0.4798071	0.4798071	0.93	0.3376
TRTPN	2	188.7619403	94.3809701	182.40	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.37922790	1
2	2.35124005	2
3	-1.52949478	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.379228	0.204446	0.554009
2	2.351240	2.090390	2.612090
3	-1.529495	-1.842195	-1.216794

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNN24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.972012	-2.284345	-1.659679
1	3	1.908723	1.551126	2.266320
2	3	3.880735	3.473525	4.287944

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	238.1247797	47.6249559	98.36	<.0001
Error	112	54.2287762	0.4841855		
Corrected Total	117	292.3535559			

R-Square	Coeff Var	Root MSE	logaval Mean
0.814510	1099.526	0.695834	0.063285

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	49.0190639	49.0190639	101.24	<.0001
SEXC	1	0.0044931	0.0044931	0.01	0.9234
UCPDGR1	1	0.9832054	0.9832054	2.03	0.1569
TRTPN	2	188.1180173	94.0590087	194.26	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	32.7519209	32.7519209	67.64	<.0001
SEXC	1	0.0005554	0.0005554	0.00	0.9730
UCPDGR1	1	0.1586144	0.1586144	0.33	0.5682
TRTPN	2	188.1180173	94.0590087	194.26	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.09965301	1
2	1.86185743	2
3	-2.01410631	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.099653	-0.271974	0.072668
2	1.861857	1.609407	2.114308
3	-2.014106	-2.316465	-1.711748

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.961510	-2.265253	-1.657768
1	3	1.914453	1.566691	2.262216
2	3	3.875964	3.481963	4.269964

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	123
Number of Observations Used	123



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17.67448416	3.53489683	16.97	<.0001
Error	117	24.37831929	0.20836170		
Corrected Total	122	42.05280345			

R-Square	Coeff Var	Root MSE	logaval Mean
0.420293	10.30246	0.456467	4.430657

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	1.82574867	1.82574867	8.76	0.0037
SEXC	1	0.06901280	0.06901280	0.33	0.5660
UCPDGR1	1	0.03007294	0.03007294	0.14	0.7047
TRTPN	2	15.74964975	7.87482488	37.79	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.70957121	0.70957121	3.41	0.0675
SEXC	1	0.18996734	0.18996734	0.91	0.3416
UCPDGR1	1	0.00080694	0.00080694	0.00	0.9505
TRTPN	2	15.74964975	7.87482488	37.79	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means**

Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.27689523	1
2	5.02511234	2
3	4.03607726	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0332
2	<.0001		<.0001
3	0.0332	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.276895	4.166995	4.386795
2	5.025112	4.861588	5.188637
3	4.036077	3.842225	4.229929

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UOTOL24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.748217	-0.944419	-0.552015
1	3	0.240818	0.019463	0.462173
2	3	0.989035	0.735054	1.243016

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.58445447	3.91689089	18.00	<.0001
Error	112	24.37839655	0.21766425		
Corrected Total	117	43.96285102			

R-Square	Coeff Var	Root MSE	logaval Mean
0.445477	11.90997	0.466545	3.917264

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	2.93181061	2.93181061	13.47	0.0004
SEXC	1	2.23590055	2.23590055	10.27	0.0018
UCPDGR1	1	0.08606345	0.08606345	0.40	0.5308
TRTPN	2	14.33067987	7.16533994	32.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.56255950	0.56255950	2.58	0.1107
SEXC	1	1.96520201	1.96520201	9.03	0.0033
UCPDGR1	1	0.00544433	0.00544433	0.03	0.8746
TRTPN	2	14.33067987	7.16533994	32.92	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.80254342	1
2	4.52159904	2
3	3.55008689	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0330
2	<.0001		<.0001
3	0.0330	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.802543	3.687647	3.917439
2	4.521599	4.350787	4.692411
3	3.550087	3.347864	3.752310

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.719056	-0.923654	-0.514457
1	3	0.252457	0.020815	0.484098
2	3	0.971512	0.706436	1.236588

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	21.27474590	4.25494918	12.65	<.0001
Error	112	37.66486122	0.33629340		
Corrected Total	117	58.93960712			

R-Square	Coeff Var	Root MSE	logaval Mean
0.360958	6.632629	0.579908	8.743262

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	19.26150433	19.26150433	57.28	<.0001
SEXC	1	0.27103023	0.27103023	0.81	0.3713
UCPDGR1	1	0.15125432	0.15125432	0.45	0.5038
TRTPN	2	1.59095701	0.79547851	2.37	0.0986

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	18.13696470	18.13696470	53.93	<.0001
SEXC	1	0.42661705	0.42661705	1.27	0.2624
UCPDGR1	1	0.19604049	0.19604049	0.58	0.4468
TRTPN	2	1.59095701	0.79547851	2.37	0.0986

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.75248836	1
2	8.59373223	2
3	8.95360890	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.2185	0.1685
2	0.2185		0.0319
3	0.1685	0.0319	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.752488	8.610249	8.894728
2	8.593732	8.382359	8.805105
3	8.953609	8.702400	9.204817



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USBMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.158756	-0.095457	0.412969
1	3	-0.201121	-0.488658	0.086417
2	3	-0.359877	-0.687947	-0.031806

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	25.92928654	5.18585731	15.92	<.0001
Error	110	35.83159283	0.32574175		
Corrected Total	115	61.76087937			

R-Square	Coeff Var	Root MSE	logaval Mean
0.419834	6.948486	0.570738	8.213845

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	23.32028614	23.32028614	71.59	<.0001
SEXC	1	0.99015607	0.99015607	3.04	0.0840
UCPDGR1	1	0.03447420	0.03447420	0.11	0.7456
TRTPN	2	1.58437014	0.79218507	2.43	0.0926

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	18.60863070	18.60863070	57.13	<.0001
SEXC	1	1.12868572	1.12868572	3.46	0.0654
UCPDGR1	1	0.05969410	0.05969410	0.18	0.6694
TRTPN	2	1.58437014	0.79218507	2.43	0.0926

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.22829054	1
2	8.07946416	2
3	8.43893411	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.2423	0.1446
2	0.2423		0.0295
3	0.1446	0.0295	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.228291	8.085965	8.370616
2	8.079464	7.872103	8.286825
3	8.438934	8.191387	8.686481

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USBMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.148826	-0.102046	0.399698
1	3	-0.210644	-0.494752	0.073465
2	3	-0.359470	-0.682486	-0.036454

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	118
Number of Observations Used	118

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	130.3986503	26.0797301	63.00	<.0001
Error	112	46.3672139	0.4139930		
Corrected Total	117	176.7658643			

R-Square	Coeff Var	Root MSE	logaval Mean
0.737691	10.84572	0.643423	5.932504

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	32.75014226	32.75014226	79.11	<.0001
SEXC	1	0.73563705	0.73563705	1.78	0.1852
UCPDGR1	1	0.94129064	0.94129064	2.27	0.1344
TRTPN	2	95.97158038	47.98579019	115.91	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	38.27611707	38.27611707	92.46	<.0001
SEXC	1	0.31361719	0.31361719	0.76	0.3860
UCPDGR1	1	0.57920751	0.57920751	1.40	0.2394
TRTPN	2	95.97158038	47.98579019	115.91	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.41065580	1
2	7.48058721	2
3	5.38324580	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8652
2	<.0001		<.0001
3	0.8652	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.410656	5.252795	5.568517
2	7.480587	7.247156	7.714019
3	5.383246	5.104526	5.661965

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.069931	-2.350802	-1.789061
1	3	0.027410	-0.291704	0.346524
2	3	2.097341	1.734198	2.460485

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USPMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	116
Number of Observations Used	116



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USPMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	143.4202832	28.6840566	72.49	<.0001
Error	110	43.5277843	0.3957071		
Corrected Total	115	186.9480674			

R-Square	Coeff Var	Root MSE	logaval Mean
0.767166	11.60413	0.629053	5.420935

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	44.14608354	44.14608354	111.56	<.0001
SEXC	1	2.60491806	2.60491806	6.58	0.0116
UCPDGR1	1	1.04121559	1.04121559	2.63	0.1076
TRTPN	2	95.62806597	47.81403299	120.83	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	41.49796040	41.49796040	104.87	<.0001
SEXC	1	1.45429220	1.45429220	3.68	0.0578
UCPDGR1	1	0.62064509	0.62064509	1.57	0.2131
TRTPN	2	95.62806597	47.81403299	120.83	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USPMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.89868861	1
2	6.97158076	2
3	4.87560284	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8841
2	<.0001		<.0001
3	0.8841	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.898689	4.741771	5.055606
2	6.971581	6.743422	7.199739
3	4.875603	4.603008	5.148197

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USPMACRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.072892	-2.348759	-1.797025
1	3	0.023086	-0.290056	0.336228
2	3	2.095978	1.740845	2.451111

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=CARBXHGB Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	79
Number of Observations Used	79

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=CARBXHGB Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13.11003293	2.62200659	27.53	<.0001
Error	73	6.95311981	0.09524822		
Corrected Total	78	20.06315274			

R-Square	Coeff Var	Root MSE	logaval Mean
0.653438	24.59765	0.308623	1.254685

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	0.55202126	0.55202126	5.80	0.0186
SEXC	1	0.05394163	0.05394163	0.57	0.4541
UCPDGR1	1	0.36400746	0.36400746	3.82	0.0544
TRTPN	2	12.14006257	6.07003129	63.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	0.86287467	0.86287467	9.06	0.0036
SEXC	1	0.17293424	0.17293424	1.82	0.1820
UCPDGR1	1	0.05136640	0.05136640	0.54	0.4651
TRTPN	2	12.14006257	6.07003129	63.73	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=CARBXHGB Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.96639367	1
2	1.75282482	2
3	0.83450616	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.3080
2	<.0001		<.0001
3	0.3080	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.966394	0.868511	1.064276
2	1.752825	1.640979	1.864670
3	0.834506	0.598969	1.070043

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=CARBXHGB Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.786431	-0.935336	-0.637526
1	3	0.131888	-0.124145	0.387920
2	3	0.918319	0.659988	1.176649

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.0603013	16.0120603	24.89	<.0001
Error	69	44.3819136	0.6432161		
Corrected Total	74	124.4422149			

R-Square	Coeff Var	Root MSE	logaval Mean
0.643353	23.63730	0.802008	3.392975

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.87064136	4.87064136	7.57	0.0076
SEXC	1	1.56383330	1.56383330	2.43	0.1235
UCPDGR1	1	4.54778620	4.54778620	7.07	0.0097
TRTPN	2	69.07804045	34.53902022	53.70	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.90108553	3.90108553	6.06	0.0163
SEXC	1	0.73238337	0.73238337	1.14	0.2897
UCPDGR1	1	1.00482938	1.00482938	1.56	0.2156
TRTPN	2	69.07804045	34.53902022	53.70	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.75397048	1
2	4.56721194	2
3	1.94150775	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0186
2	<.0001		<.0001
3	0.0186	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.753970	2.492418	3.015523
2	4.567212	4.266719	4.867705
3	1.941508	1.324902	2.558114



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.813241	-2.213635	-1.412848
1	3	0.812463	0.140128	1.484798
2	3	2.625704	1.943784	3.307624

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	80.5273027	16.1054605	27.19	<.0001
Error	67	39.6799001	0.5922373		
Corrected Total	72	120.2072028			

R-Square	Coeff Var	Root MSE	logaval Mean
0.669904	26.51594	0.769570	2.902290

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.81712781	5.81712781	9.82	0.0026
SEXC	1	0.25425175	0.25425175	0.43	0.5146
UCPDGR1	1	4.22813421	4.22813421	7.14	0.0095
TRTPN	2	70.22778891	35.11389446	59.29	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.05438510	5.05438510	8.53	0.0047
SEXC	1	0.02681784	0.02681784	0.05	0.8321
UCPDGR1	1	0.84640845	0.84640845	1.43	0.2361
TRTPN	2	70.22778891	35.11389446	59.29	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.22810382	1
2	4.09428255	2
3	1.51078015	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0308
2	<.0001		<.0001
3	0.0308	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.228104	1.969332	2.486875
2	4.094283	3.805714	4.382851
3	1.510780	0.919851	2.101709

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.866179	-2.255075	-1.477282
1	3	0.717324	0.068426	1.366221
2	3	2.583502	1.929955	3.237050

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	74
Number of Observations Used	74



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11.84974424	2.36994885	11.31	<.0001
Error	68	14.25094351	0.20957270		
Corrected Total	73	26.10068775			

R-Square	Coeff Var	Root MSE	logaval Mean
0.454001	8.582359	0.457791	5.334094

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.12719134	8.12719134	38.78	<.0001
SEXC	1	0.16903333	0.16903333	0.81	0.3723
UCPDGR1	1	0.67134632	0.67134632	3.20	0.0779
TRTPN	2	2.88217325	1.44108662	6.88	0.0019

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	7.90849476	7.90849476	37.74	<.0001
SEXC	1	0.05045823	0.05045823	0.24	0.6252
UCPDGR1	1	0.40489055	0.40489055	1.93	0.1691
TRTPN	2	2.88217325	1.44108662	6.88	0.0019



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.22351233	1
2	5.56180265	2
3	4.96623957	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.0049	0.1995
2	0.0049		0.0035
3	0.1995	0.0035	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.223512	5.069532	5.377493
2	5.561803	5.390466	5.733140
3	4.966240	4.607426	5.325053

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1OHP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.338290	-0.570388	-0.106193
1	3	0.257273	-0.138981	0.653526
2	3	0.595563	0.202678	0.988448

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	15.67570639	3.13514128	15.57	<.0001
Error	67	13.49131884	0.20136297		
Corrected Total	72	29.16702522			

R-Square	Coeff Var	Root MSE	logaval Mean
0.537446	9.269379	0.448735	4.841046

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.94837502	11.94837502	59.34	<.0001
SEXC	1	0.04577811	0.04577811	0.23	0.6351
UCPDGR1	1	0.72706048	0.72706048	3.61	0.0617
TRTPN	2	2.95449278	1.47724639	7.34	0.0013

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.66322593	9.66322593	47.99	<.0001
SEXC	1	0.13052473	0.13052473	0.65	0.4236
UCPDGR1	1	0.46093476	0.46093476	2.29	0.1350
TRTPN	2	2.95449278	1.47724639	7.34	0.0013



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.73046612	1
2	5.08527493	2
3	4.50209351	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.0028	0.2417
2	0.0028		0.0034
3	0.2417	0.0034	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.730466	4.577638	4.883294
2	5.085275	4.917377	5.253173
3	4.502094	4.153797	4.850390

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U1OHPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.354809	-0.583368	-0.126249
1	3	0.228373	-0.157521	0.614266
2	3	0.583181	0.200424	0.965939

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	65.10109335	13.02021867	32.13	<.0001
Error	69	27.96249229	0.40525351		
Corrected Total	74	93.06358564			

R-Square	Coeff Var	Root MSE	logaval Mean
0.699533	28.25090	0.636595	2.253363

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.16156794	5.16156794	12.74	0.0007
SEXC	1	1.57651711	1.57651711	3.89	0.0526
UCPDGR1	1	3.43493276	3.43493276	8.48	0.0048
TRTPN	2	54.92807554	27.46403777	67.77	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.84477932	3.84477932	9.49	0.0030
SEXC	1	0.70293154	0.70293154	1.73	0.1922
UCPDGR1	1	0.42218917	0.42218917	1.04	0.3110
TRTPN	2	54.92807554	27.46403777	67.77	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.57838101	1
2	3.33178685	2
3	1.39583035	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.4978
2	<.0001		<.0001
3	0.4978	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.578381	1.370772	1.785990
2	3.331787	3.093078	3.570496
3	1.395830	0.905622	1.886039

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U2NA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.753406	-2.071386	-1.435425
1	3	0.182551	-0.351793	0.716895
2	3	1.935957	1.393402	2.478511

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	65.98247953	13.19649591	39.30	<.0001
Error	67	22.49754287	0.33578422		
Corrected Total	72	88.48002240			

R-Square	Coeff Var	Root MSE	logaval Mean
0.745733	32.97957	0.579469	1.757054

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.70671229	5.70671229	17.00	0.0001
SEXC	1	0.21964717	0.21964717	0.65	0.4215
UCPDGR1	1	2.82912458	2.82912458	8.43	0.0050
TRTPN	2	57.22699549	28.61349775	85.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	4.55526291	4.55526291	13.57	0.0005
SEXC	1	0.01522575	0.01522575	0.05	0.8320
UCPDGR1	1	0.18606957	0.18606957	0.55	0.4592
TRTPN	2	57.22699549	28.61349775	85.21	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.03800840	1
2	2.86119051	2
3	0.96598066	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7698
2	<.0001		<.0001
3	0.7698	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.038008	0.843216	1.232801
2	2.861191	2.643771	3.078610
3	0.965981	0.520267	1.411695

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U2NACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.823182	-2.116099	-1.530266
1	3	0.072028	-0.417251	0.561307
2	3	1.895210	1.401948	2.388472

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.78819186	3.75763837	15.54	<.0001
Error	69	16.68984033	0.24188174		
Corrected Total	74	35.47803218			

R-Square	Coeff Var	Root MSE	logaval Mean
0.529573	7.643376	0.491815	6.434522

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.05707028	8.05707028	33.31	<.0001
SEXC	1	0.18056161	0.18056161	0.75	0.3906
UCPDGR1	1	0.40651164	0.40651164	1.68	0.1992
TRTPN	2	10.14404833	5.07202417	20.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.92730843	5.92730843	24.50	<.0001
SEXC	1	0.12825757	0.12825757	0.53	0.4690
UCPDGR1	1	0.06680762	0.06680762	0.28	0.6009
TRTPN	2	10.14404833	5.07202417	20.97	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.21138264	1
2	6.87374182	2
3	5.79326604	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0487
2	<.0001		<.0001
3	0.0487	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.211383	6.050998	6.371767
2	6.873742	6.689576	7.057908
3	5.793266	5.411721	6.174811

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U3HPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.662359	-0.907725	-0.416993
1	3	0.418117	0.002502	0.833731
2	3	1.080476	0.658809	1.502142

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U3HPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U3HPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.65524541	3.73104908	14.19	<.0001
Error	67	17.61936989	0.26297567		
Corrected Total	72	36.27461530			

R-Square	Coeff Var	Root MSE	logaval Mean
0.514278	8.613432	0.512812	5.953626

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	8.29091275	8.29091275	31.53	<.0001
SEXC	1	0.03022288	0.03022288	0.11	0.7357
UCPDGR1	1	0.37886690	0.37886690	1.44	0.2343
TRTPN	2	9.95524289	4.97762144	18.93	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.54007359	5.54007359	21.07	<.0001
SEXC	1	0.08291924	0.08291924	0.32	0.5763
UCPDGR1	1	0.05847055	0.05847055	0.22	0.6388
TRTPN	2	9.95524289	4.97762144	18.93	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U3HPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.73446067	1
2	6.39789668	2
3	5.33504172	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0714
2	<.0001		<.0001
3	0.0714	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.734461	5.561986	5.906935
2	6.397897	6.205529	6.590264
3	5.335042	4.938714	5.731369

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U3HPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.663436	-0.922587	-0.404285
1	3	0.399419	-0.035824	0.834661
2	3	1.062855	0.624206	1.501504

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	34.43411418	6.88682284	11.92	<.0001
Error	69	39.88145620	0.57799212		
Corrected Total	74	74.31557038			

R-Square	Coeff Var	Root MSE	logaval Mean
0.463350	34.54583	0.760258	2.200723

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.36990704	3.36990704	5.83	0.0184
SEXC	1	2.78988116	2.78988116	4.83	0.0314
UCPDGR1	1	1.72338603	1.72338603	2.98	0.0887
TRTPN	2	26.55093994	13.27546997	22.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	3.30034734	3.30034734	5.71	0.0196
SEXC	1	1.87781182	1.87781182	3.25	0.0758
UCPDGR1	1	0.43338853	0.43338853	0.75	0.3895
TRTPN	2	26.55093994	13.27546997	22.97	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.77915724	1
2	2.91631774	2
3	1.33173011	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1664
2	<.0001		<.0001
3	0.1664	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.779157	1.531203	2.027112
2	2.916318	2.631867	3.200768
3	1.331730	0.747023	1.916437

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U4ABP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.137160	-1.516193	-0.758128
1	3	0.447427	-0.190719	1.085573
2	3	1.584588	0.938872	2.230303

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	35.30314118	7.06062824	13.32	<.0001
Error	67	35.51546643	0.53008159		
Corrected Total	72	70.81860760			

R-Square	Coeff Var	Root MSE	logaval Mean
0.498501	42.82767	0.728067	1.699992

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	5.11800888	5.11800888	9.66	0.0028
SEXC	1	0.54653495	0.54653495	1.03	0.3136
UCPDGR1	1	2.35429073	2.35429073	4.44	0.0388
TRTPN	2	27.28430662	13.64215331	25.74	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.80820721	5.80820721	10.96	0.0015
SEXC	1	0.19173228	0.19173228	0.36	0.5496
UCPDGR1	1	0.67605243	0.67605243	1.28	0.2628
TRTPN	2	27.28430662	13.64215331	25.74	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.25181619	1
2	2.44332725	2
3	0.91467446	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.2776
2	<.0001		<.0001
3	0.2776	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.251816	1.006751	1.496881
2	2.443327	2.170785	2.715869
3	0.914674	0.355246	1.474103



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=U4ABPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.191511	-1.559385	-0.823637
1	3	0.337142	-0.277670	0.951954
2	3	1.528653	0.910857	2.146449

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.80400162	4.56080032	10.92	<.0001
Error	69	28.82620483	0.41777108		
Corrected Total	74	51.63020646			

R-Square	Coeff Var	Root MSE	logaval Mean
0.441679	13.42066	0.646352	4.816099

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.51446040	9.51446040	22.77	<.0001
SEXC	1	0.50372201	0.50372201	1.21	0.2760
UCPDGR1	1	1.76067233	1.76067233	4.21	0.0439
TRTPN	2	11.02514688	5.51257344	13.20	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	12.28314128	12.28314128	29.40	<.0001
SEXC	1	0.20023163	0.20023163	0.48	0.4911
UCPDGR1	1	0.85190805	0.85190805	2.04	0.1578
TRTPN	2	11.02514688	5.51257344	13.20	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.52602790	1
2	5.29460856	2
3	4.37921321	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5940
2	<.0001		0.0014
3	0.5940	0.0014	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.526028	4.313627	4.738428
2	5.294609	5.052626	5.536591
3	4.379213	3.881046	4.877381

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UBAP24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.768581	-1.093109	-0.444052
1	3	0.146815	-0.400064	0.693693
2	3	0.915395	0.367835	1.462956

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	24.52435152	4.90487030	12.02	<.0001
Error	67	27.34678609	0.40816099		
Corrected Total	72	51.87113761			

R-Square	Coeff Var	Root MSE	logaval Mean
0.472794	14.79170	0.638875	4.319145

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	11.37577171	11.37577171	27.87	<.0001
SEXC	1	0.00035876	0.00035876	0.00	0.9764
UCPDGR1	1	1.47059779	1.47059779	3.60	0.0620
TRTPN	2	11.67762327	5.83881163	14.31	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	12.13436069	12.13436069	29.73	<.0001
SEXC	1	0.00331080	0.00331080	0.01	0.9285
UCPDGR1	1	0.59270923	0.59270923	1.45	0.2324
TRTPN	2	11.67762327	5.83881163	14.31	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.00830677	1
2	4.82014353	2
3	3.91307868	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7270
2	<.0001		0.0013
3	0.7270	0.0013	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.008307	3.791022	4.225592
2	4.820144	4.580960	5.059327
3	3.913079	3.422129	4.404029

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UBAPCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.811837	-1.137582	-0.486091
1	3	0.095228	-0.447033	0.637489
2	3	0.907065	0.366572	1.447557

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	82.4648637	16.4929727	17.84	<.0001
Error	69	63.8015587	0.9246603		
Corrected Total	74	146.2664225			

R-Square	Coeff Var	Root MSE	logaval Mean
0.563799	25.70595	0.961593	3.740739

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	14.97785426	14.97785426	16.20	0.0001
SEXC	1	2.56363842	2.56363842	2.77	0.1004
UCPDGR1	1	1.13566917	1.13566917	1.23	0.2716
TRTPN	2	63.78770187	31.89385093	34.49	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.09992047	10.09992047	10.92	0.0015
SEXC	1	2.14611199	2.14611199	2.32	0.1322
UCPDGR1	1	0.03959997	0.03959997	0.04	0.8367
TRTPN	2	63.78770187	31.89385093	34.49	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.00616875	1
2	4.89026185	2
3	2.78362030	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.5837
2	<.0001		<.0001
3	0.5837	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.006169	2.692488	3.319849
2	4.890262	4.529962	5.250562
3	2.783620	2.043575	3.523666

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UCEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.884093	-2.364467	-1.403719
1	3	0.222548	-0.583740	1.028837
2	3	2.106642	1.288135	2.925148

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	82.0562449	16.4112490	18.84	<.0001
Error	67	58.3696206	0.8711884		
Corrected Total	72	140.4258656			

R-Square	Coeff Var	Root MSE	logaval Mean
0.584339	28.75748	0.933375	3.245676

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	13.28031323	13.28031323	15.24	0.0002
SEXC	1	1.48301998	1.48301998	1.70	0.1965
UCPDGR1	1	0.71939766	0.71939766	0.83	0.3668
TRTPN	2	66.57351407	33.28675703	38.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.72643335	10.72643335	12.31	0.0008
SEXC	1	1.19876062	1.19876062	1.38	0.2449
UCPDGR1	1	0.22315115	0.22315115	0.26	0.6144
TRTPN	2	66.57351407	33.28675703	38.21	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.45641779	1
2	4.41601000	2
3	2.33781925	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7644
2	<.0001		<.0001
3	0.7644	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.456418	2.142828	2.770008
2	4.416010	4.065880	4.766140
3	2.337819	1.620585	3.055053

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UCEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.959592	-2.431592	-1.487592
1	3	0.118599	-0.668166	0.905364
2	3	2.078191	1.284659	2.871723

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.85523322	5.77104664	17.19	<.0001
Error	69	23.17053938	0.33580492		
Corrected Total	74	52.02577260			

R-Square	Coeff Var	Root MSE	logaval Mean
0.554633	7.166497	0.579487	8.086053

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.46686828	12.46686828	37.13	<.0001
SEXC	1	0.02444014	0.02444014	0.07	0.7881
UCPDGR1	1	0.90868921	0.90868921	2.71	0.1045
TRTPN	2	15.45523559	7.72761780	23.01	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	11.93065514	11.93065514	35.53	<.0001
SEXC	1	0.00053666	0.00053666	0.00	0.9682
UCPDGR1	1	0.14914847	0.14914847	0.44	0.5073
TRTPN	2	15.45523559	7.72761780	23.01	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.73759135	1
2	8.66304115	2
3	7.63918183	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6861
2	<.0001		<.0001
3	0.6861	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.737591	7.548268	7.926915
2	8.663041	8.446389	8.879693
3	7.639182	7.195855	8.082508

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHEMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.925450	-1.214481	-0.636418
1	3	0.098410	-0.385233	0.582052
2	3	1.023859	0.534790	1.512929

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	32.46205323	6.49241065	19.46	<.0001
Error	67	22.34845489	0.33355903		
Corrected Total	72	54.81050812			

R-Square	Coeff Var	Root MSE	logaval Mean
0.592260	7.609342	0.577546	7.589955

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.41760976	15.41760976	46.22	<.0001
SEXC	1	0.32945205	0.32945205	0.99	0.3239
UCPDGR1	1	0.72841975	0.72841975	2.18	0.1442
TRTPN	2	15.98657166	7.99328583	23.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.05735783	10.05735783	30.15	<.0001
SEXC	1	0.33115504	0.33115504	0.99	0.3226
UCPDGR1	1	0.04971952	0.04971952	0.15	0.7007
TRTPN	2	15.98657166	7.99328583	23.96	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	7.22572074	1
2	8.18708066	2
3	7.17999763	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8512
2	<.0001		0.0001
3	0.8512	0.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	7.225721	7.030914	7.420528
2	8.187081	7.970999	8.403163
3	7.179998	6.737143	7.622853



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHEMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.961360	-1.253453	-0.669267
1	3	0.045723	-0.439043	0.530490
2	3	1.007083	0.518906	1.495260

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.32502111	3.86500422	12.24	<.0001
Error	69	21.79041327	0.31580309		
Corrected Total	74	41.11543438			

R-Square	Coeff Var	Root MSE	logaval Mean
0.470019	10.33637	0.561964	5.436758

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	9.68207272	9.68207272	30.66	<.0001
SEXC	1	0.11843980	0.11843980	0.38	0.5423
UCPDGR1	1	1.07717350	1.07717350	3.41	0.0691
TRTPN	2	8.44733509	4.22366754	13.37	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	10.42130037	10.42130037	33.00	<.0001
SEXC	1	0.00710287	0.00710287	0.02	0.8812
UCPDGR1	1	0.37501966	0.37501966	1.19	0.2796
TRTPN	2	8.44733509	4.22366754	13.37	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.17476334	1
2	5.86302581	2
3	5.12542360	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8349
2	<.0001		0.0028
3	0.8349	0.0028	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.174763	4.991480	5.358047
2	5.863026	5.652929	6.073123
3	5.125424	4.694457	5.556390

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHMPM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.688262	-0.968398	-0.408127
1	3	0.049340	-0.421162	0.519842
2	3	0.737602	0.262335	1.212870

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.32250017	3.86450003	11.24	<.0001
Error	67	23.03982469	0.34387798		
Corrected Total	72	42.36232486			

R-Square	Coeff Var	Root MSE	logaval Mean
0.456125	11.80159	0.586411	4.968915

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.63724557	10.63724557	30.93	<.0001
SEXC	1	0.00745081	0.00745081	0.02	0.8834
UCPDGR1	1	0.62660798	0.62660798	1.82	0.1816
TRTPN	2	8.05119581	4.02559790	11.71	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.86016410	9.86016410	28.67	<.0001
SEXC	1	0.03206020	0.03206020	0.09	0.7611
UCPDGR1	1	0.14226707	0.14226707	0.41	0.5223
TRTPN	2	8.05119581	4.02559790	11.71	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.70906121	1
2	5.38640055	2
3	4.65700857	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8339
2	<.0001		0.0045
3	0.8339	0.0045	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.709061	4.511545	4.906578
2	5.386401	5.167028	5.605773
3	4.657009	4.207970	5.106048

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UHMPMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.677339	-0.973839	-0.380840
1	3	0.052053	-0.441343	0.545448
2	3	0.729392	0.233869	1.224915

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	65.6926394	13.1385279	25.33	<.0001
Error	69	35.7906406	0.5187049		
Corrected Total	74	101.4832801			

R-Square	Coeff Var	Root MSE	logaval Mean
0.647325	11.00169	0.720212	6.546372

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	16.69902610	16.69902610	32.19	<.0001
SEXC	1	1.21573650	1.21573650	2.34	0.1304
UCPDGR1	1	3.44023652	3.44023652	6.63	0.0122
TRTPN	2	44.33764033	22.16882017	42.74	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.15618527	23.15618527	44.64	<.0001
SEXC	1	0.40290350	0.40290350	0.78	0.3812
UCPDGR1	1	0.79560098	0.79560098	1.53	0.2197
TRTPN	2	44.33764033	22.16882017	42.74	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.91651634	1
2	7.52060601	2
3	5.91259732	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.9898
2	<.0001		<.0001
3	0.9898	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.916516	5.679957	6.153075
2	7.520606	7.250365	7.790847
3	5.912597	5.357666	6.467529



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UMHBM24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.604090	-1.966730	-1.241450
1	3	0.003919	-0.605092	0.612930
2	3	1.608009	0.998738	2.217279

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UMHBMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UMHBMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	64.65612242	12.93122448	26.04	<.0001
Error	67	33.26741564	0.49652859		
Corrected Total	72	97.92353806			

R-Square	Coeff Var	Root MSE	logaval Mean
0.660272	11.64032	0.704648	6.053510

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	16.56239262	16.56239262	33.36	<.0001
SEXC	1	0.18105014	0.18105014	0.36	0.5480
UCPDGR1	1	2.38175441	2.38175441	4.80	0.0320
TRTPN	2	45.53092524	22.76546262	45.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.16811425	23.16811425	46.66	<.0001
SEXC	1	0.05166970	0.05166970	0.10	0.7480
UCPDGR1	1	0.23756354	0.23756354	0.48	0.4915
TRTPN	2	45.53092524	22.76546262	45.85	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UMHBMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.38741965	1
2	7.04090776	2
3	5.44694470	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8431
2	<.0001		<.0001
3	0.8431	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.387420	5.148436	5.626404
2	7.040908	6.776638	7.305178
3	5.446945	4.905047	5.988842

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UMHBMCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.653488	-2.013273	-1.293703
1	3	-0.059525	-0.657524	0.538474
2	3	1.593963	0.998108	2.189818

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	74
Number of Observations Used	74



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	50.76563826	10.15312765	18.06	<.0001
Error	68	38.22463697	0.56212701		
Corrected Total	73	88.99027523			

R-Square	Coeff Var	Root MSE	logaval Mean
0.570463	34.45897	0.749751	2.175780

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	17.87807665	17.87807665	31.80	<.0001
SEXC	1	0.00143952	0.00143952	0.00	0.9598
UCPDGR1	1	0.11052816	0.11052816	0.20	0.6589
TRTPN	2	32.77559393	16.38779696	29.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	13.77060174	13.77060174	24.50	<.0001
SEXC	1	0.09872549	0.09872549	0.18	0.6765
UCPDGR1	1	0.08476772	0.08476772	0.15	0.6990
TRTPN	2	32.77559393	16.38779696	29.15	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	2.37932731	1
2	2.40014198	2
3	0.08470326	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.9134	<.0001
2	0.9134		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	2.379327	2.128641	2.630014
2	2.400142	2.118223	2.682061
3	0.084703	-0.489298	0.658705

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNEQ24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.020815	-0.401452	0.359822
1	3	2.294624	1.666495	2.922753
2	3	2.315439	1.680129	2.950749

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	54.11734001	10.82346800	18.97	<.0001
Error	67	38.21799924	0.57041790		
Corrected Total	72	92.33533925			

R-Square	Coeff Var	Root MSE	logaval Mean
0.586096	44.55759	0.755260	1.695020

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	20.97768524	20.97768524	36.78	<.0001
SEXC	1	0.04255833	0.04255833	0.07	0.7856
UCPDGR1	1	0.18744349	0.18744349	0.33	0.5684
TRTPN	2	32.90965295	16.45482648	28.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	15.00086453	15.00086453	26.30	<.0001
SEXC	1	0.01414074	0.01414074	0.02	0.8754
UCPDGR1	1	0.04236263	0.04236263	0.07	0.7861
TRTPN	2	32.90965295	16.45482648	28.85	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	1.91203283	1
2	1.91726239	2
3	-0.39344421	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.9784	<.0001
2	0.9784		<.0001
3	<.0001	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	1.912033	1.658126	2.165939
2	1.917262	1.632712	2.201813
3	-0.393444	-0.971111	0.184223

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNEQCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.005230	-0.389355	0.378896
1	3	2.305477	1.671830	2.939124
2	3	2.310707	1.671879	2.949534

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	52.7760529	10.5552106	12.22	<.0001
Error	69	59.5759845	0.8634201		
Corrected Total	74	112.3520375			

R-Square	Coeff Var	Root MSE	logaval Mean
0.469738	19.54099	0.929204	4.755153

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	21.67291977	21.67291977	25.10	<.0001
SEXC	1	3.51976558	3.51976558	4.08	0.0474
UCPDGR1	1	0.84577317	0.84577317	0.98	0.3258
TRTPN	2	26.73759441	13.36879720	15.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.38107821	23.38107821	27.08	<.0001
SEXC	1	2.69821663	2.69821663	3.13	0.0815
UCPDGR1	1	0.01481051	0.01481051	0.02	0.8962
TRTPN	2	26.73759441	13.36879720	15.48	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.23771894	1
2	5.48660509	2
3	4.29217270	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8891
2	<.0001		0.0034
3	0.8891	0.0034	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.237719	3.934675	4.540763
2	5.486605	5.139194	5.834016
3	4.292173	3.581271	5.003074

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNAL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.248886	-1.712061	-0.785711
1	3	-0.054454	-0.830659	0.721751
2	3	1.194432	0.409963	1.978902

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNALCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNALCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	50.1239747	10.0247949	12.58	<.0001
Error	67	53.3862805	0.7968102		
Corrected Total	72	103.5102552			

R-Square	Coeff Var	Root MSE	logaval Mean
0.484242	20.79738	0.892642	4.292090

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	21.11421592	21.11421592	26.50	<.0001
SEXC	1	1.50247118	1.50247118	1.89	0.1743
UCPDGR1	1	0.64472034	0.64472034	0.81	0.3716
TRTPN	2	26.86256731	13.43128365	16.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	24.51726431	24.51726431	30.77	<.0001
SEXC	1	1.29168421	1.29168421	1.62	0.2073
UCPDGR1	1	0.00008900	0.00008900	0.00	0.9916
TRTPN	2	26.86256731	13.43128365	16.86	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNALCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.75746832	1
2	5.02687137	2
3	3.84270894	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.8212
2	<.0001		0.0025
3	0.8212	0.0025	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.757468	3.457115	4.057821
2	5.026871	4.692968	5.360775
3	3.842709	3.159723	4.525694

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNALCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.269403	-1.720721	-0.818085
1	3	-0.085241	-0.835144	0.664663
2	3	1.184162	0.430575	1.937750

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	83.0443993	16.6088799	25.67	<.0001
Error	69	44.6461715	0.6470460		
Corrected Total	74	127.6905708			

R-Square	Coeff Var	Root MSE	logaval Mean
0.650357	88.05551	0.804392	0.913505

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	12.45358598	12.45358598	19.25	<.0001
SEXC	1	0.02468185	0.02468185	0.04	0.8457
UCPDGR1	1	0.81186915	0.81186915	1.25	0.2665
TRTPN	2	69.75426231	34.87713116	53.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	14.16789312	14.16789312	21.90	<.0001
SEXC	1	0.00662165	0.00662165	0.01	0.9197
UCPDGR1	1	0.05066814	0.05066814	0.08	0.7804
TRTPN	2	69.75426231	34.87713116	53.90	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	0.36378794	1
2	2.06581915	2
3	-0.77783398	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0012
2	<.0001		<.0001
3	0.0012	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	0.363788	0.101185	0.626391
2	2.065819	1.764928	2.366710
3	-0.777834	-1.393225	-0.162443

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNN24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.702031	-2.103597	-1.300466
1	3	1.141622	0.469250	1.813994
2	3	2.843653	2.165004	3.522302

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	86.7883897	17.3576779	28.39	<.0001
Error	67	40.9598055	0.6113404		
Corrected Total	72	127.7481952			

R-Square	Coeff Var	Root MSE	logaval Mean
0.679371	172.3260	0.781883	0.453723

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	15.46570571	15.46570571	25.30	<.0001
SEXC	1	0.82241555	0.82241555	1.35	0.2502
UCPDGR1	1	0.66601716	0.66601716	1.09	0.3003
TRTPN	2	69.83425128	34.91712564	57.12	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	16.95958767	16.95958767	27.74	<.0001
SEXC	1	0.35083084	0.35083084	0.57	0.4514
UCPDGR1	1	0.01606448	0.01606448	0.03	0.8717
TRTPN	2	69.83425128	34.91712564	57.12	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	-0.12074407	1
2	1.61761177	2
3	-1.20823342	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.0016
2	<.0001		<.0001
3	0.0016	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	-0.120744	-0.385151	0.143663
2	1.617612	1.324675	1.910549
3	-1.208233	-1.806608	-0.609859



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UNNNCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.738356	-2.136164	-1.340548
1	3	1.087489	0.429369	1.745610
2	3	2.825845	2.165999	3.485691

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17.31972333	3.46394467	8.98	<.0001
Error	69	26.61002281	0.38565250		
Corrected Total	74	43.92974614			

R-Square	Coeff Var	Root MSE	logaval Mean
0.394260	13.41056	0.621009	4.630747

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	3.96719583	3.96719583	10.29	0.0020
SEXC	1	0.25862168	0.25862168	0.67	0.4157
UCPDGR1	1	0.29902815	0.29902815	0.78	0.3816
TRTPN	2	12.79487767	6.39743883	16.59	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.89986263	1.89986263	4.93	0.0297
SEXC	1	0.17106304	0.17106304	0.44	0.5076
UCPDGR1	1	0.01353641	0.01353641	0.04	0.8519
TRTPN	2	12.79487767	6.39743883	16.59	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	4.30367937	1
2	5.15680177	2
3	4.19146440	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.6674
2	<.0001		0.0005
3	0.6674	0.0005	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	4.303679	4.100284	4.507075
2	5.156802	4.921982	5.391621
3	4.191464	3.715042	4.667887

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UOTOL24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.853122	-1.167359	-0.538886
1	3	0.112215	-0.406489	0.630919
2	3	0.965337	0.436067	1.494607

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.11899378	3.62379876	9.04	<.0001
Error	67	26.86841214	0.40102108		
Corrected Total	72	44.98740592			

R-Square	Coeff Var	Root MSE	logaval Mean
0.402757	15.26512	0.633262	4.148427

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	4.83414612	4.83414612	12.05	0.0009
SEXC	1	0.31342352	0.31342352	0.78	0.3798
UCPDGR1	1	0.42238620	0.42238620	1.05	0.3084
TRTPN	2	12.54903793	6.27451897	15.65	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	1.55763627	1.55763627	3.88	0.0529
SEXC	1	0.58563032	0.58563032	1.46	0.2311
UCPDGR1	1	0.00018851	0.00018851	0.00	0.9828
TRTPN	2	12.54903793	6.27451897	15.65	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	3.83206555	1
2	4.68762473	2
3	3.74587270	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.7472
2	<.0001		0.0009
3	0.7472	0.0009	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	3.832066	3.618964	4.045167
2	4.687625	4.447322	4.927928
3	3.745873	3.260781	4.230965

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=UOTOLCRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.855559	-1.179883	-0.531235
1	3	0.086193	-0.445315	0.617701
2	3	0.941752	0.403009	1.480495

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.07078840	2.41415768	4.11	0.0025
Error	69	40.56090308	0.58783918		
Corrected Total	74	52.63169148			

R-Square	Coeff Var	Root MSE	logaval Mean
0.229344	8.762536	0.766707	8.749827

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	10.58702625	10.58702625	18.01	<.0001
SEXC	1	0.12301783	0.12301783	0.21	0.6488
UCPDGR1	1	0.58503878	0.58503878	1.00	0.3220
TRTPN	2	0.77570554	0.38785277	0.66	0.5202

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	9.67604177	9.67604177	16.46	0.0001
SEXC	1	0.00310289	0.00310289	0.01	0.9423
UCPDGR1	1	0.53716188	0.53716188	0.91	0.3424
TRTPN	2	0.77570554	0.38785277	0.66	0.5202

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.76720968	1
2	8.66031897	2
3	9.02610182	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		0.5820	0.4255
2	0.5820		0.2634
3	0.4255	0.2634	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.767210	8.515968	9.018451
2	8.660319	8.372477	8.948161
3	9.026102	8.437863	9.614340

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USBMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.106891	-0.278661	0.492443
1	3	-0.258892	-0.903167	0.385382
2	3	-0.365783	-1.012920	0.281354

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.36428826	1.67285765	2.69	0.0281
Error	67	41.61361393	0.62109872		
Corrected Total	72	49.97790219			

R-Square	Coeff Var	Root MSE	logaval Mean
0.167360	9.541583	0.788098	8.259617

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	7.01129576	7.01129576	11.29	0.0013
SEXC	1	0.06971878	0.06971878	0.11	0.7386
UCPDGR1	1	0.42923178	0.42923178	0.69	0.4087
TRTPN	2	0.85404195	0.42702097	0.69	0.5063

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	5.62962484	5.62962484	9.06	0.0037
SEXC	1	0.29046409	0.29046409	0.47	0.4964
UCPDGR1	1	0.44006420	0.44006420	0.71	0.4029
TRTPN	2	0.85404195	0.42702097	0.69	0.5063

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	8.30671003	1
2	8.16349924	2
3	8.53150479	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		0.4787	0.5013
2	0.4787		0.2734
3	0.5013	0.2734	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	8.306710	8.039931	8.573489
2	8.163499	7.868237	8.458762
3	8.531505	7.928311	9.134698



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USBMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.143211	-0.258026	0.544447
1	3	-0.224795	-0.888468	0.438879
2	3	-0.368006	-1.033114	0.297103

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	75
Number of Observations Used	75



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	72.4344987	14.4868997	14.27	<.0001
Error	69	70.0325574	1.0149646		
Corrected Total	74	142.4670561			

R-Square	Coeff Var	Root MSE	logaval Mean
0.508430	15.17457	1.007455	6.639099

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	25.66329744	25.66329744	25.28	<.0001
SEXC	1	0.28354687	0.28354687	0.28	0.5988
UCPDGR1	1	3.08713025	3.08713025	3.04	0.0856
TRTPN	2	43.40052416	21.70026208	21.38	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.42179377	23.42179377	23.08	<.0001
SEXC	1	0.04067860	0.04067860	0.04	0.8419
UCPDGR1	1	0.97120612	0.97120612	0.96	0.3314
TRTPN	2	43.40052416	21.70026208	21.38	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	6.14910524	1
2	7.57290107	2
3	5.47914479	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j) Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1177
2	<.0001		<.0001
3	0.1177	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	6.149105	5.820553	6.477658
2	7.572901	7.195969	7.949833
3	5.479145	4.706254	6.252036



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***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USPMA24U Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.423796	-1.926108	-0.921484
1	3	0.669960	-0.173627	1.513547
2	3	2.093756	1.240196	2.947317

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=USPMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	73
Number of Observations Used	73



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Dependent Variable: logaval****Parameter Code=USPMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	75.5712378	15.1142476	15.50	<.0001
Error	67	65.3156860	0.9748610		
Corrected Total	72	140.8869238			

R-Square	Coeff Var	Root MSE	logaval Mean
0.536396	16.11811	0.987350	6.125719

Source	DF	Type I SS	Mean Square	F Value	Pr > F
logbase	1	27.63994495	27.63994495	28.35	<.0001
SEXC	1	0.00651411	0.00651411	0.01	0.9351
UCPDGR1	1	2.32106722	2.32106722	2.38	0.1275
TRTPN	2	45.60371154	22.80185577	23.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
logbase	1	23.21200365	23.21200365	23.81	<.0001
SEXC	1	0.03774556	0.03774556	0.04	0.8446
UCPDGR1	1	0.45705177	0.45705177	0.47	0.4959
TRTPN	2	45.60371154	22.80185577	23.39	<.0001

**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=USPMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	logaval LSMEAN	LSMEAN Number
1	5.59155780	1
2	7.09070216	2
3	5.00342537	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: logaval			
i/j	1	2	3
1		<.0001	0.1619
2	<.0001		<.0001
3	0.1619	<.0001	

TRTPN	logaval LSMEAN	95% Confidence Limits	
1	5.591558	5.259781	5.923335
2	7.090702	6.720809	7.460595
3	5.003425	4.247020	5.759830

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=USPMACRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.499144	-1.998115	-1.000174
1	3	0.588132	-0.241950	1.418215
2	3	2.087277	1.251529	2.923025

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10756.15391	2151.23078	129.95	<.0001
Error	128	2118.92818	16.55413		
Corrected Total	133	12875.08209			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.835424	55.23836	4.068676	7.365672

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	398.12057	398.12057	24.05	<.0001
SEXC	1	6.33881	6.33881	0.38	0.5371
UCPDGR1	1	25.14655	25.14655	1.52	0.2200
TRTPN	2	10326.54798	5163.27399	311.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	299.83991	299.83991	18.11	<.0001
SEXC	1	12.51419	12.51419	0.76	0.3862
UCPDGR1	1	48.83937	48.83937	2.95	0.0883
TRTPN	2	10326.54798	5163.27399	311.90	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.2010190	1
2	22.1634650	2
3	2.0282839	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.8569
2	<.0001		<.0001
3	0.8569	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.201019	1.255223	3.146815
2	22.163465	20.796630	23.530300
3	2.028284	0.373016	3.683552

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=CO Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-19.962446	-21.612352	-18.312540
1	3	0.172735	-1.719521	2.064991
2	3	20.135181	17.998235	22.272128

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population*****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	79
Number of Observations Used	79



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4278.638815	855.727763	18.80	<.0001
Error	73	3322.221945	45.509890		
Corrected Total	78	7600.860759			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.562915	62.25958	6.746102	10.83544

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	100.228791	100.228791	2.20	0.1421
SEXC	1	24.808592	24.808592	0.55	0.4627
UCPDGR1	1	2.967333	2.967333	0.07	0.7992
TRTPN	2	4150.634099	2075.317049	45.60	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	92.423472	92.423472	2.03	0.1584
SEXC	1	24.794940	24.794940	0.54	0.4628
UCPDGR1	1	89.293590	89.293590	1.96	0.1655
TRTPN	2	4150.634099	2075.317049	45.60	<.0001



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**Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population****Least Squares Means****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.9416087	1
2	19.8218388	2
3	4.2715234	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		<.0001	0.8131
2	<.0001		<.0001
3	0.8131	<.0001	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.941609	2.800766	7.082452
2	19.821839	17.376918	22.266760
3	4.271523	-0.902660	9.445706

***Listing 15.4.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population******Least Squares Means*****Parameter Code=CO Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-14.880230	-18.137265	-11.623195
1	3	0.670085	-4.957295	6.297466
2	3	15.550315	9.885381	21.215250

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



#### **15.4.4 Secondary Endpoints**



1

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



2

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3746

Fit Statistics	
-2 Res Log Likelihood	253.3
AIC (smaller is better)	255.3
AICC (smaller is better)	255.3
BIC (smaller is better)	258.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	104.37	<.0001
SEX	1	125	1.87	0.1737
UCPDGR1	1	125	0.45	0.5026
TRTP	2	125	285.39	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.9671	0.1283	125	-7.54	<.0001	0.05	-1.2210	-0.7132
TRTP	THSm2.2	2.1755	0.07224	125	30.11	<.0001	0.05	2.0325	2.3185
TRTP	mCC	2.7001	0.1057	125	25.54	<.0001	0.05	2.4908	2.9093

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.6671	0.1653	125	-22.19	<.0001	0.05	-3.9943	-3.3400
TRTP	THSm2.2	mCC	-0.5245	0.1269	125	-4.13	<.0001	0.05	-0.7757	-0.2734





4

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set***

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



5

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2499

Fit Statistics	
-2 Res Log Likelihood	202.7
AIC (smaller is better)	204.7
AICC (smaller is better)	204.7
BIC (smaller is better)	207.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	79.23	<.0001
SEX	1	125	3.84	0.0521
UCPDGR1	1	125	0.12	0.7254
TRTP	2	125	713.68	<.0001



6

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.7814	0.1048	125	-17.00	<.0001	0.05	-1.9888	-1.5741
TRTP	THSm2.2	2.4640	0.05901	125	41.76	<.0001	0.05	2.3473	2.5808
TRTP	mCC	2.7262	0.08634	125	31.57	<.0001	0.05	2.5553	2.8971

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.5076	0.1350	125	-33.39	<.0001	0.05	-4.7748	-4.2404
TRTP	THSm2.2	mCC	-0.2621	0.1037	125	-2.53	0.0127	0.05	-0.4673	-0.05699



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Number of Observations	
Number of Observations Read	130
Number of Observations Used	130
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2600

Fit Statistics	
-2 Res Log Likelihood	206.1
AIC (smaller is better)	208.1
AICC (smaller is better)	208.1
BIC (smaller is better)	210.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	124	62.21	<.0001
SEX	1	124	2.19	0.1419
UCPDGR1	1	124	1.27	0.2617
TRTP	2	124	792.65	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-2.0393	0.1069	124	-19.08	<.0001	0.05	-2.2508	-1.8277
TRTP	THSm2.2	2.5335	0.06020	124	42.08	<.0001	0.05	2.4143	2.6526
TRTP	mCC	2.8075	0.08962	124	31.33	<.0001	0.05	2.6301	2.9849

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.8468	0.1385	124	-34.98	<.0001	0.05	-5.1210	-4.5725
TRTP	THSm2.2	mCC	-0.2740	0.1068	124	-2.57	0.0115	0.05	-0.4854	-0.06261



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2348

Fit Statistics	
-2 Res Log Likelihood	194.9
AIC (smaller is better)	196.9
AICC (smaller is better)	196.9
BIC (smaller is better)	199.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	67.23	<.0001
SEX	1	125	1.02	0.3144
UCPDGR1	1	125	0.01	0.9170
TRTP	2	125	913.54	<.0001





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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-2.2160	0.1016	125	-21.82	<.0001	0.05	-2.4170	-2.0150
TRTP	THSm2.2	2.4722	0.05720	125	43.22	<.0001	0.05	2.3590	2.5854
TRTP	mCC	2.6754	0.08370	125	31.96	<.0001	0.05	2.5097	2.8410

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.8914	0.1309	125	-37.38	<.0001	0.05	-5.1503	-4.6324
TRTP	THSm2.2	mCC	-0.2032	0.1005	125	-2.02	0.0453	0.05	-0.4021	-0.00432



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	103



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	103
Number of Observations Used	103
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2134

Fit Statistics	
-2 Res Log Likelihood	144.1
AIC (smaller is better)	146.1
AICC (smaller is better)	146.2
BIC (smaller is better)	148.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	98	41.04	<.0001
SEX	1	98	0.92	0.3391
UCPDGR1	1	98	5.01	0.0275
TRTP	1	98	5.50	0.0210



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.6439	0.05625	98	47.00	<.0001	0.05	2.5322	2.7555
TRTP	mCC	2.8709	0.07991	98	35.93	<.0001	0.05	2.7123	3.0295

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2271	0.09684	98	-2.34	0.0210	0.05	-0.4192	-0.03490



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	85



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Number of Observations	
Number of Observations Read	85
Number of Observations Used	85
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5159

Fit Statistics	
-2 Res Log Likelihood	190.7
AIC (smaller is better)	192.7
AICC (smaller is better)	192.7
BIC (smaller is better)	195.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	79	20.84	<.0001
SEX	1	79	1.67	0.2000
UCPDGR1	1	79	0.01	0.9357
TRTP	2	79	103.47	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.6022	0.2006	79	-3.00	0.0036	0.05	-1.0016	-0.2029
TRTP	THSm2.2	2.4844	0.1176	79	21.12	<.0001	0.05	2.2502	2.7186
TRTP	mCC	2.5689	0.1263	79	20.34	<.0001	0.05	2.3175	2.8203

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.1712	0.2354	79	-13.47	<.0001	0.05	-3.6397	-2.7026
TRTP	THSm2.2	mCC	-0.08452	0.1718	79	-0.49	0.6241	0.05	-0.4264	0.2574



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	83



***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set***

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60

Number of Observations	
Number of Observations Read	83
Number of Observations Used	83
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7571

Fit Statistics	
-2 Res Log Likelihood	215.7
AIC (smaller is better)	217.7
AICC (smaller is better)	217.8
BIC (smaller is better)	220.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	77	15.28	0.0002
SEX	1	77	0.07	0.7988
UCPDGR1	1	77	0.00	0.9674
TRTP	2	77	45.40	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.1995	0.2669	77	-0.75	0.4571	0.05	-0.7308	0.3319
TRTP	THSm2.2	2.4318	0.1428	77	17.03	<.0001	0.05	2.1474	2.7162
TRTP	mCC	2.5778	0.1541	77	16.73	<.0001	0.05	2.2710	2.8846

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.7773	0.3052	77	-9.10	<.0001	0.05	-3.3850	-2.1695
TRTP	THSm2.2	mCC	-0.1460	0.2103	77	-0.69	0.4896	0.05	-0.5649	0.2728

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	87

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set***

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	87
Number of Observations Used	87
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.5373

Fit Statistics	
-2 Res Log Likelihood	198.2
AIC (smaller is better)	200.2
AICC (smaller is better)	200.2
BIC (smaller is better)	202.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	81	14.15	0.0003
SEX	1	81	0.30	0.5880
UCPDGR1	1	81	0.22	0.6427
TRTP	2	81	47.84	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-0.1852	0.2494	81	-0.74	0.4598	0.05	-0.6815	0.3110
TRTP	THSm2.2	2.1891	0.1090	81	20.08	<.0001	0.05	1.9722	2.4059
TRTP	mCC	2.5178	0.1331	81	18.92	<.0001	0.05	2.2530	2.7826

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.7031	0.2808	81	-9.62	<.0001	0.05	-3.2619	-2.1443
TRTP	THSm2.2	mCC	-0.3288	0.1718	81	-1.91	0.0592	0.05	-0.6706	0.01312



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***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.06226

Fit Statistics	
-2 Res Log Likelihood	28.8
AIC (smaller is better)	30.8
AICC (smaller is better)	30.9
BIC (smaller is better)	33.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	431.39	<.0001
SEX	1	125	0.72	0.3987
UCPDGR1	1	125	1.28	0.2592
TRTP	2	125	68.80	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6060	0.05277	125	87.29	<.0001	0.05	4.5016	4.7104
TRTP	THSm2.2	5.1901	0.02955	125	175.66	<.0001	0.05	5.1316	5.2485
TRTP	mCC	5.3795	0.04308	125	124.86	<.0001	0.05	5.2942	5.4647

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7735	0.06767	125	-11.43	<.0001	0.05	-0.9074	-0.6395
TRTP	THSm2.2	mCC	-0.1894	0.05183	125	-3.65	0.0004	0.05	-0.2920	-0.08684



***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1003

Fit Statistics	
-2 Res Log Likelihood	88.5
AIC (smaller is better)	90.5
AICC (smaller is better)	90.5
BIC (smaller is better)	93.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	300.66	<.0001
SEX	1	125	2.57	0.1114
UCPDGR1	1	125	0.58	0.4490
TRTP	2	125	195.67	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.7779	0.06699	125	56.39	<.0001	0.05	3.6453	3.9105
TRTP	THSm2.2	5.1475	0.03751	125	137.23	<.0001	0.05	5.0732	5.2217
TRTP	mCC	5.3531	0.05470	125	97.87	<.0001	0.05	5.2449	5.4614

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.5753	0.08591	125	-18.34	<.0001	0.05	-1.7453	-1.4052
TRTP	THSm2.2	mCC	-0.2056	0.06580	125	-3.13	0.0022	0.05	-0.3359	-0.07542

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Number of Observations	
Number of Observations Read	130
Number of Observations Used	130
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1373

Fit Statistics	
-2 Res Log Likelihood	126.8
AIC (smaller is better)	128.8
AICC (smaller is better)	128.8
BIC (smaller is better)	131.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	124	217.65	<.0001
SEX	1	124	2.27	0.1346
UCPDGR1	1	124	0.76	0.3849
TRTP	2	124	363.12	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.9761	0.07839	124	37.97	<.0001	0.05	2.8210	3.1313
TRTP	THSm2.2	5.2363	0.04389	124	119.31	<.0001	0.05	5.1494	5.3232
TRTP	mCC	5.4038	0.06512	124	82.98	<.0001	0.05	5.2749	5.5327

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.4277	0.1011	124	-24.00	<.0001	0.05	-2.6279	-2.2275
TRTP	THSm2.2	mCC	-0.1675	0.07776	124	-2.15	0.0331	0.05	-0.3214	-0.01362

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1771

Fit Statistics	
-2 Res Log Likelihood	159.5
AIC (smaller is better)	161.5
AICC (smaller is better)	161.5
BIC (smaller is better)	164.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	125	163.79	<.0001
SEX	1	125	1.84	0.1776
UCPDGR1	1	125	0.48	0.4876
TRTP	2	125	526.86	<.0001



**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.1455	0.08898	125	24.11	<.0001	0.05	1.9694	2.3217
TRTP	THSm2.2	5.2641	0.04983	125	105.65	<.0001	0.05	5.1655	5.3627
TRTP	mCC	5.4114	0.07265	125	74.48	<.0001	0.05	5.2677	5.5552

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.2659	0.1141	125	-28.62	<.0001	0.05	-3.4917	-3.0401
TRTP	THSm2.2	mCC	-0.1474	0.08740	125	-1.69	0.0942	0.05	-0.3203	0.02560

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	104

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	104
Number of Observations Used	104
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1389

Fit Statistics	
-2 Res Log Likelihood	102.9
AIC (smaller is better)	104.9
AICC (smaller is better)	104.9
BIC (smaller is better)	107.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	99	127.08	<.0001
SEX	1	99	0.17	0.6789
UCPDGR1	1	99	0.71	0.4020
TRTP	1	99	4.91	0.0290

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.2578	0.04512	99	116.53	<.0001	0.05	5.1682	5.3473
TRTP	mCC	5.4309	0.06458	99	84.09	<.0001	0.05	5.3028	5.5591

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1732	0.07818	99	-2.22	0.0290	0.05	-0.3283	-0.01805

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	85



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Number of Observations	
Number of Observations Read	85
Number of Observations Used	85
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.9506

Fit Statistics	
-2 Res Log Likelihood	238.9
AIC (smaller is better)	240.9
AICC (smaller is better)	240.9
BIC (smaller is better)	243.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	79	25.04	<.0001
SEX	1	79	0.08	0.7831
UCPDGR1	1	79	0.03	0.8628
TRTP	2	79	21.13	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.4462	0.2763	79	12.47	<.0001	0.05	2.8962	3.9961
TRTP	THSm2.2	5.4518	0.1603	79	34.02	<.0001	0.05	5.1327	5.7708
TRTP	mCC	5.3338	0.1713	79	31.14	<.0001	0.05	4.9929	5.6747

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8876	0.3232	79	-5.84	<.0001	0.05	-2.5310	-1.2443
TRTP	THSm2.2	mCC	0.1179	0.2330	79	0.51	0.6141	0.05	-0.3457	0.5816

***Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	83



**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60

Number of Observations	
Number of Observations Read	83
Number of Observations Used	83
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.9180

Fit Statistics	
-2 Res Log Likelihood	230.3
AIC (smaller is better)	232.3
AICC (smaller is better)	232.4
BIC (smaller is better)	234.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	77	22.82	<.0001
SEX	1	77	0.02	0.8886
UCPDGR1	1	77	0.37	0.5471
TRTP	2	77	12.53	<.0001



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**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.6465	0.2940	77	12.40	<.0001	0.05	3.0611	4.2320
TRTP	THSm2.2	5.2410	0.1583	77	33.11	<.0001	0.05	4.9258	5.5561
TRTP	mCC	5.1809	0.1696	77	30.54	<.0001	0.05	4.8431	5.5187

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.5344	0.3347	77	-4.58	<.0001	0.05	-2.2008	-0.8679
TRTP	THSm2.2	mCC	0.06009	0.2330	77	0.26	0.7971	0.05	-0.4038	0.5240

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	87

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	87
Number of Observations Used	87
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.8931

Fit Statistics	
-2 Res Log Likelihood	239.2
AIC (smaller is better)	241.2
AICC (smaller is better)	241.2
BIC (smaller is better)	243.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	81	20.11	<.0001
SEX	1	81	0.37	0.5431
UCPDGR1	1	81	0.26	0.6133
TRTP	2	81	16.47	<.0001

**Listing 15.4.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.2721	0.3210	81	10.19	<.0001	0.05	2.6335	3.9108
TRTP	THSm2.2	5.2115	0.1412	81	36.90	<.0001	0.05	4.9304	5.4925
TRTP	mCC	5.1853	0.1720	81	30.14	<.0001	0.05	4.8430	5.5276

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.9132	0.3603	81	-5.31	<.0001	0.05	-2.6301	-1.1963
TRTP	THSm2.2	mCC	0.02615	0.2233	81	0.12	0.9071	0.05	-0.4181	0.4704



1

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152



2

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3798

Fit Statistics	
-2 Res Log Likelihood	295.3
AIC (smaller is better)	297.3
AICC (smaller is better)	297.4
BIC (smaller is better)	300.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	146	109.42	<.0001
SEX	1	146	2.11	0.1482
UCPDGR1	1	146	0.03	0.8701
TRTP	2	146	412.97	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.0550	0.1064	146	-9.91	<.0001	0.05	-1.2654	-0.8446
TRTP	THSm2.2	2.1790	0.07060	146	30.86	<.0001	0.05	2.0394	2.3185
TRTP	mCC	2.6990	0.09806	146	27.52	<.0001	0.05	2.5051	2.8928

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.7539	0.1438	146	-26.10	<.0001	0.05	-4.0382	-3.4697
TRTP	THSm2.2	mCC	-0.5200	0.1200	146	-4.33	<.0001	0.05	-0.7571	-0.2828





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***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	151



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Number of Observations	
Number of Observations Read	151
Number of Observations Used	151
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2376

Fit Statistics	
-2 Res Log Likelihood	225.4
AIC (smaller is better)	227.4
AICC (smaller is better)	227.4
BIC (smaller is better)	230.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	145	89.19	<.0001
SEX	1	145	6.18	0.0141
UCPDGR1	1	145	0.08	0.7715
TRTP	2	145	1053.38	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-1.8258	0.08531	145	-21.40	<.0001	0.05	-1.9944	-1.6572
TRTP	THSm2.2	2.4854	0.05584	145	44.51	<.0001	0.05	2.3750	2.5957
TRTP	mCC	2.7445	0.07757	145	35.38	<.0001	0.05	2.5912	2.8979

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.5703	0.1147	145	-39.86	<.0001	0.05	-4.7970	-4.3437
TRTP	THSm2.2	mCC	-0.2592	0.09491	145	-2.73	0.0071	0.05	-0.4468	-0.07159



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	150

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Number of Observations	
Number of Observations Read	150
Number of Observations Used	150
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2382

Fit Statistics	
-2 Res Log Likelihood	224.3
AIC (smaller is better)	226.3
AICC (smaller is better)	226.4
BIC (smaller is better)	229.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	144	73.98	<.0001
SEX	1	144	3.13	0.0791
UCPDGR1	1	144	2.22	0.1383
TRTP	2	144	1187.76	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-2.0435	0.08543	144	-23.92	<.0001	0.05	-2.2124	-1.8747
TRTP	THSm2.2	2.5431	0.05591	144	45.48	<.0001	0.05	2.4326	2.6536
TRTP	mCC	2.8277	0.07878	144	35.89	<.0001	0.05	2.6719	2.9834

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.8712	0.1155	144	-42.18	<.0001	0.05	-5.0994	-4.6429
TRTP	THSm2.2	mCC	-0.2846	0.09581	144	-2.97	0.0035	0.05	-0.4740	-0.09522



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***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	151



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Number of Observations	
Number of Observations Read	151
Number of Observations Used	151
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2197

Fit Statistics	
-2 Res Log Likelihood	214.1
AIC (smaller is better)	216.1
AICC (smaller is better)	216.1
BIC (smaller is better)	219.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	145	70.85	<.0001
SEX	1	145	1.64	0.2025
UCPDGR1	1	145	0.11	0.7379
TRTP	2	145	1334.48	<.0001





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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	-2.2072	0.08204	145	-26.90	<.0001	0.05	-2.3693	-2.0450
TRTP	THSm2.2	2.4857	0.05369	145	46.29	<.0001	0.05	2.3796	2.5918
TRTP	mCC	2.6981	0.07460	145	36.17	<.0001	0.05	2.5507	2.8455

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-4.9053	0.1103	145	-44.49	<.0001	0.05	-5.1232	-4.6873
TRTP	THSm2.2	mCC	-0.2124	0.09127	145	-2.33	0.0214	0.05	-0.3928	-0.03199



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***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	113



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	113
Number of Observations Used	113
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2011

Fit Statistics	
-2 Res Log Likelihood	151.1
AIC (smaller is better)	153.1
AICC (smaller is better)	153.2
BIC (smaller is better)	155.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	108	41.10	<.0001
SEX	1	108	0.64	0.4244
UCPDGR1	1	108	4.97	0.0278
TRTP	1	108	6.05	0.0155



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.6459	0.05291	108	50.01	<.0001	0.05	2.5410	2.7508
TRTP	mCC	2.8632	0.07148	108	40.06	<.0001	0.05	2.7215	3.0048

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2173	0.08834	108	-2.46	0.0155	0.05	-0.3924	-0.04215

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	148



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Number of Observations	
Number of Observations Read	148
Number of Observations Used	148
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7538

Fit Statistics	
-2 Res Log Likelihood	385.1
AIC (smaller is better)	387.1
AICC (smaller is better)	387.1
BIC (smaller is better)	390.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	142	38.28	<.0001
SEX	1	142	0.17	0.6798
UCPDGR1	1	142	1.79	0.1833
TRTP	2	142	88.55	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.1710	0.1520	142	1.13	0.2622	0.05	-0.1294	0.4715
TRTP	THSm2.2	2.3919	0.1008	142	23.73	<.0001	0.05	2.1926	2.5911
TRTP	mCC	2.5550	0.1398	142	18.28	<.0001	0.05	2.2787	2.8313

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.3840	0.2054	142	-11.61	<.0001	0.05	-2.7900	-1.9779
TRTP	THSm2.2	mCC	-0.1632	0.1712	142	-0.95	0.3423	0.05	-0.5016	0.1753

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	142



**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60

Number of Observations	
Number of Observations Read	142
Number of Observations Used	142
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.8112

Fit Statistics	
-2 Res Log Likelihood	379.5
AIC (smaller is better)	381.5
AICC (smaller is better)	381.5
BIC (smaller is better)	384.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	136	22.18	<.0001
SEX	1	136	0.01	0.9101
UCPDGR1	1	136	0.25	0.6195
TRTP	2	136	45.13	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.7822	0.1623	136	4.82	<.0001	0.05	0.4613	1.1031
TRTP	THSm2.2	2.4579	0.1055	136	23.30	<.0001	0.05	2.2492	2.6665
TRTP	mCC	2.6226	0.1495	136	17.54	<.0001	0.05	2.3269	2.9183

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8404	0.2195	136	-8.38	<.0001	0.05	-2.2745	-1.4062
TRTP	THSm2.2	mCC	-0.1647	0.1819	136	-0.91	0.3668	0.05	-0.5244	0.1950

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	139

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	139
Number of Observations Used	139
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6281

Fit Statistics	
-2 Res Log Likelihood	337.4
AIC (smaller is better)	339.4
AICC (smaller is better)	339.4
BIC (smaller is better)	342.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	133	23.82	<.0001
SEX	1	133	0.93	0.3371
UCPDGR1	1	133	0.38	0.5404
TRTP	2	133	35.19	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=1 Parameter Code=NIC Parameter=Nicotine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.0157	0.1428	133	7.11	<.0001	0.05	0.7333	1.2981
TRTP	THSm2.2	2.2404	0.09358	133	23.94	<.0001	0.05	2.0553	2.4255
TRTP	mCC	2.5404	0.1348	133	18.84	<.0001	0.05	2.2737	2.8070

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.5247	0.1955	133	-7.80	<.0001	0.05	-1.9114	-1.1379
TRTP	THSm2.2	mCC	-0.3000	0.1631	133	-1.84	0.0682	0.05	-0.6226	0.02269



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***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.05937

Fit Statistics	
-2 Res Log Likelihood	24.2
AIC (smaller is better)	26.2
AICC (smaller is better)	26.2
BIC (smaller is better)	29.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	146	500.48	<.0001
SEX	1	146	1.45	0.2300
UCPDGR1	1	146	1.54	0.2166
TRTP	2	146	99.52	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=101 Analysis Visit=Day 1**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6147	0.04238	146	108.89	<.0001	0.05	4.5309	4.6985
TRTP	THSm2.2	5.2055	0.02807	146	185.47	<.0001	0.05	5.1500	5.2610
TRTP	mCC	5.3818	0.03874	146	138.91	<.0001	0.05	5.3052	5.4584

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7671	0.05702	146	-13.45	<.0001	0.05	-0.8798	-0.6544
TRTP	THSm2.2	mCC	-0.1763	0.04753	146	-3.71	0.0003	0.05	-0.2702	-0.08236



**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	151

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2

Number of Observations	
Number of Observations Read	151
Number of Observations Used	151
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1053

Fit Statistics	
-2 Res Log Likelihood	107.2
AIC (smaller is better)	109.2
AICC (smaller is better)	109.3
BIC (smaller is better)	112.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	145	317.06	<.0001
SEX	1	145	4.42	0.0373
UCPDGR1	1	145	0.53	0.4663
TRTP	2	145	270.98	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=102 Analysis Visit=Day 2**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.7524	0.05717	145	65.64	<.0001	0.05	3.6394	3.8654
TRTP	THSm2.2	5.1649	0.03736	145	138.24	<.0001	0.05	5.0911	5.2388
TRTP	mCC	5.3760	0.05160	145	104.18	<.0001	0.05	5.2740	5.4780

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6235	0.07652	145	-21.22	<.0001	0.05	-1.7748	-1.4723
TRTP	THSm2.2	mCC	-0.2110	0.06330	145	-3.33	0.0011	0.05	-0.3362	-0.08592

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	150

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3

Number of Observations	
Number of Observations Read	150
Number of Observations Used	150
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1525

Fit Statistics	
-2 Res Log Likelihood	159.9
AIC (smaller is better)	161.9
AICC (smaller is better)	162.0
BIC (smaller is better)	164.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	144	218.63	<.0001
SEX	1	144	4.30	0.0399
UCPDGR1	1	144	0.97	0.3270
TRTP	2	144	478.79	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=103 Analysis Visit=Day 3**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.9090	0.06881	144	42.27	<.0001	0.05	2.7729	3.0450
TRTP	THSm2.2	5.2512	0.04496	144	116.78	<.0001	0.05	5.1623	5.3400
TRTP	mCC	5.4182	0.06300	144	86.00	<.0001	0.05	5.2937	5.5427

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.5093	0.09265	144	-27.08	<.0001	0.05	-2.6924	-2.3261
TRTP	THSm2.2	mCC	-0.1671	0.07680	144	-2.18	0.0312	0.05	-0.3189	-0.01526

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	151



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4

Number of Observations	
Number of Observations Read	151
Number of Observations Used	151
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1990

Fit Statistics	
-2 Res Log Likelihood	199.5
AIC (smaller is better)	201.5
AICC (smaller is better)	201.6
BIC (smaller is better)	204.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	145	168.76	<.0001
SEX	1	145	4.10	0.0448
UCPDGR1	1	145	0.86	0.3561
TRTP	2	145	677.78	<.0001



**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=104 Analysis Visit=Day 4**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.0649	0.07859	145	26.27	<.0001	0.05	1.9096	2.2203
TRTP	THSm2.2	5.2770	0.05137	145	102.73	<.0001	0.05	5.1754	5.3785
TRTP	mCC	5.4200	0.07094	145	76.40	<.0001	0.05	5.2798	5.5602

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-3.3551	0.1052	145	-31.89	<.0001	0.05	-3.5630	-3.1471
TRTP	THSm2.2	mCC	-0.1430	0.08703	145	-1.64	0.1024	0.05	-0.3150	0.02898

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	114

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1286

Fit Statistics	
-2 Res Log Likelihood	103.5
AIC (smaller is better)	105.5
AICC (smaller is better)	105.5
BIC (smaller is better)	108.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	109	137.80	<.0001
SEX	1	109	0.36	0.5471
UCPDGR1	1	109	0.40	0.5292
TRTP	1	109	5.64	0.0193

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.2693	0.04213	109	125.06	<.0001	0.05	5.1858	5.3528
TRTP	mCC	5.4372	0.05725	109	94.98	<.0001	0.05	5.3238	5.5507

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1679	0.07070	109	-2.37	0.0193	0.05	-0.3080	-0.02778

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	148



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**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30

Number of Observations	
Number of Observations Read	148
Number of Observations Used	148
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7792

Fit Statistics	
-2 Res Log Likelihood	389.6
AIC (smaller is better)	391.6
AICC (smaller is better)	391.6
BIC (smaller is better)	394.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	142	43.19	<.0001
SEX	1	142	0.53	0.4671
UCPDGR1	1	142	0.83	0.3638
TRTP	2	142	19.57	<.0001

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.2918	0.1556	142	27.59	<.0001	0.05	3.9842	4.5993
TRTP	THSm2.2	5.4153	0.1030	142	52.57	<.0001	0.05	5.2117	5.6190
TRTP	mCC	5.3464	0.1420	142	37.65	<.0001	0.05	5.0657	5.6271

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.0546	0.2095	142	-5.04	<.0001	0.05	-1.4687	-0.6406
TRTP	THSm2.2	mCC	0.06894	0.1744	142	0.40	0.6932	0.05	-0.2757	0.4136

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	142



**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60

Number of Observations	
Number of Observations Read	142
Number of Observations Used	142
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7243

Fit Statistics	
-2 Res Log Likelihood	363.8
AIC (smaller is better)	365.8
AICC (smaller is better)	365.9
BIC (smaller is better)	368.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	136	38.59	<.0001
SEX	1	136	0.04	0.8376
UCPDGR1	1	136	0.13	0.7170
TRTP	2	136	7.39	0.0009

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6428	0.1544	136	30.08	<.0001	0.05	4.3375	4.9481
TRTP	THSm2.2	5.3393	0.1005	136	53.13	<.0001	0.05	5.1405	5.5380
TRTP	mCC	5.2495	0.1413	136	37.16	<.0001	0.05	4.9701	5.5289

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.6067	0.2076	136	-2.92	0.0041	0.05	-1.0172	-0.1962
TRTP	THSm2.2	mCC	0.08978	0.1728	136	0.52	0.6042	0.05	-0.2519	0.4315

***Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS*****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	139

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	139
Number of Observations Used	139
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7949

Fit Statistics	
-2 Res Log Likelihood	368.5
AIC (smaller is better)	370.5
AICC (smaller is better)	370.6
BIC (smaller is better)	373.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
logbase	1	133	35.75	<.0001
SEX	1	133	0.02	0.8895
UCPDGR1	1	133	0.68	0.4097
TRTP	2	133	4.91	0.0087

**Listing 15.4.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter (N)=2 Parameter Code=COT Parameter=Cotinine (ng/mL) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.7447	0.1618	133	29.32	<.0001	0.05	4.4245	5.0648
TRTP	THSm2.2	5.3396	0.1060	133	50.37	<.0001	0.05	5.1299	5.5493
TRTP	mCC	5.2697	0.1516	133	34.75	<.0001	0.05	4.9698	5.5696

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.5250	0.2204	133	-2.38	0.0186	0.05	-0.9610	-0.08913
TRTP	THSm2.2	mCC	0.06990	0.1842	133	0.38	0.7050	0.05	-0.2945	0.4343



1

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	108



2

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set***

Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2728

Fit Statistics	
-2 Res Log Likelihood	174.3
AIC (smaller is better)	176.3
AICC (smaller is better)	176.4
BIC (smaller is better)	179.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	104	0.79	0.3760
UCPDGR1	1	104	1.01	0.3161
TRTP	1	104	2.19	0.1421

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.4024	0.06186	104	38.84	<.0001	0.05	2.2797	2.5250
TRTP	mCC	2.5625	0.09029	104	28.38	<.0001	0.05	2.3834	2.7415

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1601	0.1083	104	-1.48	0.1421	0.05	-0.3748	0.05456



***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	108



5

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2205

Fit Statistics	
-2 Res Log Likelihood	152.2
AIC (smaller is better)	154.2
AICC (smaller is better)	154.2
BIC (smaller is better)	156.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	104	0.51	0.4772
UCPDGR1	1	104	2.38	0.1260
TRTP	1	104	1.31	0.2551

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.0427	0.05562	104	54.70	<.0001	0.05	2.9324	3.1529
TRTP	mCC	3.1540	0.08118	104	38.85	<.0001	0.05	2.9931	3.3150

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1114	0.09734	104	-1.14	0.2551	0.05	-0.3044	0.08163



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***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	108

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2670

Fit Statistics	
-2 Res Log Likelihood	172.1
AIC (smaller is better)	174.1
AICC (smaller is better)	174.1
BIC (smaller is better)	176.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	104	1.07	0.3035
UCPDGR1	1	104	0.04	0.8393
TRTP	1	104	3.62	0.0599

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.2418	0.06120	104	85.65	<.0001	0.05	5.1204	5.3631
TRTP	mCC	5.4455	0.08932	104	60.96	<.0001	0.05	5.2684	5.6226

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2037	0.1071	104	-1.90	0.0599	0.05	-0.4161	0.008641



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***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	108



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***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set***

Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2023

Fit Statistics	
-2 Res Log Likelihood	143.3
AIC (smaller is better)	145.3
AICC (smaller is better)	145.3
BIC (smaller is better)	147.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	104	1.99	0.1617
UCPDGR1	1	104	0.49	0.4853
TRTP	1	104	2.88	0.0926





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***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.3828	0.05328	104	101.04	<.0001	0.05	5.2772	5.4885
TRTP	mCC	5.5411	0.07776	104	71.26	<.0001	0.05	5.3869	5.6953

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1583	0.09324	104	-1.70	0.0926	0.05	-0.3432	0.02663



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**Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set**

Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5

Wilcoxon Scores (Rank Sums) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	34	1566.0	1853.0	150.736194	46.058824
THSm2.2	74	4320.0	4033.0	150.736194	58.378378
Average scores were used for ties.					

Wilcoxon Two-Sample Test	
Statistic	1566.0000
Normal Approximation	
Z	-1.9007
One-Sided Pr < Z	0.0287
Two-Sided Pr >  Z	0.0573
t Approximation	
One-Sided Pr < Z	0.0300
Two-Sided Pr >  Z	0.0600
Z includes a continuity correction of 0.5.	



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***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5**

Kruskal-Wallis Test	
Chi-Square	3.6252
DF	1
Pr > Chi-Square	0.0569

Hodges-Lehmann Estimation			
Location Shift		-0.1833	
95% Confidence Limits	Interval Midpoint	Asymptotic Standard Error	
-1.9333	0.0000	-0.9667	0.4932



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**Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set**

Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5

Median Scores (Number of Points Above Median) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	34	11.50	17.0	2.402008	0.338235
THSm2.2	74	42.50	37.0	2.402008	0.574324
Average scores were used for ties.					

Median Two-Sample Test	
Statistic	11.5000
Z	-2.2898
One-Sided Pr < Z	0.0110
Two-Sided Pr >  Z	0.0220

Median One-Way Analysis	
Chi-Square	5.2430
DF	1
Pr > Chi-Square	0.0220



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**Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set**

Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5

Wilcoxon Scores (Rank Sums) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	34	1767.0	1853.0	151.011461	51.970588
THSm2.2	74	4119.0	4033.0	151.011461	55.662162
Average scores were used for ties.					

Wilcoxon Two-Sample Test	
Statistic	1767.0000
Normal Approximation	
Z	-0.5662
One-Sided Pr < Z	0.2856
Two-Sided Pr >  Z	0.5713
t Approximation	
One-Sided Pr < Z	0.2862
Two-Sided Pr >  Z	0.5725
Z includes a continuity correction of 0.5.	

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5**

Kruskal-Wallis Test	
Chi-Square	0.3243
DF	1
Pr > Chi-Square	0.5690

Hodges-Lehmann Estimation			
Location Shift		-0.0333	
95% Confidence Limits	Interval Midpoint	Asymptotic Standard Error	
-1.6167	0.1000	-0.7583	0.4379

***Listing 15.4.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set*****Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5**

Median Scores (Number of Points Above Median) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	34	16.333333	17.0	2.383050	0.480392
THSm2.2	74	37.666667	37.0	2.383050	0.509009
Average scores were used for ties.					

Median Two-Sample Test	
Statistic	16.3333
Z	-0.2798
One-Sided Pr < Z	0.3898
Two-Sided Pr >  Z	0.7797

Median One-Way Analysis	
Chi-Square	0.0783
DF	1
Pr > Chi-Square	0.7797



1

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	118





2

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS***

Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2521

Fit Statistics	
-2 Res Log Likelihood	181.1
AIC (smaller is better)	183.1
AICC (smaller is better)	183.2
BIC (smaller is better)	185.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	114	1.14	0.2878
UCPDGR1	1	114	1.16	0.2840
TRTP	1	114	2.91	0.0907

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=1 Parameter Code=NCAVG Parameter=Average Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.4031	0.05768	114	41.66	<.0001	0.05	2.2888	2.5173
TRTP	mCC	2.5697	0.07995	114	32.14	<.0001	0.05	2.4113	2.7281

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1666	0.09765	114	-1.71	0.0907	0.05	-0.3601	0.02683



4

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	118

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2052

Fit Statistics	
-2 Res Log Likelihood	157.7
AIC (smaller is better)	159.7
AICC (smaller is better)	159.7
BIC (smaller is better)	162.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	114	0.59	0.4450
UCPDGR1	1	114	2.39	0.1245
TRTP	1	114	1.77	0.1860

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=2 Parameter Code=NCMAX Parameter=Max Conc (ng/mL) (Nicotine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.0383	0.05204	114	58.38	<.0001	0.05	2.9352	3.1414
TRTP	mCC	3.1555	0.07213	114	43.75	<.0001	0.05	3.0126	3.2984

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1172	0.08810	114	-1.33	0.1860	0.05	-0.2917	0.05731



7

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	118

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2466

Fit Statistics	
-2 Res Log Likelihood	178.6
AIC (smaller is better)	180.6
AICC (smaller is better)	180.7
BIC (smaller is better)	183.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	114	1.81	0.1813
UCPDGR1	1	114	0.09	0.7649
TRTP	1	114	4.74	0.0315

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=4 Parameter Code=CCAVG Parameter=Average Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.2430	0.05705	114	91.90	<.0001	0.05	5.1300	5.3560
TRTP	mCC	5.4533	0.07907	114	68.96	<.0001	0.05	5.2966	5.6099

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2103	0.09659	114	-2.18	0.0315	0.05	-0.4016	-0.01893





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***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	logaval
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	7
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS***

Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1868

Fit Statistics	
-2 Res Log Likelihood	146.9
AIC (smaller is better)	148.9
AICC (smaller is better)	149.0
BIC (smaller is better)	151.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
SEX	1	114	2.84	0.0947
UCPDGR1	1	114	0.57	0.4518
TRTP	1	114	3.91	0.0503



12

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=5 Parameter Code=CCMAX Parameter=Max Conc (ng/mL) (Cotinine) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.3811	0.04965	114	108.39	<.0001	0.05	5.2827	5.4794
TRTP	mCC	5.5473	0.06881	114	80.62	<.0001	0.05	5.4110	5.6837

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1663	0.08405	114	-1.98	0.0503	0.05	-0.3328	0.000208



13

**Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS**

Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5

Wilcoxon Scores (Rank Sums) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	40	2008.0	2380.0	175.502829	50.200000
THSm2.2	78	5013.0	4641.0	175.502829	64.269231
Average scores were used for ties.					

Wilcoxon Two-Sample Test	
Statistic	2008.0000
Normal Approximation	
Z	-2.1168
One-Sided Pr < Z	0.0171
Two-Sided Pr >  Z	0.0343
t Approximation	
One-Sided Pr < Z	0.0182
Two-Sided Pr >  Z	0.0364
Z includes a continuity correction of 0.5.	

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5**

Kruskal-Wallis Test	
Chi-Square	4.4928
DF	1
Pr > Chi-Square	0.0340

Hodges-Lehmann Estimation			
Location Shift		-0.2417	
95% Confidence Limits	Interval Midpoint	Asymptotic Standard Error	
-2.0000	0.0000	-1.0000	0.5102



15

**Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS**

Parameter (N)=3 Analysis Visit (N)=105 Parameter Code=NTMAX Parameter=Time of CMAX (h) (Nicotine) Analysis Visit=Day 5

Median Scores (Number of Points Above Median) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	40	13.0	20.0	2.581989	0.325000
THSm2.2	78	46.0	39.0	2.581989	0.589744
Average scores were used for ties.					

Median Two-Sample Test	
Statistic	13.0000
Z	-2.7111
One-Sided Pr < Z	0.0034
Two-Sided Pr >  Z	0.0067

Median One-Way Analysis	
Chi-Square	7.3500
DF	1
Pr > Chi-Square	0.0067



16

**Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS**

Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5

Wilcoxon Scores (Rank Sums) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	40	2266.0	2380.0	175.740885	56.650000
THSm2.2	78	4755.0	4641.0	175.740885	60.961538
Average scores were used for ties.					

Wilcoxon Two-Sample Test	
Statistic	2266.0000
Normal Approximation	
Z	-0.6458
One-Sided Pr < Z	0.2592
Two-Sided Pr >  Z	0.5184
t Approximation	
One-Sided Pr < Z	0.2598
Two-Sided Pr >  Z	0.5196
Z includes a continuity correction of 0.5.	

***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5**

Kruskal-Wallis Test	
Chi-Square	0.4208
DF	1
Pr > Chi-Square	0.5165

Hodges-Lehmann Estimation			
Location Shift		-0.0333	
95% Confidence Limits	Interval Midpoint	Asymptotic Standard Error	
-1.6500	0.0833	-0.7833	0.4422



***Listing 15.4.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS*****Parameter (N)=6 Analysis Visit (N)=105 Parameter Code=CTMAX Parameter=Time of CMAX (h) (Cotinine) Analysis Visit=Day 5**

Median Scores (Number of Points Above Median) for Variable AVAL Classified by Variable TRTP					
TRTP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
mCC	40	18.666667	20.0	2.507991	0.466667
THSm2.2	78	40.333333	39.0	2.507991	0.517094
Average scores were used for ties.					

Median Two-Sample Test	
Statistic	18.6667
Z	-0.5316
One-Sided Pr < Z	0.2975
Two-Sided Pr >  Z	0.5950

Median One-Way Analysis	
Chi-Square	0.2826
DF	1
Pr > Chi-Square	0.5950



1

**Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130



2

**Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	130
Number of Observations Used	130
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04211

Fit Statistics	
-2 Res Log Likelihood	-20.6
AIC (smaller is better)	-18.6
AICC (smaller is better)	-18.6
BIC (smaller is better)	-15.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	124	233.30	<.0001
SEX	1	124	1.64	0.2027
UCPDGR1	1	124	4.53	0.0353
TRTP	2	124	60.99	<.0001

**Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3126	0.04307	124	100.12	<.0001	0.05	4.2274	4.3979
TRTP	THSm2.2	4.3279	0.02424	124	178.55	<.0001	0.05	4.2799	4.3759
TRTP	mCC	4.7816	0.03606	124	132.59	<.0001	0.05	4.7103	4.8530
TRTP	SA	4.3126	0.04307	124	100.12	<.0001	0.05	4.2274	4.3979
TRTP	THSm2.2	4.3279	0.02424	124	178.55	<.0001	0.05	4.2799	4.3759
TRTP	mCC	4.7816	0.03606	124	132.59	<.0001	0.05	4.7103	4.8530

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.4690	0.05586	124	-8.40	<.0001	0.05	-0.5796	-0.3585
TRTP	THSm2.2	mCC	-0.4538	0.04301	124	-10.55	<.0001	0.05	-0.5389	-0.3686
TRTP	THSm2.2	SA	0.01527	0.04903	124	0.31	0.7560	0.05	-0.08177	0.1123
TRTP	mCC	SA	0.4690	0.05586	124	8.40	<.0001	0.05	0.3585	0.5796

**Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



5

**Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1270

Fit Statistics	
-2 Res Log Likelihood	79.1
AIC (smaller is better)	81.1
AICC (smaller is better)	81.1
BIC (smaller is better)	83.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	80	43.88	<.0001
SEX	1	80	0.17	0.6849
UCPDGR1	1	80	0.15	0.6958
TRTP	2	80	4.80	0.0108

*Listing 15.4.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set*

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.2562	0.1232	80	34.54	<.0001	0.05	4.0109	4.5014
TRTP	THSm2.2	4.3082	0.05379	80	80.09	<.0001	0.05	4.2012	4.4153
TRTP	mCC	4.5494	0.06581	80	69.13	<.0001	0.05	4.4184	4.6803
TRTP	SA	4.2562	0.1232	80	34.54	<.0001	0.05	4.0109	4.5014
TRTP	THSm2.2	4.3082	0.05379	80	80.09	<.0001	0.05	4.2012	4.4153
TRTP	mCC	4.5494	0.06581	80	69.13	<.0001	0.05	4.4184	4.6803

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2932	0.1380	80	-2.12	0.0367	0.05	-0.5679	-0.01858
TRTP	THSm2.2	mCC	-0.2412	0.08483	80	-2.84	0.0057	0.05	-0.4100	-0.07236
TRTP	THSm2.2	SA	0.05206	0.1352	80	0.39	0.7012	0.05	-0.2169	0.3210
TRTP	mCC	SA	0.2932	0.1380	80	2.12	0.0367	0.05	0.01858	0.5679



1

***Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set***

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	124





2

***Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set***

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	124
Number of Observations Used	124
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04302

Fit Statistics	
-2 Res Log Likelihood	-16.4
AIC (smaller is better)	-14.4
AICC (smaller is better)	-14.4
BIC (smaller is better)	-11.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	118	217.10	<.0001
SEX	1	118	1.02	0.3136
UCPDGR1	1	118	3.76	0.0549
TRTP	2	118	57.67	<.0001



3

**Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set**

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3270	0.04361	118	99.21	<.0001	0.05	4.2406	4.4133
TRTP	THSm2.2	4.3480	0.02582	118	168.38	<.0001	0.05	4.2968	4.3991
TRTP	mCC	4.7957	0.03646	118	131.52	<.0001	0.05	4.7235	4.8679
TRTP	SA	4.3270	0.04361	118	99.21	<.0001	0.05	4.2406	4.4133
TRTP	THSm2.2	4.3480	0.02582	118	168.38	<.0001	0.05	4.2968	4.3991
TRTP	mCC	4.7957	0.03646	118	131.52	<.0001	0.05	4.7235	4.8679

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.4687	0.05647	118	-8.30	<.0001	0.05	-0.5805	-0.3569
TRTP	THSm2.2	mCC	-0.4477	0.04406	118	-10.16	<.0001	0.05	-0.5350	-0.3605
TRTP	THSm2.2	SA	0.02097	0.05015	118	0.42	0.6766	0.05	-0.07834	0.1203
TRTP	mCC	SA	0.4687	0.05647	118	8.30	<.0001	0.05	0.3569	0.5805



4

***Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set***

**Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84



5

***Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set***

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	84
Number of Observations Used	84
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1147

Fit Statistics	
-2 Res Log Likelihood	69.4
AIC (smaller is better)	71.4
AICC (smaller is better)	71.5
BIC (smaller is better)	73.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	78	53.96	<.0001
SEX	1	78	0.00	0.9944
UCPDGR1	1	78	0.16	0.6930
TRTP	2	78	4.65	0.0123



6

**Listing 15.4.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set**

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.2551	0.1172	78	36.30	<.0001	0.05	4.0217	4.4884
TRTP	THSm2.2	4.3345	0.05249	78	82.58	<.0001	0.05	4.2300	4.4390
TRTP	mCC	4.5528	0.06257	78	72.77	<.0001	0.05	4.4282	4.6774
TRTP	SA	4.2551	0.1172	78	36.30	<.0001	0.05	4.0217	4.4884
TRTP	THSm2.2	4.3345	0.05249	78	82.58	<.0001	0.05	4.2300	4.4390
TRTP	mCC	4.5528	0.06257	78	72.77	<.0001	0.05	4.4282	4.6774

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2977	0.1312	78	-2.27	0.0260	0.05	-0.5589	-0.03654
TRTP	THSm2.2	mCC	-0.2183	0.08123	78	-2.69	0.0088	0.05	-0.3800	-0.05660
TRTP	THSm2.2	SA	0.07943	0.1288	78	0.62	0.5391	0.05	-0.1769	0.3358
TRTP	mCC	SA	0.2977	0.1312	78	2.27	0.0260	0.05	0.03654	0.5589



1

**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	150



2

**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Number of Observations	
Number of Observations Read	150
Number of Observations Used	150
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04224

Fit Statistics	
-2 Res Log Likelihood	-25.7
AIC (smaller is better)	-23.7
AICC (smaller is better)	-23.7
BIC (smaller is better)	-20.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	144	272.48	<.0001
SEX	1	144	1.79	0.1828
UCPDGR1	1	144	4.93	0.0279
TRTP	2	144	71.37	<.0001

**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3555	0.03597	144	121.07	<.0001	0.05	4.2844	4.4266
TRTP	THSm2.2	4.3394	0.02357	144	184.14	<.0001	0.05	4.2928	4.3859
TRTP	mCC	4.8012	0.03315	144	144.83	<.0001	0.05	4.7357	4.8667
TRTP	SA	4.3555	0.03597	144	121.07	<.0001	0.05	4.2844	4.4266
TRTP	THSm2.2	4.3394	0.02357	144	184.14	<.0001	0.05	4.2928	4.3859
TRTP	mCC	4.8012	0.03315	144	144.83	<.0001	0.05	4.7357	4.8667

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.4457	0.04863	144	-9.17	<.0001	0.05	-0.5418	-0.3496
TRTP	THSm2.2	mCC	-0.4618	0.04033	144	-11.45	<.0001	0.05	-0.5416	-0.3821
TRTP	THSm2.2	SA	-0.01612	0.04269	144	-0.38	0.7063	0.05	-0.1005	0.06826
TRTP	mCC	SA	0.4457	0.04863	144	9.17	<.0001	0.05	0.3496	0.5418



**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	138

**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Number of Observations	
Number of Observations Read	138
Number of Observations Used	138
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1426

Fit Statistics	
-2 Res Log Likelihood	138.3
AIC (smaller is better)	140.3
AICC (smaller is better)	140.3
BIC (smaller is better)	143.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	132	58.31	<.0001
SEX	1	132	0.05	0.8250
UCPDGR1	1	132	0.02	0.9021
TRTP	2	132	6.18	0.0027

**Listing 15.4.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.4786	0.06805	132	65.82	<.0001	0.05	4.3440	4.6132
TRTP	THSm2.2	4.3069	0.04467	132	96.42	<.0001	0.05	4.2186	4.3953
TRTP	mCC	4.5676	0.06527	132	69.98	<.0001	0.05	4.4385	4.6967
TRTP	SA	4.4786	0.06805	132	65.82	<.0001	0.05	4.3440	4.6132
TRTP	THSm2.2	4.3069	0.04467	132	96.42	<.0001	0.05	4.2186	4.3953
TRTP	mCC	4.5676	0.06527	132	69.98	<.0001	0.05	4.4385	4.6967

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.08900	0.09389	132	-0.95	0.3449	0.05	-0.2747	0.09672
TRTP	THSm2.2	mCC	-0.2607	0.07855	132	-3.32	0.0012	0.05	-0.4161	-0.1053
TRTP	THSm2.2	SA	-0.1717	0.08098	132	-2.12	0.0358	0.05	-0.3319	-0.01153
TRTP	mCC	SA	0.08900	0.09389	132	0.95	0.3449	0.05	-0.09672	0.2747



1

***Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS***

**Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	142



2

***Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS***

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Number of Observations	
Number of Observations Read	142
Number of Observations Used	142
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04293

Fit Statistics	
-2 Res Log Likelihood	-21.3
AIC (smaller is better)	-19.3
AICC (smaller is better)	-19.3
BIC (smaller is better)	-16.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	136	247.32	<.0001
SEX	1	136	1.38	0.2420
UCPDGR1	1	136	4.40	0.0377
TRTP	2	136	68.90	<.0001



3

**Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=105 Analysis Visit=Day 5

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3571	0.03745	136	116.35	<.0001	0.05	4.2831	4.4312
TRTP	THSm2.2	4.3595	0.02494	136	174.78	<.0001	0.05	4.3102	4.4088
TRTP	mCC	4.8161	0.03345	136	143.99	<.0001	0.05	4.7500	4.8823
TRTP	SA	4.3571	0.03745	136	116.35	<.0001	0.05	4.2831	4.4312
TRTP	THSm2.2	4.3595	0.02494	136	174.78	<.0001	0.05	4.3102	4.4088
TRTP	mCC	4.8161	0.03345	136	143.99	<.0001	0.05	4.7500	4.8823

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.4590	0.04986	136	-9.21	<.0001	0.05	-0.5576	-0.3604
TRTP	THSm2.2	mCC	-0.4566	0.04120	136	-11.08	<.0001	0.05	-0.5381	-0.3752
TRTP	THSm2.2	SA	0.002350	0.04452	136	0.05	0.9580	0.05	-0.08570	0.09040
TRTP	mCC	SA	0.4590	0.04986	136	9.21	<.0001	0.05	0.3604	0.5576



4

***Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS***

**Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



5

***Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS***

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.1353

Fit Statistics	
-2 Res Log Likelihood	125.1
AIC (smaller is better)	127.1
AICC (smaller is better)	127.1
BIC (smaller is better)	129.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	125	64.03	<.0001
SEX	1	125	0.43	0.5112
UCPDGR1	1	125	0.18	0.6727
TRTP	2	125	6.24	0.0026





6

**Listing 15.4.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Parameter (N)=80 Parameter Code=CYP1A2 Parameter=CYP1A2 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5156	0.06856	125	65.86	<.0001	0.05	4.3799	4.6513
TRTP	THSm2.2	4.3311	0.04534	125	95.54	<.0001	0.05	4.2414	4.4209
TRTP	mCC	4.5855	0.06359	125	72.11	<.0001	0.05	4.4596	4.7114
TRTP	SA	4.5156	0.06856	125	65.86	<.0001	0.05	4.3799	4.6513
TRTP	THSm2.2	4.3311	0.04534	125	95.54	<.0001	0.05	4.2414	4.4209
TRTP	mCC	4.5855	0.06359	125	72.11	<.0001	0.05	4.4596	4.7114

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.06988	0.09304	125	-0.75	0.4540	0.05	-0.2540	0.1143
TRTP	THSm2.2	mCC	-0.2544	0.07731	125	-3.29	0.0013	0.05	-0.4074	-0.1014
TRTP	THSm2.2	SA	-0.1845	0.08161	125	-2.26	0.0255	0.05	-0.3460	-0.02298
TRTP	mCC	SA	0.06988	0.09304	125	0.75	0.4540	0.05	-0.1143	0.2540



1

**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis Value)**

**Parameter Code=CRP**

Moments			
<b>N</b>	160	<b>Sum Weights</b>	160
<b>Mean</b>	2.9229375	<b>Sum Observations</b>	467.67
<b>Std Deviation</b>	5.43850904	<b>Variance</b>	29.5773806
<b>Skewness</b>	5.3449225	<b>Kurtosis</b>	37.4352886
<b>Uncorrected SS</b>	6069.7737	<b>Corrected SS</b>	4702.80352
<b>Coeff Variation</b>	186.063132	<b>Std Error Mean</b>	0.42995189

Basic Statistical Measures			
Location		Variability	
<b>Mean</b>	2.922938	<b>Std Deviation</b>	5.43851
<b>Median</b>	1.090000	<b>Variance</b>	29.57738
<b>Mode</b>	0.100000	<b>Range</b>	48.50000
		<b>Interquartile Range</b>	2.28000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
<b>Student's t</b>	<b>t</b>	6.79829	<b>Pr &gt;  t </b>	<.0001
<b>Sign</b>	<b>M</b>	80	<b>Pr &gt;=  M </b>	<.0001
<b>Signed Rank</b>	<b>S</b>	6440	<b>Pr &gt;=  S </b>	<.0001



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis Value)**

**Parameter Code=CRP**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.475062	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.301858	Pr > D	<0.0100
Cramer-von Mises	W-Sq	4.5432	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	23.20189	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	48.600
99%	34.200
95%	9.525
90%	7.765
75% Q3	2.875
50% Median	1.090
25% Q1	0.595
10%	0.270
5%	0.100
1%	0.100
0% Min	0.100



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
Shapiro-Wilk test***

***Variable: AVAL (Analysis  
Value)***

**Parameter Code=CRP**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
0.1	120	15.7	39
0.1	112	15.8	74
0.1	94	16.4	75
0.1	87	34.2	143
0.1	76	48.6	118



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=FIBRINO**

Moments			
N	154	Sum Weights	154
Mean	337.538961	Sum Observations	51981
Std Deviation	82.899351	Variance	6872.30239
Skewness	0.87571033	Kurtosis	0.11491904
Uncorrected SS	18597075	Corrected SS	1051462.27
Coeff Variation	24.5599355	Std Error Mean	6.68022007

Basic Statistical Measures			
Location		Variability	
Mean	337.5390	Std Deviation	82.89935
Median	320.0000	Variance	6872
Mode	357.0000	Range	364.00000
		Interquartile Range	102.00000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	50.52812	Pr >  t	<.0001
Sign	M	77	Pr >=  M	<.0001
Signed Rank	S	5967.5	Pr >=  S	<.0001



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=FIBRINO**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.92882	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.112149	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.531413	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.321735	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	564
99%	559
95%	524
90%	469
75% Q3	379
50% Median	320
25% Q1	277
10%	247
5%	238
1%	217
0% Min	200



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=FIBRINO**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
200	158	531	54
217	95	533	15
226	17	543	115
228	66	559	121
228	51	564	136

Missing Values			
Missing Value	Count	Percent Of	
		All Obs	Missing Obs
	6	3.75	100.00



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=GLUC**

Moments			
N	160	Sum Weights	160
Mean	94.3375	Sum Observations	15094
Std Deviation	8.15331665	Variance	66.4765723
Skewness	1.12970941	Kurtosis	2.33932901
Uncorrected SS	1434500	Corrected SS	10569.775
Coeff Variation	8.64271011	Std Error Mean	0.64457628

Basic Statistical Measures			
Location		Variability	
Mean	94.33750	Std Deviation	8.15332
Median	93.00000	Variance	66.47657
Mode	94.00000	Range	51.00000
		Interquartile Range	10.50000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	146.3558	Pr >  t	<.0001
Sign	M	80	Pr >=  M	<.0001
Signed Rank	S	6440	Pr >=  S	<.0001





**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=GLUC**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.93603	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.110259	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.308955	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.952739	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	132.0
99%	118.0
95%	109.0
90%	105.5
75% Q3	98.5
50% Median	93.0
25% Q1	88.0
10%	85.0
5%	83.0
1%	82.0
0% Min	81.0



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
Shapiro-Wilk test***

***Variable: AVAL (Analysis  
Value)***

**Parameter Code=GLUC**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
81	104	113	10
82	81	113	24
82	80	116	128
83	150	118	49
83	108	132	64



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=HOMOCY**

Moments			
N	160	Sum Weights	160
Mean	10.1615625	Sum Observations	1625.85
Std Deviation	4.76079423	Variance	22.6651617
Skewness	6.17738003	Kurtosis	56.1856003
Uncorrected SS	20124.9371	Corrected SS	3603.76071
Coeff Variation	46.8510057	Std Error Mean	0.37637383

Basic Statistical Measures			
Location		Variability	
Mean	10.16156	Std Deviation	4.76079
Median	9.32500	Variance	22.66516
Mode	11.07000	Range	51.36000
		Interquartile Range	3.19500

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	26.99859	Pr >  t	<.0001
Sign	M	80	Pr >=  M	<.0001
Signed Rank	S	6440	Pr >=  S	<.0001



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=HOMOCY**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.566609	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.181272	Pr > D	<0.0100
Cramer-von Mises	W-Sq	2.034165	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	11.8829	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	56.400
99%	24.510
95%	15.970
90%	13.555
75% Q3	11.160
50% Median	9.325
25% Q1	7.965
10%	6.720
5%	5.920
1%	5.380
0% Min	5.040



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
Shapiro-Wilk test***

***Variable: AVAL (Analysis  
Value)***

**Parameter Code=HOMOCY**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
5.04	21	19.21	55
5.38	2	20.33	14
5.41	19	20.76	63
5.67	9	24.51	31
5.79	26	56.40	143



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=PLAT**

Moments			
N	160	Sum Weights	160
Mean	282.00625	Sum Observations	45121
Std Deviation	72.5424618	Variance	5262.40877
Skewness	1.14832497	Kurtosis	2.41678858
Uncorrected SS	13561127	Corrected SS	836722.994
Coeff Variation	25.7237071	Std Error Mean	5.73498516

Basic Statistical Measures			
Location		Variability	
Mean	282.0063	Std Deviation	72.54246
Median	274.5000	Variance	5262
Mode	207.0000	Range	452.00000
		Interquartile Range	86.00000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	49.17297	Pr >  t	<.0001
Sign	M	80	Pr >=  M	<.0001
Signed Rank	S	6440	Pr >=  S	<.0001



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=PLAT**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.932202	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.081691	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.341201	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.286698	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	563.0
99%	548.0
95%	402.5
90%	372.5
75% Q3	316.5
50% Median	274.5
25% Q1	230.5
10%	207.0
5%	192.5
1%	141.0
0% Min	111.0



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
Shapiro-Wilk test***

***Variable: AVAL (Analysis  
Value)***

**Parameter Code=PLAT**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
111	58	460	101
141	5	482	14
176	102	537	37
179	128	548	80
183	147	563	41





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	90.4653740	18.0930748	35.71	<.0001
Error	81	41.0378394	0.5066400		
Corrected Total	86	131.5032133			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.687933	239.4577	0.711786	0.297249

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	84.17095368	84.17095368	166.14	<.0001
SEXC	1	1.04042992	1.04042992	2.05	0.1557
UCPDGR1	1	1.32979953	1.32979953	2.62	0.1091
TRTPN	2	3.92419084	1.96209542	3.87	0.0248

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	79.09356888	79.09356888	156.11	<.0001
SEXC	1	0.29453652	0.29453652	0.58	0.4480
UCPDGR1	1	1.49434617	1.49434617	2.95	0.0897
TRTPN	2	3.92419084	1.96209542	3.87	0.0248



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.25443354	1
2	0.53605930	2
3	-0.09073962	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0966	0.1334
2	0.0966		0.0085
3	0.1334	0.0085	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.254434	0.025923	0.482944
2	0.536059	0.290138	0.781981
3	-0.090740	-0.485368	0.303889



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.281626	-0.614992	0.051741
1	3	0.345173	-0.107838	0.798184
2	3	0.626799	0.164363	1.089235

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	84.4428970	16.8885794	28.59	<.0001
Error	80	47.2501459	0.5906268		
Corrected Total	85	131.6930429			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.641210	275.8730	0.768522	0.278578

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	81.43581038	81.43581038	137.88	<.0001
SEXC	1	0.09084368	0.09084368	0.15	0.6960
UCPDGR1	1	2.69472891	2.69472891	4.56	0.0357
TRTPN	2	0.22151403	0.11075701	0.19	0.8294

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	76.23392583	76.23392583	129.07	<.0001
SEXC	1	0.02962526	0.02962526	0.05	0.8234
UCPDGR1	1	2.85345422	2.85345422	4.83	0.0308
TRTPN	2	0.22151403	0.11075701	0.19	0.8294



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.22312231	1
2	0.33428889	2
3	0.29503571	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5449	0.7811
2	0.5449		0.8802
3	0.7811	0.8802	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.223122	-0.028298	0.474542
2	0.334289	0.072003	0.596575
3	0.295036	-0.156426	0.746497



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.111167	-0.475022	0.252689
1	3	-0.071913	-0.585150	0.441323
2	3	0.039253	-0.477235	0.555742

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	79.8704697	15.9740939	24.54	<.0001
Error	82	53.3875982	0.6510683		
Corrected Total	87	133.2580679			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.599367	314.7692	0.806888	0.256343

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	77.79439006	77.79439006	119.49	<.0001
SEXC	1	0.52135057	0.52135057	0.80	0.3735
UCPDGR1	1	0.95595922	0.95595922	1.47	0.2291
TRTPN	2	0.59876988	0.29938494	0.46	0.6330

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	72.70127995	72.70127995	111.66	<.0001
SEXC	1	0.11148237	0.11148237	0.17	0.6801
UCPDGR1	1	1.13201414	1.13201414	1.74	0.1910
TRTPN	2	0.59876988	0.29938494	0.46	0.6330



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.20364006	1
2	0.38068333	2
3	0.23003825	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3482	0.9296
2	0.3482		0.6242
3	0.9296	0.6242	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.203640	-0.035975	0.443255
2	0.380683	0.093837	0.667529
3	0.230038	-0.315456	0.775533



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.177043	-0.550367	0.196281
1	3	-0.026398	-0.619160	0.566363
2	3	0.150645	-0.458758	0.760048

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	85
Number of Observations Used	85



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2.70914121	0.54182824	23.16	<.0001
Error	79	1.84856154	0.02339951		
Corrected Total	84	4.55770274			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.594409	2.676478	0.152969	5.715308

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.48975643	2.48975643	106.40	<.0001
SEXC	1	0.17093717	0.17093717	7.31	0.0084
UCPDGR1	1	0.00417403	0.00417403	0.18	0.6739
TRTPN	2	0.04427357	0.02213679	0.95	0.3926

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.49013281	1.49013281	63.68	<.0001
SEXC	1	0.13777278	0.13777278	5.89	0.0175
UCPDGR1	1	0.00585360	0.00585360	0.25	0.6184
TRTPN	2	0.04427357	0.02213679	0.95	0.3926



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.71436544	1
2	5.75247173	2
3	5.68868997	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2913	0.6251
2	0.2913		0.2343
3	0.6251	0.2343	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.714365	5.665129	5.763602
2	5.752472	5.699421	5.805522
3	5.688690	5.596367	5.781013



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.038106	-0.109508	0.033296
1	3	0.025675	-0.078517	0.129867
2	3	0.063782	-0.042145	0.169708

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2.70362968	0.54072594	21.25	<.0001
Error	80	2.03566600	0.02544582		
Corrected Total	85	4.73929567			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.570471	2.793688	0.159517	5.709924

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.56707751	2.56707751	100.88	<.0001
SEXC	1	0.03185097	0.03185097	1.25	0.2666
UCPDGR1	1	0.09247783	0.09247783	3.63	0.0602
TRTPN	2	0.01222336	0.00611168	0.24	0.7870

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.79122144	1.79122144	70.39	<.0001
SEXC	1	0.00934415	0.00934415	0.37	0.5462
UCPDGR1	1	0.08441915	0.08441915	3.32	0.0723
TRTPN	2	0.01222336	0.00611168	0.24	0.7870



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.72148745	1
2	5.69951303	2
3	5.72932091	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5605	0.8841
2	0.5605		0.5805
3	0.8841	0.5805	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.721487	5.669345	5.773630
2	5.699513	5.645058	5.753968
3	5.729321	5.635717	5.822925



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.021974	-0.052831	0.096780
1	3	-0.007833	-0.114451	0.098784
2	3	-0.029808	-0.136698	0.077082

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2.74318384	0.54863677	18.86	<.0001
Error	82	2.38585852	0.02909584		
Corrected Total	87	5.12904236			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.534834	2.981082	0.170575	5.721916

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.64770289	2.64770289	91.00	<.0001
SEXC	1	0.08140930	0.08140930	2.80	0.0982
UCPDGR1	1	0.00259240	0.00259240	0.09	0.7661
TRTPN	2	0.01147925	0.00573963	0.20	0.8214

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.66819074	1.66819074	57.33	<.0001
SEXC	1	0.06700232	0.06700232	2.30	0.1330
UCPDGR1	1	0.00433471	0.00433471	0.15	0.7005
TRTPN	2	0.01147925	0.00573963	0.20	0.8214



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.72035371	1
2	5.73680937	2
3	5.75573021	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6783	0.5750
2	0.6783		0.7714
3	0.5750	0.7714	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.720354	5.669747	5.770960
2	5.736809	5.675804	5.797815
3	5.755730	5.640547	5.870913



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.016456	-0.095108	0.062197
1	3	-0.035376	-0.160391	0.089638
2	3	-0.018921	-0.148033	0.110191

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.42450224	0.08490045	25.33	<.0001
Error	81	0.27148889	0.00335171		
Corrected Total	86	0.69599113			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.609925	1.275729	0.057894	4.538112

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.41937567	0.41937567	125.12	<.0001
SEXC	1	0.00060783	0.00060783	0.18	0.6713
UCPDGR1	1	0.00053763	0.00053763	0.16	0.6898
TRTPN	2	0.00398110	0.00199055	0.59	0.5546

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.41550543	0.41550543	123.97	<.0001
SEXC	1	0.00089579	0.00089579	0.27	0.6066
UCPDGR1	1	0.00026933	0.00026933	0.08	0.7775
TRTPN	2	0.00398110	0.00199055	0.59	0.5546



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.54474123	1
2	4.53091323	2
3	4.53156094	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3114	0.4794
2	0.3114		0.9728
3	0.4794	0.9728	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.544741	4.526217	4.563266
2	4.530913	4.510929	4.550898
3	4.531561	4.499420	4.563702



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.013828	-0.013184	0.040840
1	3	0.013180	-0.023726	0.050087
2	3	-0.000648	-0.038259	0.036963

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.61820344	0.12364069	15.90	<.0001
Error	80	0.62212210	0.00777653		
Corrected Total	85	1.24032553			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.498420	1.942919	0.088185	4.538769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.53599271	0.53599271	68.92	<.0001
SEXC	1	0.01281898	0.01281898	1.65	0.2029
UCPDGR1	1	0.02769848	0.02769848	3.56	0.0628
TRTPN	2	0.04169326	0.02084663	2.68	0.0747

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.43324296	0.43324296	55.71	<.0001
SEXC	1	0.00698261	0.00698261	0.90	0.3462
UCPDGR1	1	0.02955802	0.02955802	3.80	0.0547
TRTPN	2	0.04169326	0.02084663	2.68	0.0747



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.54224771	1
2	4.52312155	2
3	4.59262105	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3602	0.0963
2	0.3602		0.0233
3	0.0963	0.0233	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.542248	4.513552	4.570943
2	4.523122	4.493130	4.553113
3	4.592621	4.540186	4.645056



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.019126	-0.022232	0.060484
1	3	-0.050373	-0.109943	0.009196
2	3	-0.069500	-0.129305	-0.009694

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.13281990	0.02656398	4.01	0.0026
Error	82	0.54337142	0.00662648		
Corrected Total	87	0.67619132			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.196424	1.793166	0.081403	4.539636

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.09029343	0.09029343	13.63	0.0004
SEXC	1	0.00533762	0.00533762	0.81	0.3721
UCPDGR1	1	0.02300664	0.02300664	3.47	0.0660
TRTPN	2	0.01418221	0.00709111	1.07	0.3477

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.07197737	0.07197737	10.86	0.0015
SEXC	1	0.00123352	0.00123352	0.19	0.6673
UCPDGR1	1	0.02078898	0.02078898	3.14	0.0802
TRTPN	2	0.01418221	0.00709111	1.07	0.3477



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.54522614	1
2	4.52747472	2
3	4.57013345	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3502	0.4087
2	0.3502		0.1711
3	0.4087	0.1711	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.545226	4.521150	4.569302
2	4.527475	4.498509	4.556441
3	4.570133	4.515118	4.625149



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.017751	-0.019835	0.055338
1	3	-0.024907	-0.084573	0.034759
2	3	-0.042659	-0.104119	0.018801

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.97415105	1.39483021	51.67	<.0001
Error	81	2.18676940	0.02699715		
Corrected Total	86	9.16092045			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.761294	7.117628	0.164308	2.308467

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.78163767	6.78163767	251.20	<.0001
SEXC	1	0.10329641	0.10329641	3.83	0.0539
UCPDGR1	1	0.00777975	0.00777975	0.29	0.5929
TRTPN	2	0.08143722	0.04071861	1.51	0.2274

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.34571890	6.34571890	235.05	<.0001
SEXC	1	0.10986899	0.10986899	4.07	0.0470
UCPDGR1	1	0.00623301	0.00623301	0.23	0.6322
TRTPN	2	0.08143722	0.04071861	1.51	0.2274



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.30781800	1
2	2.26837755	2
3	2.35904666	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3091	0.3339
2	0.3091		0.0951
3	0.3339	0.0951	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.307818	2.255188	2.360448
2	2.268378	2.211643	2.325112
3	2.359047	2.267845	2.450248



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.039440	-0.037224	0.116105
1	3	-0.051229	-0.156078	0.053621
2	3	-0.090669	-0.197494	0.016156

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.29328209	1.25865642	36.85	<.0001
Error	80	2.73213383	0.03415167		
Corrected Total	85	9.02541592			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.697284	8.012235	0.184802	2.306494

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.26028076	6.26028076	183.31	<.0001
SEXC	1	0.00004265	0.00004265	0.00	0.9719
UCPDGR1	1	0.00034627	0.00034627	0.01	0.9200
TRTPN	2	0.03261241	0.01630620	0.48	0.6221

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.09715779	6.09715779	178.53	<.0001
SEXC	1	0.00005053	0.00005053	0.00	0.9694
UCPDGR1	1	0.00263772	0.00263772	0.08	0.7818
TRTPN	2	0.03261241	0.01630620	0.48	0.6221



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.32550413	1
2	2.29877231	2
3	2.26763347	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5411	0.3573
2	0.5411		0.6203
3	0.3573	0.6203	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.325504	2.265256	2.385753
2	2.298772	2.235894	2.361651
3	2.267633	2.158555	2.376711



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.026732	-0.059935	0.113399
1	3	0.057871	-0.066525	0.182266
2	3	0.031139	-0.093454	0.155732

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7.80664638	1.56132928	39.35	<.0001
Error	82	3.25350292	0.03967686		
Corrected Total	87	11.06014930			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.705836	8.396437	0.199191	2.372322

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.74581627	7.74581627	195.22	<.0001
SEXC	1	0.01486984	0.01486984	0.37	0.5421
UCPDGR1	1	0.01251024	0.01251024	0.32	0.5760
TRTPN	2	0.03345003	0.01672501	0.42	0.6575

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.31919271	7.31919271	184.47	<.0001
SEXC	1	0.00774129	0.00774129	0.20	0.6599
UCPDGR1	1	0.01768483	0.01768483	0.45	0.5062
TRTPN	2	0.03345003	0.01672501	0.42	0.6575



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.38268234	1
2	2.36443207	2
3	2.31637386	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6936	0.3690
2	0.6936		0.5278
3	0.3690	0.5278	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.382682	2.323763	2.441602
2	2.364432	2.293528	2.435336
3	2.316374	2.181742	2.451005



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.018250	-0.073573	0.110074
1	3	0.066308	-0.079718	0.212335
2	3	0.048058	-0.102712	0.198828

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	132
Number of Observations Used	132



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.69539550	4.13907910	199.58	<.0001
Error	126	2.61305895	0.02073856		
Corrected Total	131	23.30845445			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.887892	2.642910	0.144009	5.448877

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	20.52722328	20.52722328	989.81	<.0001
SEXC	1	0.00279530	0.00279530	0.13	0.7141
UCPDGR1	1	0.02365509	0.02365509	1.14	0.2876
TRTPN	2	0.14172182	0.07086091	3.42	0.0359

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	17.78122111	17.78122111	857.40	<.0001
SEXC	1	0.01183715	0.01183715	0.57	0.4514
UCPDGR1	1	0.02634413	0.02634413	1.27	0.2619
TRTPN	2	0.14172182	0.07086091	3.42	0.0359



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.43024330	1
2	5.50343306	2
3	5.42599730	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0149	0.9005
2	0.0149		0.0449
3	0.9005	0.0449	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.430243	5.396273	5.464213
2	5.503433	5.455013	5.551853
3	5.425997	5.367476	5.484518



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.073190	-0.131834	-0.014546
1	3	0.004246	-0.062853	0.071345
2	3	0.077436	0.001793	0.153078

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	15.72515691	3.14503138	127.10	<.0001
Error	80	1.97949038	0.02474363		
Corrected Total	85	17.70464729			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.888194	2.882534	0.157301	5.457042

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	15.45259585	15.45259585	624.51	<.0001
SEXC	1	0.04201204	0.04201204	1.70	0.1963
UCPDGR1	1	0.10242474	0.10242474	4.14	0.0452
TRTPN	2	0.12812429	0.06406214	2.59	0.0814

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.47200024	14.47200024	584.88	<.0001
SEXC	1	0.01117543	0.01117543	0.45	0.5035
UCPDGR1	1	0.08115110	0.08115110	3.28	0.0739
TRTPN	2	0.12812429	0.06406214	2.59	0.0814



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42486213	1
2	5.50231152	2
3	5.41799363	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0403	0.8924
2	0.0403		0.1050
3	0.8924	0.1050	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.424862	5.373863	5.475861
2	5.502312	5.447971	5.556652
3	5.417994	5.330645	5.505343



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.077449	-0.151378	-0.003520
1	3	0.006869	-0.093886	0.107623
2	3	0.084318	-0.018011	0.186647

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	84
Number of Observations Used	84



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	9.11333186	1.82266637	47.83	<.0001
Error	78	2.97208613	0.03810367		
Corrected Total	83	12.08541799			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.754077	3.573893	0.195202	5.461877

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.89907700	8.89907700	233.55	<.0001
SEXC	1	0.00901942	0.00901942	0.24	0.6280
UCPDGR1	1	0.03210706	0.03210706	0.84	0.3615
TRTPN	2	0.17312837	0.08656418	2.27	0.1099

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.40161368	7.40161368	194.25	<.0001
SEXC	1	0.00059204	0.00059204	0.02	0.9011
UCPDGR1	1	0.04694426	0.04694426	1.23	0.2704
TRTPN	2	0.17312837	0.08656418	2.27	0.1099



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42319052	1
2	5.51735439	2
3	5.42845287	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0479	0.9372
2	0.0479		0.1809
3	0.9372	0.1809	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.423191	5.357470	5.488911
2	5.517354	5.450927	5.583781
3	5.428453	5.313232	5.543674



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.094164	-0.187447	-0.000881
1	3	-0.005262	-0.137889	0.127365
2	3	0.088902	-0.042188	0.219991

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7.75719902	1.55143980	67.62	<.0001
Error	80	1.83555550	0.02294444		
Corrected Total	85	9.59275452			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.808652	2.760727	0.151474	5.486752

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.43868596	7.43868596	324.20	<.0001
SEXC	1	0.05237599	0.05237599	2.28	0.1348
UCPDGR1	1	0.02478890	0.02478890	1.08	0.3017
TRTPN	2	0.24134816	0.12067408	5.26	0.0071

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.65203431	6.65203431	289.92	<.0001
SEXC	1	0.08828207	0.08828207	3.85	0.0533
UCPDGR1	1	0.04388223	0.04388223	1.91	0.1705
TRTPN	2	0.24134816	0.12067408	5.26	0.0071



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.43737387	1
2	5.54933335	2
3	5.44502856	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0023	0.8929
2	0.0023		0.0748
3	0.8929	0.0748	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.437374	5.391285	5.483463
2	5.549333	5.495450	5.603217
3	5.445029	5.341814	5.548243



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.111959	-0.182776	-0.041143
1	3	-0.007655	-0.120459	0.105150
2	3	0.104305	-0.010672	0.219281

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.44510829	1.28902166	88.85	<.0001
Error	128	1.85705188	0.01450822		
Corrected Total	133	8.30216017			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.776317	2.143358	0.120450	5.619690

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.18943705	6.18943705	426.62	<.0001
SEXC	1	0.03160947	0.03160947	2.18	0.1424
UCPDGR1	1	0.18562536	0.18562536	12.79	0.0005
TRTPN	2	0.03843641	0.01921820	1.32	0.2695

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.90111507	5.90111507	406.74	<.0001
SEXC	1	0.00180032	0.00180032	0.12	0.7252
UCPDGR1	1	0.18325907	0.18325907	12.63	0.0005
TRTPN	2	0.03843641	0.01921820	1.32	0.2695



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.62859509	1
2	5.59244233	2
3	5.59763342	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1467	0.2753
2	0.1467		0.8714
3	0.2753	0.8714	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.628595	5.600599	5.656592
2	5.592442	5.551836	5.633048
3	5.597633	5.548699	5.646568



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.036153	-0.012844	0.085150
1	3	0.030962	-0.024958	0.086881
2	3	-0.005191	-0.068523	0.058140

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	5.39909873	1.07981975	59.58	<.0001
Error	81	1.46795841	0.01812294		
Corrected Total	86	6.86705714			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.786232	2.407947	0.134621	5.590716

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.28443226	5.28443226	291.59	<.0001
SEXC	1	0.00457652	0.00457652	0.25	0.6167
UCPDGR1	1	0.01407721	0.01407721	0.78	0.3807
TRTPN	2	0.09601274	0.04800637	2.65	0.0768

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	4.89342382	4.89342382	270.01	<.0001
SEXC	1	0.01196895	0.01196895	0.66	0.4188
UCPDGR1	1	0.02161117	0.02161117	1.19	0.2781
TRTPN	2	0.09601274	0.04800637	2.65	0.0768



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.62794484	1
2	5.55553552	2
3	5.58588114	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0245	0.3321
2	0.0245		0.4929
3	0.3321	0.4929	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.627945	5.584866	5.671024
2	5.555536	5.508921	5.602150
3	5.585881	5.511198	5.660564



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.072409	0.009534	0.135284
1	3	0.042064	-0.043713	0.127841
2	3	-0.030346	-0.117995	0.057304

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4.47845596	0.89569119	64.11	<.0001
Error	80	1.11763658	0.01397046		
Corrected Total	85	5.59609254			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.800283	2.139289	0.118197	5.525045

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	4.34210765	4.34210765	310.81	<.0001
SEXC	1	0.06165879	0.06165879	4.41	0.0388
UCPDGR1	1	0.00753117	0.00753117	0.54	0.4650
TRTPN	2	0.06715836	0.03357918	2.40	0.0969

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	4.07553441	4.07553441	291.73	<.0001
SEXC	1	0.04500988	0.04500988	3.22	0.0764
UCPDGR1	1	0.00271379	0.00271379	0.19	0.6606
TRTPN	2	0.06715836	0.03357918	2.40	0.0969



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.56003181	1
2	5.49865683	2
3	5.53108047	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0313	0.4676
2	0.0313		0.4179
3	0.4676	0.4179	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.560032	5.521551	5.598512
2	5.498657	5.458259	5.539055
3	5.531080	5.461724	5.600437



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.061375	0.005661	0.117089
1	3	0.028951	-0.049992	0.107894
2	3	-0.032424	-0.111668	0.046821

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.15085135	1.23017027	51.34	<.0001
Error	82	1.96472797	0.02396010		
Corrected Total	87	8.11557932			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.757907	2.813463	0.154790	5.501778

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.11814503	6.11814503	255.35	<.0001
SEXC	1	0.00760002	0.00760002	0.32	0.5748
UCPDGR1	1	0.00334280	0.00334280	0.14	0.7097
TRTPN	2	0.02176350	0.01088175	0.45	0.6366

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.69096859	5.69096859	237.52	<.0001
SEXC	1	0.00382455	0.00382455	0.16	0.6905
UCPDGR1	1	0.00152604	0.00152604	0.06	0.8014
TRTPN	2	0.02176350	0.01088175	0.45	0.6366



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.51830487	1
2	5.48397322	2
3	5.49710364	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3468	0.7123
2	0.3468		0.8237
3	0.7123	0.8237	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.518305	5.472394	5.564216
2	5.483973	5.428502	5.539444
3	5.497104	5.392248	5.601959



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.034332	-0.037842	0.106505
1	3	0.021201	-0.092754	0.135157
2	3	-0.013130	-0.129994	0.103734

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	124
Number of Observations Used	124



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	15.97530197	3.19506039	62.91	<.0001
Error	118	5.99294959	0.05078771		
Corrected Total	123	21.96825156			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.727200	4.122338	0.225361	5.466831

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.92690287	14.92690287	293.91	<.0001
SEXC	1	0.43728294	0.43728294	8.61	0.0040
UCPDGR1	1	0.10168955	0.10168955	2.00	0.1597
TRTPN	2	0.50942661	0.25471330	5.02	0.0081

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.45368825	11.45368825	225.52	<.0001
SEXC	1	0.26191378	0.26191378	5.16	0.0250
UCPDGR1	1	0.11691778	0.11691778	2.30	0.1319
TRTPN	2	0.50942661	0.25471330	5.02	0.0081



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.43618161	1
2	5.58478097	2
3	5.45897760	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0022	0.6866
2	0.0022		0.0468
3	0.6866	0.0468	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.436182	5.381585	5.490778
2	5.584781	5.507473	5.662089
3	5.458978	5.361205	5.556751



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.148599	-0.242688	-0.054511
1	3	-0.022796	-0.134407	0.088815
2	3	0.125803	0.001789	0.249818

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	84
Number of Observations Used	84



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.58639756	2.51727951	29.75	<.0001
Error	78	6.60078907	0.08462550		
Corrected Total	83	19.18718662			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.655979	5.130816	0.290905	5.669754

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.12980355	12.12980355	143.34	<.0001
SEXC	1	0.10990027	0.10990027	1.30	0.2579
UCPDGR1	1	0.11206420	0.11206420	1.32	0.2533
TRTPN	2	0.23462953	0.11731477	1.39	0.2561

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	9.29142881	9.29142881	109.79	<.0001
SEXC	1	0.03337986	0.03337986	0.39	0.5318
UCPDGR1	1	0.15813385	0.15813385	1.87	0.1756
TRTPN	2	0.23462953	0.11731477	1.39	0.2561



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.62752354	1
2	5.74087690	2
3	5.64609671	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1103	0.8510
2	0.1103		0.3407
3	0.8510	0.3407	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.627524	5.532046	5.723001
2	5.740877	5.638475	5.843279
3	5.646097	5.475163	5.817030



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.113353	-0.253064	0.026358
1	3	-0.018573	-0.214710	0.177564
2	3	0.094780	-0.102060	0.291620

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	82
Number of Observations Used	82



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13.25587771	2.65117554	32.34	<.0001
Error	76	6.22961881	0.08196867		
Corrected Total	81	19.48549652			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.680295	5.065226	0.286302	5.652299

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.75063399	12.75063399	155.55	<.0001
SEXC	1	0.30954769	0.30954769	3.78	0.0557
UCPDGR1	1	0.03836721	0.03836721	0.47	0.4960
TRTPN	2	0.15732882	0.07866441	0.96	0.3876

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	9.78739507	9.78739507	119.40	<.0001
SEXC	1	0.19327357	0.19327357	2.36	0.1288
UCPDGR1	1	0.05664784	0.05664784	0.69	0.4084
TRTPN	2	0.15732882	0.07866441	0.96	0.3876



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.63556117	1
2	5.71656305	2
3	5.60636616	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2478	0.7716
2	0.2478		0.2731
3	0.7716	0.2731	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.635561	5.539430	5.731693
2	5.716563	5.617218	5.815908
3	5.606366	5.430622	5.782110



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.081002	-0.219522	0.057518
1	3	0.029195	-0.170429	0.228819
2	3	0.110197	-0.088628	0.309022

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	9.51583203	1.90316641	27.04	<.0001
Error	80	5.63148809	0.07039360		
Corrected Total	85	15.14732012			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.628219	4.713913	0.265318	5.628400

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.97659467	8.97659467	127.52	<.0001
SEXC	1	0.13676550	0.13676550	1.94	0.1672
UCPDGR1	1	0.02775365	0.02775365	0.39	0.5319
TRTPN	2	0.37471821	0.18735910	2.66	0.0760

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.90868188	6.90868188	98.14	<.0001
SEXC	1	0.07752026	0.07752026	1.10	0.2972
UCPDGR1	1	0.06430005	0.06430005	0.91	0.3421
TRTPN	2	0.37471821	0.18735910	2.66	0.0760



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.57824033	1
2	5.72278059	2
3	5.63381626	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0237	0.5744
2	0.0237		0.3797
3	0.5744	0.3797	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.578240	5.497755	5.658725
2	5.722781	5.627556	5.818005
3	5.633816	5.453751	5.813881



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.144540	-0.269314	-0.019767
1	3	-0.055576	-0.251717	0.140565
2	3	0.088964	-0.111475	0.289404

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	124
Number of Observations Used	124



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.22569819	2.44513964	35.09	<.0001
Error	118	8.22312461	0.06968750		
Corrected Total	123	20.44882280			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.597868	4.188318	0.263984	6.302862

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.68009584	10.68009584	153.26	<.0001
SEXC	1	0.64311344	0.64311344	9.23	0.0029
UCPDGR1	1	0.00024283	0.00024283	0.00	0.9530
TRTPN	2	0.90224608	0.45112304	6.47	0.0021

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.90874057	8.90874057	127.84	<.0001
SEXC	1	0.52064545	0.52064545	7.47	0.0072
UCPDGR1	1	0.00340587	0.00340587	0.05	0.8254
TRTPN	2	0.90224608	0.45112304	6.47	0.0021



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.27739962	1
2	6.45184092	2
3	6.22439707	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0021	0.4230
2	0.0021		0.0025
3	0.4230	0.0025	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.277400	6.213419	6.341380
2	6.451841	6.361619	6.542063
3	6.224397	6.110060	6.338734



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.174441	-0.284135	-0.064748
1	3	0.053003	-0.077549	0.183554
2	3	0.227444	0.081938	0.372950

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	84
Number of Observations Used	84



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.16346935	1.23269387	7.16	<.0001
Error	78	13.42634721	0.17213266		
Corrected Total	83	19.58981656			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.314626	6.834950	0.414889	6.070107

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.95026845	5.95026845	34.57	<.0001
SEXC	1	0.05655248	0.05655248	0.33	0.5682
UCPDGR1	1	0.03239700	0.03239700	0.19	0.6656
TRTPN	2	0.12425142	0.06212571	0.36	0.6982

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.89928257	5.89928257	34.27	<.0001
SEXC	1	0.02939579	0.02939579	0.17	0.6806
UCPDGR1	1	0.01882683	0.01882683	0.11	0.7417
TRTPN	2	0.12425142	0.06212571	0.36	0.6982



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.04130994	1
2	6.11255334	2
3	6.01542883	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4747	0.8512
2	0.4747		0.4904
3	0.8512	0.4904	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.041310	5.905404	6.177216
2	6.112553	5.967232	6.257874
3	6.015429	5.776247	6.254611



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.071243	-0.268699	0.126213
1	3	0.025881	-0.247848	0.299610
2	3	0.097125	-0.181929	0.376178

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	82
Number of Observations Used	82



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.88573961	1.77714792	5.28	0.0003
Error	76	25.59977362	0.33683913		
Corrected Total	81	34.48551323			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.257666	9.617846	0.580378	6.034391

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.53040910	7.53040910	22.36	<.0001
SEXC	1	0.03134139	0.03134139	0.09	0.7612
UCPDGR1	1	0.20179516	0.20179516	0.60	0.4413
TRTPN	2	1.12219396	0.56109698	1.67	0.1959

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.10724897	7.10724897	21.10	<.0001
SEXC	1	0.00725391	0.00725391	0.02	0.8837
UCPDGR1	1	0.28134226	0.28134226	0.84	0.3637
TRTPN	2	1.12219396	0.56109698	1.67	0.1959



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.08953897	1
2	6.06303450	2
3	5.73188853	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8512	0.0813
2	0.8512		0.1056
3	0.0813	0.1056	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.089539	5.893726	6.285352
2	6.063034	5.862705	6.263364
3	5.731889	5.377650	6.086128



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.026504	-0.253955	0.306964
1	3	0.357650	-0.045525	0.760826
2	3	0.331146	-0.071538	0.733830

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.74089242	1.74817848	6.30	<.0001
Error	80	22.20853948	0.27760674		
Corrected Total	85	30.94943190			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.282425	8.700517	0.526884	6.055778

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.98912137	7.98912137	28.78	<.0001
SEXC	1	0.21474439	0.21474439	0.77	0.3818
UCPDGR1	1	0.49034188	0.49034188	1.77	0.1876
TRTPN	2	0.04668478	0.02334239	0.08	0.9194

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.42990719	7.42990719	26.76	<.0001
SEXC	1	0.41868840	0.41868840	1.51	0.2230
UCPDGR1	1	0.45859148	0.45859148	1.65	0.2024
TRTPN	2	0.04668478	0.02334239	0.08	0.9194



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.06067061	1
2	6.09687838	2
3	6.02264163	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.7701	0.8461
2	0.7701		0.7118
3	0.8461	0.7118	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.060671	5.900503	6.220838
2	6.096878	5.909632	6.284125
3	6.022642	5.666066	6.379217



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.036208	-0.281936	0.209521
1	3	0.038029	-0.350682	0.426740
2	3	0.074237	-0.324257	0.472731

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01213398	0.00242680	7.57	<.0001
Error	128	0.04103094	0.00032055		
Corrected Total	133	0.05316493			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.228233	38.02123	0.017904	0.047090

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.01012564	0.01012564	31.59	<.0001
SEXC	1	0.00000522	0.00000522	0.02	0.8987
UCPDGR1	1	0.00004077	0.00004077	0.13	0.7219
TRTPN	2	0.00196235	0.00098117	3.06	0.0503

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.00992530	0.00992530	30.96	<.0001
SEXC	1	0.00000502	0.00000502	0.02	0.9006
UCPDGR1	1	0.00003361	0.00003361	0.10	0.7466
TRTPN	2	0.00196235	0.00098117	3.06	0.0503



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04544909	1
2	0.05318684	2
3	0.04267320	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0369	0.5127
2	0.0369		0.0292
3	0.5127	0.0292	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.045449	0.041286	0.049612
2	0.053187	0.047173	0.059201
3	0.042673	0.035356	0.049991



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007738	-0.014997	-0.000478
1	3	0.002776	-0.005591	0.011143
2	3	0.010514	0.001083	0.019944

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01585410	0.00317082	8.07	<.0001
Error	81	0.03183096	0.00039297		
Corrected Total	86	0.04768506			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.332475	41.45799	0.019824	0.047816

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.01279100	0.01279100	32.55	<.0001
SEXC	1	0.00137876	0.00137876	3.51	0.0647
UCPDGR1	1	0.00003535	0.00003535	0.09	0.7650
TRTPN	2	0.00164899	0.00082450	2.10	0.1293

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.01271653	0.01271653	32.36	<.0001
SEXC	1	0.00140552	0.00140552	3.58	0.0622
UCPDGR1	1	0.00007302	0.00007302	0.19	0.6676
TRTPN	2	0.00164899	0.00082450	2.10	0.1293



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04446258	1
2	0.05207953	2
3	0.04065849	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1053	0.5508
2	0.1053		0.0813
3	0.5508	0.0813	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.044463	0.038116	0.050810
2	0.052080	0.045237	0.058922
3	0.040658	0.029663	0.051654



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007617	-0.016869	0.001635
1	3	0.003804	-0.008831	0.016439
2	3	0.011421	-0.001451	0.024293

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01361890	0.00272378	2.73	0.0249
Error	80	0.07978692	0.00099734		
Corrected Total	85	0.09340581			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.145804	64.51151	0.031581	0.048953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.00644009	0.00644009	6.46	0.0130
SEXC	1	0.00197626	0.00197626	1.98	0.1631
UCPDGR1	1	0.00257318	0.00257318	2.58	0.1122
TRTPN	2	0.00262937	0.00131468	1.32	0.2734

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.00811623	0.00811623	8.14	0.0055
SEXC	1	0.00089260	0.00089260	0.89	0.3470
UCPDGR1	1	0.00347326	0.00347326	3.48	0.0657
TRTPN	2	0.00262937	0.00131468	1.32	0.2734



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.05392377	1
2	0.04433307	2
3	0.03936068	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2012	0.1732
2	0.2012		0.6410
3	0.1732	0.6410	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.053924	0.043648	0.064200
2	0.044333	0.033599	0.055067
3	0.039361	0.020829	0.057892



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.009591	-0.005220	0.024401
1	3	0.014563	-0.006528	0.035654
2	3	0.004972	-0.016171	0.026116

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.00521587	0.00104317	2.25	0.0574
Error	82	0.03809209	0.00046454		
Corrected Total	87	0.04330795			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.120437	49.00972	0.021553	0.043977

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.00216763	0.00216763	4.67	0.0337
SEXC	1	0.00006990	0.00006990	0.15	0.6991
UCPDGR1	1	0.00072775	0.00072775	1.57	0.2143
TRTPN	2	0.00225058	0.00112529	2.42	0.0950

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.00266007	0.00266007	5.73	0.0190
SEXC	1	0.00001816	0.00001816	0.04	0.8438
UCPDGR1	1	0.00073461	0.00073461	1.58	0.2121
TRTPN	2	0.00225058	0.00112529	2.42	0.0950



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04366806	1
2	0.04773914	2
3	0.02973220	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4173	0.0826
2	0.4173		0.0306
3	0.0826	0.0306	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.043668	0.037296	0.050041
2	0.047739	0.040082	0.055396
3	0.029732	0.015177	0.044287



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.004071	-0.014005	0.005863
1	3	0.013936	-0.001840	0.029712
2	3	0.018007	0.001730	0.034284

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	95796.2651	19159.2530	44.47	<.0001
Error	81	34894.7923	430.7999		
Corrected Total	86	130691.0575			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.732998	11.11024	20.75572	186.8161

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	95086.51191	95086.51191	220.72	<.0001
SEXC	1	19.11489	19.11489	0.04	0.8337
UCPDGR1	1	265.92116	265.92116	0.62	0.4344
TRTPN	2	424.71717	212.35859	0.49	0.6126

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	95369.00469	95369.00469	221.38	<.0001
SEXC	1	2.64191	2.64191	0.01	0.9378
UCPDGR1	1	305.18820	305.18820	0.71	0.4024
TRTPN	2	424.71717	212.35859	0.49	0.6126



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	185.152797	1
2	186.840670	2
3	191.746158	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7297	0.3237
2	0.7297		0.4711
3	0.3237	0.4711	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	185.152797	178.511890	191.793705
2	186.840670	179.674500	194.006840
3	191.746158	180.238512	203.253803



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.687873	-11.372930	7.997184
1	3	-6.593360	-19.806494	6.619774
2	3	-4.905487	-18.383714	8.572740

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	77593.3636	15518.6727	36.74	<.0001
Error	80	33791.1946	422.3899		
Corrected Total	85	111384.5581			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.696626	11.14569	20.55213	184.3953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	76631.45789	76631.45789	181.42	<.0001
SEXC	1	96.88988	96.88988	0.23	0.6333
UCPDGR1	1	233.11290	233.11290	0.55	0.4597
TRTPN	2	631.90291	315.95145	0.75	0.4766

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	76062.42638	76062.42638	180.08	<.0001
SEXC	1	39.39981	39.39981	0.09	0.7608
UCPDGR1	1	369.81367	369.81367	0.88	0.3522
TRTPN	2	631.90291	315.95145	0.75	0.4766



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	182.037671	1
2	185.600635	2
3	190.124064	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4651	0.2445
2	0.4651		0.5151
3	0.2445	0.5151	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	182.037671	175.342130	188.733212
2	185.600635	178.608426	192.592845
3	190.124064	178.062850	202.185277



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.562964	-13.223008	6.097080
1	3	-8.086393	-21.811768	5.638983
2	3	-4.523428	-18.292021	9.245164

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	103419.7830	20683.9566	52.04	<.0001
Error	82	32594.2057	397.4903		
Corrected Total	87	136013.9886			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.760361	10.63380	19.93716	187.4886

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	102854.6196	102854.6196	258.76	<.0001
SEXC	1	260.8579	260.8579	0.66	0.4202
UCPDGR1	1	1.7893	1.7893	0.00	0.9467
TRTPN	2	302.5161	151.2581	0.38	0.6847

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	100128.2487	100128.2487	251.90	<.0001
SEXC	1	191.2254	191.2254	0.48	0.4899
UCPDGR1	1	13.5848	13.5848	0.03	0.8538
TRTPN	2	302.5161	151.2581	0.38	0.6847



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	186.257555	1
2	190.304960	2
3	187.666604	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.3860	0.8481
2	0.3860		0.7287
3	0.8481	0.7287	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	186.257555	180.346370	192.168740
2	190.304960	183.203394	197.406526
3	187.666604	174.199439	201.133769



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-4.047405	-13.285585	5.190776
1	3	-1.409049	-16.000997	13.182899
2	3	2.638356	-12.443049	17.719761

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2464.009943	492.801989	12.92	<.0001
Error	128	4881.639311	38.137807		
Corrected Total	133	7345.649254			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.335438	8.733804	6.175582	70.70896

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1863.546076	1863.546076	48.86	<.0001
SEXC	1	435.444976	435.444976	11.42	0.0010
UCPDGR1	1	32.236919	32.236919	0.85	0.3596
TRTPN	2	132.781973	66.390986	1.74	0.1795

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1569.362163	1569.362163	41.15	<.0001
SEXC	1	350.503915	350.503915	9.19	0.0029
UCPDGR1	1	32.434419	32.434419	0.85	0.3582
TRTPN	2	132.781973	66.390986	1.74	0.1795



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	69.7442502	1
2	71.9500398	2
3	69.4944745	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0841	0.8637
2	0.0841		0.1384
3	0.8637	0.1384	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	69.744250	68.309124	71.179376
2	71.950040	69.872345	74.027734
3	69.494475	66.976874	72.012075



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.205790	-4.712737	0.301158
1	3	0.249776	-2.623328	3.122880
2	3	2.455565	-0.802968	5.714099

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1843.927681	368.785536	5.78	0.0001
Error	81	5164.784963	63.762777		
Corrected Total	86	7008.712644			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.263091	11.34404	7.985160	70.39080

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1730.120849	1730.120849	27.13	<.0001
SEXC	1	31.401990	31.401990	0.49	0.4848
UCPDGR1	1	1.572522	1.572522	0.02	0.8756
TRTPN	2	80.832319	40.416160	0.63	0.5332

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1640.004765	1640.004765	25.72	<.0001
SEXC	1	23.195207	23.195207	0.36	0.5481
UCPDGR1	1	1.880423	1.880423	0.03	0.8641
TRTPN	2	80.832319	40.416160	0.63	0.5332



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	70.5125072	1
2	70.8443251	2
3	67.9947286	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8599	0.3272
2	0.8599		0.2772
3	0.3272	0.2772	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	70.512507	67.957291	73.067723
2	70.844325	68.086091	73.602560
3	67.994729	63.569742	72.419715



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.331818	-4.059999	3.396364
1	3	2.517779	-2.563850	7.599407
2	3	2.849596	-2.333396	8.032589

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2206.267539	441.253508	5.32	0.0003
Error	80	6637.046415	82.963080		
Corrected Total	85	8843.313953			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.249484	13.11440	9.108407	69.45349

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1985.666585	1985.666585	23.93	<.0001
SEXC	1	47.887333	47.887333	0.58	0.4496
UCPDGR1	1	148.472385	148.472385	1.79	0.1848
TRTPN	2	24.241236	12.120618	0.15	0.8643

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2168.926149	2168.926149	26.14	<.0001
SEXC	1	11.390736	11.390736	0.14	0.7120
UCPDGR1	1	131.042883	131.042883	1.58	0.2125
TRTPN	2	24.241236	12.120618	0.15	0.8643



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	70.1113583	1
2	68.9468552	2
3	69.6679993	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5916	0.8851
2	0.5916		0.8149
3	0.8851	0.8149	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	70.111358	67.139369	73.083347
2	68.946855	65.837643	72.056068
3	69.667999	64.322587	75.013412



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.164503	-3.137639	5.466645
1	3	0.443359	-5.640690	6.527408
2	3	-0.721144	-6.830775	5.388487

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2468.992904	493.798581	7.35	<.0001
Error	82	5507.507096	67.164721		
Corrected Total	87	7976.500000			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.309533	11.66606	8.195409	70.25000

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	2263.882285	2263.882285	33.71	<.0001
SEXC	1	22.153859	22.153859	0.33	0.5673
UCPDGR1	1	140.289742	140.289742	2.09	0.1522
TRTPN	2	42.667019	21.333509	0.32	0.7288

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2370.598036	2370.598036	35.30	<.0001
SEXC	1	75.827010	75.827010	1.13	0.2911
UCPDGR1	1	126.506399	126.506399	1.88	0.1737
TRTPN	2	42.667019	21.333509	0.32	0.7288



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	70.3824184	1
2	70.2176534	2
3	68.0087017	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9314	0.4337
2	0.9314		0.4797
3	0.4337	0.4797	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	70.382418	67.954148	72.810689
2	70.217653	67.298574	73.136732
3	68.008702	62.475511	73.541893



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.164765	-3.630287	3.959817
1	3	2.373717	-3.628212	8.375646
2	3	2.208952	-3.980206	8.398109

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.37428880	0.27485776	62.22	<.0001
Error	128	0.56543359	0.00441745		
Corrected Total	133	1.93972239			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.708498	33.70993	0.066464	0.197164

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.34369466	1.34369466	304.18	<.0001
SEXC	1	0.00045191	0.00045191	0.10	0.7496
UCPDGR1	1	0.00527654	0.00527654	1.19	0.2765
TRTPN	2	0.02486569	0.01243284	2.81	0.0637

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.13238486	1.13238486	256.34	<.0001
SEXC	1	0.00300713	0.00300713	0.68	0.4109
UCPDGR1	1	0.00624206	0.00624206	1.41	0.2368
TRTPN	2	0.02486569	0.01243284	2.81	0.0637



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.19134441	1
2	0.21942625	2
3	0.18216507	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0420	0.5578
2	0.0420		0.0379
3	0.5578	0.0379	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.191344	0.175878	0.206811
2	0.219426	0.197047	0.241806
3	0.182165	0.155035	0.209295



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.028082	-0.055129	-0.001035
1	3	0.009179	-0.021727	0.040086
2	3	0.037261	0.002118	0.072405

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.48920501	0.09784100	18.47	<.0001
Error	81	0.42908005	0.00529728		
Corrected Total	86	0.91828506			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.532738	36.60158	0.072782	0.198851

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.48547190	0.48547190	91.65	<.0001
SEXC	1	0.00003510	0.00003510	0.01	0.9353
UCPDGR1	1	0.00010804	0.00010804	0.02	0.8868
TRTPN	2	0.00358997	0.00179499	0.34	0.7136

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.43883614	0.43883614	82.84	<.0001
SEXC	1	0.00000083	0.00000083	0.00	0.9901
UCPDGR1	1	0.00027330	0.00027330	0.05	0.8209
TRTPN	2	0.00358997	0.00179499	0.34	0.7136



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.19193460	1
2	0.20540552	2
3	0.20329188	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4332	0.6336
2	0.4332		0.9313
3	0.6336	0.9313	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.191935	0.168646	0.215223
2	0.205406	0.180208	0.230603
3	0.203292	0.161851	0.244733



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.013471	-0.047499	0.020558
1	3	-0.011357	-0.058586	0.035871
2	3	0.002114	-0.046482	0.050709

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.64464104	0.12892821	22.51	<.0001
Error	80	0.45824849	0.00572811		
Corrected Total	85	1.10288953			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.584502	41.96548	0.075684	0.180349

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.63040054	0.63040054	110.05	<.0001
SEXC	1	0.00000668	0.00000668	0.00	0.9728
UCPDGR1	1	0.00640303	0.00640303	1.12	0.2936
TRTPN	2	0.00783079	0.00391539	0.68	0.5077

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.57682724	0.57682724	100.70	<.0001
SEXC	1	0.00070396	0.00070396	0.12	0.7268
UCPDGR1	1	0.00878222	0.00878222	1.53	0.2193
TRTPN	2	0.00783079	0.00391539	0.68	0.5077



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.16937262	1
2	0.18984879	2
3	0.18484579	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.2554	0.5481
2	0.2554		0.8474
3	0.5481	0.8474	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.169373	0.144733	0.194012
2	0.189849	0.164079	0.215618
3	0.184846	0.139702	0.229990



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.020476	-0.056050	0.015097
1	3	-0.015473	-0.066530	0.035583
2	3	0.005003	-0.046576	0.056582

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.17563281	0.03512656	9.78	<.0001
Error	82	0.29446606	0.00359105		
Corrected Total	87	0.47009886			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.373608	40.65869	0.059925	0.147386

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.16600855	0.16600855	46.23	<.0001
SEXC	1	0.00035965	0.00035965	0.10	0.7525
UCPDGR1	1	0.00046765	0.00046765	0.13	0.7191
TRTPN	2	0.00879697	0.00439848	1.22	0.2991

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.15264486	0.15264486	42.51	<.0001
SEXC	1	0.00000175	0.00000175	0.00	0.9824
UCPDGR1	1	0.00038508	0.00038508	0.11	0.7442
TRTPN	2	0.00879697	0.00439848	1.22	0.2991



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.14770441	1
2	0.15515305	2
3	0.11945870	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5937	0.2068
2	0.5937		0.1214
3	0.2068	0.1214	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.147704	0.129983	0.165426
2	0.155153	0.133825	0.176481
3	0.119459	0.078727	0.160190



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007449	-0.035118	0.020221
1	3	0.028246	-0.015917	0.072408
2	3	0.035694	-0.009674	0.081063

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	9.85574452	1.97114890	31.67	<.0001
Error	82	5.10414184	0.06224563		
Corrected Total	87	14.95988636			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.658811	4.599871	0.249491	5.423864

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	9.43601693	9.43601693	151.59	<.0001
SEXC	1	0.20948148	0.20948148	3.37	0.0702
UCPDGR1	1	0.00645798	0.00645798	0.10	0.7482
TRTPN	2	0.20378813	0.10189406	1.64	0.2009

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	8.79319336	8.79319336	141.27	<.0001
SEXC	1	0.12785421	0.12785421	2.05	0.1556
UCPDGR1	1	0.00479216	0.00479216	0.08	0.7821
TRTPN	2	0.20378813	0.10189406	1.64	0.2009



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	5.43458028	1
2	5.47069328	2
3	5.29787253	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5380	0.1407
2	0.5380		0.0742
3	0.1407	0.0742	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	5.434580	5.360481	5.508680
2	5.470693	5.381544	5.559843
3	5.297873	5.128682	5.467063



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.036113	-0.152290	0.080064
1	3	0.136708	-0.046107	0.319522
2	3	0.172821	-0.017253	0.362895

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10051.79634	2010.35927	31.17	<.0001
Error	81	5223.58297	64.48868		
Corrected Total	86	15275.37931			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.658039	15.66133	8.030484	51.27586

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	9912.435128	9912.435128	153.71	<.0001
SEXC	1	31.998259	31.998259	0.50	0.4832
UCPDGR1	1	77.611255	77.611255	1.20	0.2759
TRTPN	2	29.751698	14.875849	0.23	0.7945

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	9363.981848	9363.981848	145.20	<.0001
SEXC	1	69.562122	69.562122	1.08	0.3021
UCPDGR1	1	80.663372	80.663372	1.25	0.2667
TRTPN	2	29.751698	14.875849	0.23	0.7945



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	50.8223491	1
2	51.7357543	2
3	50.0815802	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6341	0.7743
2	0.6341		0.5300
3	0.7743	0.5300	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	50.822349	48.244207	53.400491
2	51.735754	48.928613	54.542896
3	50.081580	45.628932	54.534228



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.913405	-4.716829	2.890019
1	3	0.740769	-4.382711	5.864249
2	3	1.654174	-3.564708	6.873056

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12453.40107	2490.68021	60.48	<.0001
Error	80	3294.69195	41.18365		
Corrected Total	85	15748.09302			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.790788	12.49209	6.417449	51.37209

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	12303.57496	12303.57496	298.75	<.0001
SEXC	1	0.02469	0.02469	0.00	0.9805
UCPDGR1	1	132.91368	132.91368	3.23	0.0762
TRTPN	2	16.88775	8.44387	0.21	0.8150

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	11092.03638	11092.03638	269.33	<.0001
SEXC	1	11.34459	11.34459	0.28	0.6011
UCPDGR1	1	128.44733	128.44733	3.12	0.0812
TRTPN	2	16.88775	8.44387	0.21	0.8150



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	51.5503456	1
2	50.7949861	2
3	52.0204441	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6316	0.8292
2	0.6316		0.5727
3	0.8292	0.5727	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	51.550346	49.436259	53.664432
2	50.794986	48.556245	53.033727
3	52.020444	48.247722	55.793167



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.755359	-2.368009	3.878728
1	3	-0.470099	-4.792333	3.852136
2	3	-1.225458	-5.530577	3.079661

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11717.49439	2343.49888	39.57	<.0001
Error	82	4856.13061	59.22110		
Corrected Total	87	16573.62500			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.706996	14.28404	7.695525	53.87500

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	11613.21027	11613.21027	196.10	<.0001
SEXC	1	59.38347	59.38347	1.00	0.3196
UCPDGR1	1	7.12278	7.12278	0.12	0.7296
TRTPN	2	37.77788	18.88894	0.32	0.7278

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	10288.45818	10288.45818	173.73	<.0001
SEXC	1	36.05748	36.05748	0.61	0.4375
UCPDGR1	1	3.70231	3.70231	0.06	0.8032
TRTPN	2	37.77788	18.88894	0.32	0.7278



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	54.6836403	1
2	53.3137846	2
3	53.3458474	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4547	0.6397
2	0.4547		0.9913
3	0.6397	0.9913	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	54.683640	52.395343	56.971938
2	53.313785	50.531461	56.096108
3	53.345847	48.138606	58.553089



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.369856	-2.257550	4.997261
1	3	1.337793	-4.325949	7.001535
2	3	-0.032063	-5.844116	5.779991

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	72211.57993	14442.31599	57.07	<.0001
Error	81	20497.79938	253.05925		
Corrected Total	86	92709.37931			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.778903	14.11218	15.90784	112.7241

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	71757.54033	71757.54033	283.56	<.0001
SEXC	1	102.21740	102.21740	0.40	0.5269
UCPDGR1	1	58.08999	58.08999	0.23	0.6331
TRTPN	2	293.73222	146.86611	0.58	0.5620

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	71549.19193	71549.19193	282.74	<.0001
SEXC	1	151.75822	151.75822	0.60	0.4409
UCPDGR1	1	79.38069	79.38069	0.31	0.5770
TRTPN	2	293.73222	146.86611	0.58	0.5620



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	110.769002	1
2	112.956225	2
3	116.107812	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5594	0.2973
2	0.5594		0.5455
3	0.2973	0.5455	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	110.769002	105.678846	115.859158
2	112.956225	107.463753	118.448697
3	116.107812	107.288521	124.927103



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.187223	-9.611205	5.236759
1	3	-5.338810	-15.464347	4.786727
2	3	-3.151587	-13.481242	7.178068

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	58820.84182	11764.16836	45.93	<.0001
Error	80	20490.37911	256.12974		
Corrected Total	85	79311.22093			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.741646	14.46200	16.00405	110.6628

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	57993.40380	57993.40380	226.42	<.0001
SEXC	1	0.41316	0.41316	0.00	0.9681
UCPDGR1	1	176.19392	176.19392	0.69	0.4093
TRTPN	2	650.83094	325.41547	1.27	0.2863

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	57542.08360	57542.08360	224.66	<.0001
SEXC	1	2.00295	2.00295	0.01	0.9298
UCPDGR1	1	280.20945	280.20945	1.09	0.2987
TRTPN	2	650.83094	325.41547	1.27	0.2863



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	108.624999	1
2	110.712547	2
3	117.185693	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5819	0.1149
2	0.5819		0.2331
3	0.1149	0.2331	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	108.624999	103.413526	113.836473
2	110.712547	105.270862	116.154232
3	117.185693	107.791685	126.579701



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.087548	-9.601744	5.426648
1	3	-8.560694	-19.248087	2.126700
2	3	-6.473146	-17.194924	4.248631

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	76164.9544	15232.9909	43.63	<.0001
Error	82	28631.6706	349.1667		
Corrected Total	87	104796.6250			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.726788	16.59135	18.68600	112.6250

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	75827.31275	75827.31275	217.17	<.0001
SEXC	1	12.07154	12.07154	0.03	0.8530
UCPDGR1	1	10.42494	10.42494	0.03	0.8632
TRTPN	2	315.14518	157.57259	0.45	0.6384

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	73367.28349	73367.28349	210.12	<.0001
SEXC	1	5.91739	5.91739	0.02	0.8967
UCPDGR1	1	34.55926	34.55926	0.10	0.7539
TRTPN	2	315.14518	157.57259	0.45	0.6384



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	110.989636	1
2	114.299690	2
3	116.139230	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4489	0.4560
2	0.4489		0.7963
3	0.4560	0.7963	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	110.989636	105.448574	116.530697
2	114.299690	107.647985	120.951396
3	116.139230	103.518635	128.759824



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.310054	-11.963341	5.343232
1	3	-5.149594	-18.826015	8.526827
2	3	-1.839540	-15.968058	12.288978

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	36.35242039	7.27048408	41.70	<.0001
Error	128	22.31857662	0.17436388		
Corrected Total	133	58.67099701			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.619598	15.46466	0.417569	2.700149

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	35.28810744	35.28810744	202.38	<.0001
SEXC	1	0.34038634	0.34038634	1.95	0.1648
UCPDGR1	1	0.00712401	0.00712401	0.04	0.8401
TRTPN	2	0.71680260	0.35840130	2.06	0.1322

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	34.24152190	34.24152190	196.38	<.0001
SEXC	1	0.32491900	0.32491900	1.86	0.1746
UCPDGR1	1	0.00412164	0.00412164	0.02	0.8781
TRTPN	2	0.71680260	0.35840130	2.06	0.1322



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.65897394	1
2	2.80759879	2
3	2.60635230	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0869	0.5928
2	0.0869		0.0719
3	0.5928	0.0719	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.658974	2.561753	2.756195
2	2.807599	2.666651	2.948546
3	2.606352	2.436627	2.776078



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.148625	-0.319060	0.021810
1	3	0.052622	-0.141563	0.246806
2	3	0.201246	-0.018138	0.420631

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.34948365	4.46989673	15.99	<.0001
Error	81	22.64481520	0.27956562		
Corrected Total	86	44.99429885			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.496718	20.33524	0.528740	2.600115

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	22.06505172	22.06505172	78.93	<.0001
SEXC	1	0.00951887	0.00951887	0.03	0.8541
UCPDGR1	1	0.17928897	0.17928897	0.64	0.4256
TRTPN	2	0.09562409	0.04781205	0.17	0.8431

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	21.67492046	21.67492046	77.53	<.0001
SEXC	1	0.00250837	0.00250837	0.01	0.9248
UCPDGR1	1	0.16418681	0.16418681	0.59	0.4457
TRTPN	2	0.09562409	0.04781205	0.17	0.8431



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.57939983	1
2	2.59670362	2
3	2.67778732	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8894	0.5624
2	0.8894		0.6399
3	0.5624	0.6399	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.579400	2.410227	2.748572
2	2.596704	2.413931	2.779476
3	2.677787	2.384698	2.970877



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.017304	-0.264194	0.229586
1	3	-0.098387	-0.434939	0.238164
2	3	-0.081084	-0.424599	0.262432

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	21.46541301	4.29308260	18.96	<.0001
Error	80	18.11859629	0.22648245		
Corrected Total	85	39.58400930			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.542275	18.06956	0.475902	2.633721

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	20.49748804	20.49748804	90.50	<.0001
SEXC	1	0.58214049	0.58214049	2.57	0.1128
UCPDGR1	1	0.33873178	0.33873178	1.50	0.2249
TRTPN	2	0.04705271	0.02352636	0.10	0.9015

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	20.27233279	20.27233279	89.51	<.0001
SEXC	1	0.29656448	0.29656448	1.31	0.2559
UCPDGR1	1	0.30115253	0.30115253	1.33	0.2523
TRTPN	2	0.04705271	0.02352636	0.10	0.9015



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.60613632	1
2	2.60999032	2
3	2.67612722	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9727	0.6624
2	0.9727		0.6811
3	0.6624	0.6811	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.606136	2.451266	2.761006
2	2.609990	2.447777	2.772203
3	2.676127	2.396826	2.955429



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.003854	-0.227564	0.219856
1	3	-0.069991	-0.387800	0.247818
2	3	-0.066137	-0.385228	0.252954

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	13.27420374	2.65484075	15.33	<.0001
Error	82	14.20374058	0.17321635		
Corrected Total	87	27.47794432			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.483086	19.48654	0.416193	2.135795

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	12.73914391	12.73914391	73.54	<.0001
SEXC	1	0.04906799	0.04906799	0.28	0.5960
UCPDGR1	1	0.09186962	0.09186962	0.53	0.4685
TRTPN	2	0.39412222	0.19706111	1.14	0.3256

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	12.37243669	12.37243669	71.43	<.0001
SEXC	1	0.00964538	0.00964538	0.06	0.8140
UCPDGR1	1	0.15769752	0.15769752	0.91	0.3428
TRTPN	2	0.39412222	0.19706111	1.14	0.3256



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.19422963	1
2	2.05444555	2
3	2.07415338	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.1511	0.4365
2	0.1511		0.9014
3	0.4365	0.9014	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.194230	2.071165	2.317295
2	2.054446	1.906328	2.202563
3	2.074153	1.792448	2.355859



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.139784	-0.052108	0.331676
1	3	0.120076	-0.185374	0.425527
2	3	-0.019708	-0.335246	0.295831

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.78974251	0.15794850	15.56	<.0001
Error	128	1.29891122	0.01014774		
Corrected Total	133	2.08865373			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.378111	22.33393	0.100736	0.451045

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.75927528	0.75927528	74.82	<.0001
SEXC	1	0.01605747	0.01605747	1.58	0.2107
UCPDGR1	1	0.00813095	0.00813095	0.80	0.3724
TRTPN	2	0.00627881	0.00313940	0.31	0.7345

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.72698106	0.72698106	71.64	<.0001
SEXC	1	0.00986618	0.00986618	0.97	0.3260
UCPDGR1	1	0.00747467	0.00747467	0.74	0.3924
TRTPN	2	0.00627881	0.00313940	0.31	0.7345



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.4500555	1
2	0.45371512	2
3	0.43364093	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8607	0.4897
2	0.8607		0.4599
3	0.4897	0.4599	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.450056	0.426638	0.473473
2	0.453715	0.419556	0.487875
3	0.433641	0.392523	0.474759



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.003660	-0.044844	0.037525
1	3	0.016415	-0.030465	0.063294
2	3	0.020074	-0.033516	0.073664

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.92650526	0.18530105	18.46	<.0001
Error	81	0.81303497	0.01003747		
Corrected Total	86	1.73954023			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.532615	23.06505	0.100187	0.434368

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.85985642	0.85985642	85.66	<.0001
SEXC	1	0.00019195	0.00019195	0.02	0.8904
UCPDGR1	1	0.04173520	0.04173520	4.16	0.0447
TRTPN	2	0.02472168	0.01236084	1.23	0.2973

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.66583719	0.66583719	66.34	<.0001
SEXC	1	0.00763589	0.00763589	0.76	0.3857
UCPDGR1	1	0.04137816	0.04137816	4.12	0.0456
TRTPN	2	0.02472168	0.01236084	1.23	0.2973



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.44330809	1
2	0.44451311	2
3	0.39356672	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9593	0.1430
2	0.9593		0.1460
3	0.1430	0.1460	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.443308	0.411152	0.475464
2	0.444513	0.409493	0.479533
3	0.393567	0.335272	0.451862



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.001205	-0.048041	0.045631
1	3	0.049741	-0.017175	0.116658
2	3	0.050946	-0.018111	0.120004

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.56348298	0.11269660	6.30	<.0001
Error	80	1.43166586	0.01789582		
Corrected Total	85	1.99514884			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.282427	32.24404	0.133775	0.414884

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.42302273	0.42302273	23.64	<.0001
SEXC	1	0.00605983	0.00605983	0.34	0.5623
UCPDGR1	1	0.03796783	0.03796783	2.12	0.1491
TRTPN	2	0.09643259	0.04821630	2.69	0.0737

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.35906331	0.35906331	20.06	<.0001
SEXC	1	0.01386538	0.01386538	0.77	0.3814
UCPDGR1	1	0.05944270	0.05944270	3.32	0.0721
TRTPN	2	0.09643259	0.04821630	2.69	0.0737



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.44990301	1
2	0.40429583	2
3	0.35008921	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1530	0.0313
2	0.1530		0.2430
3	0.0313	0.2430	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.449903	0.406375	0.493431
2	0.404296	0.358532	0.450059
3	0.350089	0.270257	0.429922



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.045607	-0.017294	0.108509
1	3	0.099814	0.009207	0.190421
2	3	0.054207	-0.037503	0.145916

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.55265529	0.11053106	4.80	0.0007
Error	82	1.88945380	0.02304212		
Corrected Total	87	2.44210909			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.226302	36.41787	0.151796	0.416818

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.48460705	0.48460705	21.03	<.0001
SEXC	1	0.00658130	0.00658130	0.29	0.5945
UCPDGR1	1	0.01404293	0.01404293	0.61	0.4372
TRTPN	2	0.04742400	0.02371200	1.03	0.3619

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.41075108	0.41075108	17.83	<.0001
SEXC	1	0.01122489	0.01122489	0.49	0.4872
UCPDGR1	1	0.02107301	0.02107301	0.91	0.3417
TRTPN	2	0.04742400	0.02371200	1.03	0.3619



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.43663810	1
2	0.40954646	2
3	0.35921744	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.4440	0.1761
2	0.4440		0.3948
3	0.1761	0.3948	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.436638	0.391743	0.481533
2	0.409546	0.355367	0.463726
3	0.359217	0.255065	0.463370



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.027092	-0.042969	0.097152
1	3	0.077421	-0.035443	0.190284
2	3	0.050329	-0.066718	0.167376

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	151.1008044	30.2201609	34.43	<.0001
Error	128	112.3580292	0.8777971		
Corrected Total	133	263.4588336			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.573527	22.03523	0.936908	4.251866

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	139.0399758	139.0399758	158.40	<.0001
SEXC	1	3.7117514	3.7117514	4.23	0.0418
UCPDGR1	1	0.0020377	0.0020377	0.00	0.9616
TRTPN	2	8.3470394	4.1735197	4.75	0.0102

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	114.0147290	114.0147290	129.89	<.0001
SEXC	1	3.0208602	3.0208602	3.44	0.0659
UCPDGR1	1	0.0455019	0.0455019	0.05	0.8203
TRTPN	2	8.3470394	4.1735197	4.75	0.0102



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.29181031	1
2	4.59681389	2
3	3.82593372	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1163	0.0361
2	0.1163		0.0025
3	0.0361	0.0025	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.291810	4.074106	4.509515
2	4.596814	4.279768	4.913859
3	3.825934	3.445003	4.206864



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.305004	-0.686658	0.076651
1	3	0.465877	0.030658	0.901095
2	3	0.770880	0.276108	1.265653

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	86.2896685	17.2579337	13.61	<.0001
Error	81	102.6986303	1.2678843		
Corrected Total	86	188.9882989			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.456587	28.01084	1.126004	4.019885

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	79.59862170	79.59862170	62.78	<.0001
SEXC	1	1.66036947	1.66036947	1.31	0.2558
UCPDGR1	1	0.00136242	0.00136242	0.00	0.9739
TRTPN	2	5.02931495	2.51465747	1.98	0.1442

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	57.24729064	57.24729064	45.15	<.0001
SEXC	1	1.64334285	1.64334285	1.30	0.2583
UCPDGR1	1	0.03556864	0.03556864	0.03	0.8674
TRTPN	2	5.02931495	2.51465747	1.98	0.1442



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.01254450	1
2	4.29274851	2
3	3.55236235	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2925	0.2131
2	0.2925		0.0528
3	0.2131	0.0528	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.012545	3.651769	4.373320
2	4.292749	3.901051	4.684446
3	3.552362	2.917234	4.187491



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.280204	-0.806356	0.245948
1	3	0.460182	-0.269490	1.189854
2	3	0.740386	-0.009119	1.489892

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	72.8395898	14.5679180	17.64	<.0001
Error	80	66.0728428	0.8259105		
Corrected Total	85	138.9124326			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.524356	22.33680	0.908796	4.068605

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	67.96254079	67.96254079	82.29	<.0001
SEXC	1	0.19453869	0.19453869	0.24	0.6288
UCPDGR1	1	0.77161942	0.77161942	0.93	0.3367
TRTPN	2	3.91089088	1.95544544	2.37	0.1002

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	49.02203365	49.02203365	59.36	<.0001
SEXC	1	0.01263334	0.01263334	0.02	0.9019
UCPDGR1	1	0.61950015	0.61950015	0.75	0.3890
TRTPN	2	3.91089088	1.95544544	2.37	0.1002



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.13440385	1
2	4.19446289	2
3	3.52468894	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7799	0.0565
2	0.7799		0.0367
3	0.0565	0.0367	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.134404	3.837129	4.431679
2	4.194463	3.884460	4.504466
3	3.524689	2.976539	4.072839



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.060059	-0.486259	0.366140
1	3	0.609715	-0.017307	1.236737
2	3	0.669774	0.042360	1.297188

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	69.8119581	13.9623916	10.89	<.0001
Error	82	105.0968192	1.2816685		
Corrected Total	87	174.9087773			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.399134	26.15529	1.132108	4.328409

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	61.02969094	61.02969094	47.62	<.0001
SEXC	1	0.89371809	0.89371809	0.70	0.4061
UCPDGR1	1	0.45145017	0.45145017	0.35	0.5545
TRTPN	2	7.43709888	3.71854944	2.90	0.0606

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	45.33082263	45.33082263	35.37	<.0001
SEXC	1	0.91199508	0.91199508	0.71	0.4014
UCPDGR1	1	0.61633228	0.61633228	0.48	0.4900
TRTPN	2	7.43709888	3.71854944	2.90	0.0606



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.45912144	1
2	4.43874867	2
3	3.46271766	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9383	0.0216
2	0.9383		0.0282
3	0.0216	0.0282	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.459121	4.122746	4.795496
2	4.438749	4.036130	4.841367
3	3.462718	2.686078	4.239357



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.020373	-0.501521	0.542266
1	3	0.996404	0.150267	1.842540
2	3	0.976031	0.107120	1.844942

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	5485.88293	1097.17659	16.83	<.0001
Error	128	8342.50513	65.17582		
Corrected Total	133	13828.38806			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.396712	6.890463	8.073154	117.1642

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	4439.247765	4439.247765	68.11	<.0001
SEXC	1	769.466659	769.466659	11.81	0.0008
UCPDGR1	1	143.242348	143.242348	2.20	0.1407
TRTPN	2	133.926157	66.963079	1.03	0.3609

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2771.535012	2771.535012	42.52	<.0001
SEXC	1	613.478246	613.478246	9.41	0.0026
UCPDGR1	1	144.275107	144.275107	2.21	0.1393
TRTPN	2	133.926157	66.963079	1.03	0.3609



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	116.053074	1
2	118.204629	2
3	115.582150	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1960	0.8081
2	0.1960		0.2339
3	0.8081	0.2339	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	116.053074	114.177125	117.929022
2	118.204629	115.488470	120.920787
3	115.582150	112.212416	118.951883



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.151555	-5.427005	1.123894
1	3	0.470924	-3.358071	4.299918
2	3	2.622479	-1.716302	6.961261

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3821.77171	764.35434	9.99	<.0001
Error	81	6195.07886	76.48246		
Corrected Total	86	10016.85057			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.381534	7.467386	8.745425	117.1149

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	3607.574546	3607.574546	47.17	<.0001
SEXC	1	35.812476	35.812476	0.47	0.4957
UCPDGR1	1	173.728744	173.728744	2.27	0.1357
TRTPN	2	4.655946	2.327973	0.03	0.9700

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2728.161956	2728.161956	35.67	<.0001
SEXC	1	3.487489	3.487489	0.05	0.8314
UCPDGR1	1	177.891538	177.891538	2.33	0.1311
TRTPN	2	4.655946	2.327973	0.03	0.9700



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	117.297952	1
2	116.807566	2
3	116.904093	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8118	0.8894
2	0.8118		0.9732
3	0.8894	0.9732	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	117.297952	114.499496	120.096407
2	116.807566	113.786098	119.829034
3	116.904093	112.004169	121.804017



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.490386	-3.593279	4.574050
1	3	0.393858	-5.224086	6.011803
2	3	-0.096527	-5.802474	5.609419

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3650.75586	730.15117	7.72	<.0001
Error	80	7568.54647	94.60683		
Corrected Total	85	11219.30233			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.325400	8.333213	9.726604	116.7209

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	3398.045494	3398.045494	35.92	<.0001
SEXC	1	133.843298	133.843298	1.41	0.2378
UCPDGR1	1	92.876890	92.876890	0.98	0.3248
TRTPN	2	25.990176	12.995088	0.14	0.8719

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2576.301354	2576.301354	27.23	<.0001
SEXC	1	179.783636	179.783636	1.90	0.1719
UCPDGR1	1	72.670830	72.670830	0.77	0.3834
TRTPN	2	25.990176	12.995088	0.14	0.8719



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	116.978899	1
2	115.856226	2
3	115.847300	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6258	0.7343
2	0.6258		0.9979
3	0.7343	0.9979	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	116.978899	113.813809	120.143990
2	115.856226	112.549403	119.163049
3	115.847300	109.995253	121.699346



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.122673	-3.440576	5.685922
1	3	1.131600	-5.480255	7.743454
2	3	0.008926	-6.645645	6.663497

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4418.116769	883.623354	13.42	<.0001
Error	82	5401.155958	65.867756		
Corrected Total	87	9819.272727			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.449943	6.942057	8.115895	116.9091

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	4179.778418	4179.778418	63.46	<.0001
SEXC	1	187.216568	187.216568	2.84	0.0956
UCPDGR1	1	11.206922	11.206922	0.17	0.6811
TRTPN	2	39.914862	19.957431	0.30	0.7394

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	3085.734425	3085.734425	46.85	<.0001
SEXC	1	167.037105	167.037105	2.54	0.1151
UCPDGR1	1	10.898530	10.898530	0.17	0.6852
TRTPN	2	39.914862	19.957431	0.30	0.7394



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	116.455839	1
2	117.157246	2
3	114.761977	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7101	0.5753
2	0.7101		0.4430
3	0.5753	0.4430	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	116.455839	114.055606	118.856073
2	117.157246	114.274020	120.040471
3	114.761977	109.218850	120.305103



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.701406	-4.441516	3.038704
1	3	1.693863	-4.296122	7.683847
2	3	2.395269	-3.785615	8.576153

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	522486.0889	104497.2178	41.24	<.0001
Error	81	205260.8307	2534.0843		
Corrected Total	86	727746.9195			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.717950	34.89406	50.33969	144.2644

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	514293.0330	514293.0330	202.95	<.0001
SEXC	1	1967.0283	1967.0283	0.78	0.3809
UCPDGR1	1	142.9482	142.9482	0.06	0.8129
TRTPN	2	6083.0794	3041.5397	1.20	0.3064

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	500402.2473	500402.2473	197.47	<.0001
SEXC	1	2196.9623	2196.9623	0.87	0.3546
UCPDGR1	1	130.2739	130.2739	0.05	0.8212
TRTPN	2	6083.0794	3041.5397	1.20	0.3064



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	142.390007	1
2	141.401915	2
3	165.517983	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9343	0.1607
2	0.9343		0.1463
3	0.1607	0.1463	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	142.390007	126.174525	158.605489
2	141.401915	123.930176	158.873653
3	165.517983	137.388892	193.647073



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.988092	-22.787265	24.763449
1	3	-23.127976	-55.631425	9.375473
2	3	-24.116068	-56.829825	8.597689

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	263814.2141	52762.8428	38.58	<.0001
Error	80	109417.3673	1367.7171		
Corrected Total	85	373231.5814			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.706838	25.51756	36.98266	144.9302

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	257994.9035	257994.9035	188.63	<.0001
SEXC	1	1031.1838	1031.1838	0.75	0.3878
UCPDGR1	1	1754.8724	1754.8724	1.28	0.2607
TRTPN	2	3033.2544	1516.6272	1.11	0.3349

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	257566.9233	257566.9233	188.32	<.0001
SEXC	1	1899.9960	1899.9960	1.39	0.2420
UCPDGR1	1	1100.9559	1100.9559	0.80	0.3723
TRTPN	2	3033.2544	1516.6272	1.11	0.3349



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	139.413474	1
2	152.443840	2
3	148.868370	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.1448	0.4558
2	0.1448		0.7749
3	0.4558	0.7749	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	139.413474	127.282641	151.544307
2	152.443840	139.782172	165.105507
3	148.868370	126.961968	170.774772



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-13.030365	-30.641977	4.581246
1	3	-9.454895	-34.564699	15.654908
2	3	3.575470	-21.227668	28.378608

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	284233.5199	56846.7040	66.80	<.0001
Error	82	69781.9346	850.9992		
Corrected Total	87	354015.4545			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.802884	21.72585	29.17189	134.2727

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	282896.5646	282896.5646	332.43	<.0001
SEXC	1	119.7387	119.7387	0.14	0.7086
UCPDGR1	1	220.4106	220.4106	0.26	0.6122
TRTPN	2	996.8060	498.4030	0.59	0.5590

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	258890.0678	258890.0678	304.22	<.0001
SEXC	1	135.5085	135.5085	0.16	0.6909
UCPDGR1	1	279.9092	279.9092	0.33	0.5679
TRTPN	2	996.8060	498.4030	0.59	0.5590



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	136.014539	1
2	135.120166	2
3	124.365684	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.8963	0.2891
2	0.8963		0.3358
3	0.2891	0.3358	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	136.014539	127.340934	144.688143
2	135.120166	124.685152	145.555181
3	124.365684	104.436021	144.295346



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.894372	-12.718789	14.507534
1	3	11.648855	-10.068929	33.366639
2	3	10.754483	-11.344154	32.853119

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	134
Number of Observations Used	134



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	266.6659759	53.3331952	38.21	<.0001
Error	128	178.6792062	1.3959313		
Corrected Total	133	445.3451821			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.598785	15.45222	1.181495	7.646119

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	251.1769306	251.1769306	179.94	<.0001
SEXC	1	1.0955420	1.0955420	0.78	0.3773
UCPDGR1	1	0.1399054	0.1399054	0.10	0.7521
TRTPN	2	14.2535979	7.1267989	5.11	0.0074

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	214.7937029	214.7937029	153.87	<.0001
SEXC	1	0.9193627	0.9193627	0.66	0.4186
UCPDGR1	1	0.0229826	0.0229826	0.02	0.8981
TRTPN	2	14.2535979	7.1267989	5.11	0.0074



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.63651236	1
2	8.10509875	2
3	7.09924933	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0575	0.0548
2	0.0575		0.0018
3	0.0548	0.0018	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.636512	7.361857	7.911168
2	8.105099	7.703736	8.506461
3	7.099249	6.619020	7.579479



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.468586	-0.952287	0.015114
1	3	0.537263	-0.011263	1.085790
2	3	1.005849	0.381076	1.630623

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	141.1019614	28.2203923	15.74	<.0001
Error	81	145.2628202	1.7933682		
Corrected Total	86	286.3647816			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.492735	18.34591	1.339167	7.299540

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	135.0230590	135.0230590	75.29	<.0001
SEXC	1	1.1333918	1.1333918	0.63	0.4289
UCPDGR1	1	0.4919718	0.4919718	0.27	0.6019
TRTPN	2	4.4535388	2.2267694	1.24	0.2943

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	106.3025825	106.3025825	59.28	<.0001
SEXC	1	1.6654218	1.6654218	0.93	0.3381
UCPDGR1	1	0.2979999	0.2979999	0.17	0.6846
TRTPN	2	4.4535388	2.2267694	1.24	0.2943



**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.26238124	1
2	7.57947593	2
3	6.90036759	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3168	0.4098
2	0.3168		0.1352
3	0.4098	0.1352	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.262381	6.833423	7.691339
2	7.579476	7.112719	8.046232
3	6.900368	6.143038	7.657698



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.317095	-0.943435	0.309246
1	3	0.362014	-0.507314	1.231341
2	3	0.679108	-0.216250	1.574466

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	86
Number of Observations Used	86



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	129.5711849	25.9142370	17.44	<.0001
Error	80	118.9002488	1.4862531		
Corrected Total	85	248.4714337			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.521473	16.59533	1.219120	7.346163

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	126.4576059	126.4576059	85.08	<.0001
SEXC	1	0.2066251	0.2066251	0.14	0.7102
UCPDGR1	1	0.0010727	0.0010727	0.00	0.9786
TRTPN	2	2.9058812	1.4529406	0.98	0.3807

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	106.5120635	106.5120635	71.66	<.0001
SEXC	1	0.2547442	0.2547442	0.17	0.6800
UCPDGR1	1	0.0191397	0.0191397	0.01	0.9099
TRTPN	2	2.9058812	1.4529406	0.98	0.3807



302

**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.39000948	1
2	7.42985236	2
3	6.85842230	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8901	0.2090
2	0.8901		0.1803
3	0.2090	0.1803	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.390009	6.992321	7.787698
2	7.429852	7.012986	7.846718
3	6.858422	6.125794	7.591051



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.039843	-0.611792	0.532107
1	3	0.531587	-0.303715	1.366890
2	3	0.571430	-0.269812	1.412672

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	133.0178157	26.6035631	13.85	<.0001
Error	82	157.5375559	1.9211897		
Corrected Total	87	290.5553716			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.457805	19.59959	1.386070	7.071932

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	122.7984636	122.7984636	63.92	<.0001
SEXC	1	0.2054080	0.2054080	0.11	0.7445
UCPDGR1	1	1.3176363	1.3176363	0.69	0.4100
TRTPN	2	8.6963078	4.3481539	2.26	0.1105

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	97.28799464	97.28799464	50.64	<.0001
SEXC	1	0.46099646	0.46099646	0.24	0.6255
UCPDGR1	1	1.93288564	1.93288564	1.01	0.3188
TRTPN	2	8.69630783	4.34815391	2.26	0.1105



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.25873444	1
2	7.08754346	2
3	6.14826068	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5954	0.0364
2	0.5954		0.0841
3	0.0364	0.0841	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.258734	6.847172	7.670297
2	7.087543	6.594034	7.581053
3	6.148261	5.194738	7.101784



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.171191	-0.467543	0.809925
1	3	1.110474	0.072110	2.148837
2	3	0.939283	-0.129228	2.007793

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17734.90572	3546.98114	500.87	<.0001
Error	82	580.69325	7.08163		
Corrected Total	87	18315.59898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.968295	3.408580	2.661132	78.07159

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	17720.76385	17720.76385	2502.36	<.0001
SEXC	1	11.72353	11.72353	1.66	0.2018
UCPDGR1	1	0.00202	0.00202	0.00	0.9866
TRTPN	2	2.41632	1.20816	0.17	0.8435

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	16231.52873	16231.52873	2292.06	<.0001
SEXC	1	11.31855	11.31855	1.60	0.2097
UCPDGR1	1	0.02923	0.02923	0.00	0.9489
TRTPN	2	2.41632	1.20816	0.17	0.8435



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	78.0607947	1
2	78.1772793	2
3	78.6489704	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.8507	0.5615
2	0.8507		0.6497
3	0.5615	0.6497	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	78.060795	77.273314	78.848275
2	78.177279	77.231925	79.122633
3	78.648970	76.796908	80.501033



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.116485	-1.343315	1.110345
1	3	-0.588176	-2.595219	1.418867
2	3	-0.471691	-2.529922	1.586540

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	5398.93790	1079.78758	3.51	0.0063
Error	82	25221.68710	307.58155		
Corrected Total	87	30620.62500			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.176317	18.38847	17.53800	95.37500

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	4295.899249	4295.899249	13.97	0.0003
SEXC	1	23.527042	23.527042	0.08	0.7828
UCPDGR1	1	222.644406	222.644406	0.72	0.3974
TRTPN	2	856.867201	428.433600	1.39	0.2542

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	3222.192162	3222.192162	10.48	0.0017
SEXC	1	4.057106	4.057106	0.01	0.9088
UCPDGR1	1	194.492394	194.492394	0.63	0.4288
TRTPN	2	856.867201	428.433600	1.39	0.2542



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**Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model**

**Least Squares Means**

Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	95.4392160	1
2	97.5346874	2
3	86.1108894	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6082	0.1611
2	0.6082		0.0994
3	0.1611	0.0994	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	95.439216	90.244657	100.633775
2	97.534687	91.245590	103.823785
3	86.110889	74.029245	98.192534



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***Listing 15.4.4.25.1 Analysis of Risk Markers - PP Set  
GLM model***

***Least Squares Means***

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.095471	-10.195119	6.004176
1	3	9.328327	-3.792848	22.449501
2	3	11.423798	-2.211780	25.059376

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



1

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	124
Number of Observations Used	124



2

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.22569819	2.44513964	35.09	<.0001
Error	118	8.22312461	0.06968750		
Corrected Total	123	20.44882280			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.597868	4.188318	0.263984	6.302862

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.68009584	10.68009584	153.26	<.0001
SEXC	1	0.64311344	0.64311344	9.23	0.0029
UCPDGR1	1	0.00024283	0.00024283	0.00	0.9530
TRTPN	2	0.90224608	0.45112304	6.47	0.0021

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	8.90874057	8.90874057	127.84	<.0001
SEXC	1	0.52064545	0.52064545	7.47	0.0072
UCPDGR1	1	0.00340587	0.00340587	0.05	0.8254
TRTPN	2	0.90224608	0.45112304	6.47	0.0021



3

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.27739962	1
2	6.45184092	2
3	6.22439707	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0021	0.4230
2	0.0021		0.0025
3	0.4230	0.0025	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.277400	6.213419	6.341380
2	6.451841	6.361619	6.542063
3	6.224397	6.110060	6.338734



4

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.174441	-0.284135	-0.064748
1	3	0.053003	-0.077549	0.183554
2	3	0.227444	0.081938	0.372950

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





5

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	84
Number of Observations Used	84



6

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.16346935	1.23269387	7.16	<.0001
Error	78	13.42634721	0.17213266		
Corrected Total	83	19.58981656			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.314626	6.834950	0.414889	6.070107

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.95026845	5.95026845	34.57	<.0001
SEXC	1	0.05655248	0.05655248	0.33	0.5682
UCPDGR1	1	0.03239700	0.03239700	0.19	0.6656
TRTPN	2	0.12425142	0.06212571	0.36	0.6982

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.89928257	5.89928257	34.27	<.0001
SEXC	1	0.02939579	0.02939579	0.17	0.6806
UCPDGR1	1	0.01882683	0.01882683	0.11	0.7417
TRTPN	2	0.12425142	0.06212571	0.36	0.6982



7

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.04130994	1
2	6.11255334	2
3	6.01542883	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4747	0.8512
2	0.4747		0.4904
3	0.8512	0.4904	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.041310	5.905404	6.177216
2	6.112553	5.967232	6.257874
3	6.015429	5.776247	6.254611



***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.071243	-0.268699	0.126213
1	3	0.025881	-0.247848	0.299610
2	3	0.097125	-0.181929	0.376178

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	81
Number of Observations Used	81



10

***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.60794322	1.72158864	5.05	0.0005
Error	75	25.56383520	0.34085114		
Corrected Total	80	34.17177842			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.251902	9.685986	0.583825	6.027518

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.30052360	7.30052360	21.42	<.0001
SEXC	1	0.02113158	0.02113158	0.06	0.8040
UCPDGR1	1	0.18096883	0.18096883	0.53	0.4685
TRTPN	2	1.10531921	0.55265960	1.62	0.2045

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.83759994	6.83759994	20.06	<.0001
SEXC	1	0.00451684	0.00451684	0.01	0.9087
UCPDGR1	1	0.26478560	0.26478560	0.78	0.3809
TRTPN	2	1.10531921	0.55265960	1.62	0.2045



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***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.08670761	1
2	6.05441107	2
3	5.72944671	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8217	0.0834
2	0.8217		0.1159
3	0.0834	0.1159	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.086708	5.889505	6.283911
2	6.054411	5.850293	6.258530
3	5.729447	5.373031	6.085862



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***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.032297	-0.252118	0.316711
1	3	0.357261	-0.048403	0.762925
2	3	0.324964	-0.081969	0.731898

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.





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***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	85
Number of Observations Used	85



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**Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set**

**Dependent Variable: LOGAVAL**

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.50479720	1.70095944	6.07	<.0001
Error	79	22.15470949	0.28043936		
Corrected Total	84	30.65950669			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.277395	8.753896	0.529565	6.049481

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.77023145	7.77023145	27.71	<.0001
SEXC	1	0.24390128	0.24390128	0.87	0.3539
UCPDGR1	1	0.45623499	0.45623499	1.63	0.2059
TRTPN	2	0.03442948	0.01721474	0.06	0.9405

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.16134815	7.16134815	25.54	<.0001
SEXC	1	0.44082428	0.44082428	1.57	0.2136
UCPDGR1	1	0.43516328	0.43516328	1.55	0.2166
TRTPN	2	0.03442948	0.01721474	0.06	0.9405



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***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.05810088	1
2	6.08692182	2
3	6.02050515	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8186	0.8486
2	0.8186		0.7432
3	0.8486	0.7432	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.058101	5.896958	6.219243
2	6.086922	5.896165	6.277679
3	6.020505	5.662088	6.378922



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***Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.028821	-0.278117	0.220475
1	3	0.037596	-0.353175	0.428366
2	3	0.066417	-0.335755	0.468589

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis**  
**Value)**

**Parameter Code=CRP**

Moments			
<b>N</b>	160	<b>Sum Weights</b>	160
<b>Mean</b>	2.9229375	<b>Sum Observations</b>	467.67
<b>Std Deviation</b>	5.43850904	<b>Variance</b>	29.5773806
<b>Skewness</b>	5.3449225	<b>Kurtosis</b>	37.4352886
<b>Uncorrected SS</b>	6069.7737	<b>Corrected SS</b>	4702.80352
<b>Coeff Variation</b>	186.063132	<b>Std Error Mean</b>	0.42995189

Basic Statistical Measures			
Location		Variability	
<b>Mean</b>	2.922938	<b>Std Deviation</b>	5.43851
<b>Median</b>	1.090000	<b>Variance</b>	29.57738
<b>Mode</b>	0.100000	<b>Range</b>	48.50000
		<b>Interquartile Range</b>	2.28000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
<b>Student's t</b>	<b>t</b>	6.79829	<b>Pr &gt;  t </b>	<.0001
<b>Sign</b>	<b>M</b>	80	<b>Pr &gt;=  M </b>	<.0001
<b>Signed Rank</b>	<b>S</b>	6440	<b>Pr &gt;=  S </b>	<.0001



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis Value)**

**Parameter Code=CRP**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.475062	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.301858	Pr > D	<0.0100
Cramer-von Mises	W-Sq	4.5432	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	23.20189	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	48.600
99%	34.200
95%	9.525
90%	7.765
75% Q3	2.875
50% Median	1.090
25% Q1	0.595
10%	0.270
5%	0.100
1%	0.100
0% Min	0.100



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=CRP**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
0.1	120	15.7	39
0.1	112	15.8	74
0.1	94	16.4	75
0.1	87	34.2	143
0.1	76	48.6	118



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=FIBRINO**

Moments			
N	154	Sum Weights	154
Mean	337.538961	Sum Observations	51981
Std Deviation	82.899351	Variance	6872.30239
Skewness	0.87571033	Kurtosis	0.11491904
Uncorrected SS	18597075	Corrected SS	1051462.27
Coeff Variation	24.5599355	Std Error Mean	6.68022007

Basic Statistical Measures			
Location		Variability	
Mean	337.5390	Std Deviation	82.89935
Median	320.0000	Variance	6872
Mode	357.0000	Range	364.00000
		Interquartile Range	102.00000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	50.52812	Pr >  t	<.0001
Sign	M	77	Pr >=  M	<.0001
Signed Rank	S	5967.5	Pr >=  S	<.0001





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis  
Value)**

**Parameter Code=FIBRINO**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.92882	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.112149	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.531413	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	3.321735	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	564
99%	559
95%	524
90%	469
75% Q3	379
50% Median	320
25% Q1	277
10%	247
5%	238
1%	217
0% Min	200



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=FIBRINO**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
200	158	531	54
217	95	533	15
226	17	543	115
228	66	559	121
228	51	564	136

Missing Values			
Missing Value	Count	Percent Of	
		All Obs	Missing Obs
	6	3.75	100.00



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis  
Value)**

**Parameter Code=GLUC**

Moments			
<b>N</b>	160	<b>Sum Weights</b>	160
<b>Mean</b>	94.3375	<b>Sum Observations</b>	15094
<b>Std Deviation</b>	8.15331665	<b>Variance</b>	66.4765723
<b>Skewness</b>	1.12970941	<b>Kurtosis</b>	2.33932901
<b>Uncorrected SS</b>	1434500	<b>Corrected SS</b>	10569.775
<b>Coeff Variation</b>	8.64271011	<b>Std Error Mean</b>	0.64457628

Basic Statistical Measures			
Location		Variability	
<b>Mean</b>	94.33750	<b>Std Deviation</b>	8.15332
<b>Median</b>	93.00000	<b>Variance</b>	66.47657
<b>Mode</b>	94.00000	<b>Range</b>	51.00000
		<b>Interquartile Range</b>	10.50000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
<b>Student's t</b>	<b>t</b>	146.3558	<b>Pr &gt;  t </b>	<.0001
<b>Sign</b>	<b>M</b>	80	<b>Pr &gt;=  M </b>	<.0001
<b>Signed Rank</b>	<b>S</b>	6440	<b>Pr &gt;=  S </b>	<.0001



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis Value)**

**Parameter Code=GLUC**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.93603	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.110259	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.308955	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	1.952739	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	132.0
99%	118.0
95%	109.0
90%	105.5
75% Q3	98.5
50% Median	93.0
25% Q1	88.0
10%	85.0
5%	83.0
1%	82.0
0% Min	81.0



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
Shapiro-Wilk test***

***Variable: AVAL (Analysis  
Value)***

**Parameter Code=GLUC**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
81	104	113	10
82	81	113	24
82	80	116	128
83	150	118	49
83	108	132	64



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=HOMOCY**

Moments			
N	160	Sum Weights	160
Mean	10.1615625	Sum Observations	1625.85
Std Deviation	4.76079423	Variance	22.6651617
Skewness	6.17738003	Kurtosis	56.1856003
Uncorrected SS	20124.9371	Corrected SS	3603.76071
Coeff Variation	46.8510057	Std Error Mean	0.37637383

Basic Statistical Measures			
Location		Variability	
Mean	10.16156	Std Deviation	4.76079
Median	9.32500	Variance	22.66516
Mode	11.07000	Range	51.36000
		Interquartile Range	3.19500

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	26.99859	Pr >  t	<.0001
Sign	M	80	Pr >=  M	<.0001
Signed Rank	S	6440	Pr >=  S	<.0001



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=HOMOCY**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.566609	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.181272	Pr > D	<0.0100
Cramer-von Mises	W-Sq	2.034165	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	11.8829	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	56.400
99%	24.510
95%	15.970
90%	13.555
75% Q3	11.160
50% Median	9.325
25% Q1	7.965
10%	6.720
5%	5.920
1%	5.380
0% Min	5.040



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=HOMOCY**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
5.04	21	19.21	55
5.38	2	20.33	14
5.41	19	20.76	63
5.67	9	24.51	31
5.79	26	56.40	143





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis Value)**

**Parameter Code=PLAT**

Moments			
<b>N</b>	160	<b>Sum Weights</b>	160
<b>Mean</b>	282.00625	<b>Sum Observations</b>	45121
<b>Std Deviation</b>	72.5424618	<b>Variance</b>	5262.40877
<b>Skewness</b>	1.14832497	<b>Kurtosis</b>	2.41678858
<b>Uncorrected SS</b>	13561127	<b>Corrected SS</b>	836722.994
<b>Coeff Variation</b>	25.7237071	<b>Std Error Mean</b>	5.73498516

Basic Statistical Measures			
Location		Variability	
<b>Mean</b>	282.0063	<b>Std Deviation</b>	72.54246
<b>Median</b>	274.5000	<b>Variance</b>	5262
<b>Mode</b>	207.0000	<b>Range</b>	452.00000
		<b>Interquartile Range</b>	86.00000

Tests for Location: Mu0=0				
Test	Statistic		p Value	
<b>Student's t</b>	<b>t</b>	49.17297	<b>Pr &gt;  t </b>	<.0001
<b>Sign</b>	<b>M</b>	80	<b>Pr &gt;=  M </b>	<.0001
<b>Signed Rank</b>	<b>S</b>	6440	<b>Pr &gt;=  S </b>	<.0001



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable: AVAL (Analysis  
Value)**

**Parameter Code=PLAT**

Tests for Normality				
Test	Statistic		p Value	
Shapiro-Wilk	W	0.932202	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.081691	Pr > D	<0.0100
Cramer-von Mises	W-Sq	0.341201	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	2.286698	Pr > A-Sq	<0.0050

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	563.0
99%	548.0
95%	402.5
90%	372.5
75% Q3	316.5
50% Median	274.5
25% Q1	230.5
10%	207.0
5%	192.5
1%	141.0
0% Min	111.0



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**Shapiro-Wilk test**

**Variable:** AVAL (Analysis  
Value)

**Parameter Code=PLAT**

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
111	58	460	101
141	5	482	14
176	102	537	37
179	128	548	80
183	147	563	41



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	137.1593338	27.4318668	46.74	<.0001
Error	153	89.8055631	0.5869645		
Corrected Total	158	226.9648969			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.604320	310.4014	0.766136	0.246821

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	128.8408732	128.8408732	219.50	<.0001
SEXC	1	1.5167467	1.5167467	2.58	0.1100
UCPDGR1	1	2.7561796	2.7561796	4.70	0.0318
TRTPN	2	4.0455342	2.0227671	3.45	0.0344

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	123.0983147	123.0983147	209.72	<.0001
SEXC	1	0.5366885	0.5366885	0.91	0.3405
UCPDGR1	1	3.0272107	3.0272107	5.16	0.0245
TRTPN	2	4.0455342	2.0227671	3.45	0.0344



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.26861871	1
2	0.47913679	2
3	0.02872120	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.1562	0.1126
2	0.1562		0.0096
3	0.1126	0.0096	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.268619	0.096090	0.441148
2	0.479137	0.241676	0.716598
3	0.028721	-0.215868	0.273311



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.210518	-0.502383	0.081347
1	3	0.239898	-0.057123	0.536918
2	3	0.450416	0.111345	0.789487

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	112.1936300	22.4387260	27.02	<.0001
Error	153	127.0577131	0.8304426		
Corrected Total	158	239.2513431			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.468936	323.4411	0.911286	0.281747

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	109.5402307	109.5402307	131.91	<.0001
SEXC	1	1.1167126	1.1167126	1.34	0.2480
UCPDGR1	1	1.1238642	1.1238642	1.35	0.2465
TRTPN	2	0.4128225	0.2064112	0.25	0.7802

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	104.4203481	104.4203481	125.74	<.0001
SEXC	1	0.5702563	0.5702563	0.69	0.4086
UCPDGR1	1	1.2151153	1.2151153	1.46	0.2283
TRTPN	2	0.4128225	0.2064112	0.25	0.7802



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.33204591	1
2	0.31613573	2
3	0.20886361	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.9280	0.4920
2	0.9280		0.6000
3	0.4920	0.6000	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.332046	0.126830	0.537262
2	0.316136	0.033686	0.598586
3	0.208864	-0.082065	0.499792



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.015910	-0.331250	0.363071
1	3	0.123182	-0.230111	0.476475
2	3	0.107272	-0.296038	0.510583

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	121.9642184	24.3928437	33.08	<.0001
Error	153	112.8165361	0.7373630		
Corrected Total	158	234.7807545			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.519481	258.2156	0.858698	0.332551

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	118.0492230	118.0492230	160.10	<.0001
SEXC	1	0.8523586	0.8523586	1.16	0.2840
UCPDGR1	1	2.3815297	2.3815297	3.23	0.0743
TRTPN	2	0.6811071	0.3405536	0.46	0.6310

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	113.0093056	113.0093056	153.26	<.0001
SEXC	1	0.2563932	0.2563932	0.35	0.5563
UCPDGR1	1	2.3752077	2.3752077	3.22	0.0747
TRTPN	2	0.6811071	0.3405536	0.46	0.6310



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	0.31054583	1
2	0.45626025	2
3	0.29922370	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3802	0.9465
2	0.3802		0.4156
3	0.9465	0.4156	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	0.310546	0.117172	0.503919
2	0.456260	0.190110	0.722411
3	0.299224	0.025084	0.573364



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CRP Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.145714	-0.472841	0.181413
1	3	0.011322	-0.321583	0.344228
2	3	0.157037	-0.223000	0.537073

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	153
Number of Observations Used	153





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4.40948079	0.88189616	37.12	<.0001
Error	147	3.49244264	0.02375811		
Corrected Total	152	7.90192343			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.558026	2.693129	0.154137	5.723331

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	4.09733272	4.09733272	172.46	<.0001
SEXC	1	0.22562473	0.22562473	9.50	0.0025
UCPDGR1	1	0.05651329	0.05651329	2.38	0.1252
TRTPN	2	0.03001005	0.01500503	0.63	0.5332

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	3.16362392	3.16362392	133.16	<.0001
SEXC	1	0.17401438	0.17401438	7.32	0.0076
UCPDGR1	1	0.05369903	0.05369903	2.26	0.1349
TRTPN	2	0.03001005	0.01500503	0.63	0.5332



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.71659303	1
2	5.74540599	2
3	5.74366997	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3363	0.3874
2	0.3363		0.9608
3	0.3874	0.9608	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.716593	5.681327	5.751859
2	5.745406	5.697629	5.793183
3	5.743670	5.692460	5.794880



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.028813	-0.087843	0.030217
1	3	-0.027077	-0.088801	0.034647
2	3	0.001736	-0.067906	0.071378

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	153
Number of Observations Used	153



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	4.14804145	0.82960829	32.19	<.0001
Error	147	3.78866184	0.02577321		
Corrected Total	152	7.93670330			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.522640	2.811693	0.160540	5.709740

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	3.85388969	3.85388969	149.53	<.0001
SEXC	1	0.09602588	0.09602588	3.73	0.0555
UCPDGR1	1	0.14886869	0.14886869	5.78	0.0175
TRTPN	2	0.04925720	0.02462860	0.96	0.3870

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	3.09728545	3.09728545	120.17	<.0001
SEXC	1	0.05294038	0.05294038	2.05	0.1539
UCPDGR1	1	0.14101776	0.14101776	5.47	0.0207
TRTPN	2	0.04925720	0.02462860	0.96	0.3870



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.70619370	1
2	5.70082103	2
3	5.74634421	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8631	0.2191
2	0.8631		0.2168
3	0.2191	0.2168	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.706194	5.669462	5.742925
2	5.700821	5.651059	5.750583
3	5.746344	5.693007	5.799682



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.005373	-0.056110	0.066855
1	3	-0.040151	-0.104439	0.024138
2	3	-0.045523	-0.118059	0.027012

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	153
Number of Observations Used	153





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3.91911292	0.78382258	28.22	<.0001
Error	147	4.08333861	0.02777781		
Corrected Total	152	8.00245152			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.489739	2.910734	0.166667	5.725936

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	3.78472004	3.78472004	136.25	<.0001
SEXC	1	0.08620740	0.08620740	3.10	0.0802
UCPDGR1	1	0.02026292	0.02026292	0.73	0.3944
TRTPN	2	0.02792256	0.01396128	0.50	0.6060

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	3.09485595	3.09485595	111.41	<.0001
SEXC	1	0.06884032	0.06884032	2.48	0.1176
UCPDGR1	1	0.01804957	0.01804957	0.65	0.4215
TRTPN	2	0.02792256	0.01396128	0.50	0.6060



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.71931013	1
2	5.73152795	2
3	5.75313629	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.7058	0.3182
2	0.7058		0.5715
3	0.3182	0.5715	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.719310	5.681177	5.757443
2	5.731528	5.679867	5.783188
3	5.753136	5.697763	5.808509



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=FIBRINO Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.012218	-0.076047	0.051611
1	3	-0.033826	-0.100568	0.032916
2	3	-0.021608	-0.096912	0.053695

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.62058697	0.12411739	37.53	<.0001
Error	153	0.50601907	0.00330731		
Corrected Total	158	1.12660604			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.550846	1.267931	0.057509	4.535676

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.60425292	0.60425292	182.70	<.0001
SEXC	1	0.00357371	0.00357371	1.08	0.3002
UCPDGR1	1	0.00746669	0.00746669	2.26	0.1350
TRTPN	2	0.00529365	0.00264682	0.80	0.4511

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.59532253	0.59532253	180.00	<.0001
SEXC	1	0.00597167	0.00597167	1.81	0.1810
UCPDGR1	1	0.00740939	0.00740939	2.24	0.1365
TRTPN	2	0.00529365	0.00264682	0.80	0.4511



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.53791547	1
2	4.52474907	2
3	4.53806021	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2366	0.9898
2	0.2366		0.3044
3	0.9898	0.3044	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.537915	4.524976	4.550855
2	4.524749	4.506917	4.542581
3	4.538060	4.519662	4.556459



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.013166	-0.008725	0.035058
1	3	-0.000145	-0.022471	0.022181
2	3	-0.013311	-0.038832	0.012210

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.79239498	0.15847900	26.39	<.0001
Error	153	0.91896101	0.00600628		
Corrected Total	158	1.71135599			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.463022	1.709232	0.077500	4.534213

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.69144915	0.69144915	115.12	<.0001
SEXC	1	0.01057411	0.01057411	1.76	0.1865
UCPDGR1	1	0.04557152	0.04557152	7.59	0.0066
TRTPN	2	0.04480020	0.02240010	3.73	0.0262

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.65120707	0.65120707	108.42	<.0001
SEXC	1	0.00301540	0.00301540	0.50	0.4797
UCPDGR1	1	0.04109363	0.04109363	6.84	0.0098
TRTPN	2	0.04480020	0.02240010	3.73	0.0262



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.53373441	1
2	4.51458825	2
3	4.56183191	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2017	0.0670
2	0.2017		0.0074
3	0.0670	0.0074	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.533734	4.516297	4.551172
2	4.514588	4.490557	4.538619
3	4.561832	4.537038	4.586626



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.019146	-0.010355	0.048647
1	3	-0.028097	-0.058184	0.001989
2	3	-0.047244	-0.081636	-0.012851

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.45906236	0.09181247	14.81	<.0001
Error	153	0.94824326	0.00619767		
Corrected Total	158	1.40730562			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.326199	1.734187	0.078725	4.539607

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.41784170	0.41784170	67.42	<.0001
SEXC	1	0.00002774	0.00002774	0.00	0.9468
UCPDGR1	1	0.00491389	0.00491389	0.79	0.3746
TRTPN	2	0.03627904	0.01813952	2.93	0.0566

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.39516840	0.39516840	63.76	<.0001
SEXC	1	0.00024563	0.00024563	0.04	0.8425
UCPDGR1	1	0.00374461	0.00374461	0.60	0.4382
TRTPN	2	0.03627904	0.01813952	2.93	0.0566



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	4.53844864	1
2	4.51971025	2
3	4.56240361	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2186	0.1236
2	0.2186		0.0169
3	0.1236	0.0169	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	4.538449	4.520735	4.556162
2	4.519710	4.495299	4.544121
3	4.562404	4.537217	4.587590



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=GLUC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.018738	-0.011229	0.048706
1	3	-0.023955	-0.054517	0.006607
2	3	-0.042693	-0.077629	-0.007757

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.08546018	2.41709204	90.68	<.0001
Error	153	4.07838624	0.02665612		
Corrected Total	158	16.16384643			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.747685	7.220793	0.163267	2.261068

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.86598465	11.86598465	445.15	<.0001
SEXC	1	0.15112950	0.15112950	5.67	0.0185
UCPDGR1	1	0.01268420	0.01268420	0.48	0.4914
TRTPN	2	0.05566184	0.02783092	1.04	0.3545

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.92237707	10.92237707	409.75	<.0001
SEXC	1	0.11687654	0.11687654	4.38	0.0379
UCPDGR1	1	0.01580095	0.01580095	0.59	0.4425
TRTPN	2	0.05566184	0.02783092	1.04	0.3545



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.24910717	1
2	2.23558793	2
3	2.28609143	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6679	0.2501
2	0.6679		0.1693
3	0.2501	0.1693	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.249107	2.212365	2.285849
2	2.235588	2.184969	2.286206
3	2.286091	2.233965	2.338218



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.013519	-0.048607	0.075646
1	3	-0.036984	-0.100268	0.026299
2	3	-0.050503	-0.122748	0.021741

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	11.48261609	2.29652322	78.22	<.0001
Error	153	4.49218176	0.02936067		
Corrected Total	158	15.97479785			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.718796	7.540369	0.171350	2.272429

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.41397726	11.41397726	388.75	<.0001
SEXC	1	0.01031165	0.01031165	0.35	0.5543
UCPDGR1	1	0.02070513	0.02070513	0.71	0.4024
TRTPN	2	0.03762205	0.01881102	0.64	0.5283

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.86259730	10.86259730	369.97	<.0001
SEXC	1	0.00391467	0.00391467	0.13	0.7155
UCPDGR1	1	0.01842211	0.01842211	0.63	0.4295
TRTPN	2	0.03762205	0.01881102	0.64	0.5283



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.28560260	1
2	2.24954916	2
3	2.26385392	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2764	0.5187
2	0.2764		0.7099
3	0.5187	0.7099	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.285603	2.247041	2.324164
2	2.249549	2.196425	2.302673
3	2.263854	2.209147	2.318561



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.036053	-0.029149	0.101256
1	3	0.021749	-0.044668	0.088165
2	3	-0.014305	-0.090126	0.061516

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.43910929	2.48782186	70.58	<.0001
Error	153	5.39300580	0.03524840		
Corrected Total	158	17.83211509			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.697568	8.056662	0.187746	2.330315

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.35332735	12.35332735	350.46	<.0001
SEXC	1	0.05777970	0.05777970	1.64	0.2024
UCPDGR1	1	0.02305011	0.02305011	0.65	0.4200
TRTPN	2	0.00495214	0.00247607	0.07	0.9322

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.59935156	11.59935156	329.07	<.0001
SEXC	1	0.03804217	0.03804217	1.08	0.3005
UCPDGR1	1	0.02212753	0.02212753	0.63	0.4294
TRTPN	2	0.00495214	0.00247607	0.07	0.9322



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	2.33171985	1
2	2.31852514	2
3	2.32422301	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.7157	0.8390
2	0.7157		0.8924
3	0.8390	0.8924	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	2.331720	2.289469	2.373971
2	2.318525	2.260318	2.376733
3	2.324223	2.264281	2.384165



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HOMOCY Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.013195	-0.058247	0.084636
1	3	0.007497	-0.065275	0.080269
2	3	-0.005698	-0.088774	0.077378

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	157
Number of Observations Used	157



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.21540441	5.64308088	237.81	<.0001
Error	151	3.58307196	0.02372895		
Corrected Total	156	31.79847637			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.887319	2.827089	0.154042	5.448787

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	28.04879835	28.04879835	1182.05	<.0001
SEXC	1	0.00317590	0.00317590	0.13	0.7150
UCPDGR1	1	0.06486076	0.06486076	2.73	0.1003
TRTPN	2	0.09856940	0.04928470	2.08	0.1289

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	25.43373221	25.43373221	1071.84	<.0001
SEXC	1	0.01512254	0.01512254	0.64	0.4259
UCPDGR1	1	0.06413814	0.06413814	2.70	0.1022
TRTPN	2	0.09856940	0.04928470	2.08	0.1289



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42991318	1
2	5.48913807	2
3	5.43763432	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0487	0.8001
2	0.0487		0.1385
3	0.8001	0.1385	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.429913	5.394772	5.465054
2	5.489138	5.441397	5.536879
3	5.437634	5.388316	5.486952



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.059225	-0.118097	-0.000353
1	3	-0.007721	-0.067864	0.052422
2	3	0.051504	-0.016829	0.119836

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	157
Number of Observations Used	157





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	30.44723114	6.08944623	240.28	<.0001
Error	151	3.82682036	0.02534318		
Corrected Total	156	34.27405151			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.888346	2.919899	0.159195	5.452086

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	30.25105180	30.25105180	1193.66	<.0001
SEXC	1	0.00431473	0.00431473	0.17	0.6805
UCPDGR1	1	0.02428180	0.02428180	0.96	0.3292
TRTPN	2	0.16758281	0.08379141	3.31	0.0393

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	28.50951736	28.50951736	1124.94	<.0001
SEXC	1	0.00123600	0.00123600	0.05	0.8255
UCPDGR1	1	0.02438450	0.02438450	0.96	0.3282
TRTPN	2	0.16758281	0.08379141	3.31	0.0393



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42811763	1
2	5.50551993	2
3	5.43902467	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0130	0.7293
2	0.0130		0.0648
3	0.7293	0.0648	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.428118	5.391801	5.464434
2	5.505520	5.456182	5.554858
3	5.439025	5.388057	5.489993



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.077402	-0.138244	-0.016561
1	3	-0.010907	-0.073062	0.051248
2	3	0.066495	-0.004123	0.137114

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	157
Number of Observations Used	157



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	29.37063439	5.87412688	184.52	<.0001
Error	151	4.80704014	0.03183470		
Corrected Total	156	34.17767454			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.859351	3.280121	0.178423	5.439520

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	29.15355753	29.15355753	915.78	<.0001
SEXC	1	0.00073496	0.00073496	0.02	0.8794
UCPDGR1	1	0.02015189	0.02015189	0.63	0.4275
TRTPN	2	0.19619001	0.09809501	3.08	0.0488

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	26.70590781	26.70590781	838.89	<.0001
SEXC	1	0.00031025	0.00031025	0.01	0.9215
UCPDGR1	1	0.01971417	0.01971417	0.62	0.4326
TRTPN	2	0.19619001	0.09809501	3.08	0.0488



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.41479827	1
2	5.49853862	2
3	5.42656003	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0164	0.7391
2	0.0164		0.0744
3	0.7391	0.0744	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.414798	5.374096	5.455501
2	5.498539	5.443242	5.553835
3	5.426560	5.369436	5.483684



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.083740	-0.151930	-0.015551
1	3	-0.011762	-0.081423	0.057900
2	3	0.071979	-0.007169	0.151127

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	157
Number of Observations Used	157





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	29.24320595	5.84864119	186.60	<.0001
Error	151	4.73270973	0.03134245		
Corrected Total	156	33.97591567			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.860704	3.242370	0.177038	5.460142

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	29.01215204	29.01215204	925.65	<.0001
SEXC	1	0.05040778	0.05040778	1.61	0.2067
UCPDGR1	1	0.00508285	0.00508285	0.16	0.6877
TRTPN	2	0.17556327	0.08778164	2.80	0.0639

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	26.86900638	26.86900638	857.27	<.0001
SEXC	1	0.05775189	0.05775189	1.84	0.1767
UCPDGR1	1	0.00354035	0.00354035	0.11	0.7373
TRTPN	2	0.17556327	0.08778164	2.80	0.0639



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42645247	1
2	5.50725337	2
3	5.46066359	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0196	0.3297
2	0.0196		0.2430
3	0.3297	0.2430	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.426452	5.386066	5.466839
2	5.507253	5.452386	5.562121
3	5.460664	5.403983	5.517344



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=ICAM1 Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.080801	-0.148461	-0.013140
1	3	-0.034211	-0.103332	0.034910
2	3	0.046590	-0.031944	0.125123

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7.21009675	1.44201935	98.86	<.0001
Error	153	2.23179509	0.01458690		
Corrected Total	158	9.44189184			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.763628	2.150129	0.120776	5.617161

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.92938850	6.92938850	475.04	<.0001
SEXC	1	0.02026485	0.02026485	1.39	0.2404
UCPDGR1	1	0.21898597	0.21898597	15.01	0.0002
TRTPN	2	0.04145743	0.02072872	1.42	0.2446

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.68252131	6.68252131	458.12	<.0001
SEXC	1	0.00068000	0.00068000	0.05	0.8293
UCPDGR1	1	0.20395318	0.20395318	13.98	0.0003
TRTPN	2	0.04145743	0.02072872	1.42	0.2446



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.63000839	1
2	5.61153650	2
3	5.59041631	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4301	0.0972
2	0.4301		0.4363
3	0.0972	0.4363	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.630008	5.602817	5.657200
2	5.611536	5.573992	5.649081
3	5.590416	5.551835	5.628997



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.018472	-0.027658	0.064602
1	3	0.039592	-0.007279	0.086463
2	3	0.021120	-0.032342	0.074582

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7.31237847	1.46247569	82.76	<.0001
Error	153	2.70362057	0.01767072		
Corrected Total	158	10.01599904			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.730070	2.377490	0.132931	5.591245

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.19849077	7.19849077	407.37	<.0001
SEXC	1	0.00210651	0.00210651	0.12	0.7304
UCPDGR1	1	0.00149718	0.00149718	0.08	0.7714
TRTPN	2	0.11028401	0.05514201	3.12	0.0470

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.11393159	7.11393159	402.58	<.0001
SEXC	1	0.00150837	0.00150837	0.09	0.7706
UCPDGR1	1	0.00050453	0.00050453	0.03	0.8660
TRTPN	2	0.11028401	0.05514201	3.12	0.0470



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.61605120	1
2	5.55496310	2
3	5.57611287	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0187	0.1282
2	0.0187		0.4787
3	0.1282	0.4787	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.616051	5.586123	5.645979
2	5.554963	5.513641	5.596286
3	5.576113	5.533649	5.618577



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.061088	0.010315	0.111861
1	3	0.039938	-0.011650	0.091526
2	3	-0.021150	-0.079992	0.037692

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.09286903	1.21857381	73.89	<.0001
Error	153	2.52322040	0.01649164		
Corrected Total	158	8.61608943			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.707150	2.321153	0.128420	5.532586

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.99281367	5.99281367	363.39	<.0001
SEXC	1	0.03147872	0.03147872	1.91	0.1691
UCPDGR1	1	0.00882176	0.00882176	0.53	0.4657
TRTPN	2	0.05975487	0.02987743	1.81	0.1669

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.77050386	5.77050386	349.90	<.0001
SEXC	1	0.02183431	0.02183431	1.32	0.2517
UCPDGR1	1	0.00996334	0.00996334	0.60	0.4382
TRTPN	2	0.05975487	0.02987743	1.81	0.1669



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.55100260	1
2	5.50381234	2
3	5.53719127	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0592	0.5848
2	0.0592		0.2478
3	0.5848	0.2478	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.551003	5.522090	5.579915
2	5.503812	5.463892	5.543732
3	5.537191	5.496169	5.578214



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.047190	-0.001859	0.096240
1	3	0.013811	-0.036026	0.063649
2	3	-0.033379	-0.090224	0.023466

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7.77319096	1.55463819	62.73	<.0001
Error	153	3.79179715	0.02478299		
Corrected Total	158	11.56498811			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.672131	2.856671	0.157426	5.510824

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.70616663	7.70616663	310.95	<.0001
SEXC	1	0.00570056	0.00570056	0.23	0.6322
UCPDGR1	1	0.01889237	0.01889237	0.76	0.3840
TRTPN	2	0.04243141	0.02121570	0.86	0.4269

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.56782292	7.56782292	305.36	<.0001
SEXC	1	0.01044296	0.01044296	0.42	0.5172
UCPDGR1	1	0.01643896	0.01643896	0.66	0.4167
TRTPN	2	0.04243141	0.02121570	0.86	0.4269



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.50857300	1
2	5.48765488	2
3	5.53375562	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4929	0.4167
2	0.4929		0.1932
3	0.4167	0.1932	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.508573	5.473130	5.544016
2	5.487655	5.438718	5.536592
3	5.533756	5.483467	5.584044



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=PLAT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.020918	-0.039210	0.081047
1	3	-0.025183	-0.086277	0.035911
2	3	-0.046101	-0.115786	0.023584

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19.47760322	3.89552064	79.93	<.0001
Error	143	6.96933434	0.04873660		
Corrected Total	148	26.44693757			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.736479	4.031365	0.220764	5.476152

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	18.24707328	18.24707328	374.40	<.0001
SEXC	1	0.51006926	0.51006926	10.47	0.0015
UCPDGR1	1	0.06123640	0.06123640	1.26	0.2642
TRTPN	2	0.65922428	0.32961214	6.76	0.0016

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.24199623	14.24199623	292.22	<.0001
SEXC	1	0.38825354	0.38825354	7.97	0.0054
UCPDGR1	1	0.05422802	0.05422802	1.11	0.2933
TRTPN	2	0.65922428	0.32961214	6.76	0.0016



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.42850134	1
2	5.58860844	2
3	5.49306164	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0003	0.1567
2	0.0003		0.0622
3	0.1567	0.0622	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.428501	5.376831	5.480171
2	5.588608	5.519231	5.657986
3	5.493062	5.419496	5.566627



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.160107	-0.246239	-0.073975
1	3	-0.064560	-0.154191	0.025071
2	3	0.095547	-0.004926	0.196019

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	18.08039589	3.61607918	37.69	<.0001
Error	143	13.71845828	0.09593327		
Corrected Total	148	31.79885416			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.568586	5.455106	0.309731	5.677817

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	17.68987820	17.68987820	184.40	<.0001
SEXC	1	0.07989082	0.07989082	0.83	0.3630
UCPDGR1	1	0.00029656	0.00029656	0.00	0.9557
TRTPN	2	0.31033029	0.15516515	1.62	0.2020

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	15.01376844	15.01376844	156.50	<.0001
SEXC	1	0.06965780	0.06965780	0.73	0.3956
UCPDGR1	1	0.00046293	0.00046293	0.00	0.9447
TRTPN	2	0.31033029	0.15516515	1.62	0.2020



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.65084322	1
2	5.75730099	2
3	5.66243958	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0838	0.8556
2	0.0838		0.1856
3	0.8556	0.1856	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.650843	5.578350	5.723336
2	5.757301	5.659965	5.854637
3	5.662440	5.559227	5.765652



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.106458	-0.227301	0.014385
1	3	-0.011596	-0.137348	0.114156
2	3	0.094861	-0.046101	0.235824

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.62069405	4.12413881	43.07	<.0001
Error	143	13.69331697	0.09575746		
Corrected Total	148	34.31401102			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.600941	5.476573	0.309447	5.650377

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	20.16538710	20.16538710	210.59	<.0001
SEXC	1	0.19813389	0.19813389	2.07	0.1525
UCPDGR1	1	0.07350442	0.07350442	0.77	0.3824
TRTPN	2	0.18366863	0.09183432	0.96	0.3857

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	16.91890025	16.91890025	176.68	<.0001
SEXC	1	0.12060571	0.12060571	1.26	0.2636
UCPDGR1	1	0.07946915	0.07946915	0.83	0.3638
TRTPN	2	0.18366863	0.09183432	0.96	0.3857



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.63981355	1
2	5.71436506	2
3	5.62772656	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2242	0.8494
2	0.2242		0.2260
3	0.8494	0.2260	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.639814	5.567387	5.712240
2	5.714365	5.617118	5.811612
3	5.627727	5.524609	5.730844



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.074552	-0.195284	0.046181
1	3	0.012087	-0.113550	0.137724
2	3	0.086639	-0.054195	0.227472

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	17.52059166	3.50411833	46.01	<.0001
Error	143	10.89136352	0.07616338		
Corrected Total	148	28.41195518			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.616663	4.901288	0.275977	5.630706

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	17.06902797	17.06902797	224.11	<.0001
SEXC	1	0.00370037	0.00370037	0.05	0.8259
UCPDGR1	1	0.02376652	0.02376652	0.31	0.5773
TRTPN	2	0.42409680	0.21204840	2.78	0.0651

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.95949672	14.95949672	196.41	<.0001
SEXC	1	0.00013107	0.00013107	0.00	0.9670
UCPDGR1	1	0.02609144	0.02609144	0.34	0.5593
TRTPN	2	0.42409680	0.21204840	2.78	0.0651



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	5.59684081	1
2	5.71945542	2
3	5.60347378	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0259	0.9070
2	0.0259		0.0700
3	0.9070	0.0700	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	5.596841	5.532248	5.661434
2	5.719455	5.632726	5.806184
3	5.603474	5.511509	5.695438



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UPGF2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.122615	-0.230289	-0.014941
1	3	-0.006633	-0.118681	0.105415
2	3	0.115982	-0.009619	0.241582

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	14.13536537	2.82707307	42.68	<.0001
Error	143	9.47308059	0.06624532		
Corrected Total	148	23.60844596			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.598742	4.079104	0.257382	6.309759

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.35678376	12.35678376	186.53	<.0001
SEXC	1	0.70098244	0.70098244	10.58	0.0014
UCPDGR1	1	0.00679057	0.00679057	0.10	0.7493
TRTPN	2	1.07080860	0.53540430	8.08	0.0005

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.29728793	10.29728793	155.44	<.0001
SEXC	1	0.58933213	0.58933213	8.90	0.0034
UCPDGR1	1	0.01375978	0.01375978	0.21	0.6493
TRTPN	2	1.07080860	0.53540430	8.08	0.0005



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.28156805	1
2	6.46100384	2
3	6.25083602	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0005	0.5610
2	0.0005		0.0005
3	0.5610	0.0005	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.281568	6.221302	6.341834
2	6.461004	6.380212	6.541796
3	6.250836	6.165331	6.336341



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.179436	-0.279563	-0.079309
1	3	0.030732	-0.073520	0.134984
2	3	0.210168	0.092736	0.327600

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12.51018734	2.50203747	13.68	<.0001
Error	143	26.15457522	0.18289913		
Corrected Total	148	38.66476256			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.323555	6.975041	0.427667	6.131391

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.35097697	12.35097697	67.53	<.0001
SEXC	1	0.03164398	0.03164398	0.17	0.6781
UCPDGR1	1	0.01170155	0.01170155	0.06	0.8007
TRTPN	2	0.11586484	0.05793242	0.32	0.7290

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.80736730	11.80736730	64.56	<.0001
SEXC	1	0.04218861	0.04218861	0.23	0.6318
UCPDGR1	1	0.00935278	0.00935278	0.05	0.8214
TRTPN	2	0.11586484	0.05793242	0.32	0.7290



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.10167990	1
2	6.16687710	2
3	6.13985051	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4398	0.6638
2	0.4398		0.7846
3	0.6638	0.7846	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.101680	6.001542	6.201818
2	6.166877	6.032632	6.301122
3	6.139851	5.997774	6.281927



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.065197	-0.231569	0.101174
1	3	-0.038171	-0.211397	0.135056
2	3	0.027027	-0.168099	0.222153

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	25.26854620	5.05370924	17.43	<.0001
Error	143	41.47305135	0.29002134		
Corrected Total	148	66.74159756			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.378603	8.912346	0.538536	6.042587

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.61066315	24.61066315	84.86	<.0001
SEXC	1	0.30349351	0.30349351	1.05	0.3081
UCPDGR1	1	0.22818077	0.22818077	0.79	0.3766
TRTPN	2	0.12620878	0.06310439	0.22	0.8047

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	24.55161346	24.55161346	84.65	<.0001
SEXC	1	0.16430857	0.16430857	0.57	0.4529
UCPDGR1	1	0.19573257	0.19573257	0.67	0.4127
TRTPN	2	0.12620878	0.06310439	0.22	0.8047



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.05587906	1
2	6.04231319	2
3	5.98392058	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8983	0.5154
2	0.8983		0.6392
3	0.5154	0.6392	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.055879	5.929781	6.181977
2	6.042313	5.873266	6.211360
3	5.983921	5.805012	6.162829



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.013566	-0.195936	0.223068
1	3	0.071958	-0.146175	0.290092
2	3	0.058393	-0.187318	0.304103

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	149
Number of Observations Used	149





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: LOGAVAL**

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.31373590	4.46274718	15.98	<.0001
Error	143	39.93132678	0.27924005		
Corrected Total	148	62.24506268			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.358482	8.711594	0.528432	6.065844

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	21.59383366	21.59383366	77.33	<.0001
SEXC	1	0.35652739	0.35652739	1.28	0.2604
UCPDGR1	1	0.06849979	0.06849979	0.25	0.6212
TRTPN	2	0.29487506	0.14743753	0.53	0.5909

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	22.01497057	22.01497057	78.84	<.0001
SEXC	1	0.25898751	0.25898751	0.93	0.3371
UCPDGR1	1	0.09447024	0.09447024	0.34	0.5617
TRTPN	2	0.29487506	0.14743753	0.53	0.5909



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.01606671	1
2	6.06938220	2
3	6.12563750	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6090	0.3133
2	0.6090		0.6453
3	0.3133	0.6453	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.016067	5.892335	6.139799
2	6.069382	5.903507	6.235257
3	6.125638	5.950086	6.301189



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=UTXB2CRE Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.053315	-0.258887	0.152256
1	3	-0.109571	-0.323612	0.104470
2	3	-0.056255	-0.297356	0.184845

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01335781	0.00267156	5.80	<.0001
Error	153	0.07048119	0.00046066		
Corrected Total	158	0.08383899			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.159327	45.02138	0.021463	0.047673

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.01081500	0.01081500	23.48	<.0001
SEXC	1	0.00027124	0.00027124	0.59	0.4441
UCPDGR1	1	0.00069413	0.00069413	1.51	0.2215
TRTPN	2	0.00157744	0.00078872	1.71	0.1839

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.01102038	0.01102038	23.92	<.0001
SEXC	1	0.00009090	0.00009090	0.20	0.6575
UCPDGR1	1	0.00072213	0.00072213	1.57	0.2125
TRTPN	2	0.00157744	0.00078872	1.71	0.1839



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04484052	1
2	0.05249064	2
3	0.04737360	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.0662	0.5496
2	0.0662		0.2892
3	0.5496	0.2892	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.044841	0.040004	0.049677
2	0.052491	0.045842	0.059139
3	0.047374	0.040512	0.054236



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007650	-0.015818	0.000518
1	3	-0.002533	-0.010877	0.005811
2	3	0.005117	-0.004387	0.014622

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01642730	0.00328546	7.72	<.0001
Error	153	0.06511610	0.00042560		
Corrected Total	158	0.08154340			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.201455	43.38842	0.020630	0.047547

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.01220506	0.01220506	28.68	<.0001
SEXC	1	0.00153750	0.00153750	3.61	0.0592
UCPDGR1	1	0.00042378	0.00042378	1.00	0.3199
TRTPN	2	0.00226096	0.00113048	2.66	0.0734

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.01004911	0.01004911	23.61	<.0001
SEXC	1	0.00197885	0.00197885	4.65	0.0326
UCPDGR1	1	0.00046808	0.00046808	1.10	0.2960
TRTPN	2	0.00226096	0.00113048	2.66	0.0734



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04618836	1
2	0.05257650	2
3	0.04207853	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1100	0.3130
2	0.1100		0.0246
3	0.3130	0.0246	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.046188	0.041539	0.050837
2	0.052576	0.046186	0.058967
3	0.042079	0.035483	0.048674



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.006388	-0.014239	0.001463
1	3	0.004110	-0.003910	0.012130
2	3	0.010498	0.001362	0.019634

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01208560	0.00241712	3.23	0.0084
Error	153	0.11446534	0.00074814		
Corrected Total	158	0.12655094			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.095500	58.21941	0.027352	0.046981

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.00892913	0.00892913	11.94	0.0007
SEXC	1	0.00059919	0.00059919	0.80	0.3722
UCPDGR1	1	0.00201257	0.00201257	2.69	0.1030
TRTPN	2	0.00054473	0.00027236	0.36	0.6955

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.01065745	0.01065745	14.25	0.0002
SEXC	1	0.00014500	0.00014500	0.19	0.6604
UCPDGR1	1	0.00190885	0.00190885	2.55	0.1123
TRTPN	2	0.00054473	0.00027236	0.36	0.6955



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04820182	1
2	0.04656606	2
3	0.04361082	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7566	0.3950
2	0.7566		0.6305
3	0.3950	0.6305	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.048202	0.042038	0.054366
2	0.046566	0.038093	0.055039
3	0.043611	0.034866	0.052356



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=BASO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.001636	-0.008774	0.012045
1	3	0.004591	-0.006043	0.015225
2	3	0.002955	-0.009157	0.015068

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.01296613	0.00259323	6.59	<.0001
Error	153	0.06021626	0.00039357		
Corrected Total	158	0.07318239			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.177176	45.19110	0.019839	0.043899

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.01041933	0.01041933	26.47	<.0001
SEXC	1	0.00034433	0.00034433	0.87	0.3511
UCPDGR1	1	0.00001361	0.00001361	0.03	0.8527
TRTPN	2	0.00218887	0.00109443	2.78	0.0651

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.00936754	0.00936754	23.80	<.0001
SEXC	1	0.00040016	0.00040016	1.02	0.3149
UCPDGR1	1	0.00001784	0.00001784	0.05	0.8317
TRTPN	2	0.00218887	0.00109443	2.78	0.0651



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.04204875	1
2	0.04972160	2
3	0.04014794	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.0464	0.6270
2	0.0464		0.0329
3	0.6270	0.0329	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.042049	0.037578	0.046519
2	0.049722	0.043576	0.055867
3	0.040148	0.033805	0.046491



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=BASO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007673	-0.015223	-0.000123
1	3	0.001901	-0.005812	0.009613
2	3	0.009574	0.000789	0.018359

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	164152.0136	32830.4027	69.55	<.0001
Error	153	72223.0430	472.0460		
Corrected Total	158	236375.0566			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.694456	11.71663	21.72662	185.4340

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	163330.7512	163330.7512	346.01	<.0001
SEXC	1	1.0826	1.0826	0.00	0.9619
UCPDGR1	1	169.4400	169.4400	0.36	0.5500
TRTPN	2	650.7398	325.3699	0.69	0.5035

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	160169.1891	160169.1891	339.31	<.0001
SEXC	1	13.6014	13.6014	0.03	0.8654
UCPDGR1	1	126.5737	126.5737	0.27	0.6053
TRTPN	2	650.7398	325.3699	0.69	0.5035



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	183.747045	1
2	185.389635	2
3	188.754732	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6953	0.2422
2	0.6953		0.4902
3	0.2422	0.4902	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	183.747045	178.855599	188.638490
2	185.389635	178.659263	192.120006
3	188.754732	181.817718	195.691746



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.642590	-9.911377	6.626197
1	3	-5.007688	-13.433750	3.418375
2	3	-3.365098	-12.977043	6.246848

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	137794.3079	27558.8616	61.21	<.0001
Error	153	68885.6669	450.2331		
Corrected Total	158	206679.9748			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.666704	11.57304	21.21870	183.3459

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	134736.1044	134736.1044	299.26	<.0001
SEXC	1	1077.5798	1077.5798	2.39	0.1239
UCPDGR1	1	472.1678	472.1678	1.05	0.3074
TRTPN	2	1508.4559	754.2280	1.68	0.1907

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	132328.0504	132328.0504	293.91	<.0001
SEXC	1	739.3175	739.3175	1.64	0.2020
UCPDGR1	1	362.6102	362.6102	0.81	0.3709
TRTPN	2	1508.4559	754.2280	1.68	0.1907



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	181.276862	1
2	184.079663	2
3	188.895075	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4940	0.0694
2	0.4940		0.3125
3	0.0694	0.3125	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	181.276862	176.499768	186.053956
2	184.079663	177.506633	190.652692
3	188.895075	182.120234	195.669917



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.802801	-10.878281	5.272679
1	3	-7.618213	-15.847292	0.610866
2	3	-4.815412	-14.202651	4.571826

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	175261.0768	35052.2154	69.71	<.0001
Error	153	76937.9923	502.8627		
Corrected Total	158	252199.0692			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.694931	11.85501	22.42460	189.1572

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	173957.4610	173957.4610	345.93	<.0001
SEXC	1	2.5472	2.5472	0.01	0.9434
UCPDGR1	1	28.9696	28.9696	0.06	0.8106
TRTPN	2	1272.0991	636.0495	1.26	0.2852

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	171545.0456	171545.0456	341.14	<.0001
SEXC	1	11.3315	11.3315	0.02	0.8809
UCPDGR1	1	58.6723	58.6723	0.12	0.7331
TRTPN	2	1272.0991	636.0495	1.26	0.2852



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	186.492042	1
2	190.614749	2
3	193.181661	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3414	0.1307
2	0.3414		0.6100
3	0.1307	0.6100	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	186.492042	181.443455	191.540628
2	190.614749	183.668161	197.561338
3	193.181661	186.021791	200.341530



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=CHOL Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-4.122708	-12.657134	4.411719
1	3	-6.689619	-15.386374	2.007136
2	3	-2.566912	-12.487646	7.353823

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3255.854391	651.170878	17.00	<.0001
Error	153	5860.044980	38.300948		
Corrected Total	158	9115.899371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.357162	8.802356	6.188776	70.30818

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	2661.663073	2661.663073	69.49	<.0001
SEXC	1	420.284157	420.284157	10.97	0.0012
UCPDGR1	1	19.867188	19.867188	0.52	0.4725
TRTPN	2	154.039974	77.019987	2.01	0.1374

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2244.193085	2244.193085	58.59	<.0001
SEXC	1	364.536231	364.536231	9.52	0.0024
UCPDGR1	1	20.484928	20.484928	0.53	0.4657
TRTPN	2	154.039974	77.019987	2.01	0.1374



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	69.5405372	1
2	71.6146289	2
3	69.0896524	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0842	0.7119
2	0.0842		0.0724
3	0.7119	0.0724	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	69.540537	68.147967	70.933107
2	71.614629	69.692652	73.536606
3	69.089652	67.104713	71.074592



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.074092	-4.431579	0.283396
1	3	0.450885	-1.956880	2.858649
2	3	2.524976	-0.232585	5.282538

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3114.91125	622.98225	10.40	<.0001
Error	153	9166.45982	59.91150		
Corrected Total	158	12281.37107			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.253629	11.06745	7.740252	69.93711

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	2952.183691	2952.183691	49.28	<.0001
SEXC	1	67.017258	67.017258	1.12	0.2919
UCPDGR1	1	0.029864	0.029864	0.00	0.9822
TRTPN	2	95.680441	47.840220	0.80	0.4519

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2635.142166	2635.142166	43.98	<.0001
SEXC	1	67.050462	67.050462	1.12	0.2918
UCPDGR1	1	0.018227	0.018227	0.00	0.9861
TRTPN	2	95.680441	47.840220	0.80	0.4519



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	70.0145100	1
2	70.6125784	2
3	68.4920380	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6892	0.3195
2	0.6892		0.2264
3	0.3195	0.2264	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	70.014510	68.272834	71.756186
2	70.612578	68.208777	73.016380
3	68.492038	66.009491	70.974585



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.598068	-3.546559	2.350423
1	3	1.522472	-1.488900	4.533844
2	3	2.120540	-1.328319	5.569400

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	3481.38084	696.27617	10.36	<.0001
Error	153	10284.05313	67.21603		
Corrected Total	158	13765.43396			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.252907	11.83985	8.198538	69.24528

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	3266.767934	3266.767934	48.60	<.0001
SEXC	1	10.876924	10.876924	0.16	0.6880
UCPDGR1	1	127.366903	127.366903	1.89	0.1707
TRTPN	2	76.369076	38.184538	0.57	0.5678

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	3392.319257	3392.319257	50.47	<.0001
SEXC	1	33.782739	33.782739	0.50	0.4794
UCPDGR1	1	132.522567	132.522567	1.97	0.1623
TRTPN	2	76.369076	38.184538	0.57	0.5678



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	69.7063866	1
2	68.0296333	2
3	69.3013203	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2905	0.8022
2	0.2905		0.4927
3	0.8022	0.4927	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	69.706387	67.861589	71.551184
2	68.029633	65.483507	70.575759
3	69.301320	66.671786	71.930855



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.676753	-1.446312	4.799819
1	3	0.405066	-2.784603	3.594736
2	3	-1.271687	-4.924747	2.381373

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	2916.07274	583.21455	9.15	<.0001
Error	153	9751.66311	63.73636		
Corrected Total	158	12667.73585			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.230197	11.32564	7.983506	70.49057

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	2639.627916	2639.627916	41.41	<.0001
SEXC	1	194.214303	194.214303	3.05	0.0829
UCPDGR1	1	36.526762	36.526762	0.57	0.4502
TRTPN	2	45.703759	22.851879	0.36	0.6993

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	2651.610864	2651.610864	41.60	<.0001
SEXC	1	218.643164	218.643164	3.43	0.0659
UCPDGR1	1	35.426224	35.426224	0.56	0.4571
TRTPN	2	45.703759	22.851879	0.36	0.6993



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	70.3055448	1
2	69.4552076	2
3	70.9709955	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5815	0.6727
2	0.5815		0.4012
3	0.6727	0.4012	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	70.305545	68.509133	72.101957
2	69.455208	66.975862	71.934553
3	70.970996	68.410429	73.531562



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=DIABP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.850337	-2.190816	3.891490
1	3	-0.665451	-3.771461	2.440559
2	3	-1.515788	-5.073035	2.041459

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.87207655	0.37441531	90.28	<.0001
Error	153	0.63451339	0.00414715		
Corrected Total	158	2.50658994			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.746862	31.71055	0.064398	0.203082

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.84007059	1.84007059	443.70	<.0001
SEXC	1	0.00083894	0.00083894	0.20	0.6535
UCPDGR1	1	0.00528128	0.00528128	1.27	0.2609
TRTPN	2	0.02588574	0.01294287	3.12	0.0469

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.68012479	1.68012479	405.13	<.0001
SEXC	1	0.00277298	0.00277298	0.67	0.4148
UCPDGR1	1	0.00553153	0.00553153	1.33	0.2499
TRTPN	2	0.02588574	0.01294287	3.12	0.0469



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.19441771	1
2	0.22407078	2
3	0.19557732	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0185	0.9270
2	0.0185		0.0504
3	0.9270	0.0504	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.194418	0.179892	0.208943
2	0.224071	0.204088	0.244054
3	0.195577	0.175012	0.216142



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.029653	-0.054251	-0.005055
1	3	-0.001160	-0.026127	0.023807
2	3	0.028493	-0.000046045	0.057033

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.90232534	0.18046507	36.56	<.0001
Error	153	0.75519290	0.00493590		
Corrected Total	158	1.65751824			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.544383	35.31679	0.070256	0.198931

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.87168660	0.87168660	176.60	<.0001
SEXC	1	0.00006514	0.00006514	0.01	0.9087
UCPDGR1	1	0.00783698	0.00783698	1.59	0.2096
TRTPN	2	0.02273662	0.01136831	2.30	0.1034

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.78853815	0.78853815	159.76	<.0001
SEXC	1	0.00045953	0.00045953	0.09	0.7607
UCPDGR1	1	0.00863554	0.00863554	1.75	0.1879
TRTPN	2	0.02273662	0.01136831	2.30	0.1034



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.19441746	1
2	0.21849879	2
3	0.18695076	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0782	0.5889
2	0.0782		0.0471
3	0.5889	0.0471	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.194417	0.178570	0.210264
2	0.218499	0.196698	0.240300
3	0.186951	0.164515	0.209386



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.024081	-0.050917	0.002754
1	3	0.007467	-0.019771	0.034705
2	3	0.031548	0.000413	0.062683

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.23273543	0.24654709	47.45	<.0001
Error	153	0.79494884	0.00519574		
Corrected Total	158	2.02768428			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.607952	38.68026	0.072082	0.186352

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.21169093	1.21169093	233.21	<.0001
SEXC	1	0.00007183	0.00007183	0.01	0.9066
UCPDGR1	1	0.01182699	0.01182699	2.28	0.1334
TRTPN	2	0.00914568	0.00457284	0.88	0.4168

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.10199820	1.10199820	212.10	<.0001
SEXC	1	0.00161148	0.00161148	0.31	0.5784
UCPDGR1	1	0.01208173	0.01208173	2.33	0.1293
TRTPN	2	0.00914568	0.00457284	0.88	0.4168



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.18151214	1
2	0.19885057	2
3	0.18130391	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2154	0.9883
2	0.2154		0.2796
3	0.9883	0.2796	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.181512	0.165253	0.197771
2	0.198851	0.176483	0.221218
3	0.181304	0.158285	0.204322



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.017338	-0.044871	0.010195
1	3	0.000208	-0.027737	0.028154
2	3	0.017547	-0.014398	0.049491

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	0.83455844	0.16691169	31.12	<.0001
Error	153	0.82055980	0.00536314		
Corrected Total	158	1.65511824			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.504229	44.22376	0.073233	0.165597

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.80226564	0.80226564	149.59	<.0001
SEXC	1	0.00031424	0.00031424	0.06	0.8091
UCPDGR1	1	0.01425304	0.01425304	2.66	0.1051
TRTPN	2	0.01772553	0.00886276	1.65	0.1950

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.71861088	0.71861088	133.99	<.0001
SEXC	1	0.00033735	0.00033735	0.06	0.8023
UCPDGR1	1	0.01419349	0.01419349	2.65	0.1058
TRTPN	2	0.01772553	0.00886276	1.65	0.1950



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.15771252	1
2	0.18320349	2
3	0.16300855	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)  Dependent Variable: AVAL			
i/j	1	2	3
1		0.0738	0.7130
2	0.0738		0.2208
3	0.7130	0.2208	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.157713	0.141194	0.174231
2	0.183203	0.160479	0.205928
3	0.163009	0.139622	0.186395



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=EOS Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.025491	-0.053464	0.002482
1	3	-0.005296	-0.033688	0.023096
2	3	0.020195	-0.012260	0.052650

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.77237616	4.15447523	63.96	<.0001
Error	153	9.93756095	0.06495138		
Corrected Total	158	30.70993711			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.676406	4.691137	0.254856	5.432704

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	20.60845701	20.60845701	317.29	<.0001
SEXC	1	0.06943113	0.06943113	1.07	0.3028
UCPDGR1	1	0.00019335	0.00019335	0.00	0.9566
TRTPN	2	0.09429466	0.04714733	0.73	0.4856

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	19.73998852	19.73998852	303.92	<.0001
SEXC	1	0.06527702	0.06527702	1.01	0.3177
UCPDGR1	1	0.00068597	0.00068597	0.01	0.9183
TRTPN	2	0.09429466	0.04714733	0.73	0.4856



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	5.41811081	1
2	5.47788928	2
3	5.43257367	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2316	0.7736
2	0.2316		0.4392
3	0.7736	0.4392	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	5.418111	5.360728	5.475494
2	5.477889	5.397668	5.558110
3	5.432574	5.350540	5.514607



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HBA1C Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.059778	-0.158113	0.038556
1	3	-0.014463	-0.113596	0.084670
2	3	0.045316	-0.070114	0.160745

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	19510.03551	3902.00710	46.85	<.0001
Error	153	12742.56826	83.28476		
Corrected Total	158	32252.60377			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.604914	17.35488	9.126048	52.58491

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	19435.84162	19435.84162	233.37	<.0001
SEXC	1	10.35343	10.35343	0.12	0.7249
UCPDGR1	1	10.98677	10.98677	0.13	0.7170
TRTPN	2	52.85369	26.42685	0.32	0.7286

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	17749.31590	17749.31590	213.12	<.0001
SEXC	1	14.60016	14.60016	0.18	0.6760
UCPDGR1	1	8.70631	8.70631	0.10	0.7469
TRTPN	2	52.85369	26.42685	0.32	0.7286



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	52.7827977	1
2	53.2814964	2
3	51.6980414	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7774	0.5456
2	0.7774		0.4401
3	0.5456	0.4401	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	52.782798	50.729439	54.836157
2	53.281496	50.446243	56.116750
3	51.698041	48.784257	54.611826



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.498699	-3.977453	2.980056
1	3	1.084756	-2.452875	4.622388
2	3	1.583455	-2.457671	5.624581

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20845.12071	4169.02414	60.22	<.0001
Error	153	10592.58998	69.23261		
Corrected Total	158	31437.71069			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.663061	15.84404	8.320614	52.51572

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	20500.70671	20500.70671	296.11	<.0001
SEXC	1	20.39086	20.39086	0.29	0.5881
UCPDGR1	1	27.74674	27.74674	0.40	0.5276
TRTPN	2	296.27640	148.13820	2.14	0.1212

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	19217.11181	19217.11181	277.57	<.0001
SEXC	1	6.16961	6.16961	0.09	0.7657
UCPDGR1	1	42.28326	42.28326	0.61	0.4357
TRTPN	2	296.27640	148.13820	2.14	0.1212



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	53.7940369	1
2	52.2565123	2
3	50.4487364	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3397	0.0422
2	0.3397		0.3339
3	0.0422	0.3339	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	53.794037	51.921900	55.666173
2	52.256512	49.671489	54.841536
3	50.448736	47.792113	53.105360



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.537525	-1.634206	4.709255
1	3	3.345300	0.119888	6.570712
2	3	1.807776	-1.876694	5.492245

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	25138.66332	5027.73266	57.19	<.0001
Error	153	13450.44360	87.91140		
Corrected Total	158	38589.10692			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.651445	17.13959	9.376108	54.70440

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	24426.61355	24426.61355	277.85	<.0001
SEXC	1	18.80667	18.80667	0.21	0.6444
UCPDGR1	1	5.09682	5.09682	0.06	0.8100
TRTPN	2	688.14628	344.07314	3.91	0.0220

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	23271.91750	23271.91750	264.72	<.0001
SEXC	1	16.19433	16.19433	0.18	0.6684
UCPDGR1	1	0.29706	0.29706	0.00	0.9537
TRTPN	2	688.14628	344.07314	3.91	0.0220



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	56.7286972	1
2	52.6790646	2
3	52.4347511	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0266	0.0209
2	0.0266		0.9076
3	0.0209	0.9076	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	56.728697	54.619075	58.838319
2	52.679065	49.766124	55.592006
3	52.434751	49.441127	55.428375



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=HDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	4.049633	0.475558	7.623707
1	3	4.293946	0.659381	7.928511
2	3	0.244314	-3.907541	4.396169

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	122680.0416	24536.0083	73.69	<.0001
Error	153	50945.8578	332.9795		
Corrected Total	158	173625.8994			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.706577	16.43567	18.24772	111.0252

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	121785.3490	121785.3490	365.74	<.0001
SEXC	1	278.8726	278.8726	0.84	0.3616
UCPDGR1	1	288.0698	288.0698	0.87	0.3538
TRTPN	2	327.7502	163.8751	0.49	0.6123

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	116500.8868	116500.8868	349.87	<.0001
SEXC	1	407.5799	407.5799	1.22	0.2703
UCPDGR1	1	250.1445	250.1445	0.75	0.3874
TRTPN	2	327.7502	163.8751	0.49	0.6123



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	109.409582	1
2	111.127290	2
3	112.922924	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.6260	0.3296
2	0.6260		0.6612
3	0.3296	0.6612	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	109.409582	105.295057	113.524106
2	111.127290	105.474797	116.779783
3	112.922924	107.088604	118.757243



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.717708	-8.666079	5.230662
1	3	-3.513342	-10.610802	3.584118
2	3	-1.795634	-9.873603	6.282336

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	107435.2730	21487.0546	58.84	<.0001
Error	153	55874.2113	365.1909		
Corrected Total	158	163309.4843			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.657863	17.51187	19.10997	109.1258

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	103576.2066	103576.2066	283.62	<.0001
SEXC	1	271.6486	271.6486	0.74	0.3898
UCPDGR1	1	998.7512	998.7512	2.73	0.1002
TRTPN	2	2588.6666	1294.3333	3.54	0.0313

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	97829.80030	97829.80030	267.89	<.0001
SEXC	1	80.16123	80.16123	0.22	0.6401
UCPDGR1	1	801.66766	801.66766	2.20	0.1405
TRTPN	2	2588.66662	1294.33331	3.54	0.0313



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	106.221719	1
2	108.869567	2
3	116.212667	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4733	0.0088
2	0.4733		0.0884
3	0.0088	0.0884	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	106.221719	101.912774	110.530664
2	108.869567	102.949982	114.789152
3	116.212667	110.102663	122.322670



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.647848	-9.924544	4.628848
1	3	-9.990948	-17.423778	-2.558118
2	3	-7.343100	-15.802771	1.116571

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	119952.3723	23990.4745	50.68	<.0001
Error	153	72430.3572	473.4010		
Corrected Total	158	192382.7296			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.623509	19.10580	21.75778	113.8805

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	118483.8244	118483.8244	250.28	<.0001
SEXC	1	117.3550	117.3550	0.25	0.6193
UCPDGR1	1	12.6975	12.6975	0.03	0.8701
TRTPN	2	1338.4954	669.2477	1.41	0.2464

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	113759.0452	113759.0452	240.30	<.0001
SEXC	1	84.6454	84.6454	0.18	0.6730
UCPDGR1	1	33.6022	33.6022	0.07	0.7903
TRTPN	2	1338.4954	669.2477	1.41	0.2464



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	AVAL LSMEAN	LSMEAN Number
1	111.006527	1
2	114.785864	2
3	118.035520	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3689	0.1029
2	0.3689		0.5061
3	0.1029	0.5061	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	111.006527	106.100550	115.912505
2	114.785864	108.046081	121.525646
3	118.035520	111.078935	124.992104



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LDL Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-3.779337	-12.064267	4.505594
1	3	-7.028992	-15.491690	1.433705
2	3	-3.249656	-12.881469	6.382158

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	45.23069680	9.04613936	54.08	<.0001
Error	153	25.59398748	0.16728096		
Corrected Total	158	70.82468428			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.638629	15.32015	0.409000	2.669686

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	43.89143399	43.89143399	262.38	<.0001
SEXC	1	0.18687095	0.18687095	1.12	0.2922
UCPDGR1	1	0.10125490	0.10125490	0.61	0.4378
TRTPN	2	1.05113696	0.52556848	3.14	0.0460

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	41.78764123	41.78764123	249.81	<.0001
SEXC	1	0.12886948	0.12886948	0.77	0.3815
UCPDGR1	1	0.08899032	0.08899032	0.53	0.4669
TRTPN	2	1.05113696	0.52556848	3.14	0.0460



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.63197303	1
2	2.79747706	2
3	2.58309427	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0387	0.5434
2	0.0387		0.0210
3	0.5434	0.0210	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.631973	2.539827	2.724119
2	2.797477	2.669907	2.925048
3	2.583094	2.452517	2.713672



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.165504	-0.322338	-0.008671
1	3	0.048879	-0.109692	0.207450
2	3	0.214383	0.032720	0.396045

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	44.51132082	8.90226416	41.09	<.0001
Error	153	33.15077477	0.21667173		
Corrected Total	158	77.66209560			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.573141	17.91652	0.465480	2.598050

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	43.65012503	43.65012503	201.46	<.0001
SEXC	1	0.00008891	0.00008891	0.00	0.9839
UCPDGR1	1	0.33796971	0.33796971	1.56	0.2136
TRTPN	2	0.52313718	0.26156859	1.21	0.3019

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	42.22651854	42.22651854	194.89	<.0001
SEXC	1	0.02808828	0.02808828	0.13	0.7193
UCPDGR1	1	0.39753631	0.39753631	1.83	0.1776
TRTPN	2	0.52313718	0.26156859	1.21	0.3019



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.54818299	1
2	2.61279971	2
3	2.68883273	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4756	0.1257
2	0.4756		0.4686
3	0.1257	0.4686	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.548183	2.443312	2.653054
2	2.612800	2.467613	2.757987
3	2.688833	2.540223	2.837442



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.064617	-0.243108	0.113874
1	3	-0.140650	-0.321118	0.039819
2	3	-0.076033	-0.282782	0.130716

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	43.03069667	8.60613933	41.74	<.0001
Error	153	31.54732723	0.20619168		
Corrected Total	158	74.57802390			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.576989	17.59541	0.454083	2.580692

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	42.12140520	42.12140520	204.28	<.0001
SEXC	1	0.23752647	0.23752647	1.15	0.2848
UCPDGR1	1	0.20962406	0.20962406	1.02	0.3149
TRTPN	2	0.46214094	0.23107047	1.12	0.3287

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	41.23176435	41.23176435	199.97	<.0001
SEXC	1	0.11981418	0.11981418	0.58	0.4471
UCPDGR1	1	0.25336154	0.25336154	1.23	0.2694
TRTPN	2	0.46214094	0.23107047	1.12	0.3287



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.52305372	1
2	2.59458144	2
3	2.65296172	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4183	0.1469
2	0.4183		0.5683
3	0.1469	0.5683	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.523054	2.420750	2.625357
2	2.594581	2.452949	2.736214
3	2.652962	2.507991	2.797933



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.071528	-0.245649	0.102593
1	3	-0.129908	-0.305958	0.046142
2	3	-0.058380	-0.260067	0.143306

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	28.14771954	5.62954391	24.85	<.0001
Error	153	34.65557228	0.22650701		
Corrected Total	158	62.80329182			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.448189	21.30119	0.475928	2.234277

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	26.87663049	26.87663049	118.66	<.0001
SEXC	1	0.01236727	0.01236727	0.05	0.8156
UCPDGR1	1	0.02631394	0.02631394	0.12	0.7337
TRTPN	2	1.23240783	0.61620392	2.72	0.0690

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	26.79690205	26.79690205	118.30	<.0001
SEXC	1	0.01362084	0.01362084	0.06	0.8066
UCPDGR1	1	0.00849839	0.00849839	0.04	0.8467
TRTPN	2	1.23240783	0.61620392	2.72	0.0690



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	2.19459431	1
2	2.16007211	2
3	2.38534791	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7091	0.0428
2	0.7091		0.0369
3	0.0428	0.0369	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	2.194594	2.087369	2.301819
2	2.160072	2.011626	2.308518
3	2.385348	2.233403	2.537293



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=LYM Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.034522	-0.147975	0.217019
1	3	-0.190754	-0.375272	-0.006235
2	3	-0.225276	-0.436665	-0.013887

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.11915372	0.22383074	22.56	<.0001
Error	153	1.51831546	0.00992363		
Corrected Total	158	2.63746918			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.424329	22.28045	0.099617	0.447107

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.07110176	1.07110176	107.93	<.0001
SEXC	1	0.01571374	0.01571374	1.58	0.2102
UCPDGR1	1	0.02879358	0.02879358	2.90	0.0905
TRTPN	2	0.00354463	0.00177232	0.18	0.8366

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.06643060	1.06643060	107.46	<.0001
SEXC	1	0.00657936	0.00657936	0.66	0.4168
UCPDGR1	1	0.02719603	0.02719603	2.74	0.0999
TRTPN	2	0.00354463	0.00177232	0.18	0.8366



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.44831706	1
2	0.44726647	2
3	0.43699438	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9566	0.5633
2	0.9566		0.6476
3	0.5633	0.6476	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.448317	0.425877	0.470757
2	0.447266	0.416264	0.478269
3	0.436994	0.405155	0.468834



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.001051	-0.037066	0.039167
1	3	0.011323	-0.027292	0.049938
2	3	0.010272	-0.034031	0.054575

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.54964451	0.30992890	29.43	<.0001
Error	153	1.61151524	0.01053278		
Corrected Total	158	3.16115975			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.490214	24.21437	0.102629	0.423836

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.53253215	1.53253215	145.50	<.0001
SEXC	1	0.00137363	0.00137363	0.13	0.7185
UCPDGR1	1	0.00502711	0.00502711	0.48	0.4907
TRTPN	2	0.01071163	0.00535581	0.51	0.6024

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.48706756	1.48706756	141.18	<.0001
SEXC	1	0.00048990	0.00048990	0.05	0.8295
UCPDGR1	1	0.00413386	0.00413386	0.39	0.5319
TRTPN	2	0.01071163	0.00535581	0.51	0.6024



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.42501881	1
2	0.43266999	2
3	0.40990627	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7008	0.4541
2	0.7008		0.3260
3	0.4541	0.3260	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.425019	0.401900	0.448138
2	0.432670	0.400730	0.464610
3	0.409906	0.377104	0.442708



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.007651	-0.046920	0.031618
1	3	0.015113	-0.024670	0.054895
2	3	0.022764	-0.022879	0.068406

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.01097108	0.20219422	12.42	<.0001
Error	153	2.49084401	0.01628003		
Corrected Total	158	3.50181509			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.288699	31.27863	0.127593	0.407925

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	0.95624903	0.95624903	58.74	<.0001
SEXC	1	0.00007966	0.00007966	0.00	0.9443
UCPDGR1	1	0.03478220	0.03478220	2.14	0.1459
TRTPN	2	0.01986019	0.00993010	0.61	0.5447

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	0.98615088	0.98615088	60.57	<.0001
SEXC	1	0.00140107	0.00140107	0.09	0.7696
UCPDGR1	1	0.03214934	0.03214934	1.97	0.1620
TRTPN	2	0.01986019	0.00993010	0.61	0.5447



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.41938190	1
2	0.39614655	2
3	0.39785631	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3486	0.3912
2	0.3486		0.9526
3	0.3912	0.9526	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.419382	0.390640	0.448124
2	0.396147	0.356437	0.435856
3	0.397856	0.357075	0.438637



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.023235	-0.025586	0.072057
1	3	0.021526	-0.027934	0.070985
2	3	-0.001710	-0.058454	0.055035

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL** Analysis  
Value

Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	1.26519589	0.25303918	12.38	<.0001
Error	153	3.12827329	0.02044623		
Corrected Total	158	4.39346918			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.287972	34.83828	0.142990	0.410440

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	1.25965260	1.25965260	61.61	<.0001
SEXC	1	0.00088805	0.00088805	0.04	0.8352
UCPDGR1	1	0.00132165	0.00132165	0.06	0.7996
TRTPN	2	0.00333358	0.00166679	0.08	0.9218

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	1.22878088	1.22878088	60.10	<.0001
SEXC	1	0.00047016	0.00047016	0.02	0.8797
UCPDGR1	1	0.00103017	0.00103017	0.05	0.8227
TRTPN	2	0.00333358	0.00166679	0.08	0.9218



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	0.40820971	1
2	0.40841940	2
3	0.41895944	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9940	0.7021
2	0.9940		0.7438
3	0.7021	0.7438	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	0.408210	0.375999	0.440421
2	0.408419	0.363918	0.452920
3	0.418959	0.373257	0.464662



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=MONO Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.000210	-0.054922	0.054503
1	3	-0.010750	-0.066178	0.044678
2	3	-0.010540	-0.074132	0.053052

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	191.9610301	38.3922060	47.07	<.0001
Error	153	124.7867410	0.8155996		
Corrected Total	158	316.7477711			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.606038	21.35922	0.903106	4.228176

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	182.6723137	182.6723137	223.97	<.0001
SEXC	1	3.4189566	3.4189566	4.19	0.0423
UCPDGR1	1	0.0921569	0.0921569	0.11	0.7372
TRTPN	2	5.7776028	2.8888014	3.54	0.0314

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	169.3480277	169.3480277	207.64	<.0001
SEXC	1	3.2322581	3.2322581	3.96	0.0483
UCPDGR1	1	0.0327664	0.0327664	0.04	0.8414
TRTPN	2	5.7776028	2.8888014	3.54	0.0314



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.26128536	1
2	4.51935121	2
3	3.98045829	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1409	0.1151
2	0.1409		0.0086
3	0.1151	0.0086	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.261285	4.058014	4.464556
2	4.519351	4.238925	4.799777
3	3.980458	3.692144	4.268772



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.258066	-0.602535	0.086404
1	3	0.280827	-0.069259	0.630913
2	3	0.538893	0.138858	0.938928

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	161.4019511	32.2803902	28.40	<.0001
Error	153	173.8939131	1.1365615		
Corrected Total	158	335.2958642			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.481372	26.74070	1.066096	3.986792

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	157.1514461	157.1514461	138.27	<.0001
SEXC	1	0.4066432	0.4066432	0.36	0.5506
UCPDGR1	1	0.0891361	0.0891361	0.08	0.7798
TRTPN	2	3.7547257	1.8773628	1.65	0.1951

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	145.2667351	145.2667351	127.81	<.0001
SEXC	1	0.2544478	0.2544478	0.22	0.6368
UCPDGR1	1	0.1253861	0.1253861	0.11	0.7402
TRTPN	2	3.7547257	1.8773628	1.65	0.1951



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	3.93893362	1
2	4.25003410	2
3	3.84651074	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1327	0.6592
2	0.1327		0.0934
3	0.6592	0.0934	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	3.938934	3.698977	4.178891
2	4.250034	3.918997	4.581071
3	3.846511	3.506162	4.186859



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.311100	-0.717739	0.095538
1	3	0.092423	-0.320846	0.505692
2	3	0.403523	-0.068710	0.875756

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	147.5257477	29.5051495	29.83	<.0001
Error	153	151.3223467	0.9890349		
Corrected Total	158	298.8480943			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.493648	25.56437	0.994502	3.890189

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	143.6355384	143.6355384	145.23	<.0001
SEXC	1	0.0002054	0.0002054	0.00	0.9885
UCPDGR1	1	0.9064231	0.9064231	0.92	0.3399
TRTPN	2	2.9835809	1.4917904	1.51	0.2246

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	132.2617858	132.2617858	133.73	<.0001
SEXC	1	0.0662291	0.0662291	0.07	0.7962
UCPDGR1	1	1.0684112	1.0684112	1.08	0.3003
TRTPN	2	2.9835809	1.4917904	1.51	0.2246



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	3.88385997	1
2	4.08162109	2
3	3.69453988	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3047	0.3335
2	0.3047		0.0846
3	0.3335	0.0846	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	3.883860	3.660017	4.107703
2	4.081621	3.772815	4.390427
3	3.694540	3.377048	4.012032



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.197761	-0.577092	0.181570
1	3	0.189320	-0.196196	0.574836
2	3	0.387081	-0.053439	0.827601

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	147.6671183	29.5334237	18.64	<.0001
Error	153	242.4049081	1.5843458		
Corrected Total	158	390.0720264			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.378564	29.38963	1.258708	4.282830

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	145.6810948	145.6810948	91.95	<.0001
SEXC	1	0.0236896	0.0236896	0.01	0.9028
UCPDGR1	1	0.2770939	0.2770939	0.17	0.6764
TRTPN	2	1.6852400	0.8426200	0.53	0.5886

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	136.0252962	136.0252962	85.86	<.0001
SEXC	1	0.0809091	0.0809091	0.05	0.8215
UCPDGR1	1	0.2627030	0.2627030	0.17	0.6844
TRTPN	2	1.6852400	0.8426200	0.53	0.5886



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	4.19428388	1
2	4.44490312	2
3	4.27711675	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3040	0.7378
2	0.3040		0.5530
3	0.7378	0.5530	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	4.194284	3.910974	4.477594
2	4.444903	4.054058	4.835749
3	4.277117	3.875278	4.678956



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=NEUT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.250619	-0.730725	0.229487
1	3	-0.082833	-0.570767	0.405102
2	3	0.167786	-0.389765	0.725338

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6305.02838	1261.00568	20.00	<.0001
Error	153	9646.15401	63.04676		
Corrected Total	158	15951.18239			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.395270	6.812128	7.940199	116.5597

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	5240.681166	5240.681166	83.12	<.0001
SEXC	1	768.359695	768.359695	12.19	0.0006
UCPDGR1	1	104.195461	104.195461	1.65	0.2005
TRTPN	2	191.792056	95.896028	1.52	0.2218

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	3004.575358	3004.575358	47.66	<.0001
SEXC	1	684.050873	684.050873	10.85	0.0012
UCPDGR1	1	103.747704	103.747704	1.65	0.2015
TRTPN	2	191.792056	95.896028	1.52	0.2218



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	115.884208	1
2	117.761056	2
3	114.643586	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2216	0.4385
2	0.2216		0.0888
3	0.4385	0.0888	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	115.884208	114.096123	117.672294
2	117.761056	115.297125	120.224987
3	114.643586	112.033824	117.253349



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.876848	-4.898371	1.144676
1	3	1.240622	-1.914552	4.395796
2	3	3.117470	-0.478141	6.713081

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	7313.63834	1462.72767	18.47	<.0001
Error	153	12117.87110	79.20177		
Corrected Total	158	19431.50943			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.376380	7.652101	8.899538	116.3019

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	6783.936924	6783.936924	85.65	<.0001
SEXC	1	204.289533	204.289533	2.58	0.1103
UCPDGR1	1	246.954811	246.954811	3.12	0.0794
TRTPN	2	78.457072	39.228536	0.50	0.6104

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	4542.247940	4542.247940	57.35	<.0001
SEXC	1	134.321351	134.321351	1.70	0.1948
UCPDGR1	1	236.948327	236.948327	2.99	0.0857
TRTPN	2	78.457072	39.228536	0.50	0.6104



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	116.654694	1
2	116.016349	2
3	114.875755	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7101	0.3219
2	0.7101		0.5769
3	0.3219	0.5769	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	116.654694	114.650571	118.658816
2	116.016349	113.254724	118.777974
3	114.875755	111.950680	117.800830



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.638344	-2.748241	4.024930
1	3	1.778938	-1.757445	5.315322
2	3	1.140594	-2.889441	5.170629

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	5772.11023	1154.42205	13.28	<.0001
Error	153	13298.79543	86.92023		
Corrected Total	158	19070.90566			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.302666	8.055501	9.323102	115.7358

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	5297.220842	5297.220842	60.94	<.0001
SEXC	1	348.534382	348.534382	4.01	0.0470
UCPDGR1	1	94.759995	94.759995	1.09	0.2981
TRTPN	2	31.595015	15.797508	0.18	0.8340

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	4014.742783	4014.742783	46.19	<.0001
SEXC	1	403.422411	403.422411	4.64	0.0328
UCPDGR1	1	97.868391	97.868391	1.13	0.2903
TRTPN	2	31.595015	15.797508	0.18	0.8340



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	115.801270	1
2	114.727937	2
3	115.298953	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5509	0.7892
2	0.5509		0.7897
3	0.7892	0.7897	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	115.801270	113.701763	117.900777
2	114.727937	111.834876	117.620999
3	115.298953	112.234662	118.363244



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	1.073333	-2.474434	4.621099
1	3	0.502316	-3.202378	4.207011
2	3	-0.571016	-4.792856	3.650824

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	5800.90294	1160.18059	16.18	<.0001
Error	153	10972.09077	71.71301		
Corrected Total	158	16772.99371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.345848	7.237520	8.468354	117.0063

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	5248.189124	5248.189124	73.18	<.0001
SEXC	1	505.806801	505.806801	7.05	0.0088
UCPDGR1	1	37.835676	37.835676	0.53	0.4687
TRTPN	2	9.071337	4.535668	0.06	0.9387

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	3629.999776	3629.999776	50.62	<.0001
SEXC	1	420.642174	420.642174	5.87	0.0166
UCPDGR1	1	38.678996	38.678996	0.54	0.4638
TRTPN	2	9.071337	4.535668	0.06	0.9387



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	116.505229	1
2	116.438086	2
3	117.052093	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.9672	0.7486
2	0.9672		0.7522
3	0.7486	0.7522	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	116.505229	114.598207	118.412252
2	116.438086	113.810263	119.065910
3	117.052093	114.268739	119.835448



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=SYSBP Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.067143	-3.155362	3.289648
1	3	-0.546864	-3.911909	2.818181
2	3	-0.614007	-4.448786	3.220772

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	689662.162	137932.432	64.94	<.0001
Error	153	324969.549	2123.984		
Corrected Total	158	1014631.711			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.679717	33.11245	46.08670	139.1824

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	681568.6988	681568.6988	320.89	<.0001
SEXC	1	132.5984	132.5984	0.06	0.8030
UCPDGR1	1	588.5786	588.5786	0.28	0.5994
TRTPN	2	7372.2859	3686.1429	1.74	0.1798

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	661376.5256	661376.5256	311.38	<.0001
SEXC	1	1.0548	1.0548	0.00	0.9822
UCPDGR1	1	912.8549	912.8549	0.43	0.5131
TRTPN	2	7372.2859	3686.1429	1.74	0.1798



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	136.324783	1
2	133.195439	2
3	150.870390	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.7252	0.1114
2	0.7252		0.0891
3	0.1114	0.0891	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	136.324783	125.948089	146.701477
2	133.195439	118.911042	147.479835
3	150.870390	136.098686	165.642094



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	3.129345	-14.425380	20.684069
1	3	-14.545607	-32.490092	3.398878
2	3	-17.674952	-38.080178	2.730275

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	447584.6342	89516.9268	56.53	<.0001
Error	153	242261.0388	1583.4055		
Corrected Total	158	689845.6730			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.648818	28.32617	39.79203	140.4780

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	443109.8475	443109.8475	279.85	<.0001
SEXC	1	336.2256	336.2256	0.21	0.6456
UCPDGR1	1	868.6251	868.6251	0.55	0.4600
TRTPN	2	3269.9358	1634.9679	1.03	0.3586

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	435596.0419	435596.0419	275.10	<.0001
SEXC	1	662.5554	662.5554	0.42	0.5187
UCPDGR1	1	1022.7283	1022.7283	0.65	0.4228
TRTPN	2	3269.9358	1634.9679	1.03	0.3586



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	136.581283	1
2	147.326024	2
3	142.684932	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.1634	0.4376
2	0.1634		0.6035
3	0.4376	0.6035	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	136.581283	127.621872	145.540694
2	147.326024	134.992637	159.659411
3	142.684932	129.930795	155.439068



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-10.744741	-25.901783	4.412302
1	3	-6.103649	-21.597217	9.389920
2	3	4.641092	-12.977121	22.259306

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	451581.6694	90316.3339	54.38	<.0001
Error	153	254113.9532	1660.8755		
Corrected Total	158	705695.6226			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.639910	30.30663	40.75384	134.4717

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	449133.9603	449133.9603	270.42	<.0001
SEXC	1	995.9777	995.9777	0.60	0.4399
UCPDGR1	1	0.0012	0.0012	0.00	0.9993
TRTPN	2	1451.7302	725.8651	0.44	0.6468

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	438791.2171	438791.2171	264.19	<.0001
SEXC	1	994.4600	994.4600	0.60	0.4402
UCPDGR1	1	8.3518	8.3518	0.01	0.9436
TRTPN	2	1451.7302	725.8651	0.44	0.6468



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	132.011338	1
2	137.232446	2
3	138.791633	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5074	0.3999
2	0.5074		0.8647
3	0.3999	0.8647	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	132.011338	122.835369	141.187307
2	137.232446	124.600949	149.863943
3	138.791633	125.729216	151.854049



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=TRIG Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-5.221108	-20.744511	10.302295
1	3	-6.780295	-22.648358	9.087769
2	3	-1.559187	-19.603250	16.484876

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis Value**

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	335.6193842	67.1238768	52.15	<.0001
Error	153	196.9357642	1.2871619		
Corrected Total	158	532.5551484			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.630206	14.93868	1.134532	7.594591

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	321.0010523	321.0010523	249.39	<.0001
SEXC	1	1.4242467	1.4242467	1.11	0.2945
UCPDGR1	1	0.7700754	0.7700754	0.60	0.4404
TRTPN	2	12.4240099	6.2120049	4.83	0.0093

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	296.2578626	296.2578626	230.16	<.0001
SEXC	1	1.6237092	1.6237092	1.26	0.2631
UCPDGR1	1	0.4931704	0.4931704	0.38	0.5368
TRTPN	2	12.4240099	6.2120049	4.83	0.0093



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.58198537	1
2	8.03114760	2
3	7.24402565	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0429	0.1311
2	0.0429		0.0024
3	0.1311	0.0024	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.581985	7.326409	7.837562
2	8.031148	7.677602	8.384693
3	7.244026	6.881815	7.606237



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.449162	-0.883783	-0.014541
1	3	0.337960	-0.101890	0.777809
2	3	0.787122	0.283455	1.290789

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	293.0705648	58.6141130	36.73	<.0001
Error	153	244.1464025	1.5957281		
Corrected Total	158	537.2169673			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.545535	17.41226	1.263221	7.254780

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	287.6695993	287.6695993	180.27	<.0001
SEXC	1	0.3103600	0.3103600	0.19	0.6598
UCPDGR1	1	0.1903855	0.1903855	0.12	0.7303
TRTPN	2	4.9002200	2.4501100	1.54	0.2187

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	266.7965123	266.7965123	167.19	<.0001
SEXC	1	0.3737786	0.3737786	0.23	0.6291
UCPDGR1	1	0.1604835	0.1604835	0.10	0.7516
TRTPN	2	4.9002200	2.4501100	1.54	0.2187



**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.15353775	1
2	7.56404131	2
3	7.17380977	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.0958	0.9349
2	0.0958		0.1712
3	0.9349	0.1712	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.153538	6.868972	7.438104
2	7.564041	7.170394	7.957689
3	7.173810	6.770513	7.577106



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.410504	-0.894424	0.073417
1	3	-0.020272	-0.510014	0.469470
2	3	0.390232	-0.170566	0.951029

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model**

**Dependent Variable: AVAL Analysis  
Value**

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	287.2804839	57.4560968	39.29	<.0001
Error	153	223.7368720	1.4623325		
Corrected Total	158	511.0173560			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.562174	17.00320	1.209269	7.112013

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	284.4284373	284.4284373	194.50	<.0001
SEXC	1	0.3455318	0.3455318	0.24	0.6276
UCPDGR1	1	0.0087358	0.0087358	0.01	0.9385
TRTPN	2	2.4977792	1.2488896	0.85	0.4277

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	267.6298316	267.6298316	183.02	<.0001
SEXC	1	0.3942104	0.3942104	0.27	0.6044
UCPDGR1	1	0.0231193	0.0231193	0.02	0.9001
TRTPN	2	2.4977792	1.2488896	0.85	0.4277



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.05963430	1
2	7.30653763	2
3	6.97072932	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.2940	0.7084
2	0.2940		0.2184
3	0.7084	0.2184	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.059634	6.787222	7.332047
2	7.306538	6.929702	7.683373
3	6.970729	6.584657	7.356801



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.246903	-0.710155	0.216349
1	3	0.088905	-0.379920	0.557730
2	3	0.335808	-0.201038	0.872654

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	300.0823304	60.0164661	27.43	<.0001
Error	153	334.7298972	2.1877771		
Corrected Total	158	634.8122277			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.472710	20.72610	1.479114	7.136478

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	297.2788692	297.2788692	135.88	<.0001
SEXC	1	0.1970018	0.1970018	0.09	0.7645
UCPDGR1	1	0.2871942	0.2871942	0.13	0.7176
TRTPN	2	2.3192652	1.1596326	0.53	0.5897

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	279.6149224	279.6149224	127.81	<.0001
SEXC	1	0.2811948	0.2811948	0.13	0.7205
UCPDGR1	1	0.2031158	0.2031158	0.09	0.7610
TRTPN	2	2.3192652	1.1596326	0.53	0.5897



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	7.00989251	1
2	7.20584931	2
3	7.28717532	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.4955	0.3409
2	0.4955		0.8070
3	0.3409	0.8070	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	7.009893	6.676692	7.343093
2	7.205849	6.744925	7.666774
3	7.287175	6.814953	7.759398



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WBC Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.195957	-0.762582	0.370668
1	3	-0.277283	-0.850725	0.296159
2	3	-0.081326	-0.737967	0.575315

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159





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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL** Analysis  
Value

Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	27745.71535	5549.14307	778.71	<.0001
Error	153	1090.28842	7.12607		
Corrected Total	158	28836.00377			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.962190	3.426126	2.669470	77.91509

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	27727.77731	27727.77731	3891.03	<.0001
SEXC	1	8.90806	8.90806	1.25	0.2653
UCPDGR1	1	3.44692	3.44692	0.48	0.4878
TRTPN	2	5.58305	2.79153	0.39	0.6766

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	25521.58318	25521.58318	3581.44	<.0001
SEXC	1	6.13777	6.13777	0.86	0.3548
UCPDGR1	1	3.05682	3.05682	0.43	0.5135
TRTPN	2	5.58305	2.79153	0.39	0.6766



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	77.7887531	1
2	78.2363365	2
3	78.0344898	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.3878	0.6407
2	0.3878		0.7361
3	0.6407	0.7361	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	77.788753	77.187726	78.389780
2	78.236336	77.405327	79.067346
3	78.034490	77.179931	78.889049



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WEIGHT Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.447583	-1.468475	0.573309
1	3	-0.245737	-1.283935	0.792461
2	3	0.201847	-0.979286	1.382980

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	159
Number of Observations Used	159



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Dependent Variable: AVAL Analysis**  
**Value**

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	12906.32658	2581.26532	6.64	<.0001
Error	153	59446.57908	388.53973		
Corrected Total	158	72352.90566			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.178380	20.37653	19.71141	96.73585

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BASE	1	11334.54887	11334.54887	29.17	<.0001
SEXC	1	1289.54276	1289.54276	3.32	0.0704
UCPDGR1	1	41.02721	41.02721	0.11	0.7457
TRTPN	2	241.20774	120.60387	0.31	0.7336

Source	DF	Type III SS	Mean Square	F Value	Pr > F
BASE	1	11845.62625	11845.62625	30.49	<.0001
SEXC	1	1120.12811	1120.12811	2.88	0.0916
UCPDGR1	1	28.33296	28.33296	0.07	0.7875
TRTPN	2	241.20774	120.60387	0.31	0.7336



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**Listing 15.4.4.25.2 Analysis of Risk Markers - FAS**  
**GLM model**

**Least Squares Means**

Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

TRTPN	AVAL LSMEAN	LSMEAN Number
1	97.3822978	1
2	94.9690565	2
3	94.8413901	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: AVAL			
i/j	1	2	3
1		0.5264	0.5139
2	0.5264		0.9770
3	0.5139	0.9770	

TRTPN	AVAL LSMEAN	95% Confidence Limits	
1	97.382298	92.932317	101.832279
2	94.969057	88.863231	101.074882
3	94.841390	88.539742	101.143038



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***Listing 15.4.4.25.2 Analysis of Risk Markers - FAS  
GLM model***

***Least Squares Means***

**Parameter Code=WSTCIR Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	2.413241	-5.095216	9.921699
1	3	2.540908	-5.131208	10.213023
2	3	0.127666	-8.598369	8.853702

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



1

***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148





2

***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	14.29928970	2.85985794	44.41	<.0001
Error	142	9.14515291	0.06440249		
Corrected Total	147	23.44444261			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.609922	4.020230	0.253776	6.312486

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	12.42332057	12.42332057	192.90	<.0001
SEXC	1	0.72217185	0.72217185	11.21	0.0010
UCPDGR1	1	0.00973014	0.00973014	0.15	0.6981
TRTPN	2	1.14406715	0.57203357	8.88	0.0002

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.59828114	10.59828114	164.56	<.0001
SEXC	1	0.60310243	0.60310243	9.36	0.0026
UCPDGR1	1	0.02049910	0.02049910	0.32	0.5735
TRTPN	2	1.14406715	0.57203357	8.88	0.0002



3

***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.28742126	1
2	6.46624299	2
3	6.24111798	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0005	0.3789
2	0.0005		0.0002
3	0.3789	0.0002	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.287421	6.228029	6.346813
2	6.466243	6.386615	6.545871
3	6.241118	6.155706	6.326530



4

***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=105 Analysis Visit=Day 5**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.178822	-0.277554	-0.080090
1	3	0.046303	-0.057396	0.150003
2	3	0.225125	0.108592	0.341658

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	148
Number of Observations Used	148



6

**Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

**Dependent Variable: LOGAVAL**

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10.72839682	2.14567936	11.85	<.0001
Error	142	25.72024133	0.18112846		
Corrected Total	147	36.44863815			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.294343	6.929866	0.425592	6.141416

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.54262291	10.54262291	58.21	<.0001
SEXC	1	0.03774684	0.03774684	0.21	0.6487
UCPDGR1	1	0.00765031	0.00765031	0.04	0.8375
TRTPN	2	0.14037677	0.07018838	0.39	0.6795

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.23847371	10.23847371	56.53	<.0001
SEXC	1	0.04654584	0.04654584	0.26	0.6130
UCPDGR1	1	0.00444819	0.00444819	0.02	0.8757
TRTPN	2	0.14037677	0.07018838	0.39	0.6795



7

***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.10716789	1
2	6.17307180	2
3	6.16325885	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4327	0.5248
2	0.4327		0.9211
3	0.5248	0.9211	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.107168	6.007565	6.206771
2	6.173072	6.039533	6.306611
3	6.163259	6.020020	6.306498



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=130 Analysis Visit=Day 30**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.065904	-0.231481	0.099673
1	3	-0.056091	-0.229998	0.117816
2	3	0.009813	-0.185617	0.205243

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	147
Number of Observations Used	147





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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.74644752	4.54928950	15.50	<.0001
Error	141	41.37621481	0.29344833		
Corrected Total	146	64.12266233			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.354733	8.955049	0.541709	6.049199

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	22.12303437	22.12303437	75.39	<.0001
SEXC	1	0.29690818	0.29690818	1.01	0.3162
UCPDGR1	1	0.22913570	0.22913570	0.78	0.3784
TRTPN	2	0.09736927	0.04868464	0.17	0.8473

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	22.38989165	22.38989165	76.30	<.0001
SEXC	1	0.16170247	0.16170247	0.55	0.4591
UCPDGR1	1	0.19887019	0.19887019	0.68	0.4118
TRTPN	2	0.09736927	0.04868464	0.17	0.8473



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.06196594	1
2	6.04588158	2
3	5.99766968	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8813	0.5668
2	0.8813		0.7036
3	0.5668	0.7036	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.061966	5.935148	6.188784
2	6.045882	5.873947	6.217816
3	5.997670	5.815353	6.179987



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=160 Analysis Visit=Day 60**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.016084	-0.196485	0.228654
1	3	0.064296	-0.157087	0.285679
2	3	0.048212	-0.201820	0.298244

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

Class Level Information		
Class	Levels	Values
TRTPN	3	1 2 3
SEXC	2	Female Male
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	147
Number of Observations Used	147



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Dependent Variable: LOGAVAL***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	20.91112321	4.18222464	14.77	<.0001
Error	141	39.92097160	0.28312746		
Corrected Total	146	60.83209481			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.343751	8.766713	0.532097	6.069518

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	20.22303855	20.22303855	71.43	<.0001
SEXC	1	0.33830447	0.33830447	1.19	0.2762
UCPDGR1	1	0.06249295	0.06249295	0.22	0.6392
TRTPN	2	0.28728723	0.14364362	0.51	0.6032

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	20.62357604	20.62357604	72.84	<.0001
SEXC	1	0.25149833	0.25149833	0.89	0.3476
UCPDGR1	1	0.08944773	0.08944773	0.32	0.5750
TRTPN	2	0.28728723	0.14364362	0.51	0.6032



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90

TRTPN	LOGAVAL LSMEAN	LSMEAN Number
1	6.02196069	1
2	6.07266140	2
3	6.13146045	3

Least Squares Means for effect TRTPN Pr >  t  for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.6319	0.3212
2	0.6319		0.6367
3	0.3212	0.6367	

TRTPN	LOGAVAL LSMEAN	95% Confidence Limits	
1	6.021961	5.897393	6.146529
2	6.072661	5.903777	6.241545
3	6.131460	5.952378	6.310543



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***Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS***

***Least Squares Means***

**Parameter (N)=76 Parameter Code=UTXB2CRE Parameter=11-Dehydro-Thromboxane B2 (pg/mg creat) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTPN				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.050701	-0.259498	0.158097
1	3	-0.109500	-0.326955	0.107955
2	3	-0.058799	-0.304395	0.186797

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



1

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=1 Parameter=MHBMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88





2

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=1 Parameter=MHBMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	104.5666083	20.9133217	32.68	<.0001
Error	82	52.4685157	0.6398599		
Corrected Total	87	157.0351240			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.665880	14.54741	0.799912	5.498657

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	34.98299647	34.98299647	54.67	<.0001
SEX	1	0.24060136	0.24060136	0.38	0.5414
UCPDGR1	1	1.85951432	1.85951432	2.91	0.0920
TRTP	2	67.48349617	33.74174809	52.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	43.60719501	43.60719501	68.15	<.0001
SEX	1	0.07043721	0.07043721	0.11	0.7409
UCPDGR1	1	0.07723719	0.07723719	0.12	0.7292
TRTP	2	67.48349617	33.74174809	52.73	<.0001



3

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=1 Parameter=MHBMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	5.02526661	1
THSm2.2	4.79823954	2
mCC	6.67597345	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4440	<.0001
2	0.4440		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	5.025267	4.484884	5.565649
THSm2.2	4.798240	4.560422	5.036057
mCC	6.675973	6.391296	6.960651



4

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=1 Parameter=MHBMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.227027	-0.360098	0.814152
1	3	-1.650707	-2.254593	-1.046820
2	3	-1.877734	-2.248757	-1.506711

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



5

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=2 Parameter=3-HPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=2 Parameter=3-HPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	29.67532710	5.93506542	22.01	<.0001
Error	82	22.10947986	0.26962780		
Corrected Total	87	51.78480696			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.573051	9.323722	0.519257	5.569202

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.11427026	5.11427026	18.97	<.0001
SEX	1	0.51512260	0.51512260	1.91	0.1707
UCPDGR1	1	1.65190533	1.65190533	6.13	0.0154
TRTP	2	22.39402891	11.19701446	41.53	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.02662950	6.02662950	22.35	<.0001
SEX	1	0.38258615	0.38258615	1.42	0.2370
UCPDGR1	1	0.78124875	0.78124875	2.90	0.0925
TRTP	2	22.39402891	11.19701446	41.53	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means**

Parameter (N)=2 Parameter=3-HPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.84152936	1
THSm2.2	5.27997041	2
mCC	6.23081580	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.0252	<.0001
2	0.0252		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.841529	4.489881	5.193178
THSm2.2	5.279970	5.125512	5.434429
mCC	6.230816	6.046291	6.415340

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=2 Parameter=3-HPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.438441	-0.821100	-0.055782
1	3	-1.389286	-1.781955	-0.996617
2	3	-0.950845	-1.191120	-0.710571

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=3 Parameter=S-PMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=3 Parameter=S-PMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	114.0595332	22.8119066	28.20	<.0001
Error	82	66.3293014	0.8088939		
Corrected Total	87	180.3888346			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.632298	15.31357	0.899385	5.873125

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	25.80851656	25.80851656	31.91	<.0001
SEX	1	0.00877745	0.00877745	0.01	0.9173
UCPDGR1	1	1.10302523	1.10302523	1.36	0.2463
TRTP	2	87.13921395	43.56960697	53.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	32.37790253	32.37790253	40.03	<.0001
SEX	1	0.37715658	0.37715658	0.47	0.4966
UCPDGR1	1	0.01964830	0.01964830	0.02	0.8765
TRTP	2	87.13921395	43.56960697	53.86	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means**

Parameter (N)=3 Parameter=S-PMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.79735671	1
THSm2.2	5.15557401	2
mCC	7.18059973	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.2823	<.0001
2	0.2823		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.797357	4.189864	5.404850
THSm2.2	5.155574	4.887437	5.423711
mCC	7.180600	6.860973	7.500226



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***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=3 Parameter=S-PMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.358217	-1.016666	0.300232
1	3	-2.383243	-3.062788	-1.703698
2	3	-2.025026	-2.441760	-1.608291

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=4 Parameter=Total NNAL (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=4 Parameter=Total NNAL (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	63.2701225	12.6540245	16.56	<.0001
Error	82	62.6466373	0.7639834		
Corrected Total	87	125.9167599			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.502476	20.59057	0.874061	4.244961

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	25.44184451	25.44184451	33.30	<.0001
SEX	1	0.00923255	0.00923255	0.01	0.9127
UCPDGR1	1	0.05102347	0.05102347	0.07	0.7967
TRTP	2	37.76802199	18.88401100	24.72	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	27.27112194	27.27112194	35.70	<.0001
SEX	1	0.30475648	0.30475648	0.40	0.5294
UCPDGR1	1	0.14335944	0.14335944	0.19	0.6660
TRTP	2	37.76802199	18.88401100	24.72	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=4 Parameter=Total NNAL (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.49219158	1
THSm2.2	3.78378994	2
mCC	5.09895347	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.3674	<.0001
2	0.3674		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.492192	2.902085	4.082298
THSm2.2	3.783790	3.524580	4.043000
mCC	5.098953	4.788398	5.409509

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=4 Parameter=Total NNAL (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.291598	-0.931618	0.348421
1	3	-1.606762	-2.266656	-0.946868
2	3	-1.315164	-1.718783	-0.911544

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=5 Parameter=Total 1-OHP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=5 Parameter=Total 1-OHP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	21.30985415	4.26197083	27.70	<.0001
Error	82	12.61584986	0.15385183		
Corrected Total	87	33.92570400			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.628133	8.575832	0.392240	4.573778

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	14.88871266	14.88871266	96.77	<.0001
SEX	1	0.21366484	0.21366484	1.39	0.2420
UCPDGR1	1	0.54842862	0.54842862	3.56	0.0626
TRTP	2	5.65904803	2.82952401	18.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	13.08343314	13.08343314	85.04	<.0001
SEX	1	0.15248477	0.15248477	0.99	0.3224
UCPDGR1	1	0.24219062	0.24219062	1.57	0.2132
TRTP	2	5.65904803	2.82952401	18.39	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=5 Parameter=Total 1-OHP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.30658888	1
THSm2.2	4.40504572	2
mCC	4.91958191	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5075	<.0001
2	0.5075		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.306589	4.038971	4.574207
THSm2.2	4.405046	4.286214	4.523877
mCC	4.919582	4.780034	5.059130

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=5 Parameter=Total 1-OHP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.098457	-0.392718	0.195804
1	3	-0.612993	-0.910731	-0.315255
2	3	-0.514536	-0.698377	-0.330696

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=6 Parameter=NNN (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=6 Parameter=NNN (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	138.8754168	27.7750834	39.12	<.0001
Error	82	58.2208068	0.7100098		
Corrected Total	87	197.0962236			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.704607	419.7330	0.842621	0.200752

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	42.14638915	42.14638915	59.36	<.0001
SEX	1	3.43111171	3.43111171	4.83	0.0307
UCPDGR1	1	0.92125162	0.92125162	1.30	0.2580
TRTP	2	92.37666434	46.18833217	65.05	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	28.55238957	28.55238957	40.21	<.0001
SEX	1	1.45493072	1.45493072	2.05	0.1561
UCPDGR1	1	0.00542700	0.00542700	0.01	0.9305
TRTP	2	92.37666434	46.18833217	65.05	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=6 Parameter=NNN (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	-1.67403848	1
THSm2.2	-0.25585388	2
mCC	1.48510785	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	-1.674038	-2.246812	-1.101265
THSm2.2	-0.255854	-0.505164	-0.006544
mCC	1.485108	1.185435	1.784781

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=6 Parameter=NNN (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-1.418185	-2.039657	-0.796712
1	3	-3.159146	-3.800393	-2.517899
2	3	-1.740962	-2.129270	-1.352653

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=7 Parameter=4-ABP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=7 Parameter=4-ABP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	49.3362931	9.8672586	15.28	<.0001
Error	81	52.3068216	0.6457632		
Corrected Total	86	101.6431148			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.485387	49.66064	0.803594	1.618171

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.12234252	6.12234252	9.48	0.0028
SEX	1	1.44506884	1.44506884	2.24	0.1386
UCPDGR1	1	0.40309967	0.40309967	0.62	0.4318
TRTP	2	41.36578211	20.68289106	32.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	5.51199949	5.51199949	8.54	0.0045
SEX	1	0.63989371	0.63989371	0.99	0.3225
UCPDGR1	1	0.00343627	0.00343627	0.01	0.9420
TRTP	2	41.36578211	20.68289106	32.03	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=7 Parameter=4-ABP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	0.91231358	1
THSm2.2	1.15035336	2
mCC	2.54669219	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4249	<.0001
2	0.4249		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	0.912314	0.369555	1.455072
THSm2.2	1.150353	0.909257	1.391450
mCC	2.546692	2.261118	2.832266

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=7 Parameter=4-ABP (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.238040	-0.828555	0.352475
1	3	-1.634379	-2.241189	-1.027569
2	3	-1.396339	-1.769466	-1.023212

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=8 Parameter=1-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=8 Parameter=1-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	141.2669418	28.2533884	51.40	<.0001
Error	82	45.0735459	0.5496774		
Corrected Total	87	186.3404877			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.758112	29.33785	0.741402	2.527119

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.4448117	1.4448117	2.63	0.1088
SEX	1	1.5297115	1.5297115	2.78	0.0991
UCPDGR1	1	2.5636285	2.5636285	4.66	0.0337
TRTP	2	135.7287901	67.8643951	123.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.7804055	0.7804055	1.42	0.2369
SEX	1	0.6742121	0.6742121	1.23	0.2713
UCPDGR1	1	0.0198963	0.0198963	0.04	0.8496
TRTP	2	135.7287901	67.8643951	123.46	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=8 Parameter=1-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	1.41122001	1
THSm2.2	1.63944245	2
mCC	4.20267157	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4059	<.0001
2	0.4059		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	1.411220	0.910184	1.912256
THSm2.2	1.639442	1.420098	1.858787
mCC	4.202672	3.938861	4.466482

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=8 Parameter=1-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.228222	-0.771717	0.315272
1	3	-2.791452	-3.352403	-2.230500
2	3	-2.563229	-2.904938	-2.221520

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=9 Parameter=2-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=9 Parameter=2-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	68.3075227	13.6615045	30.64	<.0001
Error	82	36.5638133	0.4459002		
Corrected Total	87	104.8713360			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.651346	39.74638	0.667758	1.680046

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.87212489	1.87212489	4.20	0.0437
SEX	1	0.35122890	0.35122890	0.79	0.3774
UCPDGR1	1	0.32875043	0.32875043	0.74	0.3930
TRTP	2	65.75541851	32.87770925	73.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.31151472	2.31151472	5.18	0.0254
SEX	1	0.02023471	0.02023471	0.05	0.8318
UCPDGR1	1	0.12195045	0.12195045	0.27	0.6024
TRTP	2	65.75541851	32.87770925	73.73	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=9 Parameter=2-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	1.09373370	1
THSm2.2	1.01387025	2
mCC	2.83900546	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.7464	<.0001
2	0.7464		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	1.093734	0.642713	1.544755
THSm2.2	1.013870	0.815859	1.211881
mCC	2.839005	2.601777	3.076234

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=9 Parameter=2-NA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.079863	-0.409711	0.569438
1	3	-1.745272	-2.249630	-1.240913
2	3	-1.825135	-2.133121	-1.517150

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=10 Parameter=o-tol (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=10 Parameter=o-tol (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	14.97877513	2.99575503	8.37	<.0001
Error	82	29.36431436	0.35810139		
Corrected Total	87	44.34308949			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.337793	14.29401	0.598416	4.186478

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	2.65510880	2.65510880	7.41	0.0079
SEX	1	0.42461463	0.42461463	1.19	0.2794
UCPDGR1	1	0.04921133	0.04921133	0.14	0.7118
TRTP	2	11.84984036	5.92492018	16.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.65849801	1.65849801	4.63	0.0343
SEX	1	0.20795768	0.20795768	0.58	0.4482
UCPDGR1	1	0.04077527	0.04077527	0.11	0.7366
TRTP	2	11.84984036	5.92492018	16.55	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=10 Parameter=o-tol (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.94840451	1
THSm2.2	3.91532551	2
mCC	4.68969323	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8811	0.0016
2	0.8811		<.0001
3	0.0016	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.948405	3.544373	4.352436
THSm2.2	3.915326	3.737665	4.092987
mCC	4.689693	4.476836	4.902550

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=10 Parameter=o-tol (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.033079	-0.405383	0.471541
1	3	-0.741289	-1.193305	-0.289272
2	3	-0.774368	-1.050178	-0.498557

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=11 Parameter=CEMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=11 Parameter=CEMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	91.7185387	18.3437077	26.64	<.0001
Error	82	56.4705929	0.6886658		
Corrected Total	87	148.1891317			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.618929	27.01538	0.829859	3.071801

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	6.57544382	6.57544382	9.55	0.0027
SEX	1	0.55619537	0.55619537	0.81	0.3714
UCPDGR1	1	0.89751135	0.89751135	1.30	0.2569
TRTP	2	83.68938818	41.84469409	60.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.28576461	10.28576461	14.94	0.0002
SEX	1	1.22139980	1.22139980	1.77	0.1866
UCPDGR1	1	0.00754834	0.00754834	0.01	0.9169
TRTP	2	83.68938818	41.84469409	60.76	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=11 Parameter=CEMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	2.34509730	1
THSm2.2	2.29011431	2
mCC	4.34491541	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8575	<.0001
2	0.8575		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	2.345097	1.784460	2.905734
THSm2.2	2.290114	2.044513	2.535716
mCC	4.344915	4.050092	4.639739

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=11 Parameter=CEMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.054983	-0.552454	0.662420
1	3	-1.999818	-2.626768	-1.372868
2	3	-2.054801	-2.437502	-1.672100

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=12 Parameter=HEMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=12 Parameter=HEMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	39.49218445	7.89843689	27.82	<.0001
Error	82	23.27862977	0.28388573		
Corrected Total	87	62.77081421			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.629149	7.334330	0.532809	7.264594

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	22.83318673	22.83318673	80.43	<.0001
SEX	1	1.46929328	1.46929328	5.18	0.0255
UCPDGR1	1	1.27510800	1.27510800	4.49	0.0371
TRTP	2	13.91459645	6.95729822	24.51	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	17.60410624	17.60410624	62.01	<.0001
SEX	1	1.45908523	1.45908523	5.14	0.0260
UCPDGR1	1	0.44708228	0.44708228	1.57	0.2131
TRTP	2	13.91459645	6.95729822	24.51	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=12 Parameter=HEMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	6.96384657	1
THSm2.2	6.99682233	2
mCC	7.82451901	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8671	<.0001
2	0.8671		<.0001
3	<.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	6.963847	6.602863	7.324830
THSm2.2	6.996822	6.839217	7.154428
mCC	7.824519	7.635021	8.014017

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=12 Parameter=HEMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.032976	-0.423729	0.357778
1	3	-0.860672	-1.263461	-0.457884
2	3	-0.827697	-1.073249	-0.582144

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=13 Parameter=B[a]P (fg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=13 Parameter=B[a]P (fg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	22.94858600	4.58971720	9.89	<.0001
Error	81	37.57154912	0.46384629		
Corrected Total	86	60.52013512			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.379189	16.63528	0.681063	4.094085

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	10.56927047	10.56927047	22.79	<.0001
SEX	1	0.45634229	0.45634229	0.98	0.3242
UCPDGR1	1	0.92207703	0.92207703	1.99	0.1624
TRTP	2	11.00089621	5.50044810	11.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	11.09053017	11.09053017	23.91	<.0001
SEX	1	0.26191492	0.26191492	0.56	0.4546
UCPDGR1	1	0.33912068	0.33912068	0.73	0.3950
TRTP	2	11.00089621	5.50044810	11.86	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=13 Parameter=B[a]P (fg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	3.69674789	1
THSm2.2	3.85964108	2
mCC	4.57744813	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.5273	0.0011
2	0.5273		<.0001
3	0.0011	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	3.696748	3.233072	4.160423
THSm2.2	3.859641	3.649408	4.069874
mCC	4.577448	4.334416	4.820480

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=13 Parameter=B[a]P (fg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-0.162893	-0.673426	0.347639
1	3	-0.880700	-1.396270	-0.365131
2	3	-0.717807	-1.041468	-0.394146

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=14 Parameter=HMPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=14 Parameter=HMPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	37.41444633	7.48288927	15.04	<.0001
Error	82	40.80604884	0.49763474		
Corrected Total	87	78.22049517			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.478320	15.00481	0.705432	4.701376

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	1.09976366	1.09976366	2.21	0.1410
SEX	1	0.09648692	0.09648692	0.19	0.6609
UCPDGR1	1	6.43650761	6.43650761	12.93	0.0006
TRTP	2	29.78168814	14.89084407	29.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	0.03949602	0.03949602	0.08	0.7789
SEX	1	0.36167647	0.36167647	0.73	0.3964
UCPDGR1	1	3.86845757	3.86845757	7.77	0.0066
TRTP	2	29.78168814	14.89084407	29.92	<.0001



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=14 Parameter=HMPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	4.41528507	1
THSm2.2	4.23254563	2
mCC	5.48553752	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.4849	0.0001
2	0.4849		<.0001
3	0.0001	<.0001	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	4.415285	3.938663	4.891907
THSm2.2	4.232546	4.022473	4.442619
mCC	5.485538	5.234384	5.736691

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=14 Parameter=HMPMA (ng/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.182739	-0.335424	0.700902
1	3	-1.070252	-1.602813	-0.537692
2	3	-1.252992	-1.580753	-0.925230

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=15 Parameter=S-BMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	88
Number of Observations Used	88





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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=15 Parameter=S-BMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	8.33858656	1.66771731	3.21	0.0107
Error	82	42.61006391	0.51963493		
Corrected Total	87	50.94865047			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.163666	8.930791	0.720857	8.071593

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	7.13622095	7.13622095	13.73	0.0004
SEX	1	0.61805409	0.61805409	1.19	0.2786
UCPDGR1	1	0.00388568	0.00388568	0.01	0.9313
TRTP	2	0.58042584	0.29021292	0.56	0.5742

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	4.44927453	4.44927453	8.56	0.0044
SEX	1	0.69835639	0.69835639	1.34	0.2497
UCPDGR1	1	0.02554419	0.02554419	0.05	0.8251
TRTP	2	0.58042584	0.29021292	0.56	0.5742



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=15 Parameter=S-BMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	8.18681390	1
THSm2.2	8.15040256	2
mCC	7.98657746	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		0.8913	0.4688
2	0.8913		0.3314
3	0.4688	0.3314	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	8.186814	7.697588	8.676040
THSm2.2	8.150403	7.936162	8.364643
mCC	7.986577	7.730376	8.242779

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=15 Parameter=S-BMA (pg/mg creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	0.036411	-0.491919	0.564742
1	3	0.200236	-0.347026	0.747499
2	3	0.163825	-0.169694	0.497344

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set*****Parameter (N)=16 Parameter=NEQ (mg/g creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Number of Observations Read	87
Number of Observations Used	87



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**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Dependent Variable: LOGAVAL****Parameter (N)=16 Parameter=NEQ (mg/g creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	66.9724957	13.3944991	27.80	<.0001
Error	81	39.0240859	0.4817788		
Corrected Total	86	105.9965816			

R-Square	Coeff Var	Root MSE	LOGAVAL Mean
0.631836	41.15075	0.694103	1.686732

Source	DF	Type I SS	Mean Square	F Value	Pr > F
LOGBASE	1	21.21004104	21.21004104	44.02	<.0001
SEX	1	0.19347521	0.19347521	0.40	0.5281
UCPDGR1	1	0.14776582	0.14776582	0.31	0.5812
TRTP	2	45.42121362	22.71060681	47.14	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
LOGBASE	1	15.41909329	15.41909329	32.00	<.0001
SEX	1	0.03600437	0.03600437	0.07	0.7853
UCPDGR1	1	0.00028696	0.00028696	0.00	0.9806
TRTP	2	45.42121362	22.71060681	47.14	<.0001

**Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set****Least Squares Means****Parameter (N)=16 Parameter=NEQ (mg/g creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

TRTP	LOGAVAL LSMEAN	LSMEAN Number
SA	-0.45899643	1
THSm2.2	1.88885852	2
mCC	1.98794922	3

Least Squares Means for effect TRTP Pr > t%_for H0: LSMean(i)=LSMean(j)			
Dependent Variable: LOGAVAL			
i/j	1	2	3
1		<.0001	<.0001
2	<.0001		0.5432
3	<.0001	0.5432	

TRTP	LOGAVAL LSMEAN	95% Confidence Limits	
SA	-0.458996	-0.927761	0.009769
THSm2.2	1.888859	1.683469	2.094248
mCC	1.987949	1.735998	2.239901

***Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit – PP Set******Least Squares Means*****Parameter (N)=16 Parameter=NEQ (mg/g creat) - 4H Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means for Effect TRTP				
i	j	Difference Between Means	95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.347855	-2.855964	-1.839746
1	3	-2.446946	-2.972927	-1.920964
2	3	-0.099091	-0.421984	0.223802

**Note:** To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.



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***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132



**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.6404

Fit Statistics	
-2 Res Log Likelihood	503.7
AIC (smaller is better)	505.7
AICC (smaller is better)	505.8
BIC (smaller is better)	508.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	25.01	<.0001
SEX	1	126	0.35	0.5555
UCPDGR1	1	126	0.01	0.9124
TRTP	2	126	6.71	0.0017

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.8845	0.3337	126	17.64	<.0001	0.05	5.2242	6.5448
TRTP	THSm2.2	4.5134	0.1911	126	23.62	<.0001	0.05	4.1353	4.8916
TRTP	mCC	4.6152	0.2848	126	16.20	<.0001	0.05	4.0515	5.1788
TRTP	SA	5.8845	0.3337	126	17.64	<.0001	0.05	5.2242	6.5448
TRTP	THSm2.2	4.5134	0.1911	126	23.62	<.0001	0.05	4.1353	4.8916
TRTP	mCC	4.6152	0.2848	126	16.20	<.0001	0.05	4.0515	5.1788

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.2693	0.4368	126	2.91	0.0043	0.05	0.4049	2.1337
TRTP	THSm2.2	mCC	-0.1017	0.3400	126	-0.30	0.7653	0.05	-0.7746	0.5711
TRTP	THSm2.2	SA	-1.3711	0.3813	126	-3.60	0.0005	0.05	-2.1257	-0.6165
TRTP	mCC	SA	-1.2693	0.4368	126	-2.91	0.0043	0.05	-2.1337	-0.4049

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.2107

Fit Statistics	
-2 Res Log Likelihood	532.4
AIC (smaller is better)	534.4
AICC (smaller is better)	534.5
BIC (smaller is better)	537.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	8.65	0.0039
SEX	1	127	0.03	0.8620
UCPDGR1	1	127	0.15	0.7019
TRTP	2	127	2.84	0.0623

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.3989	0.3679	127	14.67	<.0001	0.05	4.6708	6.1269
TRTP	THSm2.2	4.4163	0.2107	127	20.96	<.0001	0.05	3.9995	4.8331
TRTP	mCC	4.4897	0.3093	127	14.52	<.0001	0.05	3.8776	5.1017
TRTP	SA	5.3989	0.3679	127	14.67	<.0001	0.05	4.6708	6.1269
TRTP	THSm2.2	4.4163	0.2107	127	20.96	<.0001	0.05	3.9995	4.8331
TRTP	mCC	4.4897	0.3093	127	14.52	<.0001	0.05	3.8776	5.1017

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.9092	0.4782	127	1.90	0.0595	0.05	-0.03712	1.8555
TRTP	THSm2.2	mCC	-0.07340	0.3706	127	-0.20	0.8433	0.05	-0.8069	0.6600
TRTP	THSm2.2	SA	-0.9826	0.4205	127	-2.34	0.0210	0.05	-1.8146	-0.1506
TRTP	mCC	SA	-0.9092	0.4782	127	-1.90	0.0595	0.05	-1.8555	0.03712



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.9504

Fit Statistics	
-2 Res Log Likelihood	517.7
AIC (smaller is better)	519.7
AICC (smaller is better)	519.7
BIC (smaller is better)	522.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	16.99	<.0001
SEX	1	126	1.21	0.2738
UCPDGR1	1	126	0.69	0.4078
TRTP	2	126	0.52	0.5976

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.7500	0.3613	126	13.15	<.0001	0.05	4.0350	5.4651
TRTP	THSm2.2	4.4575	0.2020	126	22.06	<.0001	0.05	4.0577	4.8573
TRTP	mCC	4.2781	0.2965	126	14.43	<.0001	0.05	3.6912	4.8649
TRTP	SA	4.7500	0.3613	126	13.15	<.0001	0.05	4.0350	5.4651
TRTP	THSm2.2	4.4575	0.2020	126	22.06	<.0001	0.05	4.0577	4.8573
TRTP	mCC	4.2781	0.2965	126	14.43	<.0001	0.05	3.6912	4.8649

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4720	0.4644	126	1.02	0.3115	0.05	-0.4471	1.3911
TRTP	THSm2.2	mCC	0.1794	0.3553	126	0.51	0.6144	0.05	-0.5237	0.8826
TRTP	THSm2.2	SA	-0.2925	0.4099	126	-0.71	0.4767	0.05	-1.1037	0.5186
TRTP	mCC	SA	-0.4720	0.4644	126	-1.02	0.3115	0.05	-1.3911	0.4471





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***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84



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*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	84
Number of Observations Used	84
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9092

Fit Statistics	
-2 Res Log Likelihood	292.8
AIC (smaller is better)	294.8
AICC (smaller is better)	294.9
BIC (smaller is better)	297.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	78	11.40	0.0011
SEX	1	78	7.75	0.0067
UCPDGR1	1	78	10.35	0.0019
TRTP	2	78	6.66	0.0021



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*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.0105	0.3864	78	7.79	<.0001	0.05	2.2413	3.7798
TRTP	THSm2.2	4.5346	0.2256	78	20.10	<.0001	0.05	4.0854	4.9838
TRTP	mCC	4.5488	0.2497	78	18.21	<.0001	0.05	4.0516	5.0459
TRTP	SA	3.0105	0.3864	78	7.79	<.0001	0.05	2.2413	3.7798
TRTP	THSm2.2	4.5346	0.2256	78	20.10	<.0001	0.05	4.0854	4.9838
TRTP	mCC	4.5488	0.2497	78	18.21	<.0001	0.05	4.0516	5.0459

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.5382	0.4597	78	-3.35	0.0013	0.05	-2.4534	-0.6231
TRTP	THSm2.2	mCC	-0.01417	0.3346	78	-0.04	0.9663	0.05	-0.6802	0.6519
TRTP	THSm2.2	SA	1.5241	0.4440	78	3.43	0.0010	0.05	0.6401	2.4080
TRTP	mCC	SA	1.5382	0.4597	78	3.35	0.0013	0.05	0.6231	2.4534



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***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.1973

Fit Statistics	
-2 Res Log Likelihood	531.9
AIC (smaller is better)	533.9
AICC (smaller is better)	533.9
BIC (smaller is better)	536.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	14.55	0.0002
SEX	1	127	1.95	0.1645
UCPDGR1	1	127	0.37	0.5467
TRTP	2	127	0.25	0.7772



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*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6475	0.3672	127	12.66	<.0001	0.05	3.9210	5.3741
TRTP	THSm2.2	4.4279	0.2102	127	21.06	<.0001	0.05	4.0120	4.8439
TRTP	mCC	4.6520	0.3087	127	15.07	<.0001	0.05	4.0413	5.2628
TRTP	SA	4.6475	0.3672	127	12.66	<.0001	0.05	3.9210	5.3741
TRTP	THSm2.2	4.4279	0.2102	127	21.06	<.0001	0.05	4.0120	4.8439
TRTP	mCC	4.6520	0.3087	127	15.07	<.0001	0.05	4.0413	5.2628

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.00452	0.4772	127	-0.01	0.9925	0.05	-0.9489	0.9398
TRTP	THSm2.2	mCC	-0.2241	0.3699	127	-0.61	0.5457	0.05	-0.9560	0.5078
TRTP	THSm2.2	SA	-0.2196	0.4196	127	-0.52	0.6017	0.05	-1.0499	0.6107
TRTP	mCC	SA	0.004518	0.4772	127	0.01	0.9925	0.05	-0.9398	0.9489

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.1419

Fit Statistics	
-2 Res Log Likelihood	529.7
AIC (smaller is better)	531.7
AICC (smaller is better)	531.7
BIC (smaller is better)	534.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	25.85	<.0001
SEX	1	127	0.33	0.5642
UCPDGR1	1	127	0.67	0.4131
TRTP	2	127	0.81	0.4470



*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.8236	0.3640	127	13.25	<.0001	0.05	4.1034	5.5438
TRTP	THSm2.2	4.3781	0.2084	127	21.01	<.0001	0.05	3.9658	4.7905
TRTP	mCC	4.2431	0.3060	127	13.87	<.0001	0.05	3.6376	4.8486
TRTP	SA	4.8236	0.3640	127	13.25	<.0001	0.05	4.1034	5.5438
TRTP	THSm2.2	4.3781	0.2084	127	21.01	<.0001	0.05	3.9658	4.7905
TRTP	mCC	4.2431	0.3060	127	13.87	<.0001	0.05	3.6376	4.8486

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.5805	0.4731	127	1.23	0.2221	0.05	-0.3556	1.5166
TRTP	THSm2.2	mCC	0.1350	0.3667	127	0.37	0.7133	0.05	-0.5905	0.8606
TRTP	THSm2.2	SA	-0.4455	0.4159	127	-1.07	0.2862	0.05	-1.2686	0.3776
TRTP	mCC	SA	-0.5805	0.4731	127	-1.23	0.2221	0.05	-1.5166	0.3556

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1199

Fit Statistics	
-2 Res Log Likelihood	293.6
AIC (smaller is better)	295.6
AICC (smaller is better)	295.6
BIC (smaller is better)	297.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	76	10.51	0.0018
SEX	1	76	0.84	0.3623
UCPDGR1	1	76	0.43	0.5148
TRTP	2	76	9.96	0.0001

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.9319	0.4466	76	6.56	<.0001	0.05	2.0423	3.8214
TRTP	THSm2.2	4.9056	0.2383	76	20.59	<.0001	0.05	4.4311	5.3801
TRTP	mCC	5.1645	0.2612	76	19.78	<.0001	0.05	4.6443	5.6846
TRTP	SA	2.9319	0.4466	76	6.56	<.0001	0.05	2.0423	3.8214
TRTP	THSm2.2	4.9056	0.2383	76	20.59	<.0001	0.05	4.4311	5.3801
TRTP	mCC	5.1645	0.2612	76	19.78	<.0001	0.05	4.6443	5.6846

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.2326	0.5112	76	-4.37	<.0001	0.05	-3.2508	-1.2144
TRTP	THSm2.2	mCC	-0.2588	0.3512	76	-0.74	0.4633	0.05	-0.9582	0.4405
TRTP	THSm2.2	SA	1.9737	0.5035	76	3.92	0.0002	0.05	0.9709	2.9766
TRTP	mCC	SA	2.2326	0.5112	76	4.37	<.0001	0.05	1.2144	3.2508

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5885

Fit Statistics	
-2 Res Log Likelihood	264.4
AIC (smaller is better)	266.4
AICC (smaller is better)	266.5
BIC (smaller is better)	268.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	74	36.88	<.0001
SEX	1	74	0.00	0.9501
UCPDGR1	1	74	1.50	0.2244
TRTP	2	74	6.96	0.0017

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.7319	0.4823	74	5.66	<.0001	0.05	1.7710	3.6929
TRTP	THSm2.2	4.4635	0.1890	74	23.62	<.0001	0.05	4.0869	4.8400
TRTP	mCC	4.7151	0.2457	74	19.19	<.0001	0.05	4.2256	5.2046
TRTP	SA	2.7319	0.4823	74	5.66	<.0001	0.05	1.7710	3.6929
TRTP	THSm2.2	4.4635	0.1890	74	23.62	<.0001	0.05	4.0869	4.8400
TRTP	mCC	4.7151	0.2457	74	19.19	<.0001	0.05	4.2256	5.2046

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.9832	0.5366	74	-3.70	0.0004	0.05	-3.0524	-0.9140
TRTP	THSm2.2	mCC	-0.2516	0.3072	74	-0.82	0.4154	0.05	-0.8638	0.3606
TRTP	THSm2.2	SA	1.7316	0.5168	74	3.35	0.0013	0.05	0.7018	2.7613
TRTP	mCC	SA	1.9832	0.5366	74	3.70	0.0004	0.05	0.9140	3.0524

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132



**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6540

Fit Statistics	
-2 Res Log Likelihood	444.8
AIC (smaller is better)	446.8
AICC (smaller is better)	446.8
BIC (smaller is better)	449.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	105.30	<.0001
SEX	1	126	3.81	0.0533
UCPDGR1	1	126	0.19	0.6647
TRTP	2	126	9.79	0.0001

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.7177	0.2645	126	17.84	<.0001	0.05	4.1943	5.2411
TRTP	THSm2.2	3.3800	0.1512	126	22.36	<.0001	0.05	3.0808	3.6792
TRTP	mCC	3.6746	0.2256	126	16.29	<.0001	0.05	3.2281	4.1211
TRTP	SA	4.7177	0.2645	126	17.84	<.0001	0.05	4.1943	5.2411
TRTP	THSm2.2	3.3800	0.1512	126	22.36	<.0001	0.05	3.0808	3.6792
TRTP	mCC	3.6746	0.2256	126	16.29	<.0001	0.05	3.2281	4.1211

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.0431	0.3465	126	3.01	0.0032	0.05	0.3574	1.7288
TRTP	THSm2.2	mCC	-0.2946	0.2690	126	-1.10	0.2755	0.05	-0.8270	0.2377
TRTP	THSm2.2	SA	-1.3377	0.3024	126	-4.42	<.0001	0.05	-1.9361	-0.7392
TRTP	mCC	SA	-1.0431	0.3465	126	-3.01	0.0032	0.05	-1.7288	-0.3574

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0988

Fit Statistics	
-2 Res Log Likelihood	478.4
AIC (smaller is better)	480.4
AICC (smaller is better)	480.5
BIC (smaller is better)	483.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	74.40	<.0001
SEX	1	127	0.15	0.7004
UCPDGR1	1	127	0.28	0.5946
TRTP	2	127	3.09	0.0489

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.1326	0.2979	127	13.87	<.0001	0.05	3.5431	4.7220
TRTP	THSm2.2	3.2967	0.1703	127	19.36	<.0001	0.05	2.9597	3.6338
TRTP	mCC	3.3825	0.2502	127	13.52	<.0001	0.05	2.8875	3.8776
TRTP	SA	4.1326	0.2979	127	13.87	<.0001	0.05	3.5431	4.7220
TRTP	THSm2.2	3.2967	0.1703	127	19.36	<.0001	0.05	2.9597	3.6338
TRTP	mCC	3.3825	0.2502	127	13.52	<.0001	0.05	2.8875	3.8776

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.7500	0.3873	127	1.94	0.0550	0.05	-0.01646	1.5165
TRTP	THSm2.2	mCC	-0.08579	0.2996	127	-0.29	0.7751	0.05	-0.6787	0.5071
TRTP	THSm2.2	SA	-0.8358	0.3406	127	-2.45	0.0155	0.05	-1.5099	-0.1618
TRTP	mCC	SA	-0.7500	0.3873	127	-1.94	0.0550	0.05	-1.5165	0.01646

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5978

Fit Statistics	
-2 Res Log Likelihood	440.4
AIC (smaller is better)	442.4
AICC (smaller is better)	442.5
BIC (smaller is better)	445.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	92.35	<.0001
SEX	1	126	1.39	0.2410
UCPDGR1	1	126	1.22	0.2719
TRTP	2	126	0.40	0.6708

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.4500	0.2662	126	12.96	<.0001	0.05	2.9232	3.9767
TRTP	THSm2.2	3.2329	0.1487	126	21.75	<.0001	0.05	2.9387	3.5271
TRTP	mCC	3.4177	0.2183	126	15.65	<.0001	0.05	2.9857	3.8498
TRTP	SA	3.4500	0.2662	126	12.96	<.0001	0.05	2.9232	3.9767
TRTP	THSm2.2	3.2329	0.1487	126	21.75	<.0001	0.05	2.9387	3.5271
TRTP	mCC	3.4177	0.2183	126	15.65	<.0001	0.05	2.9857	3.8498

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.03223	0.3423	126	0.09	0.9251	0.05	-0.6451	0.7096
TRTP	THSm2.2	mCC	-0.1848	0.2614	126	-0.71	0.4809	0.05	-0.7022	0.3326
TRTP	THSm2.2	SA	-0.2171	0.3021	126	-0.72	0.4737	0.05	-0.8148	0.3807
TRTP	mCC	SA	-0.03223	0.3423	126	-0.09	0.9251	0.05	-0.7096	0.6451



***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	84
Number of Observations Used	84
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1607

Fit Statistics	
-2 Res Log Likelihood	254.0
AIC (smaller is better)	256.0
AICC (smaller is better)	256.0
BIC (smaller is better)	258.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	78	73.94	<.0001
SEX	1	78	5.68	0.0196
UCPDGR1	1	78	17.83	<.0001
TRTP	2	78	14.65	<.0001

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.9212	0.3005	78	6.39	<.0001	0.05	1.3230	2.5193
TRTP	THSm2.2	2.9467	0.1774	78	16.61	<.0001	0.05	2.5935	3.3000
TRTP	mCC	3.7878	0.1938	78	19.55	<.0001	0.05	3.4020	4.1736
TRTP	SA	1.9212	0.3005	78	6.39	<.0001	0.05	1.3230	2.5193
TRTP	THSm2.2	2.9467	0.1774	78	16.61	<.0001	0.05	2.5935	3.3000
TRTP	mCC	3.7878	0.1938	78	19.55	<.0001	0.05	3.4020	4.1736

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8666	0.3544	78	-5.27	<.0001	0.05	-2.5721	-1.1611
TRTP	THSm2.2	mCC	-0.8411	0.2619	78	-3.21	0.0019	0.05	-1.3624	-0.3198
TRTP	THSm2.2	SA	1.0255	0.3483	78	2.94	0.0043	0.05	0.3322	1.7189
TRTP	mCC	SA	1.8666	0.3544	78	5.27	<.0001	0.05	1.1611	2.5721

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.2739

Fit Statistics	
-2 Res Log Likelihood	488.6
AIC (smaller is better)	490.6
AICC (smaller is better)	490.7
BIC (smaller is better)	493.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	62.28	<.0001
SEX	1	127	1.68	0.1975
UCPDGR1	1	127	0.91	0.3408
TRTP	2	127	0.68	0.5078

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.1570	0.3100	127	10.18	<.0001	0.05	2.5435	3.7705
TRTP	THSm2.2	3.2554	0.1773	127	18.36	<.0001	0.05	2.9046	3.6062
TRTP	mCC	3.5719	0.2604	127	13.72	<.0001	0.05	3.0566	4.0873
TRTP	SA	3.1570	0.3100	127	10.18	<.0001	0.05	2.5435	3.7705
TRTP	THSm2.2	3.2554	0.1773	127	18.36	<.0001	0.05	2.9046	3.6062
TRTP	mCC	3.5719	0.2604	127	13.72	<.0001	0.05	3.0566	4.0873

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.4149	0.4032	127	-1.03	0.3054	0.05	-1.2127	0.3829
TRTP	THSm2.2	mCC	-0.3166	0.3119	127	-1.01	0.3121	0.05	-0.9337	0.3006
TRTP	THSm2.2	SA	0.09837	0.3546	127	0.28	0.7819	0.05	-0.6032	0.8000
TRTP	mCC	SA	0.4149	0.4032	127	1.03	0.3054	0.05	-0.3829	1.2127

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.7626

Fit Statistics	
-2 Res Log Likelihood	456.3
AIC (smaller is better)	458.3
AICC (smaller is better)	458.3
BIC (smaller is better)	461.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	102.27	<.0001
SEX	1	127	0.00	0.9733
UCPDGR1	1	127	0.15	0.7012
TRTP	2	127	0.57	0.5659



*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.2897	0.2730	127	12.05	<.0001	0.05	2.7496	3.8299
TRTP	THSm2.2	3.1384	0.1561	127	20.11	<.0001	0.05	2.8295	3.4473
TRTP	mCC	3.4266	0.2293	127	14.95	<.0001	0.05	2.9729	3.8803
TRTP	SA	3.2897	0.2730	127	12.05	<.0001	0.05	2.7496	3.8299
TRTP	THSm2.2	3.1384	0.1561	127	20.11	<.0001	0.05	2.8295	3.4473
TRTP	mCC	3.4266	0.2293	127	14.95	<.0001	0.05	2.9729	3.8803

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.1369	0.3550	127	-0.39	0.7005	0.05	-0.8393	0.5656
TRTP	THSm2.2	mCC	-0.2882	0.2746	127	-1.05	0.2959	0.05	-0.8316	0.2552
TRTP	THSm2.2	SA	-0.1513	0.3122	127	-0.48	0.6286	0.05	-0.7691	0.4664
TRTP	mCC	SA	0.1369	0.3550	127	0.39	0.7005	0.05	-0.5656	0.8393

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.3558

Fit Statistics	
-2 Res Log Likelihood	259.6
AIC (smaller is better)	261.6
AICC (smaller is better)	261.7
BIC (smaller is better)	264.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	76	37.04	<.0001
SEX	1	76	0.15	0.7041
UCPDGR1	1	76	9.53	0.0028
TRTP	2	76	10.87	<.0001



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*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.0584	0.3575	76	5.76	<.0001	0.05	1.3464	2.7705
TRTP	THSm2.2	3.0270	0.1909	76	15.86	<.0001	0.05	2.6468	3.4072
TRTP	mCC	3.8640	0.2087	76	18.52	<.0001	0.05	3.4484	4.2795
TRTP	SA	2.0584	0.3575	76	5.76	<.0001	0.05	1.3464	2.7705
TRTP	THSm2.2	3.0270	0.1909	76	15.86	<.0001	0.05	2.6468	3.4072
TRTP	mCC	3.8640	0.2087	76	18.52	<.0001	0.05	3.4484	4.2795

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8055	0.4087	76	-4.42	<.0001	0.05	-2.6196	-0.9915
TRTP	THSm2.2	mCC	-0.8370	0.2808	76	-2.98	0.0039	0.05	-1.3962	-0.2778
TRTP	THSm2.2	SA	0.9685	0.4039	76	2.40	0.0189	0.05	0.1641	1.7730
TRTP	mCC	SA	1.8055	0.4087	76	4.42	<.0001	0.05	0.9915	2.6196

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0521

Fit Statistics	
-2 Res Log Likelihood	233.9
AIC (smaller is better)	235.9
AICC (smaller is better)	236.0
BIC (smaller is better)	238.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	74	75.88	<.0001
SEX	1	74	0.15	0.6981
UCPDGR1	1	74	6.53	0.0127
TRTP	2	74	3.95	0.0234

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.1100	0.3945	74	5.35	<.0001	0.05	1.3240	2.8960
TRTP	THSm2.2	3.0005	0.1545	74	19.43	<.0001	0.05	2.6927	3.3082
TRTP	mCC	3.3297	0.1998	74	16.66	<.0001	0.05	2.9315	3.7279
TRTP	SA	2.1100	0.3945	74	5.35	<.0001	0.05	1.3240	2.8960
TRTP	THSm2.2	3.0005	0.1545	74	19.43	<.0001	0.05	2.6927	3.3082
TRTP	mCC	3.3297	0.1998	74	16.66	<.0001	0.05	2.9315	3.7279

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2197	0.4381	74	-2.78	0.0068	0.05	-2.0925	-0.3468
TRTP	THSm2.2	mCC	-0.3292	0.2505	74	-1.31	0.1929	0.05	-0.8284	0.1700
TRTP	THSm2.2	SA	0.8904	0.4241	74	2.10	0.0392	0.05	0.04548	1.7354
TRTP	mCC	SA	1.2197	0.4381	74	2.78	0.0068	0.05	0.3468	2.0925

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132



**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8753

Fit Statistics	
-2 Res Log Likelihood	460.5
AIC (smaller is better)	462.5
AICC (smaller is better)	462.6
BIC (smaller is better)	465.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	60.22	<.0001
SEX	1	126	1.63	0.2042
UCPDGR1	1	126	0.01	0.9146
TRTP	2	126	8.84	0.0003



**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.2880	0.2813	126	18.80	<.0001	0.05	4.7313	5.8446
TRTP	THSm2.2	3.9426	0.1610	126	24.48	<.0001	0.05	3.6239	4.2613
TRTP	mCC	4.1524	0.2401	126	17.29	<.0001	0.05	3.6772	4.6275
TRTP	SA	5.2880	0.2813	126	18.80	<.0001	0.05	4.7313	5.8446
TRTP	THSm2.2	3.9426	0.1610	126	24.48	<.0001	0.05	3.6239	4.2613
TRTP	mCC	4.1524	0.2401	126	17.29	<.0001	0.05	3.6772	4.6275

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.1356	0.3683	126	3.08	0.0025	0.05	0.4067	1.8644
TRTP	THSm2.2	mCC	-0.2098	0.2864	126	-0.73	0.4653	0.05	-0.7766	0.3570
TRTP	THSm2.2	SA	-1.3454	0.3216	126	-4.18	<.0001	0.05	-1.9818	-0.7089
TRTP	mCC	SA	-1.1356	0.3683	126	-3.08	0.0025	0.05	-1.8644	-0.4067

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4341

Fit Statistics	
-2 Res Log Likelihood	497.2
AIC (smaller is better)	499.2
AICC (smaller is better)	499.2
BIC (smaller is better)	502.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	30.34	<.0001
SEX	1	127	0.12	0.7348
UCPDGR1	1	127	0.07	0.7861
TRTP	2	127	3.04	0.0511

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.7471	0.3205	127	14.81	<.0001	0.05	4.1130	5.3813
TRTP	THSm2.2	3.8560	0.1834	127	21.02	<.0001	0.05	3.4930	4.2190
TRTP	mCC	3.9420	0.2694	127	14.63	<.0001	0.05	3.4090	4.4750
TRTP	SA	4.7471	0.3205	127	14.81	<.0001	0.05	4.1130	5.3813
TRTP	THSm2.2	3.8560	0.1834	127	21.02	<.0001	0.05	3.4930	4.2190
TRTP	mCC	3.9420	0.2694	127	14.63	<.0001	0.05	3.4090	4.4750

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.8052	0.4166	127	1.93	0.0555	0.05	-0.01930	1.6296
TRTP	THSm2.2	mCC	-0.08595	0.3227	127	-0.27	0.7904	0.05	-0.7245	0.5526
TRTP	THSm2.2	SA	-0.8911	0.3664	127	-2.43	0.0164	0.05	-1.6162	-0.1660
TRTP	mCC	SA	-0.8052	0.4166	127	-1.93	0.0555	0.05	-1.6296	0.01930

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	132

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	132
Number of Observations Used	132
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9944

Fit Statistics	
-2 Res Log Likelihood	468.3
AIC (smaller is better)	470.3
AICC (smaller is better)	470.3
BIC (smaller is better)	473.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	126	39.74	<.0001
SEX	1	126	1.61	0.2068
UCPDGR1	1	126	1.26	0.2633
TRTP	2	126	0.28	0.7587

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0895	0.2972	126	13.76	<.0001	0.05	3.5013	4.6776
TRTP	THSm2.2	3.8459	0.1661	126	23.15	<.0001	0.05	3.5172	4.1746
TRTP	mCC	3.8526	0.2439	126	15.80	<.0001	0.05	3.3700	4.3352
TRTP	SA	4.0895	0.2972	126	13.76	<.0001	0.05	3.5013	4.6776
TRTP	THSm2.2	3.8459	0.1661	126	23.15	<.0001	0.05	3.5172	4.1746
TRTP	mCC	3.8526	0.2439	126	15.80	<.0001	0.05	3.3700	4.3352

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2369	0.3821	126	0.62	0.5364	0.05	-0.5193	0.9930
TRTP	THSm2.2	mCC	-0.00670	0.2921	126	-0.02	0.9817	0.05	-0.5848	0.5714
TRTP	THSm2.2	SA	-0.2436	0.3372	126	-0.72	0.4715	0.05	-0.9110	0.4238
TRTP	mCC	SA	-0.2369	0.3821	126	-0.62	0.5364	0.05	-0.9930	0.5193



***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	84
Number of Observations Used	84
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2629

Fit Statistics	
-2 Res Log Likelihood	260.4
AIC (smaller is better)	262.4
AICC (smaller is better)	262.5
BIC (smaller is better)	264.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	78	34.89	<.0001
SEX	1	78	7.59	0.0073
UCPDGR1	1	78	14.76	0.0002
TRTP	2	78	11.28	<.0001

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.4207	0.3131	78	7.73	<.0001	0.05	1.7974	3.0440
TRTP	THSm2.2	3.7542	0.1843	78	20.37	<.0001	0.05	3.3873	4.1211
TRTP	mCC	4.1768	0.2028	78	20.60	<.0001	0.05	3.7732	4.5805
TRTP	SA	2.4207	0.3131	78	7.73	<.0001	0.05	1.7974	3.0440
TRTP	THSm2.2	3.7542	0.1843	78	20.37	<.0001	0.05	3.3873	4.1211
TRTP	mCC	4.1768	0.2028	78	20.60	<.0001	0.05	3.7732	4.5805

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.7561	0.3710	78	-4.73	<.0001	0.05	-2.4948	-1.0174
TRTP	THSm2.2	mCC	-0.4226	0.2731	78	-1.55	0.1257	0.05	-0.9663	0.1210
TRTP	THSm2.2	SA	1.3335	0.3611	78	3.69	0.0004	0.05	0.6147	2.0523
TRTP	mCC	SA	1.7561	0.3710	78	4.73	<.0001	0.05	1.0174	2.4948

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4940

Fit Statistics	
-2 Res Log Likelihood	500.3
AIC (smaller is better)	502.3
AICC (smaller is better)	502.3
BIC (smaller is better)	505.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	29.69	<.0001
SEX	1	127	2.17	0.1435
UCPDGR1	1	127	0.83	0.3633
TRTP	2	127	0.36	0.6988

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.8871	0.3244	127	11.98	<.0001	0.05	3.2452	4.5290
TRTP	THSm2.2	3.8433	0.1857	127	20.70	<.0001	0.05	3.4759	4.2108
TRTP	mCC	4.1177	0.2727	127	15.10	<.0001	0.05	3.5781	4.6572
TRTP	SA	3.8871	0.3244	127	11.98	<.0001	0.05	3.2452	4.5290
TRTP	THSm2.2	3.8433	0.1857	127	20.70	<.0001	0.05	3.4759	4.2108
TRTP	mCC	4.1177	0.2727	127	15.10	<.0001	0.05	3.5781	4.6572

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2306	0.4217	127	-0.55	0.5855	0.05	-1.0651	0.6040
TRTP	THSm2.2	mCC	-0.2743	0.3266	127	-0.84	0.4026	0.05	-0.9207	0.3720
TRTP	THSm2.2	SA	-0.04376	0.3709	127	-0.12	0.9063	0.05	-0.7777	0.6902
TRTP	mCC	SA	0.2306	0.4217	127	0.55	0.5855	0.05	-0.6040	1.0651

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1201

Fit Statistics	
-2 Res Log Likelihood	479.6
AIC (smaller is better)	481.6
AICC (smaller is better)	481.7
BIC (smaller is better)	484.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	53.50	<.0001
SEX	1	127	0.17	0.6817
UCPDGR1	1	127	0.64	0.4240
TRTP	2	127	0.35	0.7044



*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0448	0.2991	127	13.52	<.0001	0.05	3.4530	4.6366
TRTP	THSm2.2	3.7584	0.1712	127	21.95	<.0001	0.05	3.4197	4.0972
TRTP	mCC	3.8388	0.2514	127	15.27	<.0001	0.05	3.3414	4.3363
TRTP	SA	4.0448	0.2991	127	13.52	<.0001	0.05	3.4530	4.6366
TRTP	THSm2.2	3.7584	0.1712	127	21.95	<.0001	0.05	3.4197	4.0972
TRTP	mCC	3.8388	0.2514	127	15.27	<.0001	0.05	3.3414	4.3363

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2060	0.3888	127	0.53	0.5972	0.05	-0.5634	0.9754
TRTP	THSm2.2	mCC	-0.08037	0.3012	127	-0.27	0.7900	0.05	-0.6763	0.5156
TRTP	THSm2.2	SA	-0.2864	0.3420	127	-0.84	0.4039	0.05	-0.9630	0.3903
TRTP	mCC	SA	-0.2060	0.3888	127	-0.53	0.5972	0.05	-0.9754	0.5634

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.3871

Fit Statistics	
-2 Res Log Likelihood	261.2
AIC (smaller is better)	263.2
AICC (smaller is better)	263.3
BIC (smaller is better)	265.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	76	20.59	<.0001
SEX	1	76	0.49	0.4873
UCPDGR1	1	76	3.51	0.0649
TRTP	2	76	12.25	<.0001

*Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.4757	0.3609	76	6.86	<.0001	0.05	1.7568	3.1945
TRTP	THSm2.2	3.9725	0.1929	76	20.60	<.0001	0.05	3.5884	4.3567
TRTP	mCC	4.5182	0.2111	76	21.40	<.0001	0.05	4.0978	4.9387
TRTP	SA	2.4757	0.3609	76	6.86	<.0001	0.05	1.7568	3.1945
TRTP	THSm2.2	3.9725	0.1929	76	20.60	<.0001	0.05	3.5884	4.3567
TRTP	mCC	4.5182	0.2111	76	21.40	<.0001	0.05	4.0978	4.9387

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-2.0426	0.4127	76	-4.95	<.0001	0.05	-2.8646	-1.2205
TRTP	THSm2.2	mCC	-0.5457	0.2840	76	-1.92	0.0585	0.05	-1.1114	0.02003
TRTP	THSm2.2	SA	1.4969	0.4072	76	3.68	0.0004	0.05	0.6858	2.3079
TRTP	mCC	SA	2.0426	0.4127	76	4.95	<.0001	0.05	1.2205	2.8646

***Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	80



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**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	80
Number of Observations Used	80
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0533

Fit Statistics	
-2 Res Log Likelihood	233.9
AIC (smaller is better)	235.9
AICC (smaller is better)	235.9
BIC (smaller is better)	238.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	74	56.39	<.0001
SEX	1	74	0.03	0.8552
UCPDGR1	1	74	3.98	0.0497
TRTP	2	74	6.84	0.0019

**Listing 15.4.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.4069	0.3933	74	6.12	<.0001	0.05	1.6232	3.1906
TRTP	THSm2.2	3.7364	0.1542	74	24.24	<.0001	0.05	3.4292	4.0436
TRTP	mCC	4.0225	0.2000	74	20.11	<.0001	0.05	3.6240	4.4210
TRTP	SA	2.4069	0.3933	74	6.12	<.0001	0.05	1.6232	3.1906
TRTP	THSm2.2	3.7364	0.1542	74	24.24	<.0001	0.05	3.4292	4.0436
TRTP	mCC	4.0225	0.2000	74	20.11	<.0001	0.05	3.6240	4.4210

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6156	0.4372	74	-3.70	0.0004	0.05	-2.4867	-0.7445
TRTP	THSm2.2	mCC	-0.2861	0.2505	74	-1.14	0.2570	0.05	-0.7852	0.2129
TRTP	THSm2.2	SA	1.3294	0.4220	74	3.15	0.0024	0.05	0.4886	2.1703
TRTP	mCC	SA	1.6156	0.4372	74	3.70	0.0004	0.05	0.7445	2.4867



1

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153





2

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.5504

Fit Statistics	
-2 Res Log Likelihood	579.7
AIC (smaller is better)	581.7
AICC (smaller is better)	581.7
BIC (smaller is better)	584.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	36.01	<.0001
SEX	1	147	1.45	0.2308
UCPDGR1	1	147	0.30	0.5826
TRTP	2	147	8.07	0.0005

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.7052	0.2724	147	20.94	<.0001	0.05	5.1668	6.2436
TRTP	THSm2.2	4.5054	0.1822	147	24.73	<.0001	0.05	4.1454	4.8655
TRTP	mCC	4.4043	0.2570	147	17.14	<.0001	0.05	3.8964	4.9121
TRTP	SA	5.7052	0.2724	147	20.94	<.0001	0.05	5.1668	6.2436
TRTP	THSm2.2	4.5054	0.1822	147	24.73	<.0001	0.05	4.1454	4.8655
TRTP	mCC	4.4043	0.2570	147	17.14	<.0001	0.05	3.8964	4.9121

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.3010	0.3724	147	3.49	0.0006	0.05	0.5651	2.0369
TRTP	THSm2.2	mCC	0.1011	0.3130	147	0.32	0.7471	0.05	-0.5175	0.7198
TRTP	THSm2.2	SA	-1.1998	0.3251	147	-3.69	0.0003	0.05	-1.8423	-0.5574
TRTP	mCC	SA	-1.3010	0.3724	147	-3.49	0.0006	0.05	-2.0369	-0.5651



4

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.1898

Fit Statistics	
-2 Res Log Likelihood	612.6
AIC (smaller is better)	614.6
AICC (smaller is better)	614.6
BIC (smaller is better)	617.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	12.32	0.0006
SEX	1	147	0.35	0.5524
UCPDGR1	1	147	0.10	0.7502
TRTP	2	147	3.05	0.0506

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.2160	0.3086	147	16.90	<.0001	0.05	4.6061	5.8259
TRTP	THSm2.2	4.3369	0.2037	147	21.29	<.0001	0.05	3.9343	4.7396
TRTP	mCC	4.4054	0.2840	147	15.51	<.0001	0.05	3.8442	4.9666
TRTP	SA	5.2160	0.3086	147	16.90	<.0001	0.05	4.6061	5.8259
TRTP	THSm2.2	4.3369	0.2037	147	21.29	<.0001	0.05	3.9343	4.7396
TRTP	mCC	4.4054	0.2840	147	15.51	<.0001	0.05	3.8442	4.9666

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.8107	0.4168	147	1.94	0.0537	0.05	-0.01304	1.6343
TRTP	THSm2.2	mCC	-0.06845	0.3469	147	-0.20	0.8439	0.05	-0.7541	0.6171
TRTP	THSm2.2	SA	-0.8791	0.3672	147	-2.39	0.0179	0.05	-1.6048	-0.1534
TRTP	mCC	SA	-0.8107	0.4168	147	-1.94	0.0537	0.05	-1.6343	0.01304



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.9332

Fit Statistics	
-2 Res Log Likelihood	596.3
AIC (smaller is better)	598.3
AICC (smaller is better)	598.3
BIC (smaller is better)	601.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	21.60	<.0001
SEX	1	146	1.50	0.2222
UCPDGR1	1	146	0.91	0.3414
TRTP	2	146	0.78	0.4591

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6599	0.3011	146	15.48	<.0001	0.05	4.0648	5.2550
TRTP	THSm2.2	4.4487	0.1955	146	22.76	<.0001	0.05	4.0624	4.8350
TRTP	mCC	4.1635	0.2723	146	15.29	<.0001	0.05	3.6253	4.7017
TRTP	SA	4.6599	0.3011	146	15.48	<.0001	0.05	4.0648	5.2550
TRTP	THSm2.2	4.4487	0.1955	146	22.76	<.0001	0.05	4.0624	4.8350
TRTP	mCC	4.1635	0.2723	146	15.29	<.0001	0.05	3.6253	4.7017

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4964	0.4031	146	1.23	0.2202	0.05	-0.3003	1.2931
TRTP	THSm2.2	mCC	0.2852	0.3327	146	0.86	0.3926	0.05	-0.3722	0.9427
TRTP	THSm2.2	SA	-0.2111	0.3562	146	-0.59	0.5543	0.05	-0.9151	0.4928
TRTP	mCC	SA	-0.4964	0.4031	146	-1.23	0.2202	0.05	-1.2931	0.3003





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***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	147



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	147
Number of Observations Used	147
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4095

Fit Statistics	
-2 Res Log Likelihood	548.7
AIC (smaller is better)	550.7
AICC (smaller is better)	550.8
BIC (smaller is better)	553.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	141	10.26	0.0017
SEX	1	141	3.14	0.0785
UCPDGR1	1	141	0.03	0.8530
TRTP	2	141	4.91	0.0087



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.6410	0.2719	141	13.39	<.0001	0.05	3.1036	4.1785
TRTP	THSm2.2	4.6529	0.1804	141	25.79	<.0001	0.05	4.2963	5.0096
TRTP	mCC	4.2658	0.2535	141	16.83	<.0001	0.05	3.7647	4.7669
TRTP	SA	3.6410	0.2719	141	13.39	<.0001	0.05	3.1036	4.1785
TRTP	THSm2.2	4.6529	0.1804	141	25.79	<.0001	0.05	4.2963	5.0096
TRTP	mCC	4.2658	0.2535	141	16.83	<.0001	0.05	3.7647	4.7669

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.6248	0.3694	141	-1.69	0.0930	0.05	-1.3552	0.1055
TRTP	THSm2.2	mCC	0.3871	0.3088	141	1.25	0.2120	0.05	-0.2233	0.9975
TRTP	THSm2.2	SA	1.0119	0.3242	141	3.12	0.0022	0.05	0.3710	1.6528
TRTP	mCC	SA	0.6248	0.3694	141	1.69	0.0930	0.05	-0.1055	1.3552



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.1437

Fit Statistics	
-2 Res Log Likelihood	610.4
AIC (smaller is better)	612.4
AICC (smaller is better)	612.5
BIC (smaller is better)	615.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	20.43	<.0001
SEX	1	147	2.64	0.1061
UCPDGR1	1	147	1.10	0.2953
TRTP	2	147	0.12	0.8852



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*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5585	0.3064	147	14.88	<.0001	0.05	3.9530	5.1640
TRTP	THSm2.2	4.3784	0.2023	147	21.65	<.0001	0.05	3.9787	4.7782
TRTP	mCC	4.4366	0.2819	147	15.74	<.0001	0.05	3.8795	4.9937
TRTP	SA	4.5585	0.3064	147	14.88	<.0001	0.05	3.9530	5.1640
TRTP	THSm2.2	4.3784	0.2023	147	21.65	<.0001	0.05	3.9787	4.7782
TRTP	mCC	4.4366	0.2819	147	15.74	<.0001	0.05	3.8795	4.9937

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1219	0.4138	147	0.29	0.7687	0.05	-0.6958	0.9396
TRTP	THSm2.2	mCC	-0.05816	0.3444	147	-0.17	0.8661	0.05	-0.7388	0.6225
TRTP	THSm2.2	SA	-0.1801	0.3646	147	-0.49	0.6221	0.05	-0.9005	0.5404
TRTP	mCC	SA	-0.1219	0.4138	147	-0.29	0.7687	0.05	-0.9396	0.6958



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.1500

Fit Statistics	
-2 Res Log Likelihood	606.7
AIC (smaller is better)	608.7
AICC (smaller is better)	608.7
BIC (smaller is better)	611.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	31.64	<.0001
SEX	1	146	0.61	0.4351
UCPDGR1	1	146	1.14	0.2867
TRTP	2	146	1.20	0.3046





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*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.6857	0.3068	146	15.27	<.0001	0.05	4.0794	5.2920
TRTP	THSm2.2	4.3651	0.2037	146	21.43	<.0001	0.05	3.9626	4.7676
TRTP	mCC	4.0455	0.2822	146	14.33	<.0001	0.05	3.4878	4.6033
TRTP	SA	4.6857	0.3068	146	15.27	<.0001	0.05	4.0794	5.2920
TRTP	THSm2.2	4.3651	0.2037	146	21.43	<.0001	0.05	3.9626	4.7676
TRTP	mCC	4.0455	0.2822	146	14.33	<.0001	0.05	3.4878	4.6033

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.6402	0.4142	146	1.55	0.1244	0.05	-0.1784	1.4588
TRTP	THSm2.2	mCC	0.3196	0.3457	146	0.92	0.3568	0.05	-0.3636	1.0028
TRTP	THSm2.2	SA	-0.3206	0.3660	146	-0.88	0.3824	0.05	-1.0439	0.4027
TRTP	mCC	SA	-0.6402	0.4142	146	-1.55	0.1244	0.05	-1.4588	0.1784



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	141

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	141
Number of Observations Used	141
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1581

Fit Statistics	
-2 Res Log Likelihood	511.3
AIC (smaller is better)	513.3
AICC (smaller is better)	513.3
BIC (smaller is better)	516.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	135	16.63	<.0001
SEX	1	135	0.04	0.8401
UCPDGR1	1	135	1.15	0.2846
TRTP	2	135	11.18	<.0001

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.4686	0.2651	135	13.08	<.0001	0.05	2.9443	3.9930
TRTP	THSm2.2	4.7943	0.1721	135	27.86	<.0001	0.05	4.4540	5.1346
TRTP	mCC	5.0192	0.2475	135	20.28	<.0001	0.05	4.5297	5.5087
TRTP	SA	3.4686	0.2651	135	13.08	<.0001	0.05	2.9443	3.9930
TRTP	THSm2.2	4.7943	0.1721	135	27.86	<.0001	0.05	4.4540	5.1346
TRTP	mCC	5.0192	0.2475	135	20.28	<.0001	0.05	4.5297	5.5087

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.5506	0.3611	135	-4.29	<.0001	0.05	-2.2647	-0.8364
TRTP	THSm2.2	mCC	-0.2249	0.2989	135	-0.75	0.4531	0.05	-0.8160	0.3662
TRTP	THSm2.2	SA	1.3257	0.3150	135	4.21	<.0001	0.05	0.7027	1.9487
TRTP	mCC	SA	1.5506	0.3611	135	4.29	<.0001	0.05	0.8364	2.2647

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.3117

Fit Statistics	
-2 Res Log Likelihood	483.3
AIC (smaller is better)	485.3
AICC (smaller is better)	485.3
BIC (smaller is better)	488.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	22.65	<.0001
SEX	1	125	2.16	0.1439
UCPDGR1	1	125	5.65	0.0189
TRTP	2	125	3.57	0.0312

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 1 - Reward Parameter Category 2 (N)=1 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.6881	0.2832	125	13.02	<.0001	0.05	3.1275	4.2486
TRTP	THSm2.2	4.5742	0.1819	125	25.14	<.0001	0.05	4.2141	4.9342
TRTP	mCC	4.4537	0.2760	125	16.14	<.0001	0.05	3.9076	4.9999
TRTP	SA	3.6881	0.2832	125	13.02	<.0001	0.05	3.1275	4.2486
TRTP	THSm2.2	4.5742	0.1819	125	25.14	<.0001	0.05	4.2141	4.9342
TRTP	mCC	4.4537	0.2760	125	16.14	<.0001	0.05	3.9076	4.9999

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7657	0.3941	125	-1.94	0.0543	0.05	-1.5456	0.01423
TRTP	THSm2.2	mCC	0.1204	0.3281	125	0.37	0.7142	0.05	-0.5289	0.7698
TRTP	THSm2.2	SA	0.8861	0.3362	125	2.64	0.0095	0.05	0.2207	1.5515
TRTP	mCC	SA	0.7657	0.3941	125	1.94	0.0543	0.05	-0.01423	1.5456



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.7117

Fit Statistics	
-2 Res Log Likelihood	521.0
AIC (smaller is better)	523.0
AICC (smaller is better)	523.1
BIC (smaller is better)	526.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	112.87	<.0001
SEX	1	147	8.54	0.0040
UCPDGR1	1	147	0.08	0.7729
TRTP	2	147	10.54	<.0001

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5683	0.2236	147	20.43	<.0001	0.05	4.1263	5.0103
TRTP	THSm2.2	3.3808	0.1492	147	22.66	<.0001	0.05	3.0860	3.6757
TRTP	mCC	3.4659	0.2106	147	16.46	<.0001	0.05	3.0498	3.8821
TRTP	SA	4.5683	0.2236	147	20.43	<.0001	0.05	4.1263	5.0103
TRTP	THSm2.2	3.3808	0.1492	147	22.66	<.0001	0.05	3.0860	3.6757
TRTP	mCC	3.4659	0.2106	147	16.46	<.0001	0.05	3.0498	3.8821

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.1024	0.3059	147	3.60	0.0004	0.05	0.4978	1.7069
TRTP	THSm2.2	mCC	-0.08510	0.2561	147	-0.33	0.7401	0.05	-0.5912	0.4210
TRTP	THSm2.2	SA	-1.1875	0.2669	147	-4.45	<.0001	0.05	-1.7149	-0.6600
TRTP	mCC	SA	-1.1024	0.3059	147	-3.60	0.0004	0.05	-1.7069	-0.4978

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0226

Fit Statistics	
-2 Res Log Likelihood	545.5
AIC (smaller is better)	547.5
AICC (smaller is better)	547.6
BIC (smaller is better)	550.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	85.75	<.0001
SEX	1	147	1.13	0.2891
UCPDGR1	1	147	0.04	0.8395
TRTP	2	147	3.68	0.0275

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9808	0.2465	147	16.15	<.0001	0.05	3.4935	4.4680
TRTP	THSm2.2	3.2205	0.1623	147	19.84	<.0001	0.05	2.8998	3.5412
TRTP	mCC	3.2340	0.2263	147	14.29	<.0001	0.05	2.7868	3.6812
TRTP	SA	3.9808	0.2465	147	16.15	<.0001	0.05	3.4935	4.4680
TRTP	THSm2.2	3.2205	0.1623	147	19.84	<.0001	0.05	2.8998	3.5412
TRTP	mCC	3.2340	0.2263	147	14.29	<.0001	0.05	2.7868	3.6812

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.7468	0.3333	147	2.24	0.0266	0.05	0.08810	1.4055
TRTP	THSm2.2	mCC	-0.01348	0.2760	147	-0.05	0.9611	0.05	-0.5590	0.5320
TRTP	THSm2.2	SA	-0.7603	0.2935	147	-2.59	0.0106	0.05	-1.3403	-0.1802
TRTP	mCC	SA	-0.7468	0.3333	147	-2.24	0.0266	0.05	-1.4055	-0.08810

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5848

Fit Statistics	
-2 Res Log Likelihood	506.3
AIC (smaller is better)	508.3
AICC (smaller is better)	508.4
BIC (smaller is better)	511.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	96.13	<.0001
SEX	1	146	2.58	0.1107
UCPDGR1	1	146	1.38	0.2418
TRTP	2	146	0.21	0.8114

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.3716	0.2219	146	15.19	<.0001	0.05	2.9330	3.8102
TRTP	THSm2.2	3.2082	0.1437	146	22.33	<.0001	0.05	2.9242	3.4921
TRTP	mCC	3.2147	0.2003	146	16.05	<.0001	0.05	2.8188	3.6107
TRTP	SA	3.3716	0.2219	146	15.19	<.0001	0.05	2.9330	3.8102
TRTP	THSm2.2	3.2082	0.1437	146	22.33	<.0001	0.05	2.9242	3.4921
TRTP	mCC	3.2147	0.2003	146	16.05	<.0001	0.05	2.8188	3.6107

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1568	0.2975	146	0.53	0.5988	0.05	-0.4311	0.7448
TRTP	THSm2.2	mCC	-0.00655	0.2443	146	-0.03	0.9786	0.05	-0.4894	0.4763
TRTP	THSm2.2	SA	-0.1634	0.2626	146	-0.62	0.5347	0.05	-0.6823	0.3555
TRTP	mCC	SA	-0.1568	0.2975	146	-0.53	0.5988	0.05	-0.7448	0.4311



***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	147

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	147
Number of Observations Used	147
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4588

Fit Statistics	
-2 Res Log Likelihood	477.9
AIC (smaller is better)	479.9
AICC (smaller is better)	480.0
BIC (smaller is better)	482.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	141	82.99	<.0001
SEX	1	141	0.37	0.5437
UCPDGR1	1	141	0.37	0.5425
TRTP	2	141	8.21	0.0004

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.2711	0.2124	141	10.69	<.0001	0.05	1.8512	2.6910
TRTP	THSm2.2	3.1250	0.1406	141	22.23	<.0001	0.05	2.8471	3.4029
TRTP	mCC	3.3830	0.1973	141	17.14	<.0001	0.05	2.9929	3.7731
TRTP	SA	2.2711	0.2124	141	10.69	<.0001	0.05	1.8512	2.6910
TRTP	THSm2.2	3.1250	0.1406	141	22.23	<.0001	0.05	2.8471	3.4029
TRTP	mCC	3.3830	0.1973	141	17.14	<.0001	0.05	2.9929	3.7731

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.1119	0.2888	141	-3.85	0.0002	0.05	-1.6828	-0.5410
TRTP	THSm2.2	mCC	-0.2580	0.2400	141	-1.07	0.2843	0.05	-0.7325	0.2166
TRTP	THSm2.2	SA	0.8539	0.2537	141	3.37	0.0010	0.05	0.3524	1.3553
TRTP	mCC	SA	1.1119	0.2888	141	3.85	0.0002	0.05	0.5410	1.6828

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1871

Fit Statistics	
-2 Res Log Likelihood	557.0
AIC (smaller is better)	559.0
AICC (smaller is better)	559.1
BIC (smaller is better)	562.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	66.60	<.0001
SEX	1	147	3.79	0.0536
UCPDGR1	1	147	1.30	0.2554
TRTP	2	147	0.37	0.6903

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.0954	0.2564	147	12.07	<.0001	0.05	2.5888	3.6020
TRTP	THSm2.2	3.2211	0.1688	147	19.09	<.0001	0.05	2.8876	3.5547
TRTP	mCC	3.3899	0.2353	147	14.41	<.0001	0.05	2.9249	3.8550
TRTP	SA	3.0954	0.2564	147	12.07	<.0001	0.05	2.5888	3.6020
TRTP	THSm2.2	3.2211	0.1688	147	19.09	<.0001	0.05	2.8876	3.5547
TRTP	mCC	3.3899	0.2353	147	14.41	<.0001	0.05	2.9249	3.8550

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2945	0.3466	147	-0.85	0.3968	0.05	-0.9795	0.3904
TRTP	THSm2.2	mCC	-0.1688	0.2870	147	-0.59	0.5575	0.05	-0.7360	0.3985
TRTP	THSm2.2	SA	0.1258	0.3052	147	0.41	0.6809	0.05	-0.4774	0.7289
TRTP	mCC	SA	0.2945	0.3466	147	0.85	0.3968	0.05	-0.3904	0.9795



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***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8038

Fit Statistics	
-2 Res Log Likelihood	525.2
AIC (smaller is better)	527.2
AICC (smaller is better)	527.3
BIC (smaller is better)	530.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	99.89	<.0001
SEX	1	146	0.26	0.6096
UCPDGR1	1	146	0.14	0.7082
TRTP	2	146	0.10	0.9066



**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 5 Analysis Visit (N)=105**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.2181	0.2329	146	13.82	<.0001	0.05	2.7577	3.6784
TRTP	THSm2.2	3.1328	0.1541	146	20.33	<.0001	0.05	2.8282	3.4374
TRTP	mCC	3.2376	0.2137	146	15.15	<.0001	0.05	2.8153	3.6599
TRTP	SA	3.2181	0.2329	146	13.82	<.0001	0.05	2.7577	3.6784
TRTP	THSm2.2	3.1328	0.1541	146	20.33	<.0001	0.05	2.8282	3.4374
TRTP	mCC	3.2376	0.2137	146	15.15	<.0001	0.05	2.8153	3.6599

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.01951	0.3148	146	-0.06	0.9507	0.05	-0.6416	0.6026
TRTP	THSm2.2	mCC	-0.1048	0.2613	146	-0.40	0.6890	0.05	-0.6211	0.4116
TRTP	THSm2.2	SA	-0.08525	0.2780	146	-0.31	0.7595	0.05	-0.6346	0.4641
TRTP	mCC	SA	0.01951	0.3148	146	0.06	0.9507	0.05	-0.6026	0.6416

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	141



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	141
Number of Observations Used	141
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4515

Fit Statistics	
-2 Res Log Likelihood	457.7
AIC (smaller is better)	459.7
AICC (smaller is better)	459.8
BIC (smaller is better)	462.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	135	67.22	<.0001
SEX	1	135	0.91	0.3407
UCPDGR1	1	135	0.29	0.5929
TRTP	2	135	8.89	0.0002



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*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.3533	0.2186	135	10.76	<.0001	0.05	1.9209	2.7857
TRTP	THSm2.2	2.9853	0.1412	135	21.14	<.0001	0.05	2.7060	3.2646
TRTP	mCC	3.6110	0.2036	135	17.73	<.0001	0.05	3.2083	4.0138
TRTP	SA	2.3533	0.2186	135	10.76	<.0001	0.05	1.9209	2.7857
TRTP	THSm2.2	2.9853	0.1412	135	21.14	<.0001	0.05	2.7060	3.2646
TRTP	mCC	3.6110	0.2036	135	17.73	<.0001	0.05	3.2083	4.0138

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.2577	0.2988	135	-4.21	<.0001	0.05	-1.8486	-0.6669
TRTP	THSm2.2	mCC	-0.6258	0.2454	135	-2.55	0.0119	0.05	-1.1110	-0.1405
TRTP	THSm2.2	SA	0.6320	0.2599	135	2.43	0.0163	0.05	0.1180	1.1459
TRTP	mCC	SA	1.2577	0.2988	135	4.21	<.0001	0.05	0.6669	1.8486

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2671

Fit Statistics	
-2 Res Log Likelihood	408.1
AIC (smaller is better)	410.1
AICC (smaller is better)	410.1
BIC (smaller is better)	412.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	107.89	<.0001
SEX	1	125	1.92	0.1687
UCPDGR1	1	125	0.40	0.5289
TRTP	2	125	3.25	0.0419

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Factor 2 - Relief Parameter Category 2 (N)=2 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.4589	0.2111	125	11.65	<.0001	0.05	2.0411	2.8766
TRTP	THSm2.2	3.0014	0.1350	125	22.23	<.0001	0.05	2.7342	3.2685
TRTP	mCC	3.1620	0.2045	125	15.47	<.0001	0.05	2.7574	3.5667
TRTP	SA	2.4589	0.2111	125	11.65	<.0001	0.05	2.0411	2.8766
TRTP	THSm2.2	3.0014	0.1350	125	22.23	<.0001	0.05	2.7342	3.2685
TRTP	mCC	3.1620	0.2045	125	15.47	<.0001	0.05	2.7574	3.5667

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7032	0.2936	125	-2.40	0.0181	0.05	-1.2842	-0.1221
TRTP	THSm2.2	mCC	-0.1606	0.2428	125	-0.66	0.5095	0.05	-0.6413	0.3200
TRTP	THSm2.2	SA	0.5425	0.2511	125	2.16	0.0327	0.05	0.04551	1.0395
TRTP	mCC	SA	0.7032	0.2936	125	2.40	0.0181	0.05	0.1221	1.2842



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***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153





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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8568

Fit Statistics	
-2 Res Log Likelihood	532.9
AIC (smaller is better)	534.9
AICC (smaller is better)	534.9
BIC (smaller is better)	537.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	71.38	<.0001
SEX	1	147	4.59	0.0338
UCPDGR1	1	147	0.10	0.7574
TRTP	2	147	10.19	<.0001

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.1304	0.2327	147	22.05	<.0001	0.05	4.6706	5.5901
TRTP	THSm2.2	3.9399	0.1554	147	25.35	<.0001	0.05	3.6328	4.2471
TRTP	mCC	3.9473	0.2192	147	18.01	<.0001	0.05	3.5142	4.3804
TRTP	SA	5.1304	0.2327	147	22.05	<.0001	0.05	4.6706	5.5901
TRTP	THSm2.2	3.9399	0.1554	147	25.35	<.0001	0.05	3.6328	4.2471
TRTP	mCC	3.9473	0.2192	147	18.01	<.0001	0.05	3.5142	4.3804

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.1831	0.3179	147	3.72	0.0003	0.05	0.5548	1.8113
TRTP	THSm2.2	mCC	-0.00738	0.2668	147	-0.03	0.9780	0.05	-0.5346	0.5198
TRTP	THSm2.2	SA	-1.1904	0.2777	147	-4.29	<.0001	0.05	-1.7392	-0.6417
TRTP	mCC	SA	-1.1831	0.3179	147	-3.72	0.0003	0.05	-1.8113	-0.5548

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.3766

Fit Statistics	
-2 Res Log Likelihood	569.2
AIC (smaller is better)	571.2
AICC (smaller is better)	571.2
BIC (smaller is better)	574.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	36.57	<.0001
SEX	1	147	0.86	0.3566
UCPDGR1	1	147	0.08	0.7772
TRTP	2	147	3.42	0.0353

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.5836	0.2668	147	17.18	<.0001	0.05	4.0564	5.1108
TRTP	THSm2.2	3.7791	0.1759	147	21.48	<.0001	0.05	3.4314	4.1267
TRTP	mCC	3.8356	0.2451	147	15.65	<.0001	0.05	3.3512	4.3200
TRTP	SA	4.5836	0.2668	147	17.18	<.0001	0.05	4.0564	5.1108
TRTP	THSm2.2	3.7791	0.1759	147	21.48	<.0001	0.05	3.4314	4.1267
TRTP	mCC	3.8356	0.2451	147	15.65	<.0001	0.05	3.3512	4.3200

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.7481	0.3603	147	2.08	0.0396	0.05	0.03600	1.4601
TRTP	THSm2.2	mCC	-0.05648	0.2993	147	-0.19	0.8506	0.05	-0.6479	0.5349
TRTP	THSm2.2	SA	-0.8045	0.3176	147	-2.53	0.0124	0.05	-1.4322	-0.1769
TRTP	mCC	SA	-0.7481	0.3603	147	-2.08	0.0396	0.05	-1.4601	-0.03600

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9756

Fit Statistics	
-2 Res Log Likelihood	538.4
AIC (smaller is better)	540.4
AICC (smaller is better)	540.5
BIC (smaller is better)	543.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	44.20	<.0001
SEX	1	146	2.40	0.1234
UCPDGR1	1	146	1.52	0.2196
TRTP	2	146	0.42	0.6554

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.0045	0.2475	146	16.18	<.0001	0.05	3.5154	4.4936
TRTP	THSm2.2	3.8304	0.1604	146	23.87	<.0001	0.05	3.5133	4.1474
TRTP	mCC	3.6996	0.2235	146	16.55	<.0001	0.05	3.2579	4.1413
TRTP	SA	4.0045	0.2475	146	16.18	<.0001	0.05	3.5154	4.4936
TRTP	THSm2.2	3.8304	0.1604	146	23.87	<.0001	0.05	3.5133	4.1474
TRTP	mCC	3.6996	0.2235	146	16.55	<.0001	0.05	3.2579	4.1413

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3049	0.3314	146	0.92	0.3590	0.05	-0.3500	0.9599
TRTP	THSm2.2	mCC	0.1308	0.2729	146	0.48	0.6324	0.05	-0.4085	0.6700
TRTP	THSm2.2	SA	-0.1742	0.2928	146	-0.59	0.5529	0.05	-0.7529	0.4045
TRTP	mCC	SA	-0.3049	0.3314	146	-0.92	0.3590	0.05	-0.9599	0.3500



***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	147



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	147
Number of Observations Used	147
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6557

Fit Statistics	
-2 Res Log Likelihood	495.7
AIC (smaller is better)	497.7
AICC (smaller is better)	497.7
BIC (smaller is better)	500.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	141	34.73	<.0001
SEX	1	141	1.53	0.2178
UCPDGR1	1	141	0.04	0.8491
TRTP	2	141	6.70	0.0017

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.9404	0.2258	141	13.02	<.0001	0.05	2.4941	3.3868
TRTP	THSm2.2	3.8928	0.1497	141	26.01	<.0001	0.05	3.5969	4.1887
TRTP	mCC	3.8360	0.2101	141	18.26	<.0001	0.05	3.4206	4.2514
TRTP	SA	2.9404	0.2258	141	13.02	<.0001	0.05	2.4941	3.3868
TRTP	THSm2.2	3.8928	0.1497	141	26.01	<.0001	0.05	3.5969	4.1887
TRTP	mCC	3.8360	0.2101	141	18.26	<.0001	0.05	3.4206	4.2514

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.8956	0.3067	141	-2.92	0.0041	0.05	-1.5020	-0.2892
TRTP	THSm2.2	mCC	0.05680	0.2558	141	0.22	0.8246	0.05	-0.4489	0.5625
TRTP	THSm2.2	SA	0.9524	0.2695	141	3.53	0.0006	0.05	0.4196	1.4851
TRTP	mCC	SA	0.8956	0.3067	141	2.92	0.0041	0.05	0.2892	1.5020

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4144

Fit Statistics	
-2 Res Log Likelihood	571.5
AIC (smaller is better)	573.5
AICC (smaller is better)	573.5
BIC (smaller is better)	576.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	34.66	<.0001
SEX	1	147	3.71	0.0562
UCPDGR1	1	147	1.56	0.2132
TRTP	2	147	0.09	0.9180

*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.8131	0.2689	147	14.18	<.0001	0.05	3.2817	4.3445
TRTP	THSm2.2	3.8027	0.1773	147	21.45	<.0001	0.05	3.4523	4.1532
TRTP	mCC	3.9238	0.2471	147	15.88	<.0001	0.05	3.4356	4.4121
TRTP	SA	3.8131	0.2689	147	14.18	<.0001	0.05	3.2817	4.3445
TRTP	THSm2.2	3.8027	0.1773	147	21.45	<.0001	0.05	3.4523	4.1532
TRTP	mCC	3.9238	0.2471	147	15.88	<.0001	0.05	3.4356	4.4121

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.1107	0.3632	147	-0.30	0.7609	0.05	-0.8284	0.6070
TRTP	THSm2.2	mCC	-0.1211	0.3016	147	-0.40	0.6887	0.05	-0.7172	0.4750
TRTP	THSm2.2	SA	-0.01037	0.3201	147	-0.03	0.9742	0.05	-0.6430	0.6223
TRTP	mCC	SA	0.1107	0.3632	147	0.30	0.7609	0.05	-0.6070	0.8284

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	152



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	152
Number of Observations Used	152
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1430

Fit Statistics	
-2 Res Log Likelihood	550.3
AIC (smaller is better)	552.3
AICC (smaller is better)	552.3
BIC (smaller is better)	555.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	146	56.49	<.0001
SEX	1	146	0.59	0.4451
UCPDGR1	1	146	0.86	0.3547
TRTP	2	146	0.38	0.6873



*Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*

Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9430	0.2534	146	15.56	<.0001	0.05	3.4421	4.4439
TRTP	THSm2.2	3.7496	0.1680	146	22.32	<.0001	0.05	3.4175	4.0817
TRTP	mCC	3.6503	0.2327	146	15.68	<.0001	0.05	3.1903	4.1103
TRTP	SA	3.9430	0.2534	146	15.56	<.0001	0.05	3.4421	4.4439
TRTP	THSm2.2	3.7496	0.1680	146	22.32	<.0001	0.05	3.4175	4.0817
TRTP	mCC	3.6503	0.2327	146	15.68	<.0001	0.05	3.1903	4.1103

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2927	0.3422	146	0.86	0.3938	0.05	-0.3836	0.9689
TRTP	THSm2.2	mCC	0.09931	0.2849	146	0.35	0.7279	0.05	-0.4637	0.6623
TRTP	THSm2.2	SA	-0.1933	0.3025	146	-0.64	0.5237	0.05	-0.7912	0.4045
TRTP	mCC	SA	-0.2927	0.3422	146	-0.86	0.3938	0.05	-0.9689	0.3836

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	141



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**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	141
Number of Observations Used	141
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4945

Fit Statistics	
-2 Res Log Likelihood	461.6
AIC (smaller is better)	463.6
AICC (smaller is better)	463.6
BIC (smaller is better)	466.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	135	34.71	<.0001
SEX	1	135	0.19	0.6602
UCPDGR1	1	135	0.27	0.6042
TRTP	2	135	11.85	<.0001

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.8952	0.2212	135	13.09	<.0001	0.05	2.4576	3.3327
TRTP	THSm2.2	3.8931	0.1433	135	27.18	<.0001	0.05	3.6098	4.1764
TRTP	mCC	4.3272	0.2063	135	20.98	<.0001	0.05	3.9192	4.7351
TRTP	SA	2.8952	0.2212	135	13.09	<.0001	0.05	2.4576	3.3327
TRTP	THSm2.2	3.8931	0.1433	135	27.18	<.0001	0.05	3.6098	4.1764
TRTP	mCC	4.3272	0.2063	135	20.98	<.0001	0.05	3.9192	4.7351

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.4320	0.3018	135	-4.74	<.0001	0.05	-2.0288	-0.8351
TRTP	THSm2.2	mCC	-0.4341	0.2488	135	-1.74	0.0833	0.05	-0.9262	0.05800
TRTP	THSm2.2	SA	0.9979	0.2629	135	3.80	0.0002	0.05	0.4779	1.5179
TRTP	mCC	SA	1.4320	0.3018	135	4.74	<.0001	0.05	0.8351	2.0288

***Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS*****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.QSU_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5272

Fit Statistics	
-2 Res Log Likelihood	431.3
AIC (smaller is better)	433.3
AICC (smaller is better)	433.4
BIC (smaller is better)	436.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	51.17	<.0001
SEX	1	125	2.70	0.1027
UCPDGR1	1	125	3.70	0.0566
TRTP	2	125	4.01	0.0204

**Listing 15.4.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter Category 2=Total Score Parameter Category 2 (N)=3 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.0573	0.2310	125	13.24	<.0001	0.05	2.6002	3.5144
TRTP	THSm2.2	3.7929	0.1481	125	25.62	<.0001	0.05	3.4998	4.0859
TRTP	mCC	3.8163	0.2243	125	17.01	<.0001	0.05	3.3723	4.2603
TRTP	SA	3.0573	0.2310	125	13.24	<.0001	0.05	2.6002	3.5144
TRTP	THSm2.2	3.7929	0.1481	125	25.62	<.0001	0.05	3.4998	4.0859
TRTP	mCC	3.8163	0.2243	125	17.01	<.0001	0.05	3.3723	4.2603

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.7590	0.3212	125	-2.36	0.0197	0.05	-1.3947	-0.1233
TRTP	THSm2.2	mCC	-0.02345	0.2666	125	-0.09	0.9301	0.05	-0.5512	0.5043
TRTP	THSm2.2	SA	0.7356	0.2745	125	2.68	0.0084	0.05	0.1923	1.2789
TRTP	mCC	SA	0.7590	0.3212	125	2.36	0.0197	0.05	0.1233	1.3947



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7841

Fit Statistics	
-2 Res Log Likelihood	283.1
AIC (smaller is better)	285.1
AICC (smaller is better)	285.1
BIC (smaller is better)	287.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	6.17	0.0146
SEX	1	102	1.95	0.1654
UCPDGR1	1	102	1.53	0.2190
TRTP	1	102	0.26	0.6099

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.3423	0.1046	102	12.84	<.0001	0.05	1.1349	1.5497
TRTP	mCC	1.4385	0.1588	102	9.06	<.0001	0.05	1.1234	1.7536

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.09621	0.1880	102	-0.51	0.6099	0.05	-0.4691	0.2767

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4288

Fit Statistics	
-2 Res Log Likelihood	225.6
AIC (smaller is better)	227.6
AICC (smaller is better)	227.7
BIC (smaller is better)	230.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	15.85	0.0001
SEX	1	104	1.38	0.2423
UCPDGR1	1	104	0.65	0.4206
TRTP	1	104	0.79	0.3759

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2652	0.07731	104	16.37	<.0001	0.05	1.1119	1.4186
TRTP	mCC	1.1442	0.1135	104	10.08	<.0001	0.05	0.9191	1.3694

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.1210	0.1361	104	0.89	0.3759	0.05	-0.1488	0.3908

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3633

Fit Statistics	
-2 Res Log Likelihood	208.4
AIC (smaller is better)	210.4
AICC (smaller is better)	210.4
BIC (smaller is better)	213.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	12.40	0.0006
SEX	1	104	0.05	0.8158
UCPDGR1	1	104	0.36	0.5497
TRTP	1	104	0.23	0.6333

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2316	0.07116	104	17.31	<.0001	0.05	1.0905	1.3727
TRTP	mCC	1.1717	0.1045	104	11.21	<.0001	0.05	0.9645	1.3790

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.05993	0.1252	104	0.48	0.6333	0.05	-0.1884	0.3083





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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	72



11

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	72
Number of Observations Used	72
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2872

Fit Statistics	
-2 Res Log Likelihood	123.5
AIC (smaller is better)	125.5
AICC (smaller is better)	125.5
BIC (smaller is better)	127.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	67	13.90	0.0004
SEX	1	67	2.20	0.1428
UCPDGR1	1	67	0.72	0.3990
TRTP	1	67	0.24	0.6247



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.1475	0.08801	67	13.04	<.0001	0.05	0.9718	1.3232
TRTP	mCC	1.2110	0.09486	67	12.77	<.0001	0.05	1.0216	1.4003

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.06347	0.1292	67	-0.49	0.6247	0.05	-0.3213	0.1943



13

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4298

Fit Statistics	
-2 Res Log Likelihood	225.9
AIC (smaller is better)	227.9
AICC (smaller is better)	227.9
BIC (smaller is better)	230.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	10.36	0.0017
SEX	1	104	0.20	0.6519
UCPDGR1	1	104	0.48	0.4880
TRTP	1	104	0.16	0.6895



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2272	0.07741	104	15.85	<.0001	0.05	1.0737	1.3807
TRTP	mCC	1.1727	0.1137	104	10.31	<.0001	0.05	0.9472	1.3981

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.05458	0.1362	104	0.40	0.6895	0.05	-0.2156	0.3247

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6844

Fit Statistics	
-2 Res Log Likelihood	274.3
AIC (smaller is better)	276.3
AICC (smaller is better)	276.3
BIC (smaller is better)	278.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	6.90	0.0099
SEX	1	104	0.41	0.5242
UCPDGR1	1	104	1.41	0.2379
TRTP	1	104	0.74	0.3914



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.3268	0.09767	104	13.58	<.0001	0.05	1.1331	1.5205
TRTP	mCC	1.1788	0.1435	104	8.22	<.0001	0.05	0.8943	1.4633

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.1480	0.1719	104	0.86	0.3914	0.05	-0.1929	0.4888

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2842

Fit Statistics	
-2 Res Log Likelihood	121.1
AIC (smaller is better)	123.1
AICC (smaller is better)	123.2
BIC (smaller is better)	125.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	0.30	0.5868
SEX	1	66	1.25	0.2677
UCPDGR1	1	66	2.04	0.1584
TRTP	1	66	0.52	0.4731

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.1006	0.08814	66	12.49	<.0001	0.05	0.9246	1.2766
TRTP	mCC	1.1948	0.09633	66	12.40	<.0001	0.05	1.0025	1.3871

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.09420	0.1305	66	-0.72	0.4731	0.05	-0.3548	0.1664

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	78

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2889

Fit Statistics	
-2 Res Log Likelihood	133.7
AIC (smaller is better)	135.7
AICC (smaller is better)	135.8
BIC (smaller is better)	138.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	73	0.42	0.5190
SEX	1	73	0.27	0.6038
UCPDGR1	1	73	4.13	0.0457
TRTP	1	73	0.41	0.5246

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2179	0.08045	73	15.14	<.0001	0.05	1.0576	1.3782
TRTP	mCC	1.1366	0.09791	73	11.61	<.0001	0.05	0.9415	1.3318

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.08126	0.1271	73	0.64	0.5246	0.05	-0.1720	0.3346

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4394

Fit Statistics	
-2 Res Log Likelihood	400.1
AIC (smaller is better)	402.1
AICC (smaller is better)	402.2
BIC (smaller is better)	404.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	19.28	<.0001
SEX	1	102	0.03	0.8556
UCPDGR1	1	102	0.02	0.8837
TRTP	1	102	22.97	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9549	0.1846	102	21.43	<.0001	0.05	3.5888	4.3210
TRTP	mCC	5.5505	0.2811	102	19.74	<.0001	0.05	4.9929	6.1081

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.5956	0.3329	102	-4.79	<.0001	0.05	-2.2559	-0.9352

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.5062

Fit Statistics	
-2 Res Log Likelihood	410.6
AIC (smaller is better)	412.6
AICC (smaller is better)	412.6
BIC (smaller is better)	415.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	20.06	<.0001
SEX	1	104	0.01	0.9310
UCPDGR1	1	104	0.05	0.8181
TRTP	1	104	19.82	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.0449	0.1868	104	21.65	<.0001	0.05	3.6745	4.4154
TRTP	mCC	5.5096	0.2747	104	20.06	<.0001	0.05	4.9648	6.0543

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.4647	0.3290	104	-4.45	<.0001	0.05	-2.1171	-0.8122

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.5097

Fit Statistics	
-2 Res Log Likelihood	410.7
AIC (smaller is better)	412.7
AICC (smaller is better)	412.8
BIC (smaller is better)	415.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	25.66	<.0001
SEX	1	104	0.12	0.7276
UCPDGR1	1	104	0.01	0.9107
TRTP	1	104	22.55	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.0903	0.1870	104	21.88	<.0001	0.05	3.7196	4.4610
TRTP	mCC	5.6538	0.2749	104	20.57	<.0001	0.05	5.1087	6.1990

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.5635	0.3292	104	-4.75	<.0001	0.05	-2.2164	-0.9107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.7992

Fit Statistics	
-2 Res Log Likelihood	244.1
AIC (smaller is better)	246.1
AICC (smaller is better)	246.2
BIC (smaller is better)	248.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	28.46	<.0001
SEX	1	66	0.05	0.8166
UCPDGR1	1	66	0.17	0.6844
TRTP	1	66	1.25	0.2675

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.0834	0.2194	66	23.17	<.0001	0.05	4.6453	5.5215
TRTP	mCC	5.4482	0.2416	66	22.55	<.0001	0.05	4.9658	5.9306

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3648	0.3262	66	-1.12	0.2675	0.05	-1.0162	0.2865

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.8209

Fit Statistics	
-2 Res Log Likelihood	422.9
AIC (smaller is better)	424.9
AICC (smaller is better)	424.9
BIC (smaller is better)	427.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	18.89	<.0001
SEX	1	104	0.02	0.8914
UCPDGR1	1	104	0.35	0.5565
TRTP	1	104	12.23	0.0007

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.1353	0.1982	104	20.86	<.0001	0.05	3.7423	4.5284
TRTP	mCC	5.3560	0.2914	104	18.38	<.0001	0.05	4.7781	5.9340

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.2207	0.3490	104	-3.50	0.0007	0.05	-1.9128	-0.5285

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



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**Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4588

Fit Statistics	
-2 Res Log Likelihood	408.6
AIC (smaller is better)	410.6
AICC (smaller is better)	410.6
BIC (smaller is better)	413.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	30.26	<.0001
SEX	1	104	0.07	0.7922
UCPDGR1	1	104	0.01	0.9257
TRTP	1	104	12.19	0.0007



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2899	0.1850	104	23.18	<.0001	0.05	3.9229	4.6568
TRTP	mCC	5.4274	0.2721	104	19.95	<.0001	0.05	4.8878	5.9670

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.1375	0.3259	104	-3.49	0.0007	0.05	-1.7837	-0.4913

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9485

Fit Statistics	
-2 Res Log Likelihood	249.3
AIC (smaller is better)	251.3
AICC (smaller is better)	251.4
BIC (smaller is better)	253.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	30.46	<.0001
SEX	1	66	0.08	0.7833
UCPDGR1	1	66	0.04	0.8520
TRTP	1	66	0.79	0.3765

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.7922	0.2313	66	20.72	<.0001	0.05	4.3304	5.2540
TRTP	mCC	5.1022	0.2565	66	19.89	<.0001	0.05	4.5900	5.6144

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3100	0.3481	66	-0.89	0.3765	0.05	-1.0050	0.3851

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	77



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	77
Number of Observations Used	77
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.7209

Fit Statistics	
-2 Res Log Likelihood	261.7
AIC (smaller is better)	263.7
AICC (smaller is better)	263.7
BIC (smaller is better)	266.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	72	22.31	<.0001
SEX	1	72	0.05	0.8282
UCPDGR1	1	72	0.50	0.4833
TRTP	1	72	4.57	0.0359

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.6028	0.1985	72	23.19	<.0001	0.05	4.2071	4.9985
TRTP	mCC	5.2782	0.2421	72	21.80	<.0001	0.05	4.7955	5.7609

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6754	0.3158	72	-2.14	0.0359	0.05	-1.3049	-0.04585

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9912

Fit Statistics	
-2 Res Log Likelihood	379.6
AIC (smaller is better)	381.6
AICC (smaller is better)	381.6
BIC (smaller is better)	384.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	71.88	<.0001
SEX	1	102	0.83	0.3658
UCPDGR1	1	102	0.77	0.3813
TRTP	1	102	12.63	0.0006

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.4352	0.1678	102	20.48	<.0001	0.05	3.1025	3.7680
TRTP	mCC	4.5233	0.2568	102	17.61	<.0001	0.05	4.0139	5.0328

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.0881	0.3061	102	-3.55	0.0006	0.05	-1.6953	-0.4809

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1619

Fit Statistics	
-2 Res Log Likelihood	395.3
AIC (smaller is better)	397.3
AICC (smaller is better)	397.4
BIC (smaller is better)	400.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	66.31	<.0001
SEX	1	104	0.01	0.9303
UCPDGR1	1	104	0.74	0.3908
TRTP	1	104	7.17	0.0086

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.7452	0.1744	104	21.47	<.0001	0.05	3.3992	4.0911
TRTP	mCC	4.5768	0.2578	104	17.75	<.0001	0.05	4.0656	5.0881

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.8317	0.3105	104	-2.68	0.0086	0.05	-1.4474	-0.2159

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0827

Fit Statistics	
-2 Res Log Likelihood	391.5
AIC (smaller is better)	393.5
AICC (smaller is better)	393.5
BIC (smaller is better)	396.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	61.31	<.0001
SEX	1	104	0.04	0.8340
UCPDGR1	1	104	0.46	0.5012
TRTP	1	104	17.18	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.6149	0.1712	104	21.11	<.0001	0.05	3.2754	3.9544
TRTP	mCC	4.8781	0.2531	104	19.28	<.0001	0.05	4.3763	5.3799

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.2632	0.3048	104	-4.14	<.0001	0.05	-1.8675	-0.6588



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	72

**Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	72
Number of Observations Used	72
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8875

Fit Statistics	
-2 Res Log Likelihood	250.8
AIC (smaller is better)	252.8
AICC (smaller is better)	252.8
BIC (smaller is better)	255.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	67	21.71	<.0001
SEX	1	67	0.07	0.7993
UCPDGR1	1	67	1.04	0.3124
TRTP	1	67	1.03	0.3132

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.6113	0.2246	67	20.53	<.0001	0.05	4.1629	5.0597
TRTP	mCC	4.9453	0.2425	67	20.40	<.0001	0.05	4.4614	5.4293

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3341	0.3287	67	-1.02	0.3132	0.05	-0.9902	0.3221

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.9588

Fit Statistics	
-2 Res Log Likelihood	428.0
AIC (smaller is better)	430.0
AICC (smaller is better)	430.0
BIC (smaller is better)	432.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	36.94	<.0001
SEX	1	104	0.07	0.7909
UCPDGR1	1	104	0.04	0.8477
TRTP	1	104	3.37	0.0694

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.7981	0.2041	104	18.61	<.0001	0.05	3.3934	4.2028
TRTP	mCC	4.4645	0.3016	104	14.80	<.0001	0.05	3.8664	5.0627

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6665	0.3632	104	-1.83	0.0694	0.05	-1.3868	0.05388

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



65

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4426

Fit Statistics	
-2 Res Log Likelihood	408.0
AIC (smaller is better)	410.0
AICC (smaller is better)	410.1
BIC (smaller is better)	412.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	59.18	<.0001
SEX	1	104	0.06	0.8140
UCPDGR1	1	104	0.54	0.4657
TRTP	1	104	3.66	0.0584



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9325	0.1854	104	21.21	<.0001	0.05	3.5648	4.3002
TRTP	mCC	4.5641	0.2740	104	16.65	<.0001	0.05	4.0207	5.1076

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6317	0.3300	104	-1.91	0.0584	0.05	-1.2862	0.02284

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5218

Fit Statistics	
-2 Res Log Likelihood	233.0
AIC (smaller is better)	235.0
AICC (smaller is better)	235.0
BIC (smaller is better)	237.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	41.21	<.0001
SEX	1	66	0.59	0.4437
UCPDGR1	1	66	0.16	0.6940
TRTP	1	66	0.81	0.3718

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5043	0.2049	66	21.98	<.0001	0.05	4.0952	4.9134
TRTP	mCC	4.7795	0.2248	66	21.26	<.0001	0.05	4.3306	5.2283

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2752	0.3060	66	-0.90	0.3718	0.05	-0.8862	0.3358

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	78

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5323

Fit Statistics	
-2 Res Log Likelihood	256.7
AIC (smaller is better)	258.7
AICC (smaller is better)	258.7
BIC (smaller is better)	261.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	73	43.19	<.0001
SEX	1	73	0.06	0.8004
UCPDGR1	1	73	3.28	0.0743
TRTP	1	73	0.28	0.5964

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5595	0.1859	73	24.53	<.0001	0.05	4.1890	4.9301
TRTP	mCC	4.7173	0.2278	73	20.71	<.0001	0.05	4.2633	5.1713

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1578	0.2966	73	-0.53	0.5964	0.05	-0.7490	0.4334

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1952

Fit Statistics	
-2 Res Log Likelihood	327.4
AIC (smaller is better)	329.4
AICC (smaller is better)	329.4
BIC (smaller is better)	332.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	121.16	<.0001
SEX	1	102	2.03	0.1568
UCPDGR1	1	102	0.13	0.7153
TRTP	1	102	15.48	0.0002

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.0962	0.1290	102	24.01	<.0001	0.05	2.8404	3.3520
TRTP	mCC	4.0095	0.1966	102	20.39	<.0001	0.05	3.6195	4.3996

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.9133	0.2321	102	-3.93	0.0002	0.05	-1.3737	-0.4529

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

**Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0154

Fit Statistics	
-2 Res Log Likelihood	316.6
AIC (smaller is better)	318.6
AICC (smaller is better)	318.6
BIC (smaller is better)	321.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	164.32	<.0001
SEX	1	104	2.25	0.1367
UCPDGR1	1	104	0.95	0.3329
TRTP	1	104	9.59	0.0025

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.0804	0.1188	104	25.93	<.0001	0.05	2.8448	3.3161
TRTP	mCC	3.7275	0.1749	104	21.32	<.0001	0.05	3.3807	4.0742

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6470	0.2089	104	-3.10	0.0025	0.05	-1.0614	-0.2327

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



80

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0954

Fit Statistics	
-2 Res Log Likelihood	324.4
AIC (smaller is better)	326.4
AICC (smaller is better)	326.5
BIC (smaller is better)	329.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	146.88	<.0001
SEX	1	104	0.31	0.5777
UCPDGR1	1	104	0.13	0.7189
TRTP	1	104	4.72	0.0321

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1595	0.1234	104	25.60	<.0001	0.05	2.9147	3.4042
TRTP	mCC	3.6309	0.1816	104	19.99	<.0001	0.05	3.2708	3.9911

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4715	0.2170	104	-2.17	0.0321	0.05	-0.9018	-0.04116



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	72

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	72
Number of Observations Used	72
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1466

Fit Statistics	
-2 Res Log Likelihood	217.2
AIC (smaller is better)	219.2
AICC (smaller is better)	219.2
BIC (smaller is better)	221.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	67	65.29	<.0001
SEX	1	67	3.71	0.0584
UCPDGR1	1	67	2.29	0.1353
TRTP	1	67	2.13	0.1488

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.6231	0.1756	67	20.63	<.0001	0.05	3.2726	3.9737
TRTP	mCC	3.9966	0.1884	67	21.21	<.0001	0.05	3.6204	4.3727

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3734	0.2557	67	-1.46	0.1488	0.05	-0.8837	0.1369

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1434

Fit Statistics	
-2 Res Log Likelihood	328.9
AIC (smaller is better)	330.9
AICC (smaller is better)	330.9
BIC (smaller is better)	333.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	146.34	<.0001
SEX	1	104	0.59	0.4452
UCPDGR1	1	104	0.00	0.9512
TRTP	1	104	4.81	0.0306

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1591	0.1261	104	25.06	<.0001	0.05	2.9091	3.4092
TRTP	mCC	3.6452	0.1855	104	19.65	<.0001	0.05	3.2773	4.0132

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4861	0.2217	104	-2.19	0.0306	0.05	-0.9257	-0.04644

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2017

Fit Statistics	
-2 Res Log Likelihood	334.1
AIC (smaller is better)	336.1
AICC (smaller is better)	336.1
BIC (smaller is better)	338.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	152.03	<.0001
SEX	1	104	2.26	0.1360
UCPDGR1	1	104	0.00	0.9625
TRTP	1	104	3.09	0.0815



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1235	0.1293	104	24.16	<.0001	0.05	2.8672	3.3799
TRTP	mCC	3.5234	0.1902	104	18.52	<.0001	0.05	3.1462	3.9006

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3998	0.2273	104	-1.76	0.0815	0.05	-0.8505	0.05089

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2723

Fit Statistics	
-2 Res Log Likelihood	220.9
AIC (smaller is better)	222.9
AICC (smaller is better)	223.0
BIC (smaller is better)	225.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	46.90	<.0001
SEX	1	66	1.21	0.2755
UCPDGR1	1	66	0.04	0.8371
TRTP	1	66	0.59	0.4463

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.5268	0.1852	66	19.05	<.0001	0.05	3.1571	3.8965
TRTP	mCC	3.7354	0.2028	66	18.42	<.0001	0.05	3.3304	4.1404

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2086	0.2722	66	-0.77	0.4463	0.05	-0.7521	0.3349

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	78

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0322

Fit Statistics	
-2 Res Log Likelihood	227.6
AIC (smaller is better)	229.6
AICC (smaller is better)	229.7
BIC (smaller is better)	231.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	73	84.13	<.0001
SEX	1	73	2.56	0.1137
UCPDGR1	1	73	0.36	0.5505
TRTP	1	73	1.65	0.2035

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.4721	0.1514	73	22.93	<.0001	0.05	3.1703	3.7738
TRTP	mCC	3.7769	0.1842	73	20.51	<.0001	0.05	3.4098	4.1440

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3048	0.2376	73	-1.28	0.2035	0.05	-0.7783	0.1686

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.7410

Fit Statistics	
-2 Res Log Likelihood	365.5
AIC (smaller is better)	367.5
AICC (smaller is better)	367.5
BIC (smaller is better)	370.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	48.32	<.0001
SEX	1	102	0.04	0.8403
UCPDGR1	1	102	0.03	0.8593
TRTP	1	102	26.17	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9718	0.1563	102	25.41	<.0001	0.05	3.6618	4.2819
TRTP	mCC	5.4278	0.2397	102	22.64	<.0001	0.05	4.9524	5.9033

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.4560	0.2846	102	-5.12	<.0001	0.05	-2.0206	-0.8914



100

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



101

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6150

Fit Statistics	
-2 Res Log Likelihood	364.6
AIC (smaller is better)	366.6
AICC (smaller is better)	366.6
BIC (smaller is better)	369.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	42.77	<.0001
SEX	1	104	0.00	0.9529
UCPDGR1	1	104	0.06	0.8065
TRTP	1	104	22.89	<.0001

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2971	0.1505	104	28.54	<.0001	0.05	3.9986	4.5957
TRTP	mCC	5.5815	0.2233	104	25.00	<.0001	0.05	5.1387	6.0243

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.2844	0.2685	104	-4.78	<.0001	0.05	-1.8167	-0.7520

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



104

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6863

Fit Statistics	
-2 Res Log Likelihood	369.1
AIC (smaller is better)	371.1
AICC (smaller is better)	371.1
BIC (smaller is better)	373.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	34.37	<.0001
SEX	1	104	0.00	0.9918
UCPDGR1	1	104	0.29	0.5920
TRTP	1	104	21.03	<.0001



105

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.3674	0.1538	104	28.39	<.0001	0.05	4.0624	4.6725
TRTP	mCC	5.6256	0.2282	104	24.65	<.0001	0.05	5.1731	6.0780

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.2582	0.2743	104	-4.59	<.0001	0.05	-1.8022	-0.7142



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	72



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***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	72
Number of Observations Used	72
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7855

Fit Statistics	
-2 Res Log Likelihood	191.6
AIC (smaller is better)	193.6
AICC (smaller is better)	193.6
BIC (smaller is better)	195.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	67	90.62	<.0001
SEX	1	67	0.36	0.5502
UCPDGR1	1	67	0.08	0.7753
TRTP	1	67	2.58	0.1127

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.1100	0.1456	67	35.10	<.0001	0.05	4.8194	5.4005
TRTP	mCC	5.4549	0.1575	67	34.62	<.0001	0.05	5.1404	5.7693

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3449	0.2145	67	-1.61	0.1127	0.05	-0.7731	0.08337

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0703

Fit Statistics	
-2 Res Log Likelihood	390.4
AIC (smaller is better)	392.4
AICC (smaller is better)	392.4
BIC (smaller is better)	395.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	30.31	<.0001
SEX	1	104	0.01	0.9419
UCPDGR1	1	104	0.01	0.9410
TRTP	1	104	13.22	0.0004

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.3917	0.1704	104	25.77	<.0001	0.05	4.0537	4.7297
TRTP	mCC	5.4970	0.2528	104	21.74	<.0001	0.05	4.9956	5.9983

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.1053	0.3040	104	-3.64	0.0004	0.05	-1.7081	-0.5025

***Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	109



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105

Number of Observations	
Number of Observations Read	109
Number of Observations Used	109
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6293

Fit Statistics	
-2 Res Log Likelihood	365.5
AIC (smaller is better)	367.5
AICC (smaller is better)	367.5
BIC (smaller is better)	370.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	104	55.05	<.0001
SEX	1	104	0.00	0.9788
UCPDGR1	1	104	0.36	0.5522
TRTP	1	104	12.60	0.0006



*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5365	0.1512	104	30.00	<.0001	0.05	4.2366	4.8363
TRTP	mCC	5.4937	0.2243	104	24.49	<.0001	0.05	5.0489	5.9384

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.9572	0.2697	104	-3.55	0.0006	0.05	-1.4919	-0.4225

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	71



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	71
Number of Observations Used	71
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1938

Fit Statistics	
-2 Res Log Likelihood	216.4
AIC (smaller is better)	218.4
AICC (smaller is better)	218.5
BIC (smaller is better)	220.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	66	42.43	<.0001
SEX	1	66	3.17	0.0795
UCPDGR1	1	66	0.12	0.7308
TRTP	1	66	1.01	0.3196

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.9336	0.1845	66	26.74	<.0001	0.05	4.5653	5.3019
TRTP	mCC	5.2156	0.2034	66	25.64	<.0001	0.05	4.8095	5.6217

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2820	0.2812	66	-1.00	0.3196	0.05	-0.8434	0.2794

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	78



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*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	78
Number of Observations Used	78
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0343

Fit Statistics	
-2 Res Log Likelihood	227.5
AIC (smaller is better)	229.5
AICC (smaller is better)	229.5
BIC (smaller is better)	231.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	73	55.62	<.0001
SEX	1	73	0.39	0.5358
UCPDGR1	1	73	1.23	0.2720
TRTP	1	73	2.22	0.1406

*Listing 15.4.4.55.1 Analysis of MCEQ Subscales - PP Set***Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	5.0144	0.1541	73	32.53	<.0001	0.05	4.7072	5.3216
TRTP	mCC	5.3872	0.1906	73	28.26	<.0001	0.05	5.0074	5.7671

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3729	0.2503	73	-1.49	0.1406	0.05	-0.8717	0.1259



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***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	117





2

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	117
Number of Observations Used	117
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.7338

Fit Statistics	
-2 Res Log Likelihood	302.1
AIC (smaller is better)	304.1
AICC (smaller is better)	304.1
BIC (smaller is better)	306.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	112	7.00	0.0093
SEX	1	112	1.37	0.2435
UCPDGR1	1	112	0.93	0.3379
TRTP	1	112	0.03	0.8710

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.3322	0.09813	112	13.58	<.0001	0.05	1.1377	1.5266
TRTP	mCC	1.3598	0.1405	112	9.68	<.0001	0.05	1.0814	1.6383

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.02765	0.1700	112	-0.16	0.8710	0.05	-0.3644	0.3091

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3924

Fit Statistics	
-2 Res Log Likelihood	235.8
AIC (smaller is better)	237.8
AICC (smaller is better)	237.9
BIC (smaller is better)	240.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	17.72	<.0001
SEX	1	114	1.34	0.2489
UCPDGR1	1	114	0.97	0.3257
TRTP	1	114	0.98	0.3243

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2526	0.07175	114	17.46	<.0001	0.05	1.1104	1.3947
TRTP	mCC	1.1315	0.1001	114	11.30	<.0001	0.05	0.9332	1.3298

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.1210	0.1222	114	0.99	0.3243	0.05	-0.1211	0.3632



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3321

Fit Statistics	
-2 Res Log Likelihood	216.8
AIC (smaller is better)	218.8
AICC (smaller is better)	218.9
BIC (smaller is better)	221.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	13.95	0.0003
SEX	1	114	0.07	0.7931
UCPDGR1	1	114	0.60	0.4395
TRTP	1	114	0.32	0.5737

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2187	0.06601	114	18.46	<.0001	0.05	1.0879	1.3495
TRTP	mCC	1.1552	0.09209	114	12.54	<.0001	0.05	0.9728	1.3377

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.06345	0.1125	114	0.56	0.5737	0.05	-0.1593	0.2863





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***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	115



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	115
Number of Observations Used	115
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2349

Fit Statistics	
-2 Res Log Likelihood	171.7
AIC (smaller is better)	173.7
AICC (smaller is better)	173.7
BIC (smaller is better)	176.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	110	18.57	<.0001
SEX	1	110	1.76	0.1872
UCPDGR1	1	110	0.58	0.4461
TRTP	1	110	0.15	0.6985



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*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.1471	0.05655	110	20.29	<.0001	0.05	1.0350	1.2591
TRTP	mCC	1.1844	0.07835	110	15.12	<.0001	0.05	1.0291	1.3397

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.03731	0.09605	110	-0.39	0.6985	0.05	-0.2277	0.1530



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3928

Fit Statistics	
-2 Res Log Likelihood	236.0
AIC (smaller is better)	238.0
AICC (smaller is better)	238.0
BIC (smaller is better)	240.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	11.64	0.0009
SEX	1	114	0.23	0.6336
UCPDGR1	1	114	0.72	0.3967
TRTP	1	114	0.22	0.6402



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*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.2148	0.07179	114	16.92	<.0001	0.05	1.0726	1.3570
TRTP	mCC	1.1575	0.1002	114	11.56	<.0001	0.05	0.9591	1.3559

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.05733	0.1223	114	0.47	0.6402	0.05	-0.1850	0.2996



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*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.6311

Fit Statistics	
-2 Res Log Likelihood	287.6
AIC (smaller is better)	289.6
AICC (smaller is better)	289.6
BIC (smaller is better)	292.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	113	7.67	0.0066
SEX	1	113	0.41	0.5250
UCPDGR1	1	113	1.80	0.1821
TRTP	1	113	0.94	0.3348



*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.3162	0.09149	113	14.39	<.0001	0.05	1.1350	1.4975
TRTP	mCC	1.1657	0.1270	113	9.18	<.0001	0.05	0.9141	1.4173

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.1505	0.1554	113	0.97	0.3348	0.05	-0.1574	0.4585



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***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	110



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	110
Number of Observations Used	110
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3314

Fit Statistics	
-2 Res Log Likelihood	200.6
AIC (smaller is better)	202.6
AICC (smaller is better)	202.7
BIC (smaller is better)	205.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	105	0.60	0.4394
SEX	1	105	3.23	0.0754
UCPDGR1	1	105	1.35	0.2482
TRTP	1	105	0.06	0.7995

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.1535	0.06771	105	17.04	<.0001	0.05	1.0193	1.2878
TRTP	mCC	1.1836	0.09766	105	12.12	<.0001	0.05	0.9899	1.3772

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.03005	0.1180	105	-0.25	0.7995	0.05	-0.2641	0.2040

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	108



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2694

Fit Statistics	
-2 Res Log Likelihood	175.8
AIC (smaller is better)	177.8
AICC (smaller is better)	177.8
BIC (smaller is better)	180.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	103	0.29	0.5933
SEX	1	103	0.17	0.6803
UCPDGR1	1	103	1.68	0.1977
TRTP	1	103	0.22	0.6365

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Aversion Subscale Parameter (N)=18 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.1743	0.06160	103	19.06	<.0001	0.05	1.0521	1.2964
TRTP	mCC	1.1233	0.08879	103	12.65	<.0001	0.05	0.9472	1.2994

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.05098	0.1075	103	0.47	0.6365	0.05	-0.1623	0.2642

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	117



**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	117
Number of Observations Used	117
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.5778

Fit Statistics	
-2 Res Log Likelihood	444.1
AIC (smaller is better)	446.1
AICC (smaller is better)	446.1
BIC (smaller is better)	448.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	112	17.15	<.0001
SEX	1	112	0.07	0.7977
UCPDGR1	1	112	0.12	0.7317
TRTP	1	112	28.00	<.0001

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9495	0.1840	112	21.47	<.0001	0.05	3.5849	4.3140
TRTP	mCC	5.6427	0.2645	112	21.33	<.0001	0.05	5.1185	6.1668

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.6932	0.3200	112	-5.29	<.0001	0.05	-2.3273	-1.0592

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.8482

Fit Statistics	
-2 Res Log Likelihood	463.2
AIC (smaller is better)	465.2
AICC (smaller is better)	465.3
BIC (smaller is better)	468.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	20.74	<.0001
SEX	1	114	0.10	0.7578
UCPDGR1	1	114	0.00	0.9975
TRTP	1	114	10.09	0.0019

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2051	0.1932	114	21.77	<.0001	0.05	3.8224	4.5877
TRTP	mCC	5.2518	0.2701	114	19.44	<.0001	0.05	4.7166	5.7870

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.0467	0.3295	114	-3.18	0.0019	0.05	-1.6995	-0.3939

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.6547

Fit Statistics	
-2 Res Log Likelihood	455.2
AIC (smaller is better)	457.2
AICC (smaller is better)	457.2
BIC (smaller is better)	459.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	28.50	<.0001
SEX	1	114	0.10	0.7571
UCPDGR1	1	114	0.07	0.7892
TRTP	1	114	17.07	<.0001

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.1956	0.1865	114	22.50	<.0001	0.05	3.8262	4.5651
TRTP	mCC	5.5102	0.2608	114	21.13	<.0001	0.05	4.9935	6.0268

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.3145	0.3181	114	-4.13	<.0001	0.05	-1.9448	-0.6843



***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	114



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	114
Number of Observations Used	114
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0542

Fit Statistics	
-2 Res Log Likelihood	408.0
AIC (smaller is better)	410.0
AICC (smaller is better)	410.0
BIC (smaller is better)	412.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	109	25.30	<.0001
SEX	1	109	0.44	0.5095
UCPDGR1	1	109	0.02	0.8755
TRTP	1	109	6.67	0.0111

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.8261	0.1670	109	28.91	<.0001	0.05	4.4952	5.1570
TRTP	mCC	5.5642	0.2343	109	23.74	<.0001	0.05	5.0997	6.0286

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.7380	0.2858	109	-2.58	0.0111	0.05	-1.3046	-0.1715

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.8291

Fit Statistics	
-2 Res Log Likelihood	462.5
AIC (smaller is better)	464.5
AICC (smaller is better)	464.5
BIC (smaller is better)	467.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	20.17	<.0001
SEX	1	114	0.00	0.9562
UCPDGR1	1	114	0.99	0.3230
TRTP	1	114	10.10	0.0019

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS***Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2307	0.1925	114	21.98	<.0001	0.05	3.8493	4.6120
TRTP	mCC	5.2746	0.2692	114	19.59	<.0001	0.05	4.7413	5.8080

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.0440	0.3284	114	-3.18	0.0019	0.05	-1.6946	-0.3933

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.5066

Fit Statistics	
-2 Res Log Likelihood	444.9
AIC (smaller is better)	446.9
AICC (smaller is better)	446.9
BIC (smaller is better)	449.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	113	30.78	<.0001
SEX	1	113	0.01	0.9118
UCPDGR1	1	113	0.06	0.8061
TRTP	1	113	8.95	0.0034



*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.3955	0.1822	113	24.12	<.0001	0.05	4.0345	4.7565
TRTP	mCC	5.3236	0.2536	113	20.99	<.0001	0.05	4.8211	5.8261

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.9281	0.3102	113	-2.99	0.0034	0.05	-1.5426	-0.3136

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	110

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	110
Number of Observations Used	110
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4140

Fit Statistics	
-2 Res Log Likelihood	410.4
AIC (smaller is better)	412.4
AICC (smaller is better)	412.5
BIC (smaller is better)	415.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	105	25.72	<.0001
SEX	1	105	0.09	0.7595
UCPDGR1	1	105	0.00	0.9586
TRTP	1	105	1.77	0.1865

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.7245	0.1827	105	25.86	<.0001	0.05	4.3622	5.0867
TRTP	mCC	5.1505	0.2653	105	19.42	<.0001	0.05	4.6245	5.6765

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4261	0.3204	105	-1.33	0.1865	0.05	-1.0614	0.2092

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	107



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	107
Number of Observations Used	107
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8903

Fit Statistics	
-2 Res Log Likelihood	374.2
AIC (smaller is better)	376.2
AICC (smaller is better)	376.2
BIC (smaller is better)	378.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	102	23.38	<.0001
SEX	1	102	0.97	0.3278
UCPDGR1	1	102	0.00	0.9507
TRTP	1	102	7.55	0.0071

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Craving Reduction Subscale Parameter (N)=19 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5340	0.1639	102	27.66	<.0001	0.05	4.2090	4.8591
TRTP	mCC	5.3211	0.2363	102	22.52	<.0001	0.05	4.8524	5.7899

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.7871	0.2865	102	-2.75	0.0071	0.05	-1.3554	-0.2188

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	117





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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	117
Number of Observations Used	117
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.2092

Fit Statistics	
-2 Res Log Likelihood	427.0
AIC (smaller is better)	429.0
AICC (smaller is better)	429.1
BIC (smaller is better)	431.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	112	59.17	<.0001
SEX	1	112	0.24	0.6227
UCPDGR1	1	112	0.02	0.8835
TRTP	1	112	13.23	0.0004

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.3657	0.1707	112	19.72	<.0001	0.05	3.0275	3.7039
TRTP	mCC	4.4494	0.2458	112	18.10	<.0001	0.05	3.9625	4.9364

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.0838	0.2980	112	-3.64	0.0004	0.05	-1.6741	-0.4934

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.3953

Fit Statistics	
-2 Res Log Likelihood	443.7
AIC (smaller is better)	445.7
AICC (smaller is better)	445.7
BIC (smaller is better)	448.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	58.75	<.0001
SEX	1	114	0.40	0.5268
UCPDGR1	1	114	0.01	0.9269
TRTP	1	114	3.80	0.0537

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.7631	0.1775	114	21.20	<.0001	0.05	3.4115	4.1147
TRTP	mCC	4.3559	0.2487	114	17.51	<.0001	0.05	3.8632	4.8487

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.5929	0.3041	114	-1.95	0.0537	0.05	-1.1953	0.009555

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0535

Fit Statistics	
-2 Res Log Likelihood	426.1
AIC (smaller is better)	428.1
AICC (smaller is better)	428.1
BIC (smaller is better)	430.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	67.70	<.0001
SEX	1	114	0.07	0.7908
UCPDGR1	1	114	0.23	0.6329
TRTP	1	114	15.85	0.0001

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 3 Analysis Visit (N)=103**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.6624	0.1643	114	22.29	<.0001	0.05	3.3368	3.9879
TRTP	mCC	4.7834	0.2303	114	20.77	<.0001	0.05	4.3271	5.2396

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.1210	0.2816	114	-3.98	0.0001	0.05	-1.6788	-0.5632



***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	115



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	115
Number of Observations Used	115
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.2022

Fit Statistics	
-2 Res Log Likelihood	419.4
AIC (smaller is better)	421.4
AICC (smaller is better)	421.4
BIC (smaller is better)	424.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	110	30.82	<.0001
SEX	1	110	0.11	0.7459
UCPDGR1	1	110	0.36	0.5489
TRTP	1	110	2.12	0.1483

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2763	0.1732	110	24.70	<.0001	0.05	3.9331	4.6195
TRTP	mCC	4.7060	0.2409	110	19.54	<.0001	0.05	4.2287	5.1834

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4297	0.2952	110	-1.46	0.1483	0.05	-1.0148	0.1553

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.9676

Fit Statistics	
-2 Res Log Likelihood	468.1
AIC (smaller is better)	470.1
AICC (smaller is better)	470.1
BIC (smaller is better)	472.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	36.70	<.0001
SEX	1	114	0.00	0.9760
UCPDGR1	1	114	0.00	0.9712
TRTP	1	114	3.69	0.0573

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.7905	0.1976	114	19.19	<.0001	0.05	3.3992	4.1819
TRTP	mCC	4.4405	0.2769	114	16.04	<.0001	0.05	3.8921	4.9890

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6500	0.3385	114	-1.92	0.0573	0.05	-1.3206	0.02053

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.4359

Fit Statistics	
-2 Res Log Likelihood	441.8
AIC (smaller is better)	443.8
AICC (smaller is better)	443.8
BIC (smaller is better)	446.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	113	55.52	<.0001
SEX	1	113	0.04	0.8362
UCPDGR1	1	113	0.00	0.9701
TRTP	1	113	3.97	0.0487



*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9181	0.1799	113	21.77	<.0001	0.05	3.5616	4.2746
TRTP	mCC	4.5302	0.2507	113	18.07	<.0001	0.05	4.0335	5.0269

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6121	0.3072	113	-1.99	0.0487	0.05	-1.2207	-0.00346

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	110



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	110
Number of Observations Used	110
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9855

Fit Statistics	
-2 Res Log Likelihood	390.1
AIC (smaller is better)	392.1
AICC (smaller is better)	392.2
BIC (smaller is better)	394.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	105	42.80	<.0001
SEX	1	105	1.31	0.2543
UCPDGR1	1	105	0.03	0.8614
TRTP	1	105	0.86	0.3567

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.3085	0.1660	105	25.95	<.0001	0.05	3.9793	4.6377
TRTP	mCC	4.5793	0.2417	105	18.95	<.0001	0.05	4.1001	5.0584

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.2708	0.2925	105	-0.93	0.3567	0.05	-0.8508	0.3092

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	108

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.1097

Fit Statistics	
-2 Res Log Likelihood	389.2
AIC (smaller is better)	391.2
AICC (smaller is better)	391.3
BIC (smaller is better)	393.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	103	37.50	<.0001
SEX	1	103	1.07	0.3037
UCPDGR1	1	103	0.72	0.3982
TRTP	1	103	1.00	0.3203

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Enjoyment of Respiratory Tract Sensation Subscale Parameter (N)=20 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.3837	0.1725	103	25.42	<.0001	0.05	4.0416	4.7257
TRTP	mCC	4.6863	0.2501	103	18.74	<.0001	0.05	4.1902	5.1823

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3026	0.3030	103	-1.00	0.3203	0.05	-0.9036	0.2984

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	117



**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	117
Number of Observations Used	117
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4137

Fit Statistics	
-2 Res Log Likelihood	376.8
AIC (smaller is better)	378.8
AICC (smaller is better)	378.9
BIC (smaller is better)	381.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	112	91.74	<.0001
SEX	1	112	0.47	0.4924
UCPDGR1	1	112	0.39	0.5310
TRTP	1	112	13.70	0.0003

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.0363	0.1360	112	22.32	<.0001	0.05	2.7668	3.3059
TRTP	mCC	3.9063	0.1950	112	20.03	<.0001	0.05	3.5199	4.2926

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.8699	0.2350	112	-3.70	0.0003	0.05	-1.3356	-0.4042

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1401

Fit Statistics	
-2 Res Log Likelihood	358.8
AIC (smaller is better)	360.8
AICC (smaller is better)	360.8
BIC (smaller is better)	363.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	150.77	<.0001
SEX	1	114	0.35	0.5556
UCPDGR1	1	114	0.25	0.6174
TRTP	1	114	4.97	0.0277

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1273	0.1222	114	25.60	<.0001	0.05	2.8853	3.3693
TRTP	mCC	3.5898	0.1704	114	21.07	<.0001	0.05	3.2523	3.9273

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4625	0.2074	114	-2.23	0.0277	0.05	-0.8733	-0.05172

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1550

Fit Statistics	
-2 Res Log Likelihood	360.3
AIC (smaller is better)	362.3
AICC (smaller is better)	362.3
BIC (smaller is better)	365.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	140.30	<.0001
SEX	1	114	0.16	0.6915
UCPDGR1	1	114	0.01	0.9221
TRTP	1	114	2.76	0.0994

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1609	0.1230	114	25.71	<.0001	0.05	2.9174	3.4045
TRTP	mCC	3.5077	0.1715	114	20.46	<.0001	0.05	3.1680	3.8474

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3467	0.2087	114	-1.66	0.0994	0.05	-0.7602	0.06674



***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	115



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	115
Number of Observations Used	115
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1971

Fit Statistics	
-2 Res Log Likelihood	352.1
AIC (smaller is better)	354.1
AICC (smaller is better)	354.1
BIC (smaller is better)	356.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	110	105.93	<.0001
SEX	1	110	1.07	0.3029
UCPDGR1	1	110	0.05	0.8181
TRTP	1	110	3.03	0.0848

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.5583	0.1276	110	27.89	<.0001	0.05	3.3054	3.8111
TRTP	mCC	3.9332	0.1763	110	22.31	<.0001	0.05	3.5838	4.2826

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3749	0.2155	110	-1.74	0.0848	0.05	-0.8021	0.05225

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1749

Fit Statistics	
-2 Res Log Likelihood	362.2
AIC (smaller is better)	364.2
AICC (smaller is better)	364.2
BIC (smaller is better)	366.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	145.57	<.0001
SEX	1	114	0.26	0.6141
UCPDGR1	1	114	0.39	0.5358
TRTP	1	114	2.83	0.0954

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1669	0.1240	114	25.54	<.0001	0.05	2.9213	3.4126
TRTP	mCC	3.5209	0.1729	114	20.36	<.0001	0.05	3.1783	3.8635

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3540	0.2105	114	-1.68	0.0954	0.05	-0.7710	0.06305

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	118

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2991

Fit Statistics	
-2 Res Log Likelihood	370.5
AIC (smaller is better)	372.5
AICC (smaller is better)	372.6
BIC (smaller is better)	375.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	113	145.15	<.0001
SEX	1	113	2.31	0.1310
UCPDGR1	1	113	0.18	0.6701
TRTP	1	113	2.46	0.1199



*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1336	0.1311	113	23.91	<.0001	0.05	2.8739	3.3932
TRTP	mCC	3.4812	0.1819	113	19.14	<.0001	0.05	3.1209	3.8415

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.3477	0.2219	113	-1.57	0.1199	0.05	-0.7872	0.09190

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	110

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	110
Number of Observations Used	110
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.2908

Fit Statistics	
-2 Res Log Likelihood	344.7
AIC (smaller is better)	346.7
AICC (smaller is better)	346.7
BIC (smaller is better)	349.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	105	91.77	<.0001
SEX	1	105	0.24	0.6273
UCPDGR1	1	105	0.36	0.5521
TRTP	1	105	0.31	0.5764

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.5089	0.1333	105	26.32	<.0001	0.05	3.2446	3.7732
TRTP	mCC	3.6388	0.1927	105	18.89	<.0001	0.05	3.2568	4.0208

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1299	0.2317	105	-0.56	0.5764	0.05	-0.5894	0.3296

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	108

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.1425

Fit Statistics	
-2 Res Log Likelihood	325.8
AIC (smaller is better)	327.8
AICC (smaller is better)	327.8
BIC (smaller is better)	330.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	103	105.15	<.0001
SEX	1	103	0.24	0.6217
UCPDGR1	1	103	0.61	0.4360
TRTP	1	103	0.80	0.3741

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Psychological Reward Subscale Parameter (N)=21 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.4345	0.1265	103	27.14	<.0001	0.05	3.1836	3.6855
TRTP	mCC	3.6311	0.1827	103	19.88	<.0001	0.05	3.2689	3.9934

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1966	0.2202	103	-0.89	0.3741	0.05	-0.6334	0.2402

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	117



**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	117
Number of Observations Used	117
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8471

Fit Statistics	
-2 Res Log Likelihood	406.5
AIC (smaller is better)	408.5
AICC (smaller is better)	408.6
BIC (smaller is better)	411.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	112	43.07	<.0001
SEX	1	112	0.17	0.6773
UCPDGR1	1	112	0.49	0.4832
TRTP	1	112	26.32	<.0001

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.9803	0.1563	112	25.46	<.0001	0.05	3.6705	4.2901
TRTP	mCC	5.3878	0.2259	112	23.85	<.0001	0.05	4.9402	5.8354

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.4075	0.2744	112	-5.13	<.0001	0.05	-1.9511	-0.8639

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.8534

Fit Statistics	
-2 Res Log Likelihood	413.9
AIC (smaller is better)	415.9
AICC (smaller is better)	415.9
BIC (smaller is better)	418.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	37.37	<.0001
SEX	1	114	0.37	0.5432
UCPDGR1	1	114	0.04	0.8334
TRTP	1	114	12.87	0.0005

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.4065	0.1566	114	28.14	<.0001	0.05	4.0962	4.7167
TRTP	mCC	5.3765	0.2204	114	24.39	<.0001	0.05	4.9398	5.8132

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.9700	0.2704	114	-3.59	0.0005	0.05	-1.5056	-0.4345

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6157

Fit Statistics	
-2 Res Log Likelihood	398.3
AIC (smaller is better)	400.3
AICC (smaller is better)	400.3
BIC (smaller is better)	403.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	41.52	<.0001
SEX	1	114	0.00	0.9584
UCPDGR1	1	114	0.65	0.4217
TRTP	1	114	20.17	<.0001

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.4779	0.1462	114	30.62	<.0001	0.05	4.1882	4.7676
TRTP	mCC	5.6115	0.2058	114	27.26	<.0001	0.05	5.2038	6.0193

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.1336	0.2524	114	-4.49	<.0001	0.05	-1.6337	-0.6336



***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	115



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	115
Number of Observations Used	115
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.3676

Fit Statistics	
-2 Res Log Likelihood	366.5
AIC (smaller is better)	368.5
AICC (smaller is better)	368.5
BIC (smaller is better)	371.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	110	52.19	<.0001
SEX	1	110	0.37	0.5423
UCPDGR1	1	110	0.02	0.8879
TRTP	1	110	5.48	0.0210

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.8720	0.1369	110	35.60	<.0001	0.05	4.6008	5.1432
TRTP	mCC	5.4213	0.1908	110	28.41	<.0001	0.05	5.0431	5.7994

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.5493	0.2346	110	-2.34	0.0210	0.05	-1.0142	-0.08440

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	119



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	119
Number of Observations Used	119
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0329

Fit Statistics	
-2 Res Log Likelihood	424.4
AIC (smaller is better)	426.4
AICC (smaller is better)	426.5
BIC (smaller is better)	429.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	114	34.05	<.0001
SEX	1	114	0.03	0.8678
UCPDGR1	1	114	0.02	0.9021
TRTP	1	114	11.77	0.0008

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.4774	0.1640	114	27.30	<.0001	0.05	4.1525	4.8024
TRTP	mCC	5.4489	0.2309	114	23.60	<.0001	0.05	4.9915	5.9062

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.9714	0.2831	114	-3.43	0.0008	0.05	-1.5323	-0.4105

**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	118



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	118
Number of Observations Used	118
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6128

Fit Statistics	
-2 Res Log Likelihood	394.7
AIC (smaller is better)	396.7
AICC (smaller is better)	396.7
BIC (smaller is better)	399.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	113	58.05	<.0001
SEX	1	113	0.12	0.7332
UCPDGR1	1	113	0.19	0.6621
TRTP	1	113	10.67	0.0014



*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.6271	0.1469	113	31.50	<.0001	0.05	4.3360	4.9181
TRTP	mCC	5.4534	0.2058	113	26.50	<.0001	0.05	5.0458	5.8611

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.8263	0.2530	113	-3.27	0.0014	0.05	-1.3276	-0.3251



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***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	110



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	110
Number of Observations Used	110
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6178

Fit Statistics	
-2 Res Log Likelihood	368.0
AIC (smaller is better)	370.0
AICC (smaller is better)	370.1
BIC (smaller is better)	372.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	105	32.07	<.0001
SEX	1	105	2.60	0.1101
UCPDGR1	1	105	0.02	0.8844
TRTP	1	105	2.23	0.1387

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.7544	0.1508	105	31.53	<.0001	0.05	4.4554	5.0534
TRTP	mCC	5.1562	0.2211	105	23.32	<.0001	0.05	4.7177	5.5947

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4018	0.2693	105	-1.49	0.1387	0.05	-0.9359	0.1322

***Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MCEQ_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	108



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**Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS****Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	108
Number of Observations Used	108
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.6362

Fit Statistics	
-2 Res Log Likelihood	362.5
AIC (smaller is better)	364.5
AICC (smaller is better)	364.5
BIC (smaller is better)	367.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	103	34.93	<.0001
SEX	1	103	3.46	0.0656
UCPDGR1	1	103	0.01	0.9412
TRTP	1	103	3.29	0.0726

*Listing 15.4.4.55.2 Analysis of MCEQ Subscales - FAS*

Parameter=Smoking Satisfaction Subscale Parameter (N)=22 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.8270	0.1525	103	31.65	<.0001	0.05	4.5246	5.1294
TRTP	mCC	5.3187	0.2228	103	23.87	<.0001	0.05	4.8768	5.7606

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.4917	0.2710	103	-1.81	0.0726	0.05	-1.0292	0.04583



1

**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133





2

**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set**

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2764

Fit Statistics	
-2 Res Log Likelihood	219.0
AIC (smaller is better)	221.0
AICC (smaller is better)	221.0
BIC (smaller is better)	223.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	95.04	<.0001
SEX	1	127	2.19	0.1412
UCPDGR1	1	127	0.26	0.6116
TRTP	2	127	10.59	<.0001

*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.2820	0.1082	127	11.85	<.0001	0.05	1.0678	1.4961
TRTP	THSm2.2	0.7138	0.06176	127	11.56	<.0001	0.05	0.5916	0.8360
TRTP	mCC	0.8330	0.09104	127	9.15	<.0001	0.05	0.6529	1.0132
TRTP	SA	1.2820	0.1082	127	11.85	<.0001	0.05	1.0678	1.4961
TRTP	THSm2.2	0.7138	0.06176	127	11.56	<.0001	0.05	0.5916	0.8360
TRTP	mCC	0.8330	0.09104	127	9.15	<.0001	0.05	0.6529	1.0132

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4489	0.1411	127	3.18	0.0018	0.05	0.1697	0.7281
TRTP	THSm2.2	mCC	-0.1192	0.1090	127	-1.09	0.2764	0.05	-0.3350	0.09658
TRTP	THSm2.2	SA	-0.5681	0.1235	127	-4.60	<.0001	0.05	-0.8126	-0.3237
TRTP	mCC	SA	-0.4489	0.1411	127	-3.18	0.0018	0.05	-0.7281	-0.1697

**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3302

Fit Statistics	
-2 Res Log Likelihood	241.5
AIC (smaller is better)	243.5
AICC (smaller is better)	243.6
BIC (smaller is better)	246.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	60.19	<.0001
SEX	1	127	2.31	0.1314
UCPDGR1	1	127	1.04	0.3097
TRTP	2	127	5.72	0.0042

*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.1840	0.1183	127	10.01	<.0001	0.05	0.9499	1.4180
TRTP	THSm2.2	0.7304	0.06750	127	10.82	<.0001	0.05	0.5968	0.8640
TRTP	mCC	0.7946	0.09950	127	7.99	<.0001	0.05	0.5977	0.9915
TRTP	SA	1.1840	0.1183	127	10.01	<.0001	0.05	0.9499	1.4180
TRTP	THSm2.2	0.7304	0.06750	127	10.82	<.0001	0.05	0.5968	0.8640
TRTP	mCC	0.7946	0.09950	127	7.99	<.0001	0.05	0.5977	0.9915

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3894	0.1542	127	2.53	0.0128	0.05	0.08426	0.6945
TRTP	THSm2.2	mCC	-0.06420	0.1192	127	-0.54	0.5911	0.05	-0.3000	0.1716
TRTP	THSm2.2	SA	-0.4536	0.1350	127	-3.36	0.0010	0.05	-0.7208	-0.1864
TRTP	mCC	SA	-0.3894	0.1542	127	-2.53	0.0128	0.05	-0.6945	-0.08426



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	85

**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	85
Number of Observations Used	85
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2889

Fit Statistics	
-2 Res Log Likelihood	145.4
AIC (smaller is better)	147.4
AICC (smaller is better)	147.5
BIC (smaller is better)	149.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	79	8.24	0.0052
SEX	1	79	0.80	0.3726
UCPDGR1	1	79	0.72	0.3978
TRTP	2	79	0.72	0.4880

*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.6436	0.1521	79	4.23	<.0001	0.05	0.3408	0.9463
TRTP	THSm2.2	0.4825	0.08757	79	5.51	<.0001	0.05	0.3081	0.6568
TRTP	mCC	0.6145	0.09512	79	6.46	<.0001	0.05	0.4252	0.8038
TRTP	SA	0.6436	0.1521	79	4.23	<.0001	0.05	0.3408	0.9463
TRTP	THSm2.2	0.4825	0.08757	79	5.51	<.0001	0.05	0.3081	0.6568
TRTP	mCC	0.6145	0.09512	79	6.46	<.0001	0.05	0.4252	0.8038

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.02905	0.1802	79	0.16	0.8723	0.05	-0.3295	0.3876
TRTP	THSm2.2	mCC	-0.1321	0.1287	79	-1.03	0.3078	0.05	-0.3882	0.1240
TRTP	THSm2.2	SA	-0.1611	0.1742	79	-0.93	0.3577	0.05	-0.5078	0.1855
TRTP	mCC	SA	-0.02905	0.1802	79	-0.16	0.8723	0.05	-0.3876	0.3295





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***Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3011

Fit Statistics	
-2 Res Log Likelihood	229.8
AIC (smaller is better)	231.8
AICC (smaller is better)	231.9
BIC (smaller is better)	234.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	60.17	<.0001
SEX	1	127	0.00	0.9626
UCPDGR1	1	127	0.86	0.3559
TRTP	2	127	3.84	0.0241



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*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.0102	0.1130	127	8.94	<.0001	0.05	0.7867	1.2337
TRTP	THSm2.2	0.6532	0.06447	127	10.13	<.0001	0.05	0.5257	0.7808
TRTP	mCC	0.7467	0.09502	127	7.86	<.0001	0.05	0.5587	0.9347
TRTP	SA	1.0102	0.1130	127	8.94	<.0001	0.05	0.7867	1.2337
TRTP	THSm2.2	0.6532	0.06447	127	10.13	<.0001	0.05	0.5257	0.7808
TRTP	mCC	0.7467	0.09502	127	7.86	<.0001	0.05	0.5587	0.9347

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2635	0.1473	127	1.79	0.0760	0.05	-0.02792	0.5549
TRTP	THSm2.2	mCC	-0.09347	0.1138	127	-0.82	0.4130	0.05	-0.3187	0.1318
TRTP	THSm2.2	SA	-0.3570	0.1289	127	-2.77	0.0065	0.05	-0.6121	-0.1018
TRTP	mCC	SA	-0.2635	0.1473	127	-1.79	0.0760	0.05	-0.5549	0.02792



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***Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3012

Fit Statistics	
-2 Res Log Likelihood	229.9
AIC (smaller is better)	231.9
AICC (smaller is better)	231.9
BIC (smaller is better)	234.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	51.85	<.0001
SEX	1	127	0.97	0.3270
UCPDGR1	1	127	1.13	0.2894
TRTP	2	127	1.14	0.3221



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*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8728	0.1130	127	7.73	<.0001	0.05	0.6492	1.0963
TRTP	THSm2.2	0.6783	0.06447	127	10.52	<.0001	0.05	0.5508	0.8059
TRTP	mCC	0.7369	0.09503	127	7.75	<.0001	0.05	0.5488	0.9249
TRTP	SA	0.8728	0.1130	127	7.73	<.0001	0.05	0.6492	1.0963
TRTP	THSm2.2	0.6783	0.06447	127	10.52	<.0001	0.05	0.5508	0.8059
TRTP	mCC	0.7369	0.09503	127	7.75	<.0001	0.05	0.5488	0.9249

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1359	0.1473	127	0.92	0.3579	0.05	-0.1556	0.4273
TRTP	THSm2.2	mCC	-0.05852	0.1138	127	-0.51	0.6081	0.05	-0.2838	0.1667
TRTP	THSm2.2	SA	-0.1944	0.1289	127	-1.51	0.1341	0.05	-0.4496	0.06075
TRTP	mCC	SA	-0.1359	0.1473	127	-0.92	0.3579	0.05	-0.4273	0.1556



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	133



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106**

Number of Observations	
Number of Observations Read	133
Number of Observations Used	133
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2868

Fit Statistics	
-2 Res Log Likelihood	223.7
AIC (smaller is better)	225.7
AICC (smaller is better)	225.7
BIC (smaller is better)	228.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	127	72.60	<.0001
SEX	1	127	0.42	0.5173
UCPDGR1	1	127	0.08	0.7775
TRTP	2	127	1.08	0.3426



*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.7873	0.1102	127	7.14	<.0001	0.05	0.5691	1.0054
TRTP	THSm2.2	0.6674	0.06292	127	10.61	<.0001	0.05	0.5430	0.7919
TRTP	mCC	0.8157	0.09274	127	8.80	<.0001	0.05	0.6322	0.9992
TRTP	SA	0.7873	0.1102	127	7.14	<.0001	0.05	0.5691	1.0054
TRTP	THSm2.2	0.6674	0.06292	127	10.61	<.0001	0.05	0.5430	0.7919
TRTP	mCC	0.8157	0.09274	127	8.80	<.0001	0.05	0.6322	0.9992

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.02846	0.1437	127	-0.20	0.8434	0.05	-0.3129	0.2559
TRTP	THSm2.2	mCC	-0.1483	0.1111	127	-1.33	0.1844	0.05	-0.3681	0.07155
TRTP	THSm2.2	SA	-0.1198	0.1258	127	-0.95	0.3428	0.05	-0.3688	0.1292
TRTP	mCC	SA	0.02846	0.1437	127	0.20	0.8434	0.05	-0.2559	0.3129



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	82



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	82
Number of Observations Used	82
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2354

Fit Statistics	
-2 Res Log Likelihood	124.9
AIC (smaller is better)	126.9
AICC (smaller is better)	126.9
BIC (smaller is better)	129.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	76	20.89	<.0001
SEX	1	76	0.51	0.4781
UCPDGR1	1	76	0.86	0.3556
TRTP	2	76	1.00	0.3734

*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.3381	0.1518	76	2.23	0.0289	0.05	0.03580	0.6404
TRTP	THSm2.2	0.4899	0.07933	76	6.18	<.0001	0.05	0.3319	0.6479
TRTP	mCC	0.5796	0.08675	76	6.68	<.0001	0.05	0.4068	0.7524
TRTP	SA	0.3381	0.1518	76	2.23	0.0289	0.05	0.03580	0.6404
TRTP	THSm2.2	0.4899	0.07933	76	6.18	<.0001	0.05	0.3319	0.6479
TRTP	mCC	0.5796	0.08675	76	6.68	<.0001	0.05	0.4068	0.7524

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2415	0.1742	76	-1.39	0.1698	0.05	-0.5886	0.1055
TRTP	THSm2.2	mCC	-0.08968	0.1172	76	-0.77	0.4464	0.05	-0.3230	0.1437
TRTP	THSm2.2	SA	0.1518	0.1704	76	0.89	0.3757	0.05	-0.1876	0.4912
TRTP	mCC	SA	0.2415	0.1742	76	1.39	0.1698	0.05	-0.1055	0.5886

**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	87



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**Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	87
Number of Observations Used	87
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2309

Fit Statistics	
-2 Res Log Likelihood	130.2
AIC (smaller is better)	132.2
AICC (smaller is better)	132.3
BIC (smaller is better)	134.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	81	6.60	0.0120
SEX	1	81	0.00	0.9609
UCPDGR1	1	81	0.00	0.9482
TRTP	2	81	0.96	0.3879

*Listing 15.4.4.57.1 Analysis of MNWS Total Scores - PP Set*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.3359	0.1644	81	2.04	0.0443	0.05	0.008761	0.6630
TRTP	THSm2.2	0.5082	0.07145	81	7.11	<.0001	0.05	0.3661	0.6504
TRTP	mCC	0.5885	0.08711	81	6.76	<.0001	0.05	0.4152	0.7619
TRTP	SA	0.3359	0.1644	81	2.04	0.0443	0.05	0.008761	0.6630
TRTP	THSm2.2	0.5082	0.07145	81	7.11	<.0001	0.05	0.3661	0.6504
TRTP	mCC	0.5885	0.08711	81	6.76	<.0001	0.05	0.4152	0.7619

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2527	0.1850	81	-1.37	0.1759	0.05	-0.6208	0.1155
TRTP	THSm2.2	mCC	-0.08032	0.1125	81	-0.71	0.4773	0.05	-0.3042	0.1435
TRTP	THSm2.2	SA	0.1723	0.1777	81	0.97	0.3351	0.05	-0.1813	0.5260
TRTP	mCC	SA	0.2527	0.1850	81	1.37	0.1759	0.05	-0.1155	0.6208



1

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153





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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS**

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2957

Fit Statistics	
-2 Res Log Likelihood	261.0
AIC (smaller is better)	263.0
AICC (smaller is better)	263.0
BIC (smaller is better)	266.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	86.86	<.0001
SEX	1	147	4.18	0.0426
UCPDGR1	1	147	1.49	0.2238
TRTP	2	147	8.49	0.0003

*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 2 Analysis Visit (N)=102

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.1752	0.09390	147	12.51	<.0001	0.05	0.9896	1.3608
TRTP	THSm2.2	0.7323	0.06197	147	11.82	<.0001	0.05	0.6099	0.8548
TRTP	mCC	0.7542	0.08646	147	8.72	<.0001	0.05	0.5834	0.9251
TRTP	SA	1.1752	0.09390	147	12.51	<.0001	0.05	0.9896	1.3608
TRTP	THSm2.2	0.7323	0.06197	147	11.82	<.0001	0.05	0.6099	0.8548
TRTP	mCC	0.7542	0.08646	147	8.72	<.0001	0.05	0.5834	0.9251

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4209	0.1269	147	3.32	0.0011	0.05	0.1702	0.6717
TRTP	THSm2.2	mCC	-0.02192	0.1056	147	-0.21	0.8358	0.05	-0.2305	0.1867
TRTP	THSm2.2	SA	-0.4429	0.1116	147	-3.97	0.0001	0.05	-0.6635	-0.2222
TRTP	mCC	SA	-0.4209	0.1269	147	-3.32	0.0011	0.05	-0.6717	-0.1702

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3328

Fit Statistics	
-2 Res Log Likelihood	278.3
AIC (smaller is better)	280.3
AICC (smaller is better)	280.4
BIC (smaller is better)	283.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	60.23	<.0001
SEX	1	147	3.95	0.0488
UCPDGR1	1	147	3.48	0.0639
TRTP	2	147	4.68	0.0107

*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 3 Analysis Visit (N)=103

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.0801	0.09962	147	10.84	<.0001	0.05	0.8832	1.2769
TRTP	THSm2.2	0.7436	0.06574	147	11.31	<.0001	0.05	0.6137	0.8735
TRTP	mCC	0.7241	0.09172	147	7.90	<.0001	0.05	0.5429	0.9054
TRTP	SA	1.0801	0.09962	147	10.84	<.0001	0.05	0.8832	1.2769
TRTP	THSm2.2	0.7436	0.06574	147	11.31	<.0001	0.05	0.6137	0.8735
TRTP	mCC	0.7241	0.09172	147	7.90	<.0001	0.05	0.5429	0.9054

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3559	0.1346	147	2.64	0.0091	0.05	0.08992	0.6219
TRTP	THSm2.2	mCC	0.01946	0.1120	147	0.17	0.8623	0.05	-0.2018	0.2408
TRTP	THSm2.2	SA	-0.3365	0.1184	147	-2.84	0.0051	0.05	-0.5705	-0.1024
TRTP	mCC	SA	-0.3559	0.1346	147	-2.64	0.0091	0.05	-0.6219	-0.08992



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	148

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	148
Number of Observations Used	148
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2837

Fit Statistics	
-2 Res Log Likelihood	246.8
AIC (smaller is better)	248.8
AICC (smaller is better)	248.9
BIC (smaller is better)	251.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	142	13.32	0.0004
SEX	1	142	3.14	0.0787
UCPDGR1	1	142	5.27	0.0231
TRTP	2	142	0.07	0.9354

*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.6187	0.09322	142	6.64	<.0001	0.05	0.4344	0.8029
TRTP	THSm2.2	0.6139	0.06184	142	9.93	<.0001	0.05	0.4916	0.7361
TRTP	mCC	0.5792	0.08573	142	6.76	<.0001	0.05	0.4097	0.7487
TRTP	SA	0.6187	0.09322	142	6.64	<.0001	0.05	0.4344	0.8029
TRTP	THSm2.2	0.6139	0.06184	142	9.93	<.0001	0.05	0.4916	0.7361
TRTP	mCC	0.5792	0.08573	142	6.76	<.0001	0.05	0.4097	0.7487

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.03946	0.1261	142	0.31	0.7547	0.05	-0.2097	0.2886
TRTP	THSm2.2	mCC	0.03467	0.1050	142	0.33	0.7418	0.05	-0.1730	0.2423
TRTP	THSm2.2	SA	-0.00479	0.1111	142	-0.04	0.9657	0.05	-0.2243	0.2148
TRTP	mCC	SA	-0.03946	0.1261	142	-0.31	0.7547	0.05	-0.2886	0.2097





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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2982

Fit Statistics	
-2 Res Log Likelihood	262.2
AIC (smaller is better)	264.2
AICC (smaller is better)	264.3
BIC (smaller is better)	267.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	57.60	<.0001
SEX	1	147	0.53	0.4660
UCPDGR1	1	147	3.28	0.0722
TRTP	2	147	3.43	0.0350



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.9369	0.09431	147	9.93	<.0001	0.05	0.7506	1.1233
TRTP	THSm2.2	0.6509	0.06223	147	10.46	<.0001	0.05	0.5279	0.7738
TRTP	mCC	0.6777	0.08683	147	7.80	<.0001	0.05	0.5061	0.8493
TRTP	SA	0.9369	0.09431	147	9.93	<.0001	0.05	0.7506	1.1233
TRTP	THSm2.2	0.6509	0.06223	147	10.46	<.0001	0.05	0.5279	0.7738
TRTP	mCC	0.6777	0.08683	147	7.80	<.0001	0.05	0.5061	0.8493

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2593	0.1274	147	2.03	0.0437	0.05	0.007435	0.5111
TRTP	THSm2.2	mCC	-0.02681	0.1060	147	-0.25	0.8007	0.05	-0.2363	0.1827
TRTP	THSm2.2	SA	-0.2861	0.1121	147	-2.55	0.0117	0.05	-0.5076	-0.06451
TRTP	mCC	SA	-0.2593	0.1274	147	-2.03	0.0437	0.05	-0.5111	-0.00743



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2855

Fit Statistics	
-2 Res Log Likelihood	255.8
AIC (smaller is better)	257.8
AICC (smaller is better)	257.8
BIC (smaller is better)	260.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	55.57	<.0001
SEX	1	147	3.56	0.0612
UCPDGR1	1	147	3.46	0.0650
TRTP	2	147	0.90	0.4093



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*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 5 Analysis Visit (N)=105

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8346	0.09227	147	9.04	<.0001	0.05	0.6522	1.0169
TRTP	THSm2.2	0.6961	0.06089	147	11.43	<.0001	0.05	0.5758	0.8164
TRTP	mCC	0.6933	0.08495	147	8.16	<.0001	0.05	0.5255	0.8612
TRTP	SA	0.8346	0.09227	147	9.04	<.0001	0.05	0.6522	1.0169
TRTP	THSm2.2	0.6961	0.06089	147	11.43	<.0001	0.05	0.5758	0.8164
TRTP	mCC	0.6933	0.08495	147	8.16	<.0001	0.05	0.5255	0.8612

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1412	0.1247	147	1.13	0.2591	0.05	-0.1052	0.3876
TRTP	THSm2.2	mCC	0.002782	0.1037	147	0.03	0.9786	0.05	-0.2022	0.2078
TRTP	THSm2.2	SA	-0.1385	0.1097	147	-1.26	0.2089	0.05	-0.3552	0.07832
TRTP	mCC	SA	-0.1412	0.1247	147	-1.13	0.2591	0.05	-0.3876	0.1052



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	153



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106**

Number of Observations	
Number of Observations Read	153
Number of Observations Used	153
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2943

Fit Statistics	
-2 Res Log Likelihood	260.3
AIC (smaller is better)	262.3
AICC (smaller is better)	262.3
BIC (smaller is better)	265.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	147	65.82	<.0001
SEX	1	147	0.04	0.8400
UCPDGR1	1	147	1.89	0.1717
TRTP	2	147	0.27	0.7642



*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 6/Discharge Confinement Analysis Visit (N)=106

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.7518	0.09368	147	8.03	<.0001	0.05	0.5667	0.9369
TRTP	THSm2.2	0.6806	0.06182	147	11.01	<.0001	0.05	0.5585	0.8028
TRTP	mCC	0.7381	0.08625	147	8.56	<.0001	0.05	0.5677	0.9086
TRTP	SA	0.7518	0.09368	147	8.03	<.0001	0.05	0.5667	0.9369
TRTP	THSm2.2	0.6806	0.06182	147	11.01	<.0001	0.05	0.5585	0.8028
TRTP	mCC	0.7381	0.08625	147	8.56	<.0001	0.05	0.5677	0.9086

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.01367	0.1266	147	0.11	0.9141	0.05	-0.2365	0.2638
TRTP	THSm2.2	mCC	-0.05750	0.1053	147	-0.55	0.5859	0.05	-0.2656	0.1506
TRTP	THSm2.2	SA	-0.07117	0.1114	147	-0.64	0.5238	0.05	-0.2913	0.1489
TRTP	mCC	SA	-0.01367	0.1266	147	-0.11	0.9141	0.05	-0.2638	0.2365



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**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	138

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	138
Number of Observations Used	138
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2247

Fit Statistics	
-2 Res Log Likelihood	199.9
AIC (smaller is better)	201.9
AICC (smaller is better)	201.9
BIC (smaller is better)	204.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	132	23.99	<.0001
SEX	1	132	0.69	0.4088
UCPDGR1	1	132	0.16	0.6869
TRTP	2	132	1.90	0.1532

*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.3369	0.08674	132	3.88	0.0002	0.05	0.1653	0.5084
TRTP	THSm2.2	0.5188	0.05631	132	9.21	<.0001	0.05	0.4074	0.6302
TRTP	mCC	0.5417	0.07955	132	6.81	<.0001	0.05	0.3843	0.6990
TRTP	SA	0.3369	0.08674	132	3.88	0.0002	0.05	0.1653	0.5084
TRTP	THSm2.2	0.5188	0.05631	132	9.21	<.0001	0.05	0.4074	0.6302
TRTP	mCC	0.5417	0.07955	132	6.81	<.0001	0.05	0.3843	0.6990

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.2048	0.1173	132	-1.75	0.0831	0.05	-0.4368	0.02719
TRTP	THSm2.2	mCC	-0.02288	0.09682	132	-0.24	0.8135	0.05	-0.2144	0.1686
TRTP	THSm2.2	SA	0.1819	0.1030	132	1.77	0.0798	0.05	-0.02189	0.3857
TRTP	mCC	SA	0.2048	0.1173	132	1.75	0.0831	0.05	-0.02719	0.4368

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MNWS_MX_F
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	139

**Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS****Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	139
Number of Observations Used	139
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2420

Fit Statistics	
-2 Res Log Likelihood	211.1
AIC (smaller is better)	213.1
AICC (smaller is better)	213.1
BIC (smaller is better)	216.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	133	9.32	0.0027
SEX	1	133	1.06	0.3043
UCPDGR1	1	133	2.83	0.0951
TRTP	2	133	1.00	0.3704

*Listing 15.4.4.57.2 Analysis of MNWS Total Scores - FAS*

Parameter=MNWS-R withdrawal score Parameter (N)=16 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.4628	0.08862	133	5.22	<.0001	0.05	0.2876	0.6381
TRTP	THSm2.2	0.6042	0.05808	133	10.40	<.0001	0.05	0.4893	0.7191
TRTP	mCC	0.5185	0.08360	133	6.20	<.0001	0.05	0.3531	0.6838
TRTP	SA	0.4628	0.08862	133	5.22	<.0001	0.05	0.2876	0.6381
TRTP	THSm2.2	0.6042	0.05808	133	10.40	<.0001	0.05	0.4893	0.7191
TRTP	mCC	0.5185	0.08360	133	6.20	<.0001	0.05	0.3531	0.6838

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.05564	0.1214	133	-0.46	0.6474	0.05	-0.2957	0.1844
TRTP	THSm2.2	mCC	0.08570	0.1011	133	0.85	0.3984	0.05	-0.1144	0.2858
TRTP	THSm2.2	SA	0.1413	0.1055	133	1.34	0.1825	0.05	-0.06728	0.3500
TRTP	mCC	SA	0.05564	0.1214	133	0.46	0.6474	0.05	-0.1844	0.2957



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	107.29

Fit Statistics	
-2 Res Log Likelihood	510.8
AIC (smaller is better)	512.8
AICC (smaller is better)	512.8
BIC (smaller is better)	514.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	75.03	<.0001
SEX	1	65	1.82	0.1814
UCPDGR1	1	65	0.03	0.8527
TRTP	1	65	1.23	0.2714

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	43.5453	1.5451	65	28.18	<.0001	0.05	40.4594	46.6311
TRTP	mCC	46.5100	2.2239	65	20.91	<.0001	0.05	42.0686	50.9514

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-2.9647	2.6726	65	-1.11	0.2714	0.05	-8.3022	2.3727

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	128.70

Fit Statistics	
-2 Res Log Likelihood	304.4
AIC (smaller is better)	306.4
AICC (smaller is better)	306.5
BIC (smaller is better)	308.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	31.74	<.0001
SEX	1	37	1.32	0.2583
UCPDGR1	1	37	0.68	0.4155
TRTP	1	37	0.57	0.4561

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	44.9069	2.4101	37	18.63	<.0001	0.05	40.0236	49.7903
TRTP	mCC	47.7537	2.8178	37	16.95	<.0001	0.05	42.0443	53.4631

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-2.8468	3.7792	37	-0.75	0.4561	0.05	-10.5043	4.8107



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	100.17

Fit Statistics	
-2 Res Log Likelihood	483.7
AIC (smaller is better)	485.7
AICC (smaller is better)	485.7
BIC (smaller is better)	487.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	64.23	<.0001
SEX	1	62	0.26	0.6099
UCPDGR1	1	62	0.62	0.4343
TRTP	1	62	3.14	0.0814

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	45.0652	1.5000	62	30.04	<.0001	0.05	42.0667	48.0637
TRTP	mCC	49.8020	2.2573	62	22.06	<.0001	0.05	45.2898	54.3143

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-4.7368	2.6737	62	-1.77	0.0814	0.05	-10.0815	0.6079





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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	207.07

Fit Statistics	
-2 Res Log Likelihood	238.7
AIC (smaller is better)	240.7
AICC (smaller is better)	240.8
BIC (smaller is better)	241.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	6.20	0.0193
SEX	1	27	0.00	0.9665
UCPDGR1	1	27	0.00	0.9474
TRTP	1	27	0.01	0.9196



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	44.9695	3.5303	27	12.74	<.0001	0.05	37.7259	52.2132
TRTP	mCC	45.5717	4.3905	27	10.38	<.0001	0.05	36.5632	54.5802

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.6022	5.9131	27	-0.10	0.9196	0.05	-12.7349	11.5306



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	126.31

Fit Statistics	
-2 Res Log Likelihood	280.2
AIC (smaller is better)	282.2
AICC (smaller is better)	282.3
BIC (smaller is better)	283.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	71.06	<.0001
SEX	1	34	0.05	0.8185
UCPDGR1	1	34	2.05	0.1612
TRTP	1	34	4.62	0.0388



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak flow (mL/s) (average over visit) Parameter (N)=56 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	43.1251	2.3868	34	18.07	<.0001	0.05	38.2745	47.9757
TRTP	mCC	52.0549	3.2118	34	16.21	<.0001	0.05	45.5278	58.5819

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-8.9298	4.1539	34	-2.15	0.0388	0.05	-17.3715	-0.4881

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 1 Analysis Visit (N)=101

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	8938.93

Fit Statistics	
-2 Res Log Likelihood	802.7
AIC (smaller is better)	804.7
AICC (smaller is better)	804.7
BIC (smaller is better)	806.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	150.62	<.0001
SEX	1	65	2.25	0.1384
UCPDGR1	1	65	0.05	0.8305
TRTP	1	65	4.52	0.0372





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*Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 1 Analysis Visit (N)=101

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	370.63	14.1138	65	26.26	<.0001	0.05	342.44	398.81
TRTP	mCC	422.67	20.3453	65	20.77	<.0001	0.05	382.04	463.30

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-52.0424	24.4687	65	-2.13	0.0372	0.05	-100.91	-3.1750



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	13755

Fit Statistics	
-2 Res Log Likelihood	481.8
AIC (smaller is better)	483.8
AICC (smaller is better)	483.9
BIC (smaller is better)	485.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	23.72	<.0001
SEX	1	37	0.25	0.6198
UCPDGR1	1	37	1.55	0.2215
TRTP	1	37	1.03	0.3157

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	427.53	25.4650	37	16.79	<.0001	0.05	375.93	479.12
TRTP	mCC	385.68	30.0895	37	12.82	<.0001	0.05	324.71	446.64

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	41.8497	41.1466	37	1.02	0.3157	0.05	-41.5211	125.22

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	7023.56

Fit Statistics	
-2 Res Log Likelihood	751.6
AIC (smaller is better)	753.6
AICC (smaller is better)	753.7
BIC (smaller is better)	755.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	156.10	<.0001
SEX	1	62	0.03	0.8718
UCPDGR1	1	62	1.48	0.2280
TRTP	1	62	4.07	0.0479

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	398.53	12.5589	62	31.73	<.0001	0.05	373.43	423.64
TRTP	mCC	443.71	18.9048	62	23.47	<.0001	0.05	405.92	481.50

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-45.1741	22.3875	62	-2.02	0.0479	0.05	-89.9261	-0.4221

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	22246

Fit Statistics	
-2 Res Log Likelihood	369.6
AIC (smaller is better)	371.6
AICC (smaller is better)	371.8
BIC (smaller is better)	372.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	7.29	0.0118
SEX	1	27	0.91	0.3484
UCPDGR1	1	27	0.46	0.5018
TRTP	1	27	1.07	0.3096

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	462.69	37.6063	27	12.30	<.0001	0.05	385.53	539.85
TRTP	mCC	394.71	47.8662	27	8.25	<.0001	0.05	296.50	492.93

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	67.9776	65.6464	27	1.04	0.3096	0.05	-66.7177	202.67

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	19262

Fit Statistics	
-2 Res Log Likelihood	456.0
AIC (smaller is better)	458.0
AICC (smaller is better)	458.1
BIC (smaller is better)	459.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	21.90	<.0001
SEX	1	34	0.46	0.5014
UCPDGR1	1	34	1.05	0.3135
TRTP	1	34	0.25	0.6225

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Peak pressure drop (mmWg) (average over visit) Parameter (N)=63 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	489.86	29.4482	34	16.63	<.0001	0.05	430.01	549.70
TRTP	mCC	464.38	39.6887	34	11.70	<.0001	0.05	383.72	545.04

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	25.4770	51.2725	34	0.50	0.6225	0.05	-78.7213	129.68

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3611.56

Fit Statistics	
-2 Res Log Likelihood	742.4
AIC (smaller is better)	744.4
AICC (smaller is better)	744.5
BIC (smaller is better)	746.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	117.31	<.0001
SEX	1	65	2.97	0.0896
UCPDGR1	1	65	0.05	0.8258
TRTP	1	65	0.01	0.9184

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	153.31	8.9655	65	17.10	<.0001	0.05	135.40	171.21
TRTP	mCC	154.92	13.0681	65	11.85	<.0001	0.05	128.82	181.02

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.6129	15.6745	65	-0.10	0.9184	0.05	-32.9171	29.6912



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3190.95

Fit Statistics	
-2 Res Log Likelihood	426.4
AIC (smaller is better)	428.4
AICC (smaller is better)	428.6
BIC (smaller is better)	430.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	54.80	<.0001
SEX	1	37	0.53	0.4709
UCPDGR1	1	37	0.04	0.8507
TRTP	1	37	0.19	0.6653

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	158.85	12.0188	37	13.22	<.0001	0.05	134.50	183.20
TRTP	mCC	150.53	14.1925	37	10.61	<.0001	0.05	121.77	179.29

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	8.3168	19.0718	37	0.44	0.6653	0.05	-30.3262	46.9599

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4711.24

Fit Statistics	
-2 Res Log Likelihood	725.6
AIC (smaller is better)	727.6
AICC (smaller is better)	727.6
BIC (smaller is better)	729.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	70.88	<.0001
SEX	1	62	1.58	0.2136
UCPDGR1	1	62	0.11	0.7414
TRTP	1	62	0.00	0.9854

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	168.41	10.2862	62	16.37	<.0001	0.05	147.85	188.98
TRTP	mCC	168.07	15.6043	62	10.77	<.0001	0.05	136.88	199.27

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.3396	18.4506	62	0.02	0.9854	0.05	-36.5425	37.2218

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4724.61

Fit Statistics	
-2 Res Log Likelihood	326.3
AIC (smaller is better)	328.3
AICC (smaller is better)	328.4
BIC (smaller is better)	329.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	17.59	0.0003
SEX	1	27	0.61	0.4413
UCPDGR1	1	27	0.15	0.7061
TRTP	1	27	0.93	0.3443



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	175.38	16.9042	27	10.37	<.0001	0.05	140.69	210.06
TRTP	mCC	147.88	21.1978	27	6.98	<.0001	0.05	104.39	191.38

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	27.4949	28.5652	27	0.96	0.3443	0.05	-31.1161	86.1059

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3632.19

Fit Statistics	
-2 Res Log Likelihood	397.5
AIC (smaller is better)	399.5
AICC (smaller is better)	399.6
BIC (smaller is better)	401.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	38.86	<.0001
SEX	1	34	0.00	0.9447
UCPDGR1	1	34	1.97	0.1691
TRTP	1	34	0.07	0.7965



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average Work (mJ) (average over visit) Parameter (N)=61 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	167.59	12.8137	34	13.08	<.0001	0.05	141.55	193.63
TRTP	mCC	173.40	17.2724	34	10.04	<.0001	0.05	138.30	208.50

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-5.8112	22.3582	34	-0.26	0.7965	0.05	-51.2484	39.6261

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	49.7756

Fit Statistics	
-2 Res Log Likelihood	460.0
AIC (smaller is better)	462.0
AICC (smaller is better)	462.1
BIC (smaller is better)	464.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	61.94	<.0001
SEX	1	65	1.53	0.2202
UCPDGR1	1	65	0.00	0.9474
TRTP	1	65	1.18	0.2805

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	28.8639	1.0529	65	27.41	<.0001	0.05	26.7611	30.9666
TRTP	mCC	30.8448	1.5139	65	20.37	<.0001	0.05	27.8213	33.8683

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-1.9809	1.8203	65	-1.09	0.2805	0.05	-5.6163	1.6545

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	53.6723

Fit Statistics	
-2 Res Log Likelihood	271.2
AIC (smaller is better)	273.2
AICC (smaller is better)	273.3
BIC (smaller is better)	274.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	24.63	<.0001
SEX	1	37	0.97	0.3311
UCPDGR1	1	37	0.94	0.3374
TRTP	1	37	0.84	0.3654

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	29.6277	1.5658	37	18.92	<.0001	0.05	26.4551	32.8004
TRTP	mCC	31.8856	1.8272	37	17.45	<.0001	0.05	28.1833	35.5878

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-2.2578	2.4639	37	-0.92	0.3654	0.05	-7.2502	2.7346

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	46.0136

Fit Statistics	
-2 Res Log Likelihood	434.6
AIC (smaller is better)	436.6
AICC (smaller is better)	436.7
BIC (smaller is better)	438.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	59.14	<.0001
SEX	1	62	0.10	0.7588
UCPDGR1	1	62	0.54	0.4665
TRTP	1	62	2.90	0.0936

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	30.1222	1.0172	62	29.61	<.0001	0.05	28.0888	32.1556
TRTP	mCC	33.2102	1.5300	62	21.71	<.0001	0.05	30.1517	36.2687

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-3.0881	1.8134	62	-1.70	0.0936	0.05	-6.7130	0.5368

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	112.60

Fit Statistics	
-2 Res Log Likelihood	221.2
AIC (smaller is better)	223.2
AICC (smaller is better)	223.4
BIC (smaller is better)	224.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	1.85	0.1850
SEX	1	27	0.07	0.7915
UCPDGR1	1	27	0.05	0.8309
TRTP	1	27	0.01	0.9399

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	30.7797	2.6032	27	11.82	<.0001	0.05	25.4385	36.1210
TRTP	mCC	30.4478	3.2396	27	9.40	<.0001	0.05	23.8008	37.0948

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.3319	4.3621	27	0.08	0.9399	0.05	-8.6183	9.2822



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	58.0659

Fit Statistics	
-2 Res Log Likelihood	252.9
AIC (smaller is better)	254.9
AICC (smaller is better)	255.1
BIC (smaller is better)	256.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	73.25	<.0001
SEX	1	34	0.01	0.9284
UCPDGR1	1	34	1.27	0.2668
TRTP	1	34	6.84	0.0132

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average flow (mL/s) (average over visit) Parameter (N)=55 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	28.0793	1.6227	34	17.30	<.0001	0.05	24.7817	31.3770
TRTP	mCC	35.4928	2.1863	34	16.23	<.0001	0.05	31.0497	39.9359

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-7.4135	2.8338	34	-2.62	0.0132	0.05	-13.1725	-1.6545



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	30.7000

Fit Statistics	
-2 Res Log Likelihood	427.8
AIC (smaller is better)	429.8
AICC (smaller is better)	429.8
BIC (smaller is better)	431.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	26.76	<.0001
SEX	1	65	0.48	0.4917
UCPDGR1	1	65	1.44	0.2345
TRTP	1	65	18.12	<.0001

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	17.4374	0.8357	65	20.87	<.0001	0.05	15.7684	19.1063
TRTP	mCC	23.7601	1.2221	65	19.44	<.0001	0.05	21.3194	26.2007

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-6.3227	1.4854	65	-4.26	<.0001	0.05	-9.2893	-3.3561

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	47.2079

Fit Statistics	
-2 Res Log Likelihood	266.0
AIC (smaller is better)	268.0
AICC (smaller is better)	268.1
BIC (smaller is better)	269.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	2.95	0.0943
SEX	1	37	3.02	0.0906
UCPDGR1	1	37	1.07	0.3083
TRTP	1	37	22.26	<.0001



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 30 Analysis Visit (N)=130

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	13.9573	1.4477	37	9.64	<.0001	0.05	11.0240	16.8905
TRTP	mCC	24.6768	1.7162	37	14.38	<.0001	0.05	21.1996	28.1541

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-10.7196	2.2720	37	-4.72	<.0001	0.05	-15.3231	-6.1160

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	43.2676

Fit Statistics	
-2 Res Log Likelihood	429.9
AIC (smaller is better)	431.9
AICC (smaller is better)	432.0
BIC (smaller is better)	434.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	12.49	0.0008
SEX	1	62	0.45	0.5064
UCPDGR1	1	62	1.13	0.2910
TRTP	1	62	23.37	<.0001

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.6156	0.9909	62	15.76	<.0001	0.05	13.6350	17.5963
TRTP	mCC	24.3402	1.5159	62	16.06	<.0001	0.05	21.3099	27.3705

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-8.7246	1.8047	62	-4.83	<.0001	0.05	-12.3321	-5.1170

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	60.2920

Fit Statistics	
-2 Res Log Likelihood	204.4
AIC (smaller is better)	206.4
AICC (smaller is better)	206.6
BIC (smaller is better)	207.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	4.63	0.0406
SEX	1	27	0.33	0.5680
UCPDGR1	1	27	0.74	0.3969
TRTP	1	27	10.81	0.0028

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.9585	1.9158	27	8.33	<.0001	0.05	12.0277	19.8893
TRTP	mCC	26.4553	2.3693	27	11.17	<.0001	0.05	21.5939	31.3168

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-10.4969	3.1920	27	-3.29	0.0028	0.05	-17.0464	-3.9473

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	105.84

Fit Statistics	
-2 Res Log Likelihood	273.1
AIC (smaller is better)	275.1
AICC (smaller is better)	275.2
BIC (smaller is better)	276.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	8.10	0.0074
SEX	1	34	0.12	0.7326
UCPDGR1	1	34	0.55	0.4639
TRTP	1	34	12.13	0.0014



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average inter puff interval (s) (average over visit) Parameter (N)=58 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.7971	2.1826	34	7.24	<.0001	0.05	11.3616	20.2327
TRTP	mCC	29.0685	2.9556	34	9.83	<.0001	0.05	23.0619	35.0751

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-13.2714	3.8106	34	-3.48	0.0014	0.05	-21.0155	-5.5272

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 1 Analysis Visit (N)=101

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3495.35

Fit Statistics	
-2 Res Log Likelihood	740.7
AIC (smaller is better)	742.7
AICC (smaller is better)	742.8
BIC (smaller is better)	744.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	151.21	<.0001
SEX	1	65	3.01	0.0876
UCPDGR1	1	65	0.16	0.6883
TRTP	1	65	5.65	0.0204

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	226.96	8.8273	65	25.71	<.0001	0.05	209.33	244.59
TRTP	mCC	263.28	12.6993	65	20.73	<.0001	0.05	237.92	288.64

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-36.3187	15.2771	65	-2.38	0.0204	0.05	-66.8291	-5.8082

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	5237.30

Fit Statistics	
-2 Res Log Likelihood	445.2
AIC (smaller is better)	447.2
AICC (smaller is better)	447.3
BIC (smaller is better)	448.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	14.30	0.0006
SEX	1	37	0.01	0.9059
UCPDGR1	1	37	1.92	0.1742
TRTP	1	37	1.23	0.2741

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	262.49	15.8265	37	16.59	<.0001	0.05	230.42	294.56
TRTP	mCC	233.83	18.7755	37	12.45	<.0001	0.05	195.79	271.87

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	28.6611	25.8191	37	1.11	0.2741	0.05	-23.6534	80.9755



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2710.42

Fit Statistics	
-2 Res Log Likelihood	691.7
AIC (smaller is better)	693.7
AICC (smaller is better)	693.8
BIC (smaller is better)	695.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	170.58	<.0001
SEX	1	62	0.08	0.7751
UCPDGR1	1	62	1.94	0.1685
TRTP	1	62	5.40	0.0234

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	245.91	7.8031	62	31.51	<.0001	0.05	230.31	261.51
TRTP	mCC	278.23	11.7376	62	23.70	<.0001	0.05	254.76	301.69

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-32.3167	13.9041	62	-2.32	0.0234	0.05	-60.1106	-4.5227

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 60 Analysis Visit (N)=160

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	8222.15

Fit Statistics	
-2 Res Log Likelihood	341.8
AIC (smaller is better)	343.8
AICC (smaller is better)	344.0
BIC (smaller is better)	345.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	3.31	0.0802
SEX	1	27	1.06	0.3133
UCPDGR1	1	27	0.46	0.5019
TRTP	1	27	1.57	0.2211

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	287.28	22.9612	27	12.51	<.0001	0.05	240.17	334.39
TRTP	mCC	236.95	29.2060	27	8.11	<.0001	0.05	177.02	296.87

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	50.3330	40.1834	27	1.25	0.2211	0.05	-32.1166	132.78

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 90 Analysis Visit (N)=190

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	7040.24

Fit Statistics	
-2 Res Log Likelihood	421.0
AIC (smaller is better)	423.0
AICC (smaller is better)	423.1
BIC (smaller is better)	424.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	27.05	<.0001
SEX	1	34	0.72	0.4035
UCPDGR1	1	34	1.13	0.2959
TRTP	1	34	0.01	0.9331



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average pressure drop (mmWg) (average over visit) Parameter (N)=62 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	292.79	17.8047	34	16.44	<.0001	0.05	256.61	328.97
TRTP	mCC	295.40	23.9458	34	12.34	<.0001	0.05	246.74	344.07

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-2.6156	30.9380	34	-0.08	0.9331	0.05	-65.4891	60.2579

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2403

Fit Statistics	
-2 Res Log Likelihood	107.4
AIC (smaller is better)	109.4
AICC (smaller is better)	109.5
BIC (smaller is better)	111.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	86.06	<.0001
SEX	1	65	3.12	0.0820
UCPDGR1	1	65	0.02	0.8949
TRTP	1	65	7.52	0.0079

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.0950	0.07372	65	28.42	<.0001	0.05	1.9477	2.2422
TRTP	mCC	1.7464	0.1052	65	16.61	<.0001	0.05	1.5364	1.9564

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.3486	0.1271	65	2.74	0.0079	0.05	0.09475	0.6024

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2268

Fit Statistics	
-2 Res Log Likelihood	62.9
AIC (smaller is better)	64.9
AICC (smaller is better)	65.0
BIC (smaller is better)	66.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	36.61	<.0001
SEX	1	37	0.94	0.3396
UCPDGR1	1	37	0.01	0.9082
TRTP	1	37	5.65	0.0227

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.1070	0.1081	37	19.48	<.0001	0.05	1.8879	2.3261
TRTP	mCC	1.6889	0.1241	37	13.61	<.0001	0.05	1.4374	1.9405

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.4180	0.1759	37	2.38	0.0227	0.05	0.06173	0.7744

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2405

Fit Statistics	
-2 Res Log Likelihood	102.8
AIC (smaller is better)	104.8
AICC (smaller is better)	104.9
BIC (smaller is better)	107.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	87.45	<.0001
SEX	1	62	4.89	0.0308
UCPDGR1	1	62	0.06	0.8066
TRTP	1	62	13.67	0.0005

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.1850	0.07400	62	29.53	<.0001	0.05	2.0371	2.3329
TRTP	mCC	1.6986	0.1106	62	15.36	<.0001	0.05	1.4775	1.9196

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.4864	0.1316	62	3.70	0.0005	0.05	0.2235	0.7494



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



101

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2714

Fit Statistics	
-2 Res Log Likelihood	52.6
AIC (smaller is better)	54.6
AICC (smaller is better)	54.8
BIC (smaller is better)	55.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	30.62	<.0001
SEX	1	27	0.85	0.3659
UCPDGR1	1	27	0.36	0.5561
TRTP	1	27	3.86	0.0598



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2.1667	0.1314	27	16.49	<.0001	0.05	1.8970	2.4364
TRTP	mCC	1.7311	0.1612	27	10.74	<.0001	0.05	1.4004	2.0619

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.4356	0.2217	27	1.96	0.0598	0.05	-0.01930	0.8904

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2693

Fit Statistics	
-2 Res Log Likelihood	64.2
AIC (smaller is better)	66.2
AICC (smaller is better)	66.3
BIC (smaller is better)	67.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	39.16	<.0001
SEX	1	34	0.07	0.7970
UCPDGR1	1	34	0.71	0.4038
TRTP	1	34	2.71	0.1088



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff duration (s) (average over visit) Parameter (N)=53 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	1.9826	0.1103	34	17.97	<.0001	0.05	1.7583	2.2068
TRTP	mCC	1.6658	0.1486	34	11.21	<.0001	0.05	1.3639	1.9677

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.3167	0.1923	34	1.65	0.1088	0.05	-0.07409	0.7076



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 1 Analysis Visit (N)=101

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	302.69

Fit Statistics	
-2 Res Log Likelihood	578.2
AIC (smaller is better)	580.2
AICC (smaller is better)	580.3
BIC (smaller is better)	582.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	37.18	<.0001
SEX	1	65	5.74	0.0195
UCPDGR1	1	65	0.27	0.6073
TRTP	1	65	2.72	0.1041

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	55.9336	2.5973	65	21.54	<.0001	0.05	50.7464	61.1207
TRTP	mCC	48.5593	3.7316	65	13.01	<.0001	0.05	41.1068	56.0117

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	7.3743	4.4739	65	1.65	0.1041	0.05	-1.5608	16.3094

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	185.09

Fit Statistics	
-2 Res Log Likelihood	318.0
AIC (smaller is better)	320.0
AICC (smaller is better)	320.1
BIC (smaller is better)	321.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	33.25	<.0001
SEX	1	37	2.33	0.1352
UCPDGR1	1	37	0.03	0.8590
TRTP	1	37	0.48	0.4924



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	54.5068	2.8846	37	18.90	<.0001	0.05	48.6621	60.3516
TRTP	mCC	51.3579	3.3898	37	15.15	<.0001	0.05	44.4895	58.2264

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	3.1489	4.5414	37	0.69	0.4924	0.05	-6.0528	12.3506

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 4 Analysis Visit (N)=104

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	431.66

Fit Statistics	
-2 Res Log Likelihood	574.4
AIC (smaller is better)	576.4
AICC (smaller is better)	576.4
BIC (smaller is better)	578.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	30.07	<.0001
SEX	1	62	4.32	0.0418
UCPDGR1	1	62	0.21	0.6501
TRTP	1	62	2.27	0.1371



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	60.1947	3.1170	62	19.31	<.0001	0.05	53.9639	66.4254
TRTP	mCC	51.8460	4.6849	62	11.07	<.0001	0.05	42.4811	61.2109

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	8.3487	5.5436	62	1.51	0.1371	0.05	-2.7329	19.4303

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	533.94

Fit Statistics	
-2 Res Log Likelihood	264.4
AIC (smaller is better)	266.4
AICC (smaller is better)	266.6
BIC (smaller is better)	267.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	6.32	0.0182
SEX	1	27	3.82	0.0611
UCPDGR1	1	27	0.99	0.3298
TRTP	1	27	0.88	0.3560



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	59.2645	5.8166	27	10.19	<.0001	0.05	47.3299	71.1992
TRTP	mCC	49.9601	7.2133	27	6.93	<.0001	0.05	35.1597	64.7604

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	9.3045	9.9074	27	0.94	0.3560	0.05	-11.0238	29.6327

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	221.92

Fit Statistics	
-2 Res Log Likelihood	299.6
AIC (smaller is better)	301.6
AICC (smaller is better)	301.7
BIC (smaller is better)	303.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	40.67	<.0001
SEX	1	34	0.00	0.9886
UCPDGR1	1	34	1.01	0.3212
TRTP	1	34	0.00	0.9820



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*Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*

Parameter=Average puff volume (mL) (average over visit) Parameter (N)=52 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	51.2662	3.1603	34	16.22	<.0001	0.05	44.8437	57.6887
TRTP	mCC	51.3911	4.2522	34	12.09	<.0001	0.05	42.7497	60.0326

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-0.1249	5.4939	34	-0.02	0.9820	0.05	-11.2899	11.0400

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.0464

Fit Statistics	
-2 Res Log Likelihood	205.1
AIC (smaller is better)	207.1
AICC (smaller is better)	207.2
BIC (smaller is better)	209.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	0.45	0.5042
SEX	1	65	4.96	0.0294
UCPDGR1	1	65	0.35	0.5571
TRTP	1	65	7.76	0.0070



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.5269	0.1526	65	23.11	<.0001	0.05	3.2222	3.8317
TRTP	mCC	2.7933	0.2191	65	12.75	<.0001	0.05	2.3557	3.2309

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	0.7337	0.2633	65	2.79	0.0070	0.05	0.2078	1.2595

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4046

Fit Statistics	
-2 Res Log Likelihood	133.2
AIC (smaller is better)	135.2
AICC (smaller is better)	135.3
BIC (smaller is better)	136.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	0.52	0.4755
SEX	1	37	7.54	0.0093
UCPDGR1	1	37	0.41	0.5268
TRTP	1	37	23.80	<.0001

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5010	0.2518	37	17.88	<.0001	0.05	3.9908	5.0112
TRTP	mCC	2.5705	0.2949	37	8.72	<.0001	0.05	1.9729	3.1680

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.9305	0.3957	37	4.88	<.0001	0.05	1.1287	2.7323

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.4662

Fit Statistics	
-2 Res Log Likelihood	217.2
AIC (smaller is better)	219.2
AICC (smaller is better)	219.2
BIC (smaller is better)	221.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	0.00	0.9847
SEX	1	62	1.38	0.2440
UCPDGR1	1	62	1.24	0.2695
TRTP	1	62	10.39	0.0020



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.8867	0.1814	62	21.42	<.0001	0.05	3.5240	4.2494
TRTP	mCC	2.8450	0.2729	62	10.43	<.0001	0.05	2.2995	3.3904

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.0417	0.3231	62	3.22	0.0020	0.05	0.3958	1.6876



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9713

Fit Statistics	
-2 Res Log Likelihood	109.2
AIC (smaller is better)	111.2
AICC (smaller is better)	111.4
BIC (smaller is better)	112.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	0.34	0.5633
SEX	1	27	4.45	0.0443
UCPDGR1	1	27	0.06	0.8122
TRTP	1	27	9.73	0.0043

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.2431	0.3501	27	12.12	<.0001	0.05	3.5247	4.9615
TRTP	mCC	2.3936	0.4347	27	5.51	<.0001	0.05	1.5016	3.2855

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.8495	0.5929	27	3.12	0.0043	0.05	0.6329	3.0660

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4.9210

Fit Statistics	
-2 Res Log Likelihood	165.9
AIC (smaller is better)	167.9
AICC (smaller is better)	168.0
BIC (smaller is better)	169.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	0.27	0.6085
SEX	1	34	0.78	0.3842
UCPDGR1	1	34	0.70	0.4078
TRTP	1	34	7.32	0.0106



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puff Frequency (puffs/min) (average over visit) Parameter (N)=66 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	4.5576	0.4722	34	9.65	<.0001	0.05	3.5979	5.5173
TRTP	mCC	2.3331	0.6347	34	3.68	0.0008	0.05	1.0433	3.6229

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	2.2245	0.8224	34	2.70	0.0106	0.05	0.5532	3.8959

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	24.5210

Fit Statistics	
-2 Res Log Likelihood	412.0
AIC (smaller is better)	414.0
AICC (smaller is better)	414.1
BIC (smaller is better)	416.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	0.29	0.5949
SEX	1	65	1.24	0.2697
UCPDGR1	1	65	0.01	0.9389
TRTP	1	65	8.86	0.0041



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	11.6100	0.7416	65	15.66	<.0001	0.05	10.1289	13.0911
TRTP	mCC	7.8059	1.0610	65	7.36	<.0001	0.05	5.6869	9.9250

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	3.8041	1.2784	65	2.98	0.0041	0.05	1.2510	6.3572

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	33.6486

Fit Statistics	
-2 Res Log Likelihood	252.6
AIC (smaller is better)	254.6
AICC (smaller is better)	254.7
BIC (smaller is better)	256.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	0.00	0.9922
SEX	1	37	0.12	0.7301
UCPDGR1	1	37	0.46	0.5030
TRTP	1	37	10.02	0.0031



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	13.9106	1.2217	37	11.39	<.0001	0.05	11.4351	16.3860
TRTP	mCC	7.8580	1.4357	37	5.47	<.0001	0.05	4.9489	10.7670

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	6.0526	1.9116	37	3.17	0.0031	0.05	2.1793	9.9260

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	32.6596

Fit Statistics	
-2 Res Log Likelihood	411.5
AIC (smaller is better)	413.5
AICC (smaller is better)	413.6
BIC (smaller is better)	415.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	0.18	0.6703
SEX	1	62	2.95	0.0907
UCPDGR1	1	62	0.02	0.8761
TRTP	1	62	13.59	0.0005

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	13.2561	0.8576	62	15.46	<.0001	0.05	11.5417	14.9704
TRTP	mCC	7.6288	1.2878	62	5.92	<.0001	0.05	5.0545	10.2030

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	5.6273	1.5264	62	3.69	0.0005	0.05	2.5760	8.6786

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	60.3086

Fit Statistics	
-2 Res Log Likelihood	203.4
AIC (smaller is better)	205.4
AICC (smaller is better)	205.6
BIC (smaller is better)	206.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	0.17	0.6827
SEX	1	27	0.21	0.6529
UCPDGR1	1	27	0.02	0.9000
TRTP	1	27	4.11	0.0525



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	14.0351	1.9137	27	7.33	<.0001	0.05	10.1086	17.9616
TRTP	mCC	7.5044	2.3822	27	3.15	0.0040	0.05	2.6166	12.3923

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	6.5306	3.2195	27	2.03	0.0525	0.05	-0.07516	13.1364

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	45.1100

Fit Statistics	
-2 Res Log Likelihood	243.0
AIC (smaller is better)	245.0
AICC (smaller is better)	245.1
BIC (smaller is better)	246.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	0.08	0.7858
SEX	1	34	0.03	0.8607
UCPDGR1	1	34	1.69	0.2024
TRTP	1	34	10.97	0.0022



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Puffing Time Index (%) (average over visit) Parameter (N)=65 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	14.5352	1.4391	34	10.10	<.0001	0.05	11.6106	17.4598
TRTP	mCC	6.1937	1.9333	34	3.20	0.0029	0.05	2.2648	10.1226

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	8.3415	2.5182	34	3.31	0.0022	0.05	3.2239	13.4591

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.9540

Fit Statistics	
-2 Res Log Likelihood	245.3
AIC (smaller is better)	247.3
AICC (smaller is better)	247.4
BIC (smaller is better)	249.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	0.39	0.5355
SEX	1	65	1.50	0.2250
UCPDGR1	1	65	0.43	0.5152
TRTP	1	65	7.88	0.0066



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.1316	0.2088	65	15.00	<.0001	0.05	2.7145	3.5486
TRTP	mCC	2.1223	0.2993	65	7.09	<.0001	0.05	1.5246	2.7199

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.0093	0.3596	65	2.81	0.0066	0.05	0.2911	1.7275



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.0056

Fit Statistics	
-2 Res Log Likelihood	145.9
AIC (smaller is better)	147.9
AICC (smaller is better)	148.0
BIC (smaller is better)	149.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	0.00	0.9510
SEX	1	37	0.17	0.6864
UCPDGR1	1	37	0.04	0.8443
TRTP	1	37	11.86	0.0014

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.8132	0.2989	37	12.76	<.0001	0.05	3.2077	4.4188
TRTP	mCC	2.2025	0.3507	37	6.28	<.0001	0.05	1.4918	2.9132

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.6107	0.4678	37	3.44	0.0014	0.05	0.6629	2.5586

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.2346

Fit Statistics	
-2 Res Log Likelihood	242.9
AIC (smaller is better)	244.9
AICC (smaller is better)	245.0
BIC (smaller is better)	247.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	0.23	0.6347
SEX	1	62	2.92	0.0926
UCPDGR1	1	62	0.30	0.5862
TRTP	1	62	11.84	0.0010

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.6289	0.2241	62	16.19	<.0001	0.05	3.1809	4.0769
TRTP	mCC	2.2566	0.3368	62	6.70	<.0001	0.05	1.5834	2.9299

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.3723	0.3989	62	3.44	0.0010	0.05	0.5749	2.1696



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	2.7938

Fit Statistics	
-2 Res Log Likelihood	118.1
AIC (smaller is better)	120.1
AICC (smaller is better)	120.3
BIC (smaller is better)	121.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	1.07	0.3095
SEX	1	27	0.68	0.4159
UCPDGR1	1	27	0.05	0.8299
TRTP	1	27	5.54	0.0261



**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.7332	0.4109	27	9.09	<.0001	0.05	2.8901	4.5763
TRTP	mCC	2.1102	0.5110	27	4.13	0.0003	0.05	1.0618	3.1586

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.6230	0.6893	27	2.35	0.0261	0.05	0.2088	3.0373

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3.5069

Fit Statistics	
-2 Res Log Likelihood	153.9
AIC (smaller is better)	155.9
AICC (smaller is better)	156.0
BIC (smaller is better)	157.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	0.00	0.9702
SEX	1	34	0.25	0.6210
UCPDGR1	1	34	0.78	0.3845
TRTP	1	34	4.39	0.0436

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Smoking Intensity (mL/s) (average over visit) Parameter (N)=64 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	3.6244	0.3990	34	9.08	<.0001	0.05	2.8136	4.4353
TRTP	mCC	2.1682	0.5358	34	4.05	0.0003	0.05	1.0793	3.2571

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.4562	0.6947	34	2.10	0.0436	0.05	0.04441	2.8680

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3086.91

Fit Statistics	
-2 Res Log Likelihood	732.1
AIC (smaller is better)	734.1
AICC (smaller is better)	734.2
BIC (smaller is better)	736.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	11.00	0.0015
SEX	1	65	0.10	0.7496
UCPDGR1	1	65	0.01	0.9419
TRTP	1	65	17.38	<.0001

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	238.51	8.4172	65	28.34	<.0001	0.05	221.70	255.32
TRTP	mCC	299.68	12.0384	65	24.89	<.0001	0.05	275.64	323.73

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-61.1718	14.6734	65	-4.17	<.0001	0.05	-90.4767	-31.8670

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42





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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	6041.27

Fit Statistics	
-2 Res Log Likelihood	450.2
AIC (smaller is better)	452.2
AICC (smaller is better)	452.3
BIC (smaller is better)	453.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	4.81	0.0347
SEX	1	37	0.32	0.5734
UCPDGR1	1	37	2.01	0.1651
TRTP	1	37	19.60	<.0001



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	207.21	16.3906	37	12.64	<.0001	0.05	174.00	240.42
TRTP	mCC	321.39	19.3592	37	16.60	<.0001	0.05	282.16	360.61

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-114.18	25.7880	37	-4.43	<.0001	0.05	-166.43	-61.9261

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 4 Analysis Visit (N)=104

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4227.99

Fit Statistics	
-2 Res Log Likelihood	718.8
AIC (smaller is better)	720.8
AICC (smaller is better)	720.9
BIC (smaller is better)	722.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	6.09	0.0163
SEX	1	62	0.22	0.6439
UCPDGR1	1	62	0.09	0.7645
TRTP	1	62	17.77	<.0001



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	225.73	9.8561	62	22.90	<.0001	0.05	206.02	245.43
TRTP	mCC	300.25	14.7741	62	20.32	<.0001	0.05	270.71	329.78

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-74.5210	17.6788	62	-4.22	<.0001	0.05	-109.86	-39.1816

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	9678.27

Fit Statistics	
-2 Res Log Likelihood	346.0
AIC (smaller is better)	348.0
AICC (smaller is better)	348.2
BIC (smaller is better)	349.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	3.03	0.0931
SEX	1	27	0.00	0.9862
UCPDGR1	1	27	1.47	0.2361
TRTP	1	27	8.53	0.0070



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	232.43	24.3198	27	9.56	<.0001	0.05	182.53	282.33
TRTP	mCC	351.70	30.1405	27	11.67	<.0001	0.05	289.85	413.54

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-119.27	40.8312	27	-2.92	0.0070	0.05	-203.05	-35.4931



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	6015.02

Fit Statistics	
-2 Res Log Likelihood	414.8
AIC (smaller is better)	416.8
AICC (smaller is better)	416.9
BIC (smaller is better)	418.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	0.15	0.6988
SEX	1	34	4.54	0.0404
UCPDGR1	1	34	0.98	0.3295
TRTP	1	34	12.83	0.0011



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total inter puff interval (s) (average over visit) Parameter (N)=57 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	210.84	16.4549	34	12.81	<.0001	0.05	177.40	244.28
TRTP	mCC	313.71	22.2632	34	14.09	<.0001	0.05	268.46	358.95

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-102.87	28.7212	34	-3.58	0.0011	0.05	-161.24	-44.5021

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	8.5884

Fit Statistics	
-2 Res Log Likelihood	343.5
AIC (smaller is better)	345.5
AICC (smaller is better)	345.6
BIC (smaller is better)	347.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	32.21	<.0001
SEX	1	65	2.32	0.1329
UCPDGR1	1	65	0.56	0.4566
TRTP	1	65	2.59	0.1124

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	14.7418	0.4369	65	33.74	<.0001	0.05	13.8693	15.6144
TRTP	mCC	13.5183	0.6355	65	21.27	<.0001	0.05	12.2490	14.7875

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.2236	0.7602	65	1.61	0.1124	0.05	-0.2947	2.7418

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	15.6958

Fit Statistics	
-2 Res Log Likelihood	223.6
AIC (smaller is better)	225.6
AICC (smaller is better)	225.7
BIC (smaller is better)	227.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	7.74	0.0085
SEX	1	37	0.76	0.3880
UCPDGR1	1	37	0.26	0.6120
TRTP	1	37	2.30	0.1380



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.8159	0.8369	37	18.90	<.0001	0.05	14.1201	17.5118
TRTP	mCC	13.8367	0.9834	37	14.07	<.0001	0.05	11.8441	15.8292

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.9793	1.3055	37	1.52	0.1380	0.05	-0.6659	4.6245

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	6.9788

Fit Statistics	
-2 Res Log Likelihood	315.4
AIC (smaller is better)	317.4
AICC (smaller is better)	317.4
BIC (smaller is better)	319.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	39.23	<.0001
SEX	1	62	0.00	0.9699
UCPDGR1	1	62	0.50	0.4828
TRTP	1	62	7.01	0.0102

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.2238	0.3962	62	38.42	<.0001	0.05	14.4318	16.0158
TRTP	mCC	13.3485	0.6012	62	22.20	<.0001	0.05	12.1468	14.5501

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	1.8753	0.7081	62	2.65	0.0102	0.05	0.4599	3.2908



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	14.5188

Fit Statistics	
-2 Res Log Likelihood	164.0
AIC (smaller is better)	166.0
AICC (smaller is better)	166.2
BIC (smaller is better)	167.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	15.13	0.0006
SEX	1	27	0.28	0.6011
UCPDGR1	1	27	0.15	0.6970
TRTP	1	27	3.58	0.0692

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	16.1688	0.9351	27	17.29	<.0001	0.05	14.2501	18.0875
TRTP	mCC	13.1580	1.1902	27	11.06	<.0001	0.05	10.7158	15.6001

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	3.0108	1.5910	27	1.89	0.0692	0.05	-0.2537	6.2753

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	21.1058

Fit Statistics	
-2 Res Log Likelihood	216.6
AIC (smaller is better)	218.6
AICC (smaller is better)	218.7
BIC (smaller is better)	220.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	15.48	0.0004
SEX	1	34	0.99	0.3261
UCPDGR1	1	34	0.12	0.7358
TRTP	1	34	3.83	0.0586

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total number of puffs (average over visit) Parameter (N)=50 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	15.7341	0.9760	34	16.12	<.0001	0.05	13.7506	17.7176
TRTP	mCC	12.3965	1.3188	34	9.40	<.0001	0.05	9.7164	15.0766

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	3.3376	1.7053	34	1.96	0.0586	0.05	-0.1279	6.8031

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	92.7352

Fit Statistics	
-2 Res Log Likelihood	499.5
AIC (smaller is better)	501.5
AICC (smaller is better)	501.5
BIC (smaller is better)	503.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	30.76	<.0001
SEX	1	65	1.56	0.2164
UCPDGR1	1	65	0.02	0.8812
TRTP	1	65	9.54	0.0030

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	30.1052	1.4512	65	20.74	<.0001	0.05	27.2069	33.0034
TRTP	mCC	22.2269	2.1003	65	10.58	<.0001	0.05	18.0324	26.4215

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	7.8782	2.5508	65	3.09	0.0030	0.05	2.7839	12.9725

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	96.0115

Fit Statistics	
-2 Res Log Likelihood	292.1
AIC (smaller is better)	294.1
AICC (smaller is better)	294.2
BIC (smaller is better)	295.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	7.79	0.0083
SEX	1	37	1.41	0.2423
UCPDGR1	1	37	0.43	0.5178
TRTP	1	37	5.26	0.0276



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	31.1922	2.1440	37	14.55	<.0001	0.05	26.8481	35.5363
TRTP	mCC	23.1415	2.5521	37	9.07	<.0001	0.05	17.9704	28.3125

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	8.0507	3.5101	37	2.29	0.0276	0.05	0.9387	15.1628



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	106.18

Fit Statistics	
-2 Res Log Likelihood	485.6
AIC (smaller is better)	487.6
AICC (smaller is better)	487.7
BIC (smaller is better)	489.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	32.38	<.0001
SEX	1	62	5.31	0.0246
UCPDGR1	1	62	0.39	0.5367
TRTP	1	62	15.94	0.0002

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	32.2905	1.5492	62	20.84	<.0001	0.05	29.1938	35.3873
TRTP	mCC	21.1703	2.3439	62	9.03	<.0001	0.05	16.4849	25.8556

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	11.1203	2.7856	62	3.99	0.0002	0.05	5.5519	16.6887



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	113.00

Fit Statistics	
-2 Res Log Likelihood	220.5
AIC (smaller is better)	222.5
AICC (smaller is better)	222.7
BIC (smaller is better)	223.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	10.00	0.0039
SEX	1	27	2.18	0.1509
UCPDGR1	1	27	0.23	0.6320
TRTP	1	27	6.89	0.0141

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	33.8249	2.7249	27	12.41	<.0001	0.05	28.2339	39.4158
TRTP	mCC	21.1560	3.4805	27	6.08	<.0001	0.05	14.0147	28.2973

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	12.6689	4.8263	27	2.62	0.0141	0.05	2.7661	22.5716

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	172.10

Fit Statistics	
-2 Res Log Likelihood	289.2
AIC (smaller is better)	291.2
AICC (smaller is better)	291.3
BIC (smaller is better)	292.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	9.05	0.0049
SEX	1	34	0.99	0.3273
UCPDGR1	1	34	0.02	0.8931
TRTP	1	34	6.97	0.0124





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff duration (s) (average over visit) Parameter (N)=54 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	31.9195	2.7882	34	11.45	<.0001	0.05	26.2532	37.5858
TRTP	mCC	19.1272	3.7452	34	5.11	<.0001	0.05	11.5161	26.7383

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	12.7923	4.8456	34	2.64	0.0124	0.05	2.9449	22.6398

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 1 Analysis Visit (N)=101**

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	95355

Fit Statistics	
-2 Res Log Likelihood	958.0
AIC (smaller is better)	960.0
AICC (smaller is better)	960.0
BIC (smaller is better)	962.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	7.67	0.0073
SEX	1	65	3.46	0.0675
UCPDGR1	1	65	0.04	0.8443
TRTP	1	65	2.52	0.1175

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	779.95	46.0852	65	16.92	<.0001	0.05	687.92	871.99
TRTP	mCC	653.65	66.2186	65	9.87	<.0001	0.05	521.41	785.90

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	126.30	79.6188	65	1.59	0.1175	0.05	-32.7101	285.31

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 30 Analysis Visit (N)=130

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	77823

Fit Statistics	
-2 Res Log Likelihood	547.5
AIC (smaller is better)	549.5
AICC (smaller is better)	549.7
BIC (smaller is better)	551.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	11.82	0.0015
SEX	1	37	0.25	0.6208
UCPDGR1	1	37	0.03	0.8655
TRTP	1	37	1.42	0.2415



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	827.33	58.8638	37	14.05	<.0001	0.05	708.06	946.60
TRTP	mCC	716.77	69.7130	37	10.28	<.0001	0.05	575.51	858.02

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	110.56	92.8767	37	1.19	0.2415	0.05	-77.6249	298.75

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	88987

Fit Statistics	
-2 Res Log Likelihood	910.6
AIC (smaller is better)	912.6
AICC (smaller is better)	912.7
BIC (smaller is better)	914.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	11.72	0.0011
SEX	1	62	6.04	0.0168
UCPDGR1	1	62	0.14	0.7111
TRTP	1	62	5.53	0.0219

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	868.42	44.7095	62	19.42	<.0001	0.05	779.04	957.79
TRTP	mCC	680.90	67.3197	62	10.11	<.0001	0.05	546.33	815.47

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	187.51	79.7379	62	2.35	0.0219	0.05	28.1191	346.91

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	101659

Fit Statistics	
-2 Res Log Likelihood	412.0
AIC (smaller is better)	414.0
AICC (smaller is better)	414.1
BIC (smaller is better)	415.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	2.75	0.1086
SEX	1	27	4.92	0.0352
UCPDGR1	1	27	0.02	0.8934
TRTP	1	27	2.03	0.1652

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	873.76	80.7249	27	10.82	<.0001	0.05	708.12	1039.39
TRTP	mCC	671.45	103.17	27	6.51	<.0001	0.05	459.76	883.14

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	202.30	141.83	27	1.43	0.1652	0.05	-88.7018	493.31

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	100774

Fit Statistics	
-2 Res Log Likelihood	513.5
AIC (smaller is better)	515.5
AICC (smaller is better)	515.6
BIC (smaller is better)	517.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	13.63	0.0008
SEX	1	34	0.45	0.5088
UCPDGR1	1	34	0.05	0.8263
TRTP	1	34	2.07	0.1592



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total puff volume (mL) (average over visit) Parameter (N)=51 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	792.98	67.4700	34	11.75	<.0001	0.05	655.87	930.10
TRTP	mCC	623.15	91.2128	34	6.83	<.0001	0.05	437.78	808.51

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	169.84	117.98	34	1.44	0.1592	0.05	-69.9350	409.61



***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	3166.07

Fit Statistics	
-2 Res Log Likelihood	733.8
AIC (smaller is better)	735.8
AICC (smaller is better)	735.9
BIC (smaller is better)	738.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	11.09	0.0014
SEX	1	65	0.45	0.5055
UCPDGR1	1	65	0.00	0.9988
TRTP	1	65	14.13	0.0004

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	267.86	8.4988	65	31.52	<.0001	0.05	250.89	284.83
TRTP	mCC	323.38	12.1547	65	26.61	<.0001	0.05	299.11	347.66

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-55.5245	14.7723	65	-3.76	0.0004	0.05	-85.0269	-26.0221

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 30 Analysis Visit (N)=130

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	6037.47

Fit Statistics	
-2 Res Log Likelihood	450.2
AIC (smaller is better)	452.2
AICC (smaller is better)	452.3
BIC (smaller is better)	453.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	4.51	0.0405
SEX	1	37	0.53	0.4692
UCPDGR1	1	37	1.61	0.2130
TRTP	1	37	17.57	0.0002



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	237.71	16.3699	37	14.52	<.0001	0.05	204.54	270.88
TRTP	mCC	345.36	19.2962	37	17.90	<.0001	0.05	306.26	384.46

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-107.65	25.6830	37	-4.19	0.0002	0.05	-159.69	-55.6142

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4148.93

Fit Statistics	
-2 Res Log Likelihood	717.7
AIC (smaller is better)	719.7
AICC (smaller is better)	719.7
BIC (smaller is better)	721.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	6.91	0.0108
SEX	1	62	0.81	0.3726
UCPDGR1	1	62	0.13	0.7229
TRTP	1	62	14.10	0.0004





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	257.38	9.7482	62	26.40	<.0001	0.05	237.89	276.86
TRTP	mCC	322.92	14.6079	62	22.11	<.0001	0.05	293.72	352.12

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-65.5427	17.4522	62	-3.76	0.0004	0.05	-100.43	-30.6561

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 60 Analysis Visit (N)=160

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	8945.87

Fit Statistics	
-2 Res Log Likelihood	343.9
AIC (smaller is better)	345.9
AICC (smaller is better)	346.1
BIC (smaller is better)	347.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	2.88	0.1013
SEX	1	27	0.05	0.8275
UCPDGR1	1	27	1.66	0.2080
TRTP	1	27	8.04	0.0086

*Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 60 Analysis Visit (N)=160

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	264.15	23.4386	27	11.27	<.0001	0.05	216.05	312.24
TRTP	mCC	375.94	29.0549	27	12.94	<.0001	0.05	316.33	435.56

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-111.80	39.4378	27	-2.83	0.0086	0.05	-192.72	-30.8773

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set***

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 90 Analysis Visit (N)=190

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	5987.83

Fit Statistics	
-2 Res Log Likelihood	414.7
AIC (smaller is better)	416.7
AICC (smaller is better)	416.8
BIC (smaller is better)	418.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	0.03	0.8733
SEX	1	34	5.13	0.0300
UCPDGR1	1	34	0.95	0.3359
TRTP	1	34	9.56	0.0040



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*Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*

Parameter=Total smoking duration (s) (average over visit) Parameter (N)=59 Analysis Visit=Day 90 Analysis Visit (N)=190

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	243.31	16.4192	34	14.82	<.0001	0.05	209.94	276.68
TRTP	mCC	331.93	22.2146	34	14.94	<.0001	0.05	286.78	377.07

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	-88.6202	28.6658	34	-3.09	0.0040	0.05	-146.88	-30.3641



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***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 1 Analysis Visit (N)=101**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	70





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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 1 Analysis Visit (N)=101

Number of Observations	
Number of Observations Read	70
Number of Observations Used	70
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1186727

Fit Statistics	
-2 Res Log Likelihood	1124.5
AIC (smaller is better)	1126.5
AICC (smaller is better)	1126.6
BIC (smaller is better)	1128.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	65	34.60	<.0001
SEX	1	65	2.03	0.1587
UCPDGR1	1	65	0.12	0.7321
TRTP	1	65	0.40	0.5310



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**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 1 Analysis Visit (N)=101**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2134.95	162.41	65	13.15	<.0001	0.05	1810.59	2459.31
TRTP	mCC	1958.23	233.64	65	8.38	<.0001	0.05	1491.63	2424.83

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	176.72	280.55	65	0.63	0.5310	0.05	-383.57	737.00

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 30 Analysis Visit (N)=130**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	42



245

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 30 Analysis Visit (N)=130**

Number of Observations	
Number of Observations Read	42
Number of Observations Used	42
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	689376

Fit Statistics	
-2 Res Log Likelihood	630.8
AIC (smaller is better)	632.8
AICC (smaller is better)	632.9
BIC (smaller is better)	634.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	37	49.55	<.0001
SEX	1	37	0.23	0.6373
UCPDGR1	1	37	0.02	0.8833
TRTP	1	37	2.36	0.1332



246

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 30 Analysis Visit (N)=130**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2418.31	176.09	37	13.73	<.0001	0.05	2061.53	2775.10
TRTP	mCC	1993.89	206.34	37	9.66	<.0001	0.05	1575.80	2411.97

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	424.43	276.43	37	1.54	0.1332	0.05	-135.67	984.53

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 4 Analysis Visit (N)=104**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	67

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 4 Analysis Visit (N)=104**

Number of Observations	
Number of Observations Read	67
Number of Observations Used	67
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	977920

Fit Statistics	
-2 Res Log Likelihood	1061.8
AIC (smaller is better)	1063.8
AICC (smaller is better)	1063.8
BIC (smaller is better)	1065.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	62	33.82	<.0001
SEX	1	62	2.66	0.1080
UCPDGR1	1	62	0.03	0.8653
TRTP	1	62	1.24	0.2705



249

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 4 Analysis Visit (N)=104**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2409.04	148.19	62	16.26	<.0001	0.05	2112.83	2705.26
TRTP	mCC	2115.55	222.89	62	9.49	<.0001	0.05	1669.99	2561.11

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	293.49	263.96	62	1.11	0.2705	0.05	-234.16	821.15





250

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 60 Analysis Visit (N)=160**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	32



251

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 60 Analysis Visit (N)=160**

Number of Observations	
Number of Observations Read	32
Number of Observations Used	32
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	844852

Fit Statistics	
-2 Res Log Likelihood	471.7
AIC (smaller is better)	473.7
AICC (smaller is better)	473.9
BIC (smaller is better)	475.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	27	12.43	0.0015
SEX	1	27	0.91	0.3485
UCPDGR1	1	27	0.58	0.4532
TRTP	1	27	5.55	0.0260

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 60 Analysis Visit (N)=160**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2674.32	225.47	27	11.86	<.0001	0.05	2211.70	3136.94
TRTP	mCC	1784.83	280.36	27	6.37	<.0001	0.05	1209.59	2360.07

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	889.49	377.54	27	2.36	0.0260	0.05	114.84	1664.13

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 90 Analysis Visit (N)=190**

Model Information	
Data Set	WORK.MIX
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	2	THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	8
Columns in Z	0
Subjects	1
Max Obs Per Subject	39



254

***Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set*****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 90 Analysis Visit (N)=190**

Number of Observations	
Number of Observations Read	39
Number of Observations Used	39
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1296450

Fit Statistics	
-2 Res Log Likelihood	602.8
AIC (smaller is better)	604.8
AICC (smaller is better)	604.9
BIC (smaller is better)	606.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	34	23.18	<.0001
SEX	1	34	0.22	0.6401
UCPDGR1	1	34	0.73	0.3995
TRTP	1	34	1.10	0.3007



255

**Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set****Parameter=Total work (mJ) (average over visit) Parameter (N)=60 Analysis Visit=Day 90 Analysis Visit (N)=190**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	2587.96	241.68	34	10.71	<.0001	0.05	2096.81	3079.11
TRTP	mCC	2146.32	325.08	34	6.60	<.0001	0.05	1485.67	2806.97

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	THSm2.2	mCC	441.64	420.25	34	1.05	0.3007	0.05	-412.42	1295.70



1

**Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130

**Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Number of Observations	
Number of Observations Read	130
Number of Observations Used	130
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.06337

Fit Statistics	
-2 Res Log Likelihood	30.3
AIC (smaller is better)	32.3
AICC (smaller is better)	32.4
BIC (smaller is better)	35.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	124	163.54	<.0001
SEX	1	124	11.89	0.0008
UCPDGR1	1	124	0.65	0.4216
TRTP	2	124	113.71	<.0001



*Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set*

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3455	0.05284	124	82.24	<.0001	0.05	4.2409	4.4501
TRTP	THSm2.2	3.4905	0.02973	124	117.42	<.0001	0.05	3.4317	3.5493
TRTP	mCC	3.4352	0.04414	124	77.82	<.0001	0.05	3.3479	3.5226
TRTP	SA	4.3455	0.05284	124	82.24	<.0001	0.05	4.2409	4.4501
TRTP	THSm2.2	3.4905	0.02973	124	117.42	<.0001	0.05	3.4317	3.5493
TRTP	mCC	3.4352	0.04414	124	77.82	<.0001	0.05	3.3479	3.5226

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.9103	0.06847	124	13.29	<.0001	0.05	0.7747	1.0458
TRTP	THSm2.2	mCC	0.05526	0.05280	124	1.05	0.2973	0.05	-0.04923	0.1598
TRTP	THSm2.2	SA	-0.8550	0.06024	124	-14.19	<.0001	0.05	-0.9742	-0.7358
TRTP	mCC	SA	-0.9103	0.06847	124	-13.29	<.0001	0.05	-1.0458	-0.7747



4

**Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	87



5

**Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Number of Observations	
Number of Observations Read	87
Number of Observations Used	87
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.08403

Fit Statistics	
-2 Res Log Likelihood	47.1
AIC (smaller is better)	49.1
AICC (smaller is better)	49.1
BIC (smaller is better)	51.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	81	54.09	<.0001
SEX	1	81	0.19	0.6649
UCPDGR1	1	81	2.07	0.1545
TRTP	2	81	9.51	0.0002

**Listing 15.4.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.8831	0.09883	81	39.29	<.0001	0.05	3.6865	4.0798
TRTP	THSm2.2	3.4168	0.04310	81	79.27	<.0001	0.05	3.3310	3.5025
TRTP	mCC	3.4876	0.05253	81	66.40	<.0001	0.05	3.3831	3.5922
TRTP	SA	3.8831	0.09883	81	39.29	<.0001	0.05	3.6865	4.0798
TRTP	THSm2.2	3.4168	0.04310	81	79.27	<.0001	0.05	3.3310	3.5025
TRTP	mCC	3.4876	0.05253	81	66.40	<.0001	0.05	3.3831	3.5922

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3955	0.1112	81	3.56	0.0006	0.05	0.1743	0.6167
TRTP	THSm2.2	mCC	-0.07087	0.06784	81	-1.04	0.2993	0.05	-0.2058	0.06411
TRTP	THSm2.2	SA	-0.4664	0.1069	81	-4.36	<.0001	0.05	-0.6792	-0.2536
TRTP	mCC	SA	-0.3955	0.1112	81	-3.56	0.0006	0.05	-0.6167	-0.1743



1

***Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set***

**Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	126



2

***Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	126
Number of Observations Used	126
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.06345

Fit Statistics	
-2 Res Log Likelihood	30.0
AIC (smaller is better)	32.0
AICC (smaller is better)	32.0
BIC (smaller is better)	34.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	120	140.90	<.0001
SEX	1	120	8.77	0.0037
UCPDGR1	1	120	0.99	0.3229
TRTP	2	120	113.70	<.0001



3

**Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set**

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3345	0.05286	120	82.00	<.0001	0.05	4.2299	4.4392
TRTP	THSm2.2	3.4744	0.03070	120	113.18	<.0001	0.05	3.4136	3.5352
TRTP	mCC	3.4264	0.04417	120	77.58	<.0001	0.05	3.3390	3.5138
TRTP	SA	4.3345	0.05286	120	82.00	<.0001	0.05	4.2299	4.4392
TRTP	THSm2.2	3.4744	0.03070	120	113.18	<.0001	0.05	3.4136	3.5352
TRTP	mCC	3.4264	0.04417	120	77.58	<.0001	0.05	3.3390	3.5138

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.9081	0.06852	120	13.25	<.0001	0.05	0.7724	1.0438
TRTP	THSm2.2	mCC	0.04797	0.05334	120	0.90	0.3702	0.05	-0.05763	0.1536
TRTP	THSm2.2	SA	-0.8601	0.06063	120	-14.19	<.0001	0.05	-0.9802	-0.7401
TRTP	mCC	SA	-0.9081	0.06852	120	-13.25	<.0001	0.05	-1.0438	-0.7724



4

***Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set***

**Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84





5

***Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	84
Number of Observations Used	84
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.07723

Fit Statistics	
-2 Res Log Likelihood	39.2
AIC (smaller is better)	41.2
AICC (smaller is better)	41.2
BIC (smaller is better)	43.5

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	78	61.93	<.0001
SEX	1	78	0.10	0.7533
UCPDGR1	1	78	1.25	0.2670
TRTP	2	78	11.31	<.0001



6

**Listing 15.4.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set**

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9141	0.1017	78	38.51	<.0001	0.05	3.7117	4.1165
TRTP	THSm2.2	3.3993	0.04243	78	80.11	<.0001	0.05	3.3148	3.4838
TRTP	mCC	3.4868	0.05036	78	69.23	<.0001	0.05	3.3866	3.5871
TRTP	SA	3.9141	0.1017	78	38.51	<.0001	0.05	3.7117	4.1165
TRTP	THSm2.2	3.3993	0.04243	78	80.11	<.0001	0.05	3.3148	3.4838
TRTP	mCC	3.4868	0.05036	78	69.23	<.0001	0.05	3.3866	3.5871

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4273	0.1126	78	3.80	0.0003	0.05	0.2032	0.6514
TRTP	THSm2.2	mCC	-0.08753	0.06555	78	-1.34	0.1856	0.05	-0.2180	0.04296
TRTP	THSm2.2	SA	-0.5148	0.1083	78	-4.75	<.0001	0.05	-0.7305	-0.2991
TRTP	mCC	SA	-0.4273	0.1126	78	-3.80	0.0003	0.05	-0.6514	-0.2032



1

**Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	150



2

**Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Number of Observations	
Number of Observations Read	150
Number of Observations Used	150
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.07939

Fit Statistics	
-2 Res Log Likelihood	65.4
AIC (smaller is better)	67.4
AICC (smaller is better)	67.5
BIC (smaller is better)	70.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	144	186.28	<.0001
SEX	1	144	10.33	0.0016
UCPDGR1	1	144	1.49	0.2237
TRTP	2	144	141.32	<.0001

*Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS*

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.4019	0.04936	144	89.18	<.0001	0.05	4.3043	4.4995
TRTP	THSm2.2	3.4844	0.03227	144	107.97	<.0001	0.05	3.4206	3.5482
TRTP	mCC	3.4353	0.04532	144	75.80	<.0001	0.05	3.3457	3.5249
TRTP	SA	4.4019	0.04936	144	89.18	<.0001	0.05	4.3043	4.4995
TRTP	THSm2.2	3.4844	0.03227	144	107.97	<.0001	0.05	3.4206	3.5482
TRTP	mCC	3.4353	0.04532	144	75.80	<.0001	0.05	3.3457	3.5249

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.9666	0.06673	144	14.49	<.0001	0.05	0.8347	1.0985
TRTP	THSm2.2	mCC	0.04909	0.05526	144	0.89	0.3758	0.05	-0.06014	0.1583
TRTP	THSm2.2	SA	-0.9175	0.05859	144	-15.66	<.0001	0.05	-1.0333	-0.8017
TRTP	mCC	SA	-0.9666	0.06673	144	-14.49	<.0001	0.05	-1.0985	-0.8347



4

**Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	139

**Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Number of Observations	
Number of Observations Read	139
Number of Observations Used	139
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.07421

Fit Statistics	
-2 Res Log Likelihood	52.7
AIC (smaller is better)	54.7
AICC (smaller is better)	54.7
BIC (smaller is better)	57.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	133	130.93	<.0001
SEX	1	133	0.55	0.4609
UCPDGR1	1	133	1.11	0.2930
TRTP	2	133	10.23	<.0001

**Listing 15.4.4.63.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90**

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.7284	0.04911	133	75.92	<.0001	0.05	3.6312	3.8255
TRTP	THSm2.2	3.4676	0.03216	133	107.81	<.0001	0.05	3.4039	3.5312
TRTP	mCC	3.5062	0.04631	133	75.71	<.0001	0.05	3.4146	3.5978
TRTP	SA	3.7284	0.04911	133	75.92	<.0001	0.05	3.6312	3.8255
TRTP	THSm2.2	3.4676	0.03216	133	107.81	<.0001	0.05	3.4039	3.5312
TRTP	mCC	3.5062	0.04631	133	75.71	<.0001	0.05	3.4146	3.5978

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2222	0.06727	133	3.30	0.0012	0.05	0.08913	0.3552
TRTP	THSm2.2	mCC	-0.03862	0.05603	133	-0.69	0.4918	0.05	-0.1494	0.07219
TRTP	THSm2.2	SA	-0.2608	0.05843	133	-4.46	<.0001	0.05	-0.3764	-0.1452
TRTP	mCC	SA	-0.2222	0.06727	133	-3.30	0.0012	0.05	-0.3552	-0.08913





1

***Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	142



2

***Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	142
Number of Observations Used	142
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.07035

Fit Statistics	
-2 Res Log Likelihood	46.2
AIC (smaller is better)	48.2
AICC (smaller is better)	48.2
BIC (smaller is better)	51.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	136	175.26	<.0001
SEX	1	136	6.91	0.0096
UCPDGR1	1	136	1.46	0.2285
TRTP	2	136	127.19	<.0001



3

**Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3207	0.04890	136	88.36	<.0001	0.05	4.2240	4.4174
TRTP	THSm2.2	3.4617	0.03133	136	110.48	<.0001	0.05	3.3997	3.5236
TRTP	mCC	3.4277	0.04332	136	79.13	<.0001	0.05	3.3421	3.5134
TRTP	SA	4.3207	0.04890	136	88.36	<.0001	0.05	4.2240	4.4174
TRTP	THSm2.2	3.4617	0.03133	136	110.48	<.0001	0.05	3.3997	3.5236
TRTP	mCC	3.4277	0.04332	136	79.13	<.0001	0.05	3.3421	3.5134

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.8930	0.06490	136	13.76	<.0001	0.05	0.7646	1.0213
TRTP	THSm2.2	mCC	0.03392	0.05296	136	0.64	0.5230	0.05	-0.07081	0.1386
TRTP	THSm2.2	SA	-0.8591	0.05749	136	-14.94	<.0001	0.05	-0.9728	-0.7454
TRTP	mCC	SA	-0.8930	0.06490	136	-13.76	<.0001	0.05	-1.0213	-0.7646



4

***Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Model Information	
Data Set	WORK.ANL1
Dependent Variable	LOGAVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130



5

***Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS***

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Number of Observations	
Number of Observations Read	130
Number of Observations Used	130
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.07039

Fit Statistics	
-2 Res Log Likelihood	43.5
AIC (smaller is better)	45.5
AICC (smaller is better)	45.6
BIC (smaller is better)	48.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
LOGBASE	1	124	126.58	<.0001
SEX	1	124	0.05	0.8167
UCPDGR1	1	124	0.60	0.4412
TRTP	2	124	10.97	<.0001



6

**Listing 15.4.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Parameter (N)=5 Parameter Code=CYP2A6 Parameter=CYP2A6 Activity (%) Analysis Visit (N)=190 Analysis Visit=Day 90

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.7213	0.05150	124	72.25	<.0001	0.05	3.6194	3.8232
TRTP	THSm2.2	3.4399	0.03267	124	105.29	<.0001	0.05	3.3752	3.5046
TRTP	mCC	3.4949	0.04515	124	77.41	<.0001	0.05	3.4055	3.5842
TRTP	SA	3.7213	0.05150	124	72.25	<.0001	0.05	3.6194	3.8232
TRTP	THSm2.2	3.4399	0.03267	124	105.29	<.0001	0.05	3.3752	3.5046
TRTP	mCC	3.4949	0.04515	124	77.41	<.0001	0.05	3.4055	3.5842

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.2264	0.06813	124	3.32	0.0012	0.05	0.09159	0.3613
TRTP	THSm2.2	mCC	-0.05495	0.05526	124	-0.99	0.3220	0.05	-0.1643	0.05443
TRTP	THSm2.2	SA	-0.2814	0.06039	124	-4.66	<.0001	0.05	-0.4009	-0.1619
TRTP	mCC	SA	-0.2264	0.06813	124	-3.32	0.0012	0.05	-0.3613	-0.09159



1

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	130
Number of Observations Used	126
Number of Observations Not Used	4

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	4.2399

Fit Statistics	
-2 Res Log Likelihood	539.3
AIC (smaller is better)	541.3
AICC (smaller is better)	541.4
BIC (smaller is better)	544.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	120	545.49	<.0001
SEX	1	120	3.12	0.0797
UCPDGR1	1	120	7.01	0.0092
TRTP	2	120	1.00	0.3718



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	23.5281	0.4554	120	51.67	<.0001	0.05	22.6265	24.4297
TRTP	THSm2.2	23.6921	0.2525	120	93.82	<.0001	0.05	23.1921	24.1921
TRTP	mCC	23.0824	0.3555	120	64.93	<.0001	0.05	22.3786	23.7863
TRTP	SA	23.5281	0.4554	120	51.67	<.0001	0.05	22.6265	24.4297
TRTP	THSm2.2	23.6921	0.2525	120	93.82	<.0001	0.05	23.1921	24.1921
TRTP	mCC	23.0824	0.3555	120	64.93	<.0001	0.05	22.3786	23.7863

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.4456	0.5742	120	0.78	0.4392	0.05	-0.6913	1.5826
TRTP	THSm2.2	mCC	0.6096	0.4320	120	1.41	0.1608	0.05	-0.2457	1.4650
TRTP	THSm2.2	SA	0.1640	0.5117	120	0.32	0.7492	0.05	-0.8492	1.1771
TRTP	mCC	SA	-0.4456	0.5742	120	-0.78	0.4392	0.05	-1.5826	0.6913

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	84

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	84
Number of Observations Used	83
Number of Observations Not Used	1

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	8.4841

Fit Statistics	
-2 Res Log Likelihood	405.9
AIC (smaller is better)	407.9
AICC (smaller is better)	408.0
BIC (smaller is better)	410.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	77	202.69	<.0001
SEX	1	77	0.43	0.5132
UCPDGR1	1	77	0.00	0.9508
TRTP	2	77	1.46	0.2390

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=1 Parameter Code=DLCO Parameter=Diffusion Capacity for Lung CO (mL/min/mmHg) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	22.6135	1.0601	77	21.33	<.0001	0.05	20.5025	24.7246
TRTP	THSm2.2	24.5590	0.4590	77	53.50	<.0001	0.05	23.6449	25.4731
TRTP	mCC	24.2466	0.5364	77	45.20	<.0001	0.05	23.1785	25.3147
TRTP	SA	22.6135	1.0601	77	21.33	<.0001	0.05	20.5025	24.7246
TRTP	THSm2.2	24.5590	0.4590	77	53.50	<.0001	0.05	23.6449	25.4731
TRTP	mCC	24.2466	0.5364	77	45.20	<.0001	0.05	23.1785	25.3147

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.6330	1.1741	77	-1.39	0.1682	0.05	-3.9709	0.7048
TRTP	THSm2.2	mCC	0.3124	0.7026	77	0.44	0.6578	0.05	-1.0866	1.7114
TRTP	THSm2.2	SA	1.9454	1.1391	77	1.71	0.0917	0.05	-0.3228	4.2137
TRTP	mCC	SA	1.6330	1.1741	77	1.39	0.1682	0.05	-0.7048	3.9709



7

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	130

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	130
Number of Observations Used	126
Number of Observations Not Used	4

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.01231

Fit Statistics	
-2 Res Log Likelihood	-167.4
AIC (smaller is better)	-165.4
AICC (smaller is better)	-165.4
BIC (smaller is better)	-162.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	120	530.16	<.0001
SEX	1	120	0.08	0.7799
UCPDGR1	1	120	0.23	0.6305
TRTP	2	120	0.31	0.7340

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.3631	0.02436	120	55.96	<.0001	0.05	1.3148	1.4113
TRTP	THSm2.2	1.3662	0.01340	120	101.98	<.0001	0.05	1.3396	1.3927
TRTP	mCC	1.3480	0.01920	120	70.22	<.0001	0.05	1.3100	1.3861
TRTP	SA	1.3631	0.02436	120	55.96	<.0001	0.05	1.3148	1.4113
TRTP	THSm2.2	1.3662	0.01340	120	101.98	<.0001	0.05	1.3396	1.3927
TRTP	mCC	1.3480	0.01920	120	70.22	<.0001	0.05	1.3100	1.3861

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.01502	0.03081	120	0.49	0.6269	0.05	-0.04598	0.07602
TRTP	THSm2.2	mCC	0.01813	0.02323	120	0.78	0.4367	0.05	-0.02786	0.06413
TRTP	THSm2.2	SA	0.003115	0.02759	120	0.11	0.9103	0.05	-0.05151	0.05774
TRTP	mCC	SA	-0.01502	0.03081	120	-0.49	0.6269	0.05	-0.07602	0.04598



10

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	83





11

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	83
Number of Observations Used	82
Number of Observations Not Used	1

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.02094

Fit Statistics	
-2 Res Log Likelihood	-61.4
AIC (smaller is better)	-59.4
AICC (smaller is better)	-59.4
BIC (smaller is better)	-57.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	76	262.36	<.0001
SEX	1	76	0.12	0.7281
UCPDGR1	1	76	0.00	0.9456
TRTP	2	76	1.03	0.3614



12

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=2 Parameter Code=KCO Parameter=Rate Constant of CO (mmol/min/kPa/L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	1.3763	0.05637	76	24.42	<.0001	0.05	1.2640	1.4886
TRTP	THSm2.2	1.4116	0.02220	76	63.58	<.0001	0.05	1.3674	1.4559
TRTP	mCC	1.3629	0.02665	76	51.14	<.0001	0.05	1.3098	1.4160
TRTP	SA	1.3763	0.05637	76	24.42	<.0001	0.05	1.2640	1.4886
TRTP	THSm2.2	1.4116	0.02220	76	63.58	<.0001	0.05	1.3674	1.4559
TRTP	mCC	1.3629	0.02665	76	51.14	<.0001	0.05	1.3098	1.4160

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.01338	0.06169	76	0.22	0.8289	0.05	-0.1095	0.1362
TRTP	THSm2.2	mCC	0.04875	0.03448	76	1.41	0.1616	0.05	-0.01994	0.1174
TRTP	THSm2.2	SA	0.03537	0.06014	76	0.59	0.5583	0.05	-0.08442	0.1551
TRTP	mCC	SA	-0.01338	0.06169	76	-0.22	0.8289	0.05	-0.1362	0.1095



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***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

**PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.03956

Fit Statistics	
-2 Res Log Likelihood	-27.3
AIC (smaller is better)	-25.3
AICC (smaller is better)	-25.2
BIC (smaller is better)	-22.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	1236.16	<.0001
SEX	1	125	3.13	0.0793
UCPDGR1	1	125	1.78	0.1849
TRTP	2	125	3.85	0.0238



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.5576	0.04265	125	83.42	<.0001	0.05	3.4732	3.6420
TRTP	THSm2.2	3.4431	0.02393	125	143.90	<.0001	0.05	3.3957	3.4904
TRTP	mCC	3.4114	0.03455	125	98.75	<.0001	0.05	3.3431	3.4798
TRTP	SA	3.5576	0.04265	125	83.42	<.0001	0.05	3.4732	3.6420
TRTP	THSm2.2	3.4431	0.02393	125	143.90	<.0001	0.05	3.3957	3.4904
TRTP	mCC	3.4114	0.03455	125	98.75	<.0001	0.05	3.3431	3.4798

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1462	0.05524	125	2.65	0.0092	0.05	0.03686	0.2555
TRTP	THSm2.2	mCC	0.03162	0.04208	125	0.75	0.4538	0.05	-0.05166	0.1149
TRTP	THSm2.2	SA	-0.1146	0.04769	125	-2.40	0.0178	0.05	-0.2090	-0.02018
TRTP	mCC	SA	-0.1462	0.05524	125	-2.65	0.0092	0.05	-0.2555	-0.03686

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04444

Fit Statistics	
-2 Res Log Likelihood	-3.0
AIC (smaller is better)	-1.0
AICC (smaller is better)	-1.0
BIC (smaller is better)	1.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	762.05	<.0001
SEX	1	80	0.57	0.4544
UCPDGR1	1	80	0.11	0.7379
TRTP	2	80	0.45	0.6388

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=3 Parameter Code=WFEVMEAS Parameter=Best measured FEV1 value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.4304	0.07206	80	47.60	<.0001	0.05	3.2870	3.5738
TRTP	THSm2.2	3.4534	0.03221	80	107.22	<.0001	0.05	3.3893	3.5175
TRTP	mCC	3.4057	0.03883	80	87.72	<.0001	0.05	3.3284	3.4830
TRTP	SA	3.4304	0.07206	80	47.60	<.0001	0.05	3.2870	3.5738
TRTP	THSm2.2	3.4534	0.03221	80	107.22	<.0001	0.05	3.3893	3.5175
TRTP	mCC	3.4057	0.03883	80	87.72	<.0001	0.05	3.3284	3.4830

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.02471	0.08114	80	0.30	0.7615	0.05	-0.1368	0.1862
TRTP	THSm2.2	mCC	0.04768	0.05032	80	0.95	0.3462	0.05	-0.05245	0.1478
TRTP	THSm2.2	SA	0.02297	0.07758	80	0.30	0.7680	0.05	-0.1314	0.1774
TRTP	mCC	SA	-0.02471	0.08114	80	-0.30	0.7615	0.05	-0.1862	0.1368



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.03358

Fit Statistics	
-2 Res Log Likelihood	-47.4
AIC (smaller is better)	-45.4
AICC (smaller is better)	-45.4
BIC (smaller is better)	-42.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	1888.59	<.0001
SEX	1	125	10.61	0.0014
UCPDGR1	1	125	2.59	0.1100
TRTP	2	125	0.76	0.4675

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3938	0.03954	125	111.13	<.0001	0.05	4.3155	4.4720
TRTP	THSm2.2	4.3432	0.02214	125	196.13	<.0001	0.05	4.2994	4.3871
TRTP	mCC	4.3366	0.03191	125	135.90	<.0001	0.05	4.2735	4.3998
TRTP	SA	4.3938	0.03954	125	111.13	<.0001	0.05	4.3155	4.4720
TRTP	THSm2.2	4.3432	0.02214	125	196.13	<.0001	0.05	4.2994	4.3871
TRTP	mCC	4.3366	0.03191	125	135.90	<.0001	0.05	4.2735	4.3998

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.05715	0.05133	125	1.11	0.2677	0.05	-0.04444	0.1587
TRTP	THSm2.2	mCC	0.006601	0.03902	125	0.17	0.8659	0.05	-0.07062	0.08383
TRTP	THSm2.2	SA	-0.05055	0.04400	125	-1.15	0.2528	0.05	-0.1376	0.03653
TRTP	mCC	SA	-0.05715	0.05133	125	-1.11	0.2677	0.05	-0.1587	0.04444

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.03836

Fit Statistics	
-2 Res Log Likelihood	-14.5
AIC (smaller is better)	-12.5
AICC (smaller is better)	-12.4
BIC (smaller is better)	-10.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	1258.67	<.0001
SEX	1	80	1.46	0.2306
UCPDGR1	1	80	0.65	0.4211
TRTP	2	80	0.62	0.5430

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=4 Parameter Code=WFVCMEAS Parameter=Best measured FVC value (with bronchodilator) (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3353	0.06690	80	64.80	<.0001	0.05	4.2021	4.4684
TRTP	THSm2.2	4.3744	0.03019	80	144.91	<.0001	0.05	4.3143	4.4345
TRTP	mCC	4.3238	0.03611	80	119.74	<.0001	0.05	4.2519	4.3957
TRTP	SA	4.3353	0.06690	80	64.80	<.0001	0.05	4.2021	4.4684
TRTP	THSm2.2	4.3744	0.03019	80	144.91	<.0001	0.05	4.3143	4.4345
TRTP	mCC	4.3238	0.03611	80	119.74	<.0001	0.05	4.2519	4.3957

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.01148	0.07544	80	0.15	0.8794	0.05	-0.1387	0.1616
TRTP	THSm2.2	mCC	0.05060	0.04713	80	1.07	0.2862	0.05	-0.04319	0.1444
TRTP	THSm2.2	SA	0.03912	0.07207	80	0.54	0.5888	0.05	-0.1043	0.1825
TRTP	mCC	SA	-0.01148	0.07544	80	-0.15	0.8794	0.05	-0.1616	0.1387



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***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.03367

Fit Statistics	
-2 Res Log Likelihood	-47.1
AIC (smaller is better)	-45.1
AICC (smaller is better)	-45.1
BIC (smaller is better)	-42.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	1781.48	<.0001
SEX	1	125	18.50	<.0001
UCPDGR1	1	125	3.40	0.0675
TRTP	2	125	0.82	0.4427



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.4284	0.03961	125	111.79	<.0001	0.05	4.3500	4.5068
TRTP	THSm2.2	4.4278	0.02215	125	199.91	<.0001	0.05	4.3840	4.4717
TRTP	mCC	4.3795	0.03192	125	137.19	<.0001	0.05	4.3163	4.4427
TRTP	SA	4.4284	0.03961	125	111.79	<.0001	0.05	4.3500	4.5068
TRTP	THSm2.2	4.4278	0.02215	125	199.91	<.0001	0.05	4.3840	4.4717
TRTP	mCC	4.3795	0.03192	125	137.19	<.0001	0.05	4.3163	4.4427

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.04897	0.05137	125	0.95	0.3423	0.05	-0.05270	0.1506
TRTP	THSm2.2	mCC	0.04836	0.03900	125	1.24	0.2173	0.05	-0.02883	0.1255
TRTP	THSm2.2	SA	-0.00061	0.04408	125	-0.01	0.9889	0.05	-0.08785	0.08662
TRTP	mCC	SA	-0.04897	0.05137	125	-0.95	0.3423	0.05	-0.1506	0.05270

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.04135

Fit Statistics	
-2 Res Log Likelihood	-8.5
AIC (smaller is better)	-6.5
AICC (smaller is better)	-6.5
BIC (smaller is better)	-4.1

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	1142.29	<.0001
SEX	1	80	0.58	0.4485
UCPDGR1	1	80	0.30	0.5857
TRTP	2	80	2.23	0.1144

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=5 Parameter Code=VC Parameter=Vital Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	4.3764	0.06936	80	63.10	<.0001	0.05	4.2384	4.5145
TRTP	THSm2.2	4.4301	0.03141	80	141.06	<.0001	0.05	4.3676	4.4926
TRTP	mCC	4.3272	0.03748	80	115.45	<.0001	0.05	4.2526	4.4018
TRTP	SA	4.3764	0.06936	80	63.10	<.0001	0.05	4.2384	4.5145
TRTP	THSm2.2	4.4301	0.03141	80	141.06	<.0001	0.05	4.3676	4.4926
TRTP	mCC	4.3272	0.03748	80	115.45	<.0001	0.05	4.2526	4.4018

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.04926	0.07820	80	0.63	0.5305	0.05	-0.1064	0.2049
TRTP	THSm2.2	mCC	0.1030	0.04895	80	2.10	0.0386	0.05	0.005534	0.2004
TRTP	THSm2.2	SA	0.05370	0.07484	80	0.72	0.4752	0.05	-0.09525	0.2026
TRTP	mCC	SA	-0.04926	0.07820	80	-0.63	0.5305	0.05	-0.2049	0.1064

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.5108

Fit Statistics	
-2 Res Log Likelihood	429.5
AIC (smaller is better)	431.5
AICC (smaller is better)	431.6
BIC (smaller is better)	434.4

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	30.98	<.0001
SEX	1	125	6.61	0.0113
UCPDGR1	1	125	1.23	0.2698
TRTP	2	125	0.14	0.8674

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	6.0492	0.2580	125	23.45	<.0001	0.05	5.5386	6.5598
TRTP	THSm2.2	5.9452	0.1465	125	40.59	<.0001	0.05	5.6554	6.2351
TRTP	mCC	6.0681	0.2122	125	28.60	<.0001	0.05	5.6482	6.4880
TRTP	SA	6.0492	0.2580	125	23.45	<.0001	0.05	5.5386	6.5598
TRTP	THSm2.2	5.9452	0.1465	125	40.59	<.0001	0.05	5.6554	6.2351
TRTP	mCC	6.0681	0.2122	125	28.60	<.0001	0.05	5.6482	6.4880

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.01891	0.3324	125	-0.06	0.9547	0.05	-0.6768	0.6389
TRTP	THSm2.2	mCC	-0.1229	0.2557	125	-0.48	0.6316	0.05	-0.6289	0.3831
TRTP	THSm2.2	SA	-0.1040	0.2935	125	-0.35	0.7237	0.05	-0.6848	0.4768
TRTP	mCC	SA	0.01891	0.3324	125	0.06	0.9547	0.05	-0.6389	0.6768

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86





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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.4987

Fit Statistics	
-2 Res Log Likelihood	191.8
AIC (smaller is better)	193.8
AICC (smaller is better)	193.9
BIC (smaller is better)	196.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	87.53	<.0001
SEX	1	80	19.21	<.0001
UCPDGR1	1	80	1.55	0.2162
TRTP	2	80	1.13	0.3284

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=6 Parameter Code=TLC Parameter=Total Lung Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	5.3831	0.2399	80	22.44	<.0001	0.05	4.9057	5.8604
TRTP	THSm2.2	5.7752	0.1074	80	53.77	<.0001	0.05	5.5614	5.9889
TRTP	mCC	5.6893	0.1300	80	43.75	<.0001	0.05	5.4305	5.9481
TRTP	SA	5.3831	0.2399	80	22.44	<.0001	0.05	4.9057	5.8604
TRTP	THSm2.2	5.7752	0.1074	80	53.77	<.0001	0.05	5.5614	5.9889
TRTP	mCC	5.6893	0.1300	80	43.75	<.0001	0.05	5.4305	5.9481

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.3063	0.2700	80	-1.13	0.2600	0.05	-0.8435	0.2310
TRTP	THSm2.2	mCC	0.08584	0.1681	80	0.51	0.6111	0.05	-0.2488	0.4204
TRTP	THSm2.2	SA	0.3921	0.2616	80	1.50	0.1379	0.05	-0.1285	0.9127
TRTP	mCC	SA	0.3063	0.2700	80	1.13	0.2600	0.05	-0.2310	0.8435

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	1.3522

Fit Statistics	
-2 Res Log Likelihood	415.1
AIC (smaller is better)	417.1
AICC (smaller is better)	417.2
BIC (smaller is better)	420.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	19.00	<.0001
SEX	1	125	0.00	0.9817
UCPDGR1	1	125	1.66	0.1999
TRTP	2	125	0.70	0.4996

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.1627	0.2442	125	12.95	<.0001	0.05	2.6793	3.6461
TRTP	THSm2.2	2.8854	0.1376	125	20.98	<.0001	0.05	2.6132	3.1576
TRTP	mCC	3.0974	0.2008	125	15.42	<.0001	0.05	2.6999	3.4948
TRTP	SA	3.1627	0.2442	125	12.95	<.0001	0.05	2.6793	3.6461
TRTP	THSm2.2	2.8854	0.1376	125	20.98	<.0001	0.05	2.6132	3.1576
TRTP	mCC	3.0974	0.2008	125	15.42	<.0001	0.05	2.6999	3.4948

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.06535	0.3149	125	0.21	0.8359	0.05	-0.5578	0.6885
TRTP	THSm2.2	mCC	-0.2120	0.2415	125	-0.88	0.3817	0.05	-0.6899	0.2659
TRTP	THSm2.2	SA	-0.2773	0.2777	125	-1.00	0.3199	0.05	-0.8270	0.2723
TRTP	mCC	SA	-0.06535	0.3149	125	-0.21	0.8359	0.05	-0.6885	0.5578

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2110

Fit Statistics	
-2 Res Log Likelihood	122.3
AIC (smaller is better)	124.3
AICC (smaller is better)	124.3
BIC (smaller is better)	126.7

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	76.82	<.0001
SEX	1	80	1.75	0.1892
UCPDGR1	1	80	5.56	0.0209
TRTP	2	80	3.04	0.0533

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=7 Parameter Code=RV Parameter=Residual Volume (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.2127	0.1560	80	20.60	<.0001	0.05	2.9023	3.5231
TRTP	THSm2.2	2.7972	0.06882	80	40.65	<.0001	0.05	2.6602	2.9341
TRTP	mCC	2.8881	0.08456	80	34.15	<.0001	0.05	2.7198	3.0564
TRTP	SA	3.2127	0.1560	80	20.60	<.0001	0.05	2.9023	3.5231
TRTP	THSm2.2	2.7972	0.06882	80	40.65	<.0001	0.05	2.6602	2.9341
TRTP	mCC	2.8881	0.08456	80	34.15	<.0001	0.05	2.7198	3.0564

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.3246	0.1756	80	1.85	0.0683	0.05	-0.02494	0.6741
TRTP	THSm2.2	mCC	-0.09096	0.1084	80	-0.84	0.4040	0.05	-0.3067	0.1248
TRTP	THSm2.2	SA	-0.4155	0.1691	80	-2.46	0.0162	0.05	-0.7520	-0.07903
TRTP	mCC	SA	-0.3246	0.1756	80	-1.85	0.0683	0.05	-0.6741	0.02494



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.2276

Fit Statistics	
-2 Res Log Likelihood	191.9
AIC (smaller is better)	193.9
AICC (smaller is better)	194.0
BIC (smaller is better)	196.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	110.83	<.0001
SEX	1	125	34.08	<.0001
UCPDGR1	1	125	0.33	0.5682
TRTP	2	125	1.52	0.2238



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1  
Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.8872	0.09997	125	28.88	<.0001	0.05	2.6893	3.0850
TRTP	THSm2.2	3.0748	0.05692	125	54.02	<.0001	0.05	2.9621	3.1874
TRTP	mCC	2.9754	0.08238	125	36.12	<.0001	0.05	2.8124	3.1384
TRTP	SA	2.8872	0.09997	125	28.88	<.0001	0.05	2.6893	3.0850
TRTP	THSm2.2	3.0748	0.05692	125	54.02	<.0001	0.05	2.9621	3.1874
TRTP	mCC	2.9754	0.08238	125	36.12	<.0001	0.05	2.8124	3.1384

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.08821	0.1288	125	-0.68	0.4948	0.05	-0.3432	0.1668
TRTP	THSm2.2	mCC	0.09940	0.09908	125	1.00	0.3177	0.05	-0.09670	0.2955
TRTP	THSm2.2	SA	0.1876	0.1141	125	1.64	0.1026	0.05	-0.03822	0.4134
TRTP	mCC	SA	0.08821	0.1288	125	0.68	0.4948	0.05	-0.1668	0.3432



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3611

Fit Statistics	
-2 Res Log Likelihood	164.9
AIC (smaller is better)	166.9
AICC (smaller is better)	167.0
BIC (smaller is better)	169.3

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	71.32	<.0001
SEX	1	80	14.70	0.0003
UCPDGR1	1	80	0.29	0.5939
TRTP	2	80	7.73	0.0009

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=8 Parameter Code=IC Parameter=Inspiratory Capacity (L) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4  
Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	2.1314	0.2047	80	10.41	<.0001	0.05	1.7240	2.5388
TRTP	THSm2.2	3.0077	0.09155	80	32.85	<.0001	0.05	2.8255	3.1899
TRTP	mCC	2.7928	0.1107	80	25.23	<.0001	0.05	2.5725	3.0132
TRTP	SA	2.1314	0.2047	80	10.41	<.0001	0.05	1.7240	2.5388
TRTP	THSm2.2	3.0077	0.09155	80	32.85	<.0001	0.05	2.8255	3.1899
TRTP	mCC	2.7928	0.1107	80	25.23	<.0001	0.05	2.5725	3.0132

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-0.6614	0.2300	80	-2.88	0.0052	0.05	-1.1192	-0.2036
TRTP	THSm2.2	mCC	0.2149	0.1434	80	1.50	0.1380	0.05	-0.07055	0.5003
TRTP	THSm2.2	SA	0.8763	0.2242	80	3.91	0.0002	0.05	0.4302	1.3224
TRTP	mCC	SA	0.6614	0.2300	80	2.88	0.0052	0.05	0.2036	1.1192

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.3709

Fit Statistics	
-2 Res Log Likelihood	253.4
AIC (smaller is better)	255.4
AICC (smaller is better)	255.4
BIC (smaller is better)	258.2

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	306.01	<.0001
SEX	1	125	0.25	0.6188
UCPDGR1	1	125	0.28	0.5963
TRTP	2	125	0.28	0.7559



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.4023	0.1281	125	26.55	<.0001	0.05	3.1487	3.6559
TRTP	THSm2.2	3.3203	0.07220	125	45.99	<.0001	0.05	3.1774	3.4631
TRTP	mCC	3.2795	0.1051	125	31.19	<.0001	0.05	3.0714	3.4876
TRTP	SA	3.4023	0.1281	125	26.55	<.0001	0.05	3.1487	3.6559
TRTP	THSm2.2	3.3203	0.07220	125	45.99	<.0001	0.05	3.1774	3.4631
TRTP	mCC	3.2795	0.1051	125	31.19	<.0001	0.05	3.0714	3.4876

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.1228	0.1651	125	0.74	0.4582	0.05	-0.2038	0.4495
TRTP	THSm2.2	mCC	0.04077	0.1265	125	0.32	0.7479	0.05	-0.2097	0.2912
TRTP	THSm2.2	SA	-0.08207	0.1455	125	-0.56	0.5737	0.05	-0.3700	0.2058
TRTP	mCC	SA	-0.1228	0.1651	125	-0.74	0.4582	0.05	-0.4495	0.2038

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	145.61

Fit Statistics	
-2 Res Log Likelihood	645.4
AIC (smaller is better)	647.4
AICC (smaller is better)	647.4
BIC (smaller is better)	649.8

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	3.76	0.0560
SEX	1	80	0.48	0.4898
UCPDGR1	1	80	0.01	0.9148
TRTP	2	80	0.09	0.9156

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=9 Parameter Code=WMEF Parameter=Mid expiratory flow 25-75 (with bronchodilator) (L/s) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	3.9852	4.1090	80	0.97	0.3350	0.05	-4.1920	12.1623
TRTP	THSm2.2	5.2116	1.8047	80	2.89	0.0050	0.05	1.6202	8.8030
TRTP	mCC	5.8812	2.2218	80	2.65	0.0098	0.05	1.4597	10.3028
TRTP	SA	3.9852	4.1090	80	0.97	0.3350	0.05	-4.1920	12.1623
TRTP	THSm2.2	5.2116	1.8047	80	2.89	0.0050	0.05	1.6202	8.8030
TRTP	mCC	5.8812	2.2218	80	2.65	0.0098	0.05	1.4597	10.3028

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	-1.8961	4.6210	80	-0.41	0.6827	0.05	-11.0922	7.3001
TRTP	THSm2.2	mCC	-0.6697	2.8433	80	-0.24	0.8144	0.05	-6.3279	4.9886
TRTP	THSm2.2	SA	1.2264	4.4420	80	0.28	0.7832	0.05	-7.6134	10.0663
TRTP	mCC	SA	1.8961	4.6210	80	0.41	0.6827	0.05	-7.3001	11.0922



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.001793

Fit Statistics	
-2 Res Log Likelihood	-418.8
AIC (smaller is better)	-416.8
AICC (smaller is better)	-416.8
BIC (smaller is better)	-414.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	202.95	<.0001
SEX	1	125	1.16	0.2833
UCPDGR1	1	125	0.10	0.7523
TRTP	2	125	1.76	0.1759

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=1 Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.8078	0.008873	125	91.04	<.0001	0.05	0.7902	0.8253
TRTP	THSm2.2	0.7890	0.005004	125	157.67	<.0001	0.05	0.7791	0.7989
TRTP	mCC	0.7909	0.007315	125	108.12	<.0001	0.05	0.7765	0.8054
TRTP	SA	0.8078	0.008873	125	91.04	<.0001	0.05	0.7902	0.8253
TRTP	THSm2.2	0.7890	0.005004	125	157.67	<.0001	0.05	0.7791	0.7989
TRTP	mCC	0.7909	0.007315	125	108.12	<.0001	0.05	0.7765	0.8054

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.01682	0.01144	125	1.47	0.1442	0.05	-0.00583	0.03947
TRTP	THSm2.2	mCC	-0.00192	0.008794	125	-0.22	0.8279	0.05	-0.01932	0.01549
TRTP	THSm2.2	SA	-0.01873	0.01011	125	-1.85	0.0662	0.05	-0.03874	0.001271
TRTP	mCC	SA	-0.01682	0.01144	125	-1.47	0.1442	0.05	-0.03947	0.005831

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

**PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory**

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86





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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	0.001326

Fit Statistics	
-2 Res Log Likelihood	-289.0
AIC (smaller is better)	-287.0
AICC (smaller is better)	-287.0
BIC (smaller is better)	-284.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	159.99	<.0001
SEX	1	80	0.26	0.6107
UCPDGR1	1	80	0.01	0.9413
TRTP	2	80	0.22	0.8047

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=10 Parameter Code=DFEVFVC Parameter=Ratio between FEV1/FVC (Derived) (RATIO) Analysis Product Use Time Period=4 Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	0.7980	0.01238	80	64.46	<.0001	0.05	0.7734	0.8227
TRTP	THSm2.2	0.7897	0.005424	80	145.59	<.0001	0.05	0.7789	0.8005
TRTP	mCC	0.7892	0.006715	80	117.53	<.0001	0.05	0.7758	0.8026
TRTP	SA	0.7980	0.01238	80	64.46	<.0001	0.05	0.7734	0.8227
TRTP	THSm2.2	0.7897	0.005424	80	145.59	<.0001	0.05	0.7789	0.8005
TRTP	mCC	0.7892	0.006715	80	117.53	<.0001	0.05	0.7758	0.8026

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	0.008822	0.01392	80	0.63	0.5281	0.05	-0.01888	0.03653
TRTP	THSm2.2	mCC	0.000503	0.008595	80	0.06	0.9535	0.05	-0.01660	0.01761
TRTP	THSm2.2	SA	-0.00832	0.01343	80	-0.62	0.5375	0.05	-0.03506	0.01842
TRTP	mCC	SA	-0.00882	0.01392	80	-0.63	0.5281	0.05	-0.03653	0.01888

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	45.1605

Fit Statistics	
-2 Res Log Likelihood	858.8
AIC (smaller is better)	860.8
AICC (smaller is better)	860.8
BIC (smaller is better)	863.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	431.68	<.0001
SEX	1	125	4.12	0.0446
UCPDGR1	1	125	0.90	0.3451
TRTP	2	125	2.09	0.1274

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	96.2736	1.4136	125	68.11	<.0001	0.05	93.4760	99.0713
TRTP	THSm2.2	93.2191	0.7938	125	117.44	<.0001	0.05	91.6481	94.7900
TRTP	mCC	92.8969	1.1662	125	79.66	<.0001	0.05	90.5889	95.2050
TRTP	SA	96.2736	1.4136	125	68.11	<.0001	0.05	93.4760	99.0713
TRTP	THSm2.2	93.2191	0.7938	125	117.44	<.0001	0.05	91.6481	94.7900
TRTP	mCC	92.8969	1.1662	125	79.66	<.0001	0.05	90.5889	95.2050

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	3.3767	1.8314	125	1.84	0.0676	0.05	-0.2479	7.0013
TRTP	THSm2.2	mCC	0.3221	1.4008	125	0.23	0.8185	0.05	-2.4502	3.0945
TRTP	THSm2.2	SA	-3.0545	1.6073	125	-1.90	0.0597	0.05	-6.2355	0.1264
TRTP	mCC	SA	-3.3767	1.8314	125	-1.84	0.0676	0.05	-7.0013	0.2479

***Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set***

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86



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**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	49.6671

Fit Statistics	
-2 Res Log Likelihood	564.5
AIC (smaller is better)	566.5
AICC (smaller is better)	566.5
BIC (smaller is better)	568.9

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	251.59	<.0001
SEX	1	80	0.17	0.6775
UCPDGR1	1	80	0.06	0.8147
TRTP	2	80	0.28	0.7598

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=12 Parameter Code=WFEVPCT Parameter=Percent of predicted FEV1 value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	92.6400	2.3932	80	38.71	<.0001	0.05	87.8774	97.4026
TRTP	THSm2.2	91.1776	1.0502	80	86.82	<.0001	0.05	89.0875	93.2676
TRTP	mCC	90.6447	1.3007	80	69.69	<.0001	0.05	88.0563	93.2331
TRTP	SA	92.6400	2.3932	80	38.71	<.0001	0.05	87.8774	97.4026
TRTP	THSm2.2	91.1776	1.0502	80	86.82	<.0001	0.05	89.0875	93.2676
TRTP	mCC	90.6447	1.3007	80	69.69	<.0001	0.05	88.0563	93.2331

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.9953	2.6941	80	0.74	0.4611	0.05	-3.3661	7.3567
TRTP	THSm2.2	mCC	0.5328	1.6658	80	0.32	0.7499	0.05	-2.7822	3.8479
TRTP	THSm2.2	SA	-1.4625	2.5962	80	-0.56	0.5748	0.05	-6.6290	3.7040
TRTP	mCC	SA	-1.9953	2.6941	80	-0.74	0.4611	0.05	-7.3567	3.3661



**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	131

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Number of Observations	
Number of Observations Read	131
Number of Observations Used	131
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	28.3685

Fit Statistics	
-2 Res Log Likelihood	800.8
AIC (smaller is better)	802.8
AICC (smaller is better)	802.8
BIC (smaller is better)	805.6

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	125	732.50	<.0001
SEX	1	125	2.61	0.1087
UCPDGR1	1	125	1.27	0.2612
TRTP	2	125	1.11	0.3326

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=1  
Analysis Product Use Time Period (C)=Period 1 Analysis Visit (N)=106 Analysis Visit=Day 6/Discharge Confinement

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	96.6817	1.1237	125	86.04	<.0001	0.05	94.4578	98.9057
TRTP	THSm2.2	95.4645	0.6297	125	151.61	<.0001	0.05	94.2183	96.7106
TRTP	mCC	94.4977	0.9324	125	101.35	<.0001	0.05	92.6523	96.3431
TRTP	SA	96.6817	1.1237	125	86.04	<.0001	0.05	94.4578	98.9057
TRTP	THSm2.2	95.4645	0.6297	125	151.61	<.0001	0.05	94.2183	96.7106
TRTP	mCC	94.4977	0.9324	125	101.35	<.0001	0.05	92.6523	96.3431

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	2.1840	1.4668	125	1.49	0.1390	0.05	-0.7190	5.0870
TRTP	THSm2.2	mCC	0.9668	1.1202	125	0.86	0.3898	0.05	-1.2502	3.1838
TRTP	THSm2.2	SA	-1.2172	1.2753	125	-0.95	0.3417	0.05	-3.7411	1.3066
TRTP	mCC	SA	-2.1840	1.4668	125	-1.49	0.1390	0.05	-5.0870	0.7190

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Model Information	
Data Set	WORK.ANAL
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information		
Class	Levels	Values
TRTP	3	SA THSm2.2 mCC
SEX	2	F M
UCPDGR1	2	10-19 cig/day >19 cig/day

Dimensions	
Covariance Parameters	1
Columns in X	9
Columns in Z	0
Subjects	1
Max Obs Per Subject	86

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Number of Observations	
Number of Observations Read	86
Number of Observations Used	86
Number of Observations Not Used	0

Covariance Parameter Estimates	
Cov Parm	Estimate
Residual	28.6884

Fit Statistics	
-2 Res Log Likelihood	520.6
AIC (smaller is better)	522.6
AICC (smaller is better)	522.7
BIC (smaller is better)	525.0

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
BASE	1	80	530.83	<.0001
SEX	1	80	1.20	0.2770
UCPDGR1	1	80	0.21	0.6479
TRTP	2	80	0.35	0.7039

**Listing 15.4.4.71 Analysis of Full Lung Function Results – PP Set**

PARAMN=13 Parameter Code=WFVCPCT Parameter=Percent of predicted FVC value (with bronchodilator) (%) Analysis Product Use Time Period=4  
Analysis Product Use Time Period (C)=Period 4 Analysis Visit (N)=191 Analysis Visit=Day 91/Discharge Ambulatory

Least Squares Means									
Effect	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	95.0739	1.8194	80	52.26	<.0001	0.05	91.4532	98.6946
TRTP	THSm2.2	93.8147	0.7997	80	117.31	<.0001	0.05	92.2232	95.4062
TRTP	mCC	93.3568	0.9953	80	93.80	<.0001	0.05	91.3761	95.3374
TRTP	SA	95.0739	1.8194	80	52.26	<.0001	0.05	91.4532	98.6946
TRTP	THSm2.2	93.8147	0.7997	80	117.31	<.0001	0.05	92.2232	95.4062
TRTP	mCC	93.3568	0.9953	80	93.80	<.0001	0.05	91.3761	95.3374

Differences of Least Squares Means										
Effect	Planned Treatment	Planned Treatment	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
TRTP	SA	mCC	1.7171	2.0487	80	0.84	0.4044	0.05	-2.3599	5.7942
TRTP	THSm2.2	mCC	0.4579	1.2770	80	0.36	0.7209	0.05	-2.0834	2.9992
TRTP	THSm2.2	SA	-1.2592	1.9753	80	-0.64	0.5256	0.05	-5.1902	2.6718
TRTP	mCC	SA	-1.7171	2.0487	80	-0.84	0.4044	0.05	-5.7942	2.3599