



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-REXA-08-US** **Clinical Study Report Appendix 16.1.6** **Randomization Scheme and Codes**

<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>Sponsor:</b>	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
<b>Sponsor Signatories:</b>	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Andrea Donelli, Clinical Scientist Ruben Rosoky, MD PhD MFPM, Medical Safety Officer
<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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## 16.1.6.1 RANDOMIZATION SCHEME AND CODES



## FILE NOTE

COVANCE STUDY No. 8276793		CDARO FILE NOTE No. 13
SPONSOR REF No. ZRHM- REXA-08-US		
Written by: J. Ropers Date: 22Feb2016	Checked by: J. Hunter Date: 15Apr2016	Reviewed by: G. de La Bourdonnaye Date: 15Apr2016
(NB: include where relevant) Subject No, ID Code, Initials, Group, Treatment Period, Study Day, Date, Time Point.		
<b>DOCUMENTATION</b>		
Analysis of effect of randomization error on study ZRHM-REXA-08-US		
<p>Per the protocol, stratified randomization was conducted by sex and by daily average cigarette consumption in the 4 weeks prior to the Screening Visit (those smoking 10 to 19 mCC and those smoking &gt;19 mCC per day) reported by the subject. In each arm, each sex and each of the smoking strata had a quota applied to ensure they represent at least 40% of the study population. Thirteen subjects (4 in the THS Menthol 2.2 arm, 4 in the mCC arm, and 5 in the SA arm) were randomized incorrectly at the Daytona Beach Clinical Research Unit due to site staff not following the protocol correctly. Instead of using the cigarette consumption recorded at Screening, the cigarette consumption from Day -2 was used as a stratification factor for these subjects. The database was unlocked, protocol deviations were added, and the database was relocked.</p> <p>The SAP states a minimal number of subjects are expected to be excluded from the PP Set in the confinement period. No more than 50% of subjects are expected to be excluded from the PP Set in the THS 2.2 Menthol arm and a minimal number of subjects to be excluded in the CC arm in the ambulatory period. Thus the expected populations on which the reductions will be assessed as described in SAP Table 19 (see below).</p>		



SAP Table 19: Sample Size to Assess the Reductions

Sample size to assess the reduction (THS 2.2 Menthol:mcc)	
COHb	80:40
3-HPMA	80:40
MHBMA	80:40
S-PMA	80:40
Total NNAL	40:40

The FAS and PP Set in Period 1 tables below shows there is no imbalance in the 2:1 randomization ratio; the stratification is still balanced when using the cigarette consumption recorded at Screening, especially for the THS Menthol 2.2 and mCC arms. The PP Set in Period 4 table shows that the ratio is ~1.5:1 for the THS and mCC arms and this is expected to be closer to 1:1 based on the table above.

Using the strata of sex and daily average cigarette consumption in the 4 weeks prior to the Screening Visit, the FAS consists of the following:

ARM	Total FAS	Male, 10-19	Male, >19	Female, 10-19	Female, >19	Female, Unknown (1042)	Total Male	Total Female	Total 10-19	Total >19
THSm2.2	80	31 (38.8%)	17 (21.3%)	12 (15.0%)	19 (23.8%)	1 (1.3%)	48 (60.0%)	32 (40.0%)	43 (53.8%)	36 (45.0%)
mCC	41	15 (36.6%)	9 (22.0%)	6 (14.6%)	11 (26.8%)	0	24 (58.5%)	17 (41.5%)	21 (51.2%)	20 (48.8%)
SA	39	13 (33.3%)	11 (28.2%)	5 (12.8%)	10 (25.6%)	0	24 (61.5%)	15 (38.5%)	18 (46.2%)	21 (53.8%)
Total	160	59 (36.9%)	37 (23.1%)	23 (14.4%)	40 (25.0%)	1 (0.6%)	96 (60.0%)	64 (40.0%)	82 (51.3%)	77 (48.1%)

Using the strata of sex and daily average cigarette consumption in the 4 weeks prior to the Screening Visit, the PP Set during Period 1 consists of the following:

ARM	Total PP Set in Period 1	Male, 10-19	Male, >19	Female, 10-19	Female, >19	Total Male	Total Female	Total 10-19	Total >19
THSm2.2	75	31 (41.3%)	15 (20.0%)	12 (16.0%)	17 (22.7%)	46 (61.3%)	29 (38.7%)	43 (57.3%)	32 (42.7%)
mCC	35	14 (40.0%)	6 (17.1%)	6 (17.1%)	9 (25.7%)	20 (57.1%)	15 (42.9%)	20 (57.1%)	15 (42.9%)
SA	24	10 (41.7%)	5 (20.8%)	3 (12.5%)	6 (25.0%)	15 (62.5%)	9 (37.5%)	13 (54.2%)	11 (45.8%)
Total	134	55 (41.0%)	26 (19.4%)	21 (15.7%)	32 (23.9%)	81 (60.4%)	53 (39.6%)	76 (56.7%)	58 (43.3%)

Using the strata of sex and daily average cigarette consumption in the 4 weeks prior to the Screening Visit, the PP Set during Period 4 consists of the following:



ARM	Total PP Set in Period 4	Male, 10-19	Male, >19	Female, 10-19	Female, >19	Total Male	Total Female	Total 10-19	Total >19
THSm2.2	47	17 (36.2%)	11 (23.4%)	4 (8.5%)	15 (31.9%)	28 (59.6%)	19 (40.4%)	21 (44.7%)	26 (55.3%)
mCC	32	13 (40.6%)	6 (18.8%)	6 (18.8%)	7 (21.9%)	19 (59.4%)	13 (40.6%)	19 (59.4%)	13 (40.6%)
SA	9	5 (55.6%)	2 (22.2%)	1 (11.1%)	1 (11.1%)	7 (77.8%)	2 (22.2%)	6 (66.7%)	3 (33.3%)
Total	88	35 (39.8%)	19 (21.6%)	11 (12.5%)	23 (26.1%)	54 (61.4%)	34 (38.6%)	46 (52.3%)	42 (47.7%)

In general, these numbers are in line with the SAP sample size text above (analyses were done using Period 1 for confinement and Period 4 for ambulatory), though there were slightly more subjects removed from the THS Menthol 2.2 and mCC arms during confinement and from the mCC arm during ambulatory than expected. Note that these exclusions from the PP Set were based on a combination of subjects who were mis-randomized as well as subjects having other issues that required exclusion.

The Covance statistician consulted the PMI statistician and it was confirmed that no sensitivity analysis would be done, other than those originally planned in the SAP.

**DISTRIBUTION – 8276793 TMF and Sponsor**



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAL	2001	Screen Failed	--- X ---	29	Male					
USA	DAL	2002 <sup>1</sup>	Screen Failed		24	Male					
USA	DAL	2003	Screen Failed		44	Female					
USA	DAL	2004	Screen Failed		39	Male					
USA	DAL	2005	Randomized		23	Male	10-19 cig/day	1003	16JAN2014 [1:50 PM]	mCC	101
USA	DAL	2006	Screen Failed		46	Female					
USA	DAL	2007	Randomized		55	Female	10-19 cig/day	3006	16JAN2014 [1:51 PM]	THSm2.2	182
USA	DAL	2008	Screen Failed		45	Male					
USA	DAL	2009	Screen Failed		52	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2010	Screen Failed	--- X ---	63	Male					
USA	DAL	2011	Screen Failed		35	Male					
USA	DAL	2012	Screen Failed		35	Female					
USA	DAL	2013	Screen Failed		27	Male					
USA	DAL	2014	Screen Failed		41	Female					
USA	DAL	2015	Screen Failed		42	Male					
USA	DAL	2016	Screen Failed		50	Female					
USA	DAL	2017	Screen Failed		33	Male					
USA	DAL	2018	Screen Failed		37	Male					





## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2019	Screen Failed	--- X ---	31	Male					
USA	DAL	2020 <sup>1</sup>	Screen Failed		38	Male					
USA	DAL	2021	Screen Failed		61	Male					
USA	DAL	2022	Screen Failed		55	Male					
USA	DAL	2023	Randomized		44	Male	10-19 cig/day	1004	16JAN2014 [1:53 PM]	THSm2.2	101
USA	DAL	2024	Screen Failed		37	Male					
USA	DAL	2025	Screen Failed		30	Male					
USA	DAL	2026	Screen Failed		23	Female					
USA	DAL	2027	Screen Failed		29	Male					



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Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2028	Screen Failed	--- X ---	62	Female					
USA	DAL	2029	Randomized		41	Male	10-19 cig/day	1005	16JAN2014 [1:54 PM]	SA	102
USA	DAL	2030	Screen Failed		38	Male					
USA	DAL	2031	Screen Failed		24	Female					
USA	DAL	2032	Screen Failed		43	Male					
USA	DAL	2033	Screen Failed		41	Male					
USA	DAL	2034	Screen Failed		63	Male					
USA	DAL	2035	Screen Failed		47	Female					
USA	DAL	2036	Screen Failed		60	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2037	Screen Failed	--- X ---	65	Female	10-19 cig/day	3007	23JAN2014 [2:00 PM]	mCC	182
USA	DAL	2038	Randomized		33	Female					
USA	DAL	2039	Screen Failed		30	Female					
USA	DAL	2040	Screen Failed		28	Male					
USA	DAL	2041	Screen Failed		33	Female					
USA	DAL	2042	Screen Failed		45	Male					
USA	DAL	2043	Screen Failed		34	Female					
USA	DAL	2044	Screen Failed		52	Male					
USA	DAL	2045	Randomized		45	Male	10-19 cig/day	1010	23JAN2014 [2:02 PM]	SA	103



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAL	2046	Randomized	--- X ---	25	Male	>19 cig/day	2002	30JAN2014 [1:13 PM]	THSm2.2	141
USA	DAL	2047	Screen Failed		41	Male					
USA	DAL	2048	Randomized		46	Male	10-19 cig/day	1014	30JAN2014 [1:18 PM]	THSm2.2	104
USA	DAL	2049	Screen Failed		27	Female					
USA	DAL	2050	Screen Failed		30	Male					
USA	DAL	2051	Screen Failed		27	Male					
USA	DAL	2052	Screen Failed		31	Male					
USA	DAL	2053	Randomized		34	Male	10-19 cig/day	1015	30JAN2014 [1:20 PM]	mOC	104
USA	DAL	2054	Randomized		26	Male	10-19 cig/day	1022	07FEB2014 [2:20 PM]	THSm2.2	106



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2055 <sup>1</sup>	Screen Failed	--- X ---	47	Male					
USA	DAL	2056	Screen Failed		38	Male					
USA	DAL	2057	Screen Failed		44	Female					
USA	DAL	2058	Randomized		55	Male	10-19 cig/day	1016	30JAN2014 [1:21 PM]	THSm2.2	104
USA	DAL	2059	Screen Failed		45	Male					
USA	DAL	2060	Screen Failed		64	Male					
USA	DAL	2061	Screen Failed		48	Female					
USA	DAL	2062	Screen Failed		34	Male					
USA	DAL	2063	Screen Failed		28	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2064	Screen Failed	--- X ---	54	Male					
USA	DAL	2065	Randomized		60	Male	10-19 cig/day	1023	07FEB2014 [2:20 PM]	THSm2.2	106
USA	DAL	2066	Screen Failed		30	Male					
USA	DAL	2067	Screen Failed		41	Male					
USA	DAL	2068	Screen Failed		35	Male					
USA	DAL	2069	Screen Failed		41	Male					
USA	DAL	2070	Screen Failed		63	Male					
USA	DAL	2071	Randomized		24	Male	10-19 cig/day	1024	07FEB2014 [2:22 PM]	mCC	106
USA	DAL	2072	Randomized		32	Male	10-19 cig/day	1025	07FEB2014 [2:23 PM]	THSm2.2	107



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2073	Randomized	--- X ---	50	Male	10-19 cig/day	1026	07FEB2014 [2:25 PM]	SA	107
USA	DAL	2074	Screen Failed		44	Female					
USA	DAL	2075	Randomized		52	Male	10-19 cig/day	1027	07FEB2014 [2:26 PM]	THSm2.2	107
USA	DAL	2076	Randomized		34	Male	>19 cig/day	2003	30JAN2014 [1:22 PM]	mCC	141
USA	DAL	2077	Randomized		32	Male	10-19 cig/day	1017	30JAN2014 [1:23 PM]	THSm2.2	105
USA	DAL	2078	Screen Failed		26	Male					
USA	DAL	2079	Randomized		43	Male	10-19 cig/day	1029	12FEB2014 [12:24 PM]	SA	108
USA	DAL	2080	Screen Failed		35	Male					
USA	DAL	2081	Screen Failed		32	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAL	2082	Screen Failed	--- X ---	31	Female					
USA	DAL	2083	Screen Failed		31	Male					
USA	DAL	2084	Screen Failed		54	Female					
USA	DAL	2085	Randomized		23	Male	10-19 cig/day	1030	12FEB2014 [12:25 PM]	mCC	108
USA	DAL	2086	Randomized		32	Female	10-19 cig/day	3012	12FEB2014 [12:26 PM]	mCC	183
USA	DAL	2087	Randomized		53	Female	>19 cig/day	4005	12FEB2014 [12:27 PM]	SA	222
USA	DAL	2088	Screen Failed		22	Female					
USA	DAL	2089	Randomized		26	Male	10-19 cig/day	1028	07FEB2014 [2:28 PM]	mCC	107
USA	DAL	2090	Screen Failed		29	Male					





## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2091	Screen Failed	--- X ---	28	Male					
USA	DAL	2092	Screen Failed		52	Male					
USA	DAL	2093	Screen Failed		61	Male					
USA	DAL	2094 <sup>1</sup>	Screen Failed		43	Male					
USA	DAL	2095	Randomized		42	Female	10-19 cig/day	3011	07FEB2014 [2:29 PM]	THSm2.2	183
USA	DAL	2096 <sup>1</sup>	Screen Failed		34	Male					
USA	DAL	2097	Screen Failed		35	Male					
USA	DAL	2098	Screen Failed		54	Female					
USA	DAL	2099	Screen Failed		57	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2100	Randomized	--- X ---	40	Male	10-19 cig/day	1031	12FEB2014 [12:30 PM]	THSm2.2	108
USA	DAL	2101	Screen Failed		32	Male					
USA	DAL	2102	Screen Failed		31	Male					
USA	DAL	2103	Screen Failed		31	Male					
USA	DAL	2104	Screen Failed		62	Male					
USA	DAL	2105	Screen Failed		23	Male					
USA	DAL	2106	Randomized		31	Male	10-19 cig/day	1032	12FEB2014 [12:31 PM]	THSm2.2	108
USA	DAL	2107 <sup>1</sup>	Screen Failed		32	Female					
USA	DAL	2108	Screen Failed		27	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2109	Randomized	--- X ---	28	Male	10-19 cig/day	1035	19FEB2014 [12:53 PM]	THSm2.2	109
USA	DAL	2110	Randomized		31	Male	10-19 cig/day	1033	12FEB2014 [12:32 PM]	THSm2.2	109
USA	DAL	2111	Screen Failed		53	Male					
USA	DAL	2112	Screen Failed		33	Female					
USA	DAL	2113	Randomized		60	Male	>19 cig/day	2006	19FEB2014 [12:54 PM]	mCC	142
USA	DAL	2114 <sup>1</sup>	Screen Failed		26	Female					
USA	DAL	2115	Randomized		24	Female	10-19 cig/day	3015	19FEB2014 [12:55 PM]	THSm2.2	184
USA	DAL	2116	Randomized		28	Male	10-19 cig/day	1034	12FEB2014 [12:33 PM]	mCC	109
USA	DAL	2117	Screen Failed		30	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2118	Screen Failed	--- X ---	52	Female					
USA	DAL	2119	Screen Failed		55	Female					
USA	DAL	2120	Randomized		50	Male	>19 cig/day	2008	27FEB2014 [1:09 PM]	THSm2.2	142
USA	DAL	2121	Screen Failed		50	Male					
USA	DAL	2122	Screen Failed		32	Male					
USA	DAL	2123	Screen Failed		33	Male					
USA	DAL	2124	Screen Failed		32	Male					
USA	DAL	2125	Screen Failed		28	Male					
USA	DAL	2126	Screen Failed		33	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2127	Randomized	--- X ---	55	Female	>19 cig/day	4009	27FEB2014 [1:11 PM]	mCC	223
USA	DAL	2128	Screen Failed		26	Male					
USA	DAL	2129	Screen Failed		35	Male					
USA	DAL	2130	Screen Failed		23	Male					
USA	DAL	2131	Screen Failed		39	Female					
USA	DAL	2132	Screen Failed		53	Female					
USA	DAL	2133	Screen Failed		52	Male					
USA	DAL	2134	Screen Failed		60	Female					
USA	DAL	2135	Screen Failed		49	Female					



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Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2136	Randomized	--- X ---	57	Male	>19 cig/day	2007	19FEB2014 [12:56 PM]	THSm2.2	142
USA	DAL	2137	Randomized		37	Male	10-19 cig/day	1036	19FEB2014 [12:58 PM]	SA	109
USA	DAL	2138	Randomized		51	Female	10-19 cig/day	3020	27FEB2014 [1:12 PM]	mCC	185
USA	DAL	2139	Screen Failed		31	Female					
USA	DAL	2140	Randomized		30	Female	10-19 cig/day	3016	19FEB2014 [12:57 PM]	THSm2.2	184
USA	DAL	2141	Screen Failed		30	Female					
USA	DAL	2142	Screen Failed		55	Female					
USA	DAL	2143	Randomized		45	Male	10-19 cig/day	1046	27FEB2014 [1:14 PM]	THSm2.2	112
USA	DAL	2144	Screen Failed		59	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2145	Screen Failed	--- X ---	56	Male					
USA	DAL	2146	Randomized		22	Male	10-19 cig/day	1047	27FEB2014 [1:17 PM]	THSm2.2	112
USA	DAL	2147	Screen Failed		25	Male					
USA	DAL	2148	Randomized		58	Male	10-19 cig/day	1048	27FEB2014 [1:19 PM]	mCC	112
USA	DAL	2149	Screen Failed		48	Male					
USA	DAL	2150	Screen Failed		26	Male					
USA	DAL	2151	Screen Failed		58	Male					
USA	DAL	2152 <sup>1</sup>	Screen Failed		65	Male					
USA	DAL	2153	Screen Failed		27	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2154	Screen Failed	--- X ---	36	Male					
USA	DAL	2155	Randomized		32	Female	10-19 cig/day	3021	27FEB2014 [1:26 PM]	mCC	186
USA	DAL	2156	Screen Failed		38	Female					
USA	DAL	2157	Screen Failed		41	Female					
USA	DAL	2158	Screen Failed		25	Male					
USA	DAL	2159	Screen Failed		51	Male					
USA	DAL	2160	Screen Failed		45	Female					
USA	DAL	2161	Screen Failed		39	Male					
USA	DAL	2162	Randomized		36	Male	10-19 cig/day	1056	11MAR2014 [12:30 PM]	mCC	114





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2163	Screen Failed	--- X ---	53	Male					
USA	DAL	2164	Randomized		35	Male	10-19 cig/day	1057	11MAR2014 [12:31 PM]	mCC	115
USA	DAL	2165	Randomized		49	Male	>19 cig/day	2009	06MAR2014 [12:41 PM]	THSm2.2	143
USA	DAL	2166	Screen Failed		53	Male					
USA	DAL	2167	Screen Failed		22	Female					
USA	DAL	2168	Screen Failed		22	Male					
USA	DAL	2169	Randomized		42	Male	10-19 cig/day	1058	11MAR2014 [12:32 PM]	THSm2.2	115
USA	DAL	2170	Screen Failed		38	Female					
USA	DAL	2171	Screen Failed		49	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAL	2172	Screen Failed	---	31	Male					
USA	DAL	2173	Screen Failed	X	49	Female					
USA	DAL	2174	Randomized		32	Female	10-19 cig/day	3023	06MAR2014 [12:44 PM]	THSm2.2	186
USA	DAL	2175	Screen Failed		35	Male					
USA	DAL	2176	Randomized		37	Male	10-19 cig/day	1052	06MAR2014 [12:46 PM]	THSm2.2	113
USA	DAL	2177	Screen Failed		37	Male					
USA	DAL	2178	Screen Failed		50	Male					
USA	DAL	2179	Screen Failed		47	Female					
USA	DAL	2180	Screen Failed		42	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2181	Screen Failed	--- X ---	35	Male					
USA	DAL	2182	Screen Failed		37	Female					
USA	DAL	2183	Screen Failed		45	Male					
USA	DAL	2184	Screen Failed		57	Male					
USA	DAL	2185	Screen Failed		51	Male					
USA	DAL	2186	Screen Failed		57	Male					
USA	DAL	2187	Randomized		26	Male	10-19 cig/day	1053	06MAR2014 [12:49 PM]	SA	114
USA	DAL	2188	Randomized		56	Female	10-19 cig/day	3027	14MAR2014 [2:08 PM]	THSm2.2	187
USA	DAL	2189	Screen Failed		29	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAL	2190	Screen Failed	--- X ---	54	Female					
USA	DAL	2191	Screen Failed		35	Male					
USA	DAL	2192 <sup>1</sup>	Screen Failed		35	Female					
USA	DAL	2193	Screen Failed		37	Female					
USA	DAL	2194	Randomized		32	Male	10-19 cig/day	1059	11MAR2014 [12:33 PM]	SA	115
USA	DAL	2195	Screen Failed		59	Male					
USA	DAL	2196	Randomized		56	Male	10-19 cig/day	1060	11MAR2014 [12:34 PM]	THSm2.2	115
USA	DAL	2197	Randomized		24	Male	>19 cig/day	2010	06MAR2014 [12:50 PM]	mCC	143
USA	DAL	2198	Screen Failed		49	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2199	Screen Failed	--- X ---	45	Female					
USA	DAL	2200	Randomized		33	Male	10-19 cig/day	1061	11MAR2014 [12:35 PM]	THSm2.2	116
USA	DAL	2201	Screen Failed		34	Male					
USA	DAL	2202	Screen Failed		41	Male					
USA	DAL	2203	Screen Failed		36	Male					
USA	DAL	2204	Screen Failed		44	Male					
USA	DAL		Discontinued from Enrollment		40	Male					
USA	DAL	2206	Screen Failed		48	Female					
USA	DAL	2207	Screen Failed		54	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2208	Screen Failed	--- X ---	52	Male					
USA	DAL	2209	Randomized		38	Male	>19 cig/day	2011	06MAR2014 [12:53 PM]	SA	143
USA	DAL	2210	Screen Failed		55	Female					
USA	DAL	2211	Screen Failed		68	Female					
USA	DAL	2212	Randomized		32	Male	10-19 cig/day	1062	11MAR2014 [12:36 PM]	THSm2.2	116
USA	DAL	2213	Screen Failed		31	Male					
USA	DAL	2214	Randomized		57	Female	10-19 cig/day	3028	14MAR2014 [2:09 PM]	SA	187
USA	DAL	2215	Screen Failed		54	Male					
USA	DAL	2216	Screen Failed		42	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2217	Screen Failed	--- X ---	34	Female					
USA	DAL	2218	Screen Failed		47	Female					
USA	DAL	2219	Screen Failed		42	Female					
USA	DAL	2220	Screen Failed		23	Male					
USA	DAL	2221	Screen Failed		35	Male					
USA	DAL	2222 <sup>1</sup>	Screen Failed		28	Female					
USA	DAL	2223	Screen Failed		42	Male					
USA	DAL	2224	Screen Failed		33	Female					
USA	DAL	2225	Randomized		30	Male	10-19 cig/day	1066	14MAR2014 [2:12 PM]	mCC	117



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2226 <sup>1</sup>	Screen Failed	--- X ---	43	Male					
USA	DAL	2227	Screen Failed		24	Female					
USA	DAL	2228	Screen Failed		22	Male					
USA	DAL	2229	Screen Failed		51	Male					
USA	DAL	2230	Randomized		34	Female	10-19 cig/day	3030	16MAR2014 [12:20 PM]	mCC	188
USA	DAL	2231	Screen Failed		48	Female					
USA	DAL	2232	Randomized		50	Female	10-19 cig/day	3029	14MAR2014 [2:13 PM]	THSm2.2	188
USA	DAL	2233	Screen Failed		37	Male					
USA	DAL	2234	Screen Failed		26	Female					





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2235	Screen Failed	--- X ---	27	Female					
USA	DAL	2236	Screen Failed		39	Male					
USA	DAL	2237	Screen Failed		46	Female					
USA	DAL	2238	Screen Failed		44	Male					
USA	DAL	2239	Screen Failed		54	Female					
USA	DAL	2240	Screen Failed		43	Male					
USA	DAL	2241	Screen Failed		57	Female					
USA	DAL	2242 <sup>1</sup>	Screen Failed		44	Female					
USA	DAL	2243	Screen Failed		26	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2244	Screen Failed	--- X ---	47	Female					
USA	DAL	2245	Screen Failed		51	Female					
USA	DAL	2246	Screen Failed		71	Female					
USA	DAL	2247	Screen Failed		22	Female					
USA	DAL	2248	Screen Failed		37	Male					
USA	DAL	2249	Screen Failed		25	Male					
USA	DAL	2250	Screen Failed		35	Male					
USA	DAL	2251	Randomized		48	Male	>19 cig/day	2015	19MAR2014 [11:36 AM]	THSm2.2	144
USA	DAL	2252	Screen Failed		29	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2253	Screen Failed	--- X ---	29	Male					
USA	DAL	2254	Screen Failed		34	Male					
USA	DAL	2255	Screen Failed		61	Female					
USA	DAL	2256	Screen Failed		64	Male					
USA	DAL	2257	Randomized		51	Female	>19 cig/day	4013	19MAR2014 [11:37 AM]	mCC	224
USA	DAL	2258	Screen Failed		45	Female					
USA	DAL	2259	Screen Failed		43	Male					
USA	DAL	2260	Randomized		33	Male	>19 cig/day	2016	24MAR2014 [1:48 PM]	mCC	144
USA	DAL	2261	Screen Failed		50	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2262	Randomized	--- X ---	29	Male	>19 cig/day	2017	24MAR2014 [1:50 PM]	THSm2.2	145
USA	DAL	2263	Screen Failed		33	Male					
USA	DAL	2264	Screen Failed		38	Male					
USA	DAL	2265	Screen Failed		22	Male					
USA	DAL	2266	Screen Failed		35	Female					
USA	DAL	2267	Screen Failed		22	Male					
USA	DAL	2268	Screen Failed		58	Female					
USA	DAL	2269	Screen Failed		47	Male					
USA	DAL	2270	Screen Failed		57	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2271	Screen Failed	--- X ---	49	Male					
USA	DAL	2272	Screen Failed		24	Male					
USA	DAL	2273 <sup>1</sup>	Screen Failed		25	Male					
USA	DAL	2274	Randomized		24	Female	>19 cig/day	4017	08APR2014 [2:53 PM]	THSm2.2	225
USA	DAL	2275	Screen Failed		26	Female					
USA	DAL	2276	Screen Failed		44	Male					
USA	DAL	2277	Screen Failed		33	Female					
USA	DAL	2278	Screen Failed		28	Female					
USA	DAL	2279	Screen Failed		55	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2280	Screen Failed	--- X ---	59	Male					
USA	DAL	2281	Screen Failed		44	Male					
USA	DAL	2282	Screen Failed		36	Male					
USA	DAL	2283	Screen Failed		32	Male					
USA	DAL	2284	Screen Failed		37	Female					
USA	DAL	2285	Randomized		37	Male	>19 cig/day	2024	23APR2014 [3:45 PM]	SA	146
USA	DAL	2286	Screen Failed		29	Male					
USA	DAL	2287	Randomized		31	Male	>19 cig/day	2026	30APR2014 [1:47 PM]	THSm2.2	147
USA	DAL	2288	Screen Failed		22	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2289	Screen Failed	--- X ---	48	Male					
USA	DAL	2290	Screen Failed		50	Male					
USA	DAL	2291	Screen Failed		43	Male					
USA	DAL	2292	Randomized		41	Female	>19 cig/day	4020	23APR2014 [3:50 PM]	SA	225
USA	DAL	2293	Screen Failed		50	Male					
USA	DAL	2294	Screen Failed		28	Male					
USA	DAL	2295	Screen Failed		52	Male					
USA	DAL	2296	Screen Failed		57	Male					
USA	DAL	2297	Screen Failed		48	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2298	Randomized	--- X ---	22	Female	>19 cig/day	4027	16MAY2014 [11:53 AM]	SA	227
USA	DAL	2299	Randomized		29	Female	>19 cig/day	4021	23APR2014 [3:54 PM]	mCC	226
USA	DAL	2300	Screen Failed		25	Male					
USA	DAL	2301	Screen Failed		28	Female					
USA	DAL	2302	Screen Failed		32	Male					
USA	DAL	2303	Randomized		54	Male	>19 cig/day	2027	30APR2014 [1:49 PM]	SA	147
USA	DAL	2304	Screen Failed		48	Male					
USA	DAL	2305	Screen Failed		29	Male					
USA	DAL	2307	Randomized		29	Female	>19 cig/day	4025	30APR2014 [1:52 PM]	mCC	227





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2308	Screen Failed	--- X ---	39	Female					
USA	DAL	2309	Screen Failed		31	Female					
USA	DAL	2310	Randomized		41	Male	>19 cig/day	2028	30APR2014 [1:57 PM]	mCC	147
USA	DAL	2311	Screen Failed		44	Female					
USA	DAL	2312	Screen Failed		25	Female					
USA	DAL	2313	Screen Failed		53	Female					
USA	DAL	2314	Screen Failed		35	Female					
USA	DAL	2315	Screen Failed		38	Female					
USA	DAL	2316	Randomized		42	Female	>19 cig/day	4028	16MAY2014 [11:54 AM]	THSm2.2	227



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2317	Screen Failed	--- X ---	46	Female					
USA	DAL	2318	Screen Failed		27	Male					
USA	DAL	2319	Screen Failed		22	Male					
USA	DAL	2320	Screen Failed		38	Male					
USA	DAL	2321	Screen Failed		29	Male					
USA	DAL	2322	Screen Failed		57	Male					
USA	DAL	2323	Screen Failed		28	Male					
USA	DAL	2324	Screen Failed		26	Male					
USA	DAL	2325	Screen Failed		48	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2326	Screen Failed	--- X ---	43	Female					
USA	DAL	2327	Screen Failed		33	Female					
USA	DAL	2328	Screen Failed		37	Female					
USA	DAL	2329	Screen Failed		26	Female					
USA	DAL	2330	Randomized		51	Female	>19 cig/day	4029	16MAY2014 [11:56 AM]	SA	228
USA	DAL	2331	Screen Failed		46	Female					
USA	DAL	2332	Screen Failed		25	Female					
USA	DAL	2333 <sup>1</sup>	Screen Failed		29	Female					
USA	DAL	2334	Randomized		29	Female	>19 cig/day	4030	16MAY2014 [11:58 AM]	mCC	228



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2335	Screen Failed	--- X ---	1	Female					
USA	DAL	2336	Randomized		8	Female	>19 cig/day	4031	16MAY2014 [12:01 PM]	THSm2.2	228
USA	DAL	2337	Screen Failed		0	Female					
USA	DAL	2338	Screen Failed		6	Female					
USA	DAL	2339	Screen Failed		6	Female					
USA	DAL	2340	Randomized		9	Female	>19 cig/day	4032	16MAY2014 [12:02 PM]	THSm2.2	228
USA	DAL	2341	Screen Failed		6	Female					
USA	DAL	2342	Screen Failed		7	Female					
USA	DAL	2343	Screen Failed		2	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAL	2344	Randomized	--- X ---	35	Female	>19 cig/day	4033	31MAY2014 [12:26 PM]	THSm2.2	229
USA	DAL	2345	Screen Failed		36	Female					
USA	DAL	2346	Screen Failed		59	Female					
USA	DAL	2347	Screen Failed		39	Female					
USA	DAL	2348	Screen Failed		28	Female					
USA	DAL	2349	Screen Failed		38	Female					
USA	DAL	2350	Screen Failed		23	Female					
USA	DAL	2351	Randomized		26	Female	>19 cig/day	4034	06JUN2014 [9:43 AM]	mCC	229
USA	DAL	2352	Screen Failed		45	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1001	Randomized	--- X ---	53	Female	10-19 cig/day	3001	16JAN2014 [11:18 AM]	THSm2.2	181
USA	DAY	1002	Randomized		23	Female	10-19 cig/day <sup>2</sup>	3002	16JAN2014 [11:21 AM]	mCC	181
USA	DAY	1003	Screen Failed		46	Male					
USA	DAY	1004	Screen Failed		24	Male					
USA	DAY	1005	Screen Failed		24	Male					
USA	DAY	1006	Screen Failed		63	Male					
USA	DAY	1007	Screen Failed		32	Female					
USA	DAY	1008	Screen Failed		25	Male					
USA	DAY	1009	Randomized		51	Female	10-19 cig/day	3003	16JAN2014 [11:24 AM]	SA	181



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1010	Randomized	--- X ---	28	Male	10-19 cig/day	1001	16JAN2014 [11:29 AM]	SA	101
USA	DAY	1011	Screen Failed		32	Female					
USA	DAY	1012	Screen Failed		24	Male					
USA	DAY	1013	Screen Failed		38	Male					
USA	DAY	1014	Screen Failed		42	Female					
USA	DAY	1015	Screen Failed		31	Female					
USA	DAY	1016	Screen Failed		58	Female					
USA	DAY	1017	Screen Failed		25	Female					
USA	DAY	1018 <sup>1</sup>	Screen Failed		57	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1019	Screen Failed	--- X ---	27	Male					
USA	DAY	1020	Screen Failed		30	Male					
USA	DAY	1021	Screen Failed		37	Male					
USA	DAY	1022	Screen Failed		42	Female					
USA	DAY	1023	Screen Failed		43	Female					
USA	DAY	1025	Screen Failed		32	Female					
USA	DAY	1026	Screen Failed		51	Female					
USA	DAY	1027	Screen Failed		28	Male					
USA	DAY	1028	Randomized		55	Female	10-19 cig/day	3004	16JAN2014 [11:26 AM]	THSm2.2	181





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1029	Screen Failed	--- X ---	49	Male					
USA	DAY	1030	Screen Failed		37	Female					
USA	DAY	1031	Randomized		25	Male	10-19 cig/day	1002	16JAN2014 [11:31 AM]	THSm2.2	101
USA	DAY	1032	Screen Failed		57	Male					
USA	DAY	1033	Screen Failed		52	Female					
USA	DAY	1034	Screen Failed		29	Male					
USA	DAY	1035	Screen Failed		60	Male					
USA	DAY	1036	Screen Failed		24	Male					
USA	DAY	1037	Screen Failed		48	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1038	Randomized	--- X ---	46	Male	10-19 cig/day	1007	19JAN2014 [10:52 AM]	THSm2.2	102
USA	DAY	1039	Screen Failed		43	Female					
USA	DAY	1040	Screen Failed		38	Male					
USA	DAY	1041	Randomized		25	Male	10-19 cig/day	1006	19JAN2014 [10:49 AM]	mCC	102
USA	DAY	1042	Randomized		48	Female	10-19 cig/day	3005	16JAN2014 [11:27 AM]	THSm2.2	182
USA	DAY	1043	Screen Failed		51	Female					
USA	DAY	1044	Screen Failed		29	Female					
USA	DAY	1045	Screen Failed		48	Male					
USA	DAY	1046	Screen Failed		23	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1047	Screen Failed	--- X ---	32	Male					
USA	DAY	1048	Screen Failed		59	Female					
USA	DAY	1049	Screen Failed		47	Male					
USA	DAY	1050	Screen Failed		31	Male					
USA	DAY	1051	Screen Failed		54	Male					
USA	DAY	1052	Randomized		47	Female	>19 cig/day	4002	30JAN2014 [1:57 PM]	SA	221
USA	DAY	1053	Screen Failed		60	Male					
USA	DAY	1054	Screen Failed		27	Male					
USA	DAY	1055	Screen Failed		32	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1056	Screen Failed	--- X ---	55	Female					
USA	DAY	1057	Randomized		50	Female	>19 cig/day	4003	30JAN2014 [2:03 PM]	mCC	221
USA	DAY	1058	Screen Failed		45	Male					
USA	DAY	1060	Randomized		24	Male	10-19 cig/day	1011	30JAN2014 [1:28 PM]	THSm2.2	103
USA	DAY	1061	Screen Failed		52	Male					
USA	DAY	1062	Randomized		49	Male	10-19 cig/day	1008	19JAN2014 [10:55 AM]	THSm2.2	102
USA	DAY	1063	Screen Failed		63	Female					
USA	DAY	1064	Screen Failed		31	Male					
USA	DAY	1065	Randomized		38	Female	>19 cig/day	4001	19JAN2014 [10:56 AM]	THSm2.2	221



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1066	Screen Failed	--- X ---	51	Male					
USA	DAY	1067	Screen Failed		46	Male					
USA	DAY	1068	Screen Failed		51	Female					
USA	DAY	1069	Randomized		35	Male	10-19 cig/day <sup>2</sup>	1009	19JAN2014 [10:58 AM]	THSm2.2	103
USA	DAY	1070	Screen Failed		34	Male					
USA	DAY	1071	Screen Failed		26	Male					
USA	DAY	1072	Screen Failed		44	Female					
USA	DAY	1073	Screen Failed		33	Female					
USA	DAY	1074	Randomized		32	Male	10-19 cig/day <sup>2</sup>	1012	30JAN2014 [1:31 PM]	mCC	103



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1075	Screen Failed	--- X ---	54	Male					
USA	DAY	1076	Screen Failed		49	Male					
USA	DAY	1077	Randomized		48	Male	>19 cig/day	2004	13FEB2014 [1:11 PM]	SA	141
USA	DAY	1078	Screen Failed		35	Male					
USA	DAY	1079	Randomized		58	Male	10-19 cig/day <sup>2</sup>	1018	30JAN2014 [4:29 PM]	SA	105
USA	DAY	1080	Screen Failed		34	Male					
USA	DAY	1081	Randomized		24	Female	>19 cig/day	4004	01FEB2014 [10:07 AM]	THSm2.2	221
USA	DAY	1082	Screen Failed		53	Male					
USA	DAY	1083	Screen Failed		31	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1084	Screen Failed	--- X ---	52	Male					
USA	DAY	1085	Screen Failed		31	Male					
USA	DAY	1086	Screen Failed		48	Female					
USA	DAY	1087	Randomized		29	Male	>19 cig/day	2001	30JAN2014 [1:51 PM]	THSm2.2	141
USA	DAY	1088	Screen Failed		50	Female					
USA	DAY	1089	Randomized		22	Female	10-19 cig/day	3008	30JAN2014 [2:05 PM]	SA	182
USA	DAY	1090	Screen Failed		43	Female					
USA	DAY	1091	Screen Failed		25	Male					
USA	DAY	1092	Randomized		23	Female	>19 cig/day	4007	13FEB2014 [1:16 PM]	mCC	222



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1093	Randomized	--- X ---	38	Female	10-19 cig/day <sup>2</sup>	3013	13FEB2014 [1:18 PM]	mCC	184
USA	DAY	1094	Screen Failed		53	Female					
USA	DAY	1095	Screen Failed		27	Female					
USA	DAY	1096	Screen Failed		52	Female					
USA	DAY	1097	Randomized		32	Male	10-19 cig/day <sup>2</sup>	1013	30JAN2014 [2:00 PM]	SA	104
USA	DAY		Discontinued from Enrollment		51	Female					
USA	DAY	1099	Randomized		48	Female	10-19 cig/day <sup>2</sup>	3009	01FEB2014 [10:13 AM]	THSm2.2	183
USA	DAY	1100	Screen Failed		56	Female					
USA	DAY	1101	Randomized		45	Female	>19 cig/day	4008	20FEB2014 [3:36 PM]	THSm2.2	222





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1102	Randomized	--- X ---	31	Male	10-19 cig/day	1020	01FEB2014 [10:17 AM]	THSm2.2	105
USA	DAY	1103	Screen Failed		27	Male					
USA	DAY	1104	Randomized		44	Male	10-19 cig/day <sup>2</sup>	1019	01FEB2014 [10:15 AM]	mOC	105
USA	DAY	1105	Randomized		29	Male	10-19 cig/day	1038	20FEB2014 [3:41 PM]	SA	110
USA	DAY	1106	Randomized		26	Male	10-19 cig/day	1021	01FEB2014 [10:20 AM]	SA	106
USA	DAY	1107	Screen Failed		32	Female					
USA	DAY	1108 <sup>1</sup>	Screen Failed		41	Female					
USA	DAY	1109 <sup>1</sup>	Screen Failed		30	Male					
USA	DAY	1110	Randomized		54	Female	>19 cig/day	4006	13FEB2014 [1:13 PM]	THSm2.2	222



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1111 <sup>1</sup>	Screen Failed	--- X ---	48	Female					
USA	DAY	1112	Screen Failed		36	Male					
USA	DAY	1113	Screen Failed		46	Female					
USA	DAY	1114	Screen Failed		23	Male					
USA	DAY	1115	Screen Failed		29	Male					
USA	DAY	1117	Randomized		39	Male	>19 cig/day	2005	13FEB2014 [1:20 PM]	SA	142
USA	DAY	1118	Randomized		33	Female	10-19 cig/day	3010	01FEB2014 [10:18 AM]	SA	183
USA	DAY		Discontinued from Enrollment		36	Female					
USA	DAY	1120	Screen Failed		29	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1121	Screen Failed	--- X ---	43	Female					
USA	DAY	1122	Screen Failed		57	Female					
USA	DAY	1123	Screen Failed		61	Female					
USA	DAY	1124	Randomized		40	Male	10-19 cig/day	1037	20FEB2014 [3:26 PM]	mCC	110
USA	DAY	1125	Randomized		42	Female	10-19 cig/day	3017	20FEB2014 [3:31 PM]	THSm2.2	185
USA	DAY	1126	Screen Failed		55	Male					
USA	DAY	1127	Screen Failed		30	Male					
USA	DAY	1128	Screen Failed		50	Male					
USA	DAY	1129	Screen Failed		46	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1130	Screen Failed	--- X ---	35	Female					
USA	DAY	1131	Screen Failed		24	Male					
USA	DAY	1132 <sup>1</sup>	Screen Failed		23	Female					
USA	DAY	1133	Screen Failed		47	Male					
USA	DAY	1134	Screen Failed		50	Female					
USA	DAY	1135	Screen Failed		60	Male					
USA	DAY	1136	Screen Failed		32	Male					
USA	DAY	1137	Screen Failed		35	Male					
USA	DAY	1138	Screen Failed		24	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1139	Screen Failed	--- X ---	50	Male					
USA	DAY	1140	Screen Failed		53	Male					
USA	DAY	1141	Screen Failed		22	Male					
USA	DAY	1142	Screen Failed		33	Female					
USA	DAY	1143	Randomized		29	Female	10-19 cig/day	3014	13FEB2014 [1:22 PM]	SA	184
USA	DAY	1144	Randomized		26	Male	10-19 cig/day	1041	27FEB2014 [12:03 PM]	THSm2.2	111
USA	DAY	1145	Screen Failed		50	Female					
USA	DAY	1146	Screen Failed		63	Male					
USA	DAY	1147	Randomized		26	Male	10-19 cig/day	1042	27FEB2014 [12:04 PM]	mCC	111



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1148	Screen Failed	--- X ---	31	Female					
USA	DAY	1149	Screen Failed		29	Male					
USA	DAY	1150	Randomized		24	Male	10-19 cig/day <sup>2</sup>	1049	28FEB2014 [1:41 PM]	SA	113
USA	DAY	1151	Screen Failed		31	Male					
USA	DAY	1152	Screen Failed		63	Male					
USA	DAY	1153	Screen Failed		45	Male					
USA	DAY	1154	Screen Failed		40	Female					
USA	DAY	1155	Randomized		42	Female	>19 cig/day	4010	08MAR2014 [10:01 AM]	THSm2.2	223
USA	DAY	1156	Randomized		24	Female	10-19 cig/day	3018	27FEB2014 [12:08 PM]	THSm2.2	185



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1157	Screen Failed	---	34	Male					
USA	DAY	1158	Screen Failed	X	46	Female					
USA	DAY	1159	Randomized		42	Male	10-19 cig/day	1040	20FEB2014 [3:48 PM]	THSm2.2	110
USA	DAY	1160	Randomized		27	Male	10-19 cig/day	1039	20FEB2014 [3:45 PM]	THSm2.2	110
USA	DAY	1161	Screen Failed		53	Male					
USA	DAY	1162	Screen Failed		45	Female					
USA	DAY	1163	Screen Failed		39	Male					
USA	DAY	1164	Screen Failed		59	Male					
USA	DAY	1165	Randomized		35	Female	10-19 cig/day <sup>2</sup>	3019	27FEB2014 [12:09 PM]	SA	185



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1166	Screen Failed	--- X ---	24	Female					
USA	DAY	1167	Randomized		23	Female	10-19 cig/day <sup>2</sup>	3022	28FEB2014 [1:43 PM]	THSm2.2	186
USA	DAY	1168	Randomized		52	Male	10-19 cig/day <sup>2</sup>	1043	27FEB2014 [12:11 PM]	THSm2.2	111
USA	DAY	1169	Randomized		51	Male	10-19 cig/day	1044	27FEB2014 [12:12 PM]	SA	111
USA	DAY	1170	Randomized		50	Male	10-19 cig/day	1045	27FEB2014 [12:13 PM]	SA	112
USA	DAY	1171 <sup>1</sup>	Screen Failed		22	Female					
USA	DAY	1172	Screen Failed		31	Male					
USA	DAY	1173	Screen Failed		23	Female					
USA	DAY	1174	Screen Failed		47	Female					





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1175	Screen Failed	--- X ---	47	Female					
USA	DAY	1176	Screen Failed		33	Male					
USA	DAY	1177	Randomized		28	Male	10-19 cig/day	1050	28FEB2014 [1:52 PM]	THSm2.2	113
USA	DAY	1178	Screen Failed		30	Female					
USA	DAY	1179	Screen Failed		51	Female					
USA	DAY	1180	Screen Failed		46	Male					
USA	DAY	1181	Randomized		24	Male	10-19 cig/day	1051	28FEB2014 [1:56 PM]	mCC	113
USA	DAY	1182	Screen Failed		46	Female					
USA	DAY	1183	Screen Failed		52	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1184	Screen Failed	--- X ---	31	Male					
USA	DAY	1185	Screen Failed		30	Female					
USA	DAY	1186	Screen Failed		47	Male					
USA	DAY	1187	Screen Failed		42	Male					
USA	DAY	1188	Screen Failed		38	Female					
USA	DAY	1189	Screen Failed		49	Male					
USA	DAY	1190	Screen Failed		52	Female					
USA	DAY	1191	Screen Failed		32	Male					
USA	DAY	1192	Screen Failed		49	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1193	Screen Failed	--- X ---	61	Female					
USA	DAY	1194	Randomized		32	Male	10-19 cig/day	1054	08MAR2014 [10:06 AM]	THSm2.2	114
USA	DAY	1195	Randomized		56	Female	>19 cig/day	4011	08MAR2014 [10:04 AM]	THSm2.2	223
USA	DAY	1196	Screen Failed		32	Female					
USA	DAY	1197	Randomized		39	Male	10-19 cig/day	1055	08MAR2014 [10:14 AM]	THSm2.2	114
USA	DAY	1198	Randomized		58	Female	10-19 cig/day <sup>2</sup>	3024	08MAR2014 [10:11 AM]	SA	186
USA	DAY	1199	Screen Failed		40	Female					
USA	DAY	1200	Screen Failed		52	Female					
USA	DAY	1201	Screen Failed		25	Female					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1202	Randomized	--- X ---	35	Male	10-19 cig/day	1064	13MAR2014 [2:40 PM]	SA	116
USA	DAY	1203	Randomized		34	Female	10-19 cig/day	3026	13MAR2014 [2:42 PM]	THSm2.2	187
USA	DAY	1204	Screen Failed		39	Male					
USA	DAY	1205	Screen Failed		53	Female					
USA	DAY	1206	Screen Failed		30	Female					
USA	DAY	1207	Screen Failed		51	Female					
USA	DAY	1208	Screen Failed		34	Female					
USA	DAY	1209	Randomized		36	Male	>19 cig/day	2012	13MAR2014 [2:43 PM]	THSm2.2	143
USA	DAY	1210	Randomized		28	Female	10-19 cig/day	3025	13MAR2014 [2:37 PM]	mCC	187



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1211 <sup>1</sup>	Screen Failed	--- X ---	28	Female					
USA	DAY	1212	Randomized		35	Male	10-19 cig/day	1063	13MAR2014 [2:38 PM]	mCC	116
USA	DAY	1213	Screen Failed		50	Male					
USA	DAY	1214 <sup>1</sup>	Screen Failed		53	Male					
USA	DAY	1215	Screen Failed		57	Male					
USA	DAY	1216	Screen Failed		42	Male					
USA	DAY	1217	Screen Failed		46	Male					
USA	DAY	1218	Randomized		26	Male	>19 cig/day	2013	13MAR2014 [2:45 PM]	THSm2.2	144
USA	DAY	1219	Randomized		23	Male	>19 cig/day	2014	16MAR2014 [8:42 AM]	SA	144



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1220	Screen Failed	--- X ---	47	Male	10-19 cig/day	1065	13MAR2014 [2:47 PM]	THSm2.2	117
USA	DAY	1221	Randomized		51	Male					
USA	DAY	1222	Screen Failed		57	Male					
USA	DAY	1223	Screen Failed		45	Female					
USA	DAY	1224	Screen Failed		22	Female					
USA	DAY	1225	Screen Failed		29	Male					
USA	DAY	1226	Screen Failed		23	Male					
USA	DAY	1227	Screen Failed		29	Male					
USA	DAY	1228	Screen Failed		58	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1229	Screen Failed	--- X ---	22	Female					
USA	DAY	1230	Randomized		31	Female	>19 cig/day	4012	16MAR2014 [8:41 AM]	SA	223
USA	DAY	1231	Screen Failed		49	Female					
USA	DAY	1232	Screen Failed		43	Male					
USA	DAY		Discontinued from Enrollment		33	Male					
USA	DAY	1234	Randomized		27	Female	>19 cig/day	4015	04APR2014 [12:15 PM]	THSm2.2	224
USA	DAY	1235	Randomized		24	Male	>19 cig/day	2018	28MAR2014 [1:04 PM]	mCC	145
USA	DAY	1236	Screen Failed		58	Female					
USA	DAY	1237	Screen Failed		55	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization #	Date and Time	Product Arm	Block #
USA	DAY	1238	Randomized	--- X ---	25	Female	>19 cig/day	4014	28MAR2014 [1:42 PM]	SA	224
USA	DAY	1239	Screen Failed		25	Female					
USA	DAY	1240	Screen Failed		33	Female					
USA	DAY	1241	Screen Failed		46	Female					
USA	DAY	1242	Screen Failed		50	Male					
USA	DAY	1243	Screen Failed		57	Male					
USA	DAY	1244	Screen Failed		40	Female					
USA	DAY	1245	Screen Failed		61	Male					
USA	DAY	1246	Randomized		26	Male	>19 cig/day	2020	04APR2014 [12:13 PM]	SA	145





Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1247	Randomized	--- X ---	35	Female	>19 cig/day	4016	04APR2014 [12:16 PM]	THSm2.2	224
USA	DAY	1248	Screen Failed		34	Male					
USA	DAY	1249	Screen Failed		62	Female					
USA	DAY	1250	Screen Failed		38	Male					
USA	DAY	1251	Randomized		31	Male	>19 cig/day	2019	04APR2014 [12:11 PM]	THSm2.2	145
USA	DAY	1252	Randomized		48	Male	>19 cig/day	2021	04APR2014 [12:18 PM]	THSm2.2	146
USA	DAY	1253	Randomized		26	Male	>19 cig/day	2022	04APR2014 [12:19 PM]	mCC	146
USA	DAY	1254	Screen Failed		61	Female					
USA	DAY	1255	Screen Failed		51	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1256	Screen Failed	--- X ---	57	Male					
USA	DAY	1257	Screen Failed		50	Female					
USA	DAY	1258	Screen Failed		25	Female					
USA	DAY	1259 <sup>1</sup>	Screen Failed		31	Male					
USA	DAY	1260	Screen Failed		24	Male					
USA	DAY	1261	Randomized		32	Female	>19 cig/day	4019	13APR2014 [10:09 AM]	mCC	225
USA	DAY	1262	Screen Failed		35	Male					
USA	DAY	1263	Screen Failed		26	Male					
USA	DAY	1264	Screen Failed		43	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1265	Randomized	--- X ---	66	Male	>19 cig/day	2023	13APR2014 [10:11 AM]	THSm2.2	146
USA	DAY	1266	Screen Failed		53	Female					
USA	DAY	1267	Randomized		64	Female	>19 cig/day	4018	13APR2014 [10:05 AM]	THSm2.2	225
USA	DAY	1268	Screen Failed		64	Male					
USA	DAY	1269	Screen Failed		32	Female					
USA	DAY	1270	Screen Failed		34	Male					
USA	DAY	1271	Screen Failed		33	Male					
USA	DAY	1272	Screen Failed		24	Male					
USA	DAY	1273	Screen Failed		45	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1274	Screen Failed	--- X ---	56	Male					
USA	DAY	1275	Screen Failed		44	Female					
USA	DAY	1276	Screen Failed		46	Female					
USA	DAY	1277	Screen Failed		28	Male					
USA	DAY	1278	Screen Failed		40	Male					
USA	DAY	1279	Screen Failed		27	Male					
USA	DAY	1280	Randomized		54	Female	>19 cig/day	4022	26APR2014 [7:11 AM]	SA	226
USA	DAY	1281	Randomized		25	Male	>19 cig/day	2025	26APR2014 [7:12 AM]	THSm2.2	147
USA	DAY	1282	Screen Failed		29	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1283	Randomized	--- X ---	28	Female	>19 cig/day	4023	26APR2014 [7:14 AM]	THSm2.2	226
USA	DAY	1284	Screen Failed		70	Male					
USA	DAY	1285	Screen Failed		42	Male					
USA	DAY	1286	Randomized		31	Female	>19 cig/day	4024	26APR2014 [7:15 AM]	THSm2.2	226
USA	DAY	1287	Screen Failed		24	Female					
USA	DAY	1288	Screen Failed		45	Male					
USA	DAY	1289	Screen Failed		67	Male					
USA	DAY	1290	Screen Failed		39	Female					
USA	DAY	1291	Screen Failed		53	Male					



Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1292 <sup>1</sup>	Screen Failed	--- X ---	27	Female					
USA	DAY	1293	Screen Failed		30	Male					
USA	DAY	1294	Screen Failed		39	Female					
USA	DAY	1295	Screen Failed		37	Female					
USA	DAY	1296	Screen Failed		42	Male					
USA	DAY	1297	Randomized		33	Male	>19 cig/day	2029	07MAY2014 [12:49 PM]	THSm2.2	148
USA	DAY	1298	Screen Failed		55	Female					
USA	DAY	1299	Screen Failed		52	Female					
USA	DAY	1300	Screen Failed		48	Male					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1301	Screen Failed	--- X ---	49	Male					
USA	DAY	1302	Randomized		31	Male	>19 cig/day	2030	07MAY2014 [12:50 PM]	SA	148
USA	DAY	1303	Screen Failed		37	Female					
USA	DAY	1304	Randomized		52	Female	>19 cig/day	4026	07MAY2014 [12:47 PM]	THSm2.2	227
USA	DAY	1305	Screen Failed		30	Female					
USA	DAY	1306	Screen Failed		31	Female					
USA	DAY	1307	Screen Failed		45	Female					
USA	DAY	1308	Screen Failed		54	Female					
USA	DAY	1309	Screen Failed		29	Female					



## Listing 16.1.7 Listing of Randomization Schemes and Codes

Country	Site	Screening #	Current Subject Status	Date of Birth	Entry Age (Years)	Gender	Avg Cigarette Consumption	Randomization		Product Arm	Block #
								#	Date and Time		
USA	DAY	1310	Screen Failed	---	X	---	27				
USA	DAY	1311	Screen Failed		29	Female					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Cigarette consumption was not collected for screening failures.

Note 1: Subject discontinued, refer to listing 15.3.1.8.

Note 2: Subject was randomized using average cigarette consumption collected at Day -2 rather than Screening. For these subjects, the Screening average cigarette consumption was >19 cig/day.

Source: RAND.IWRS RAND.IVRBLKNO SDTM.DM SDTM.SUPPDM ADAM.ADDS ADAM.ADSL

Study ID: ZRHM-REXA-08-US Program: L\_rand.sas Status: Final 21SEP15

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## 16.1.6.2 BIostatistical Addendum to (b) (4)



	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) (4) Project Code: COVNCREXA0801		Version: 2.0

(b) (4)	<b>PMI</b> <b><u>Protocol: ZRHM-REXA-08-US</u></b> <b><u>(Covance)</u></b>  <b>Biostatistical Addendum</b> <b>Subject Randomization List (BA-S)</b>
	Web: (b) (4) E-mail: (b) (4)  Phone: (b) (4) Facsimile: (b) (4)  Mail: (b) (4)

### Confidentiality Statement

This document contains information that is confidential and proprietary, and is not for distribution beyond the (b) (4) (b) (4) and/or the Client organization designated on title page.



(b) (4)

Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 - SOP 30.7-8 Form 3b
Name of Client: PMI / Covance	Protocol Number: ZRHM-REXA-08-US
Project Code: COVNCREXA0801	Version: 2.0

(b) (4)

## Change History

Document	Version	Author	Date	Description
Initial	1.0	M. Baldwin	06-Mar-2013	This document captures the requirements for creation of the Subject Randomization List for Protocol ZRHM-REXA-08-US (Covance) (COVNCREXA0801). Creation of this document began on 21-Feb-2013.
Revision	2.0	K. Vonnor	04-Feb-2015	Revised to include additional recipient of LIVE Subject Randomization List. Updates to this document include: <ul style="list-style-type: none"><li>• Approvals updated in BA-S Approval Signatures section</li><li>• Section 1.2 added to include BA-S v2.0 timelines</li><li>• Note added in Section 6 to indicate Sections 6.1-6.3 refer to BA-S v1.0 only and are not to be resent as part of BA-S v2.0</li><li>• Section 6.4 added to include approval requirements for BA-S v2.0</li></ul> Note: the Subject Randomization List will not be re-generated as a result of this revision.

Any changes, after approval, either requested by the Client or (b) (4) will be captured in an amendment to this document. Each amendment requires approval signatures by both the Client and (b) (4) before any changes are implemented. Approved changes may require renegotiation and reassessment of the cost, resource, and schedule commitments for this project. Versions will increment by 1 (i.e. Version 1.0 to 2.0 to 3.0, etc.).

## BA-S Approval Signatures

(b) (4)

(b) (4) utilizes a document management system to record the approval of the internal design team. The (b) (4) signatures below represent the collective team approval.

By signing below, I agree that this document represents my best understanding of the requirements and an accurate interpretation of the Protocol for the project described within and is in line with my expectations.

(b) (4)

Guillaume de La Bourdonnaye

PRINT NAME

PMI Staff Scientist - Expert Statistician

TITLE

SIGNATURE

DATE

04 FEB 2015

Andrew Hedge

PRINT NAME

Covance Principal Statistician

TITLE

SIGNATURE

DATE

04 FEB 2015

(b) (4)

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(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) (4)	Project Code: COVNCREXA0801	Version: 2.0

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(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) (4)	Project Code: COVNCREXA0801	Version: 2.0

## 1. Timelines

1.1	Version 1.0 Milestone Dates / Timelines	
1	BA-S Approval Date:	06-Mar-2013
2	Pre-load DUMMY List Provided to Client / Designee:	25-Mar-2013
3	Pre-load DUMMY List Provided to Additional Client / Designee:	25-Mar-2013
4	Client / Designee Approval of Pre-load DUMMY List:	28-Mar-2013
5	Additional Client / Designee Approval of Pre-load DUMMY List:	28-Mar-2013
1.2	Version 2.0 Milestone Dates / Timelines	
1	BA-S Approval Date:	04-Feb-2015
2	Pre-load LIVE List Provided to Client / Designee:	06-Feb-2015
3	Client / Designee Approval of LIVE list:	Not Applicable

## 2. Purpose

The Biostatistical Addendum – Subject Randomization List (BA-S) document captures the requirements related to the generation of a subject randomization schedule to be utilized for the randomization of subjects in (b) (4) IXR system for a given study.

## 3. General Requirements

3.1	General Requirements	
1	Version of the List(s):	Initial
2	Number of Randomization Lists Generated / Provided:	1
	Note: This number refers to the number of files to be produced for loading into the (b) (4). If the overall file (list) includes sub-lists (e.g. for individual strata, cohorts, subject replacements), then the overall number of randomization lists to be loaded into the (b) (4) is 1 (one) list (this number does not refer to sub-lists which will be concatenated into a single overall list).	
3	Purpose Statement:	To generate subject randomization list(s).
4	Forced Randomization:	Not Allowed



(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) Project Code: COVNCREXA0801		Version: 2.0

#### 4. Subject Randomization List Details

<b>4.1 File Configuration</b>																																				
1	File Format:	ASCII comma delimited (.txt)																																		
	Note: This file format refers to list(s) that are to be generated for loading into the (b) (4) and provided for approval (see Section 5); this does <u>not</u> refer to file formats relating to Live data transfers (mid / end of study) that will be described / captured in a separate Data Transfer specification document (with other file formats available).																																			
2	Sorting:	Sorted ascending by Randomization Number																																		
3	Subject Randomization List File Names*:	DUMMY Subject Randomization List: - PMI_Covance_ZRHM-REXA-08-US_DUMMY_9.XX.YYY_SRL.txt LIVE Subject Randomization List: - PMI_Covance_ZRHM-REXA-08-US_LIVE_9.XX.YYY_SRL.txt																																		
*Filename versioning 9.XX.YYY: - 9 (b) (4) internal reference code for Subject Randomization List - XX = 00, 01, 02, etc. refers to Client versions of Subject Randomization Lists generated / sent for approval and version of BA-S - YYY = 000, 001, 002, etc. refers to (b) (4) versions generated to provide a Subject Randomization List that has passed internal testing and ready for Client approval																																				
<b>4.2 Treatment Group Definitions</b>																																				
	<table border="1"> <thead> <tr> <th>Treatment (Product) Group (Treatment)</th> <th>Treatment (Product) Group Description (TrtDC)</th> <th>Treatment Group Allocation Ratio</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>THS 2.2 Menthol</td> <td>2</td> </tr> <tr> <td>2</td> <td>mCC</td> <td>1</td> </tr> <tr> <td>3</td> <td>SA</td> <td>1</td> </tr> </tbody> </table>	Treatment (Product) Group (Treatment)	Treatment (Product) Group Description (TrtDC)	Treatment Group Allocation Ratio	1	THS 2.2 Menthol	2	2	mCC	1	3	SA	1																							
Treatment (Product) Group (Treatment)	Treatment (Product) Group Description (TrtDC)	Treatment Group Allocation Ratio																																		
1	THS 2.2 Menthol	2																																		
2	mCC	1																																		
3	SA	1																																		
<b>4.3 List Structure / Content</b>																																				
1	Maximum Number of Subjects to be Randomized:	160																																		
2	Block Size:	4																																		
3	Overall Number of Randomization Numbers:	640																																		
4	Overall Number of Blocks:	160																																		
5	Overall Number of Randomization Numbers per Treatment Group:	1=320, 2=160, 3=160																																		
6	Number of Strata (with randomization blocks pre-assigned):	4 (see Section 4.4)																																		
7	Number of Randomization Numbers per Stratum:	160																																		
8	Number of Blocks per Stratum:	40																																		
9	Number of Randomization Numbers per Stratum per Treatment Group:	1=80; 2=40; 3=40																																		
<b>4.4 Stratum Definitions</b>																																				
	<table border="1"> <thead> <tr> <th rowspan="2">Stratum</th> <th rowspan="2">Stratum Description (StratDC)</th> <th colspan="2">Randomization Number (RandNo)</th> <th colspan="2">Block Number (BlockNo)</th> </tr> <tr> <th>Start</th> <th>End</th> <th>Start</th> <th>End</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Gender=Males; Smoking=10-19 mCC per day</td> <td>1001</td> <td>1160</td> <td>101</td> <td>140</td> </tr> <tr> <td>2</td> <td>Gender=Males; Smoking=&gt;19 mCC per day</td> <td>2001</td> <td>2160</td> <td>141</td> <td>180</td> </tr> <tr> <td>3</td> <td>Gender=Females; Smoking=10-19 mCC per day</td> <td>3001</td> <td>3160</td> <td>181</td> <td>220</td> </tr> <tr> <td>4</td> <td>Gender=Females; Smoking=&gt;19 mCC per day</td> <td>4001</td> <td>4160</td> <td>221</td> <td>260</td> </tr> </tbody> </table>	Stratum	Stratum Description (StratDC)	Randomization Number (RandNo)		Block Number (BlockNo)		Start	End	Start	End	1	Gender=Males; Smoking=10-19 mCC per day	1001	1160	101	140	2	Gender=Males; Smoking=>19 mCC per day	2001	2160	141	180	3	Gender=Females; Smoking=10-19 mCC per day	3001	3160	181	220	4	Gender=Females; Smoking=>19 mCC per day	4001	4160	221	260	
Stratum	Stratum Description (StratDC)			Randomization Number (RandNo)		Block Number (BlockNo)																														
		Start	End	Start	End																															
1	Gender=Males; Smoking=10-19 mCC per day	1001	1160	101	140																															
2	Gender=Males; Smoking=>19 mCC per day	2001	2160	141	180																															
3	Gender=Females; Smoking=10-19 mCC per day	3001	3160	181	220																															
4	Gender=Females; Smoking=>19 mCC per day	4001	4160	221	260																															





(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) (4) Project Code: COVNCREXA0801		Version: 2.0

4.5	<b>Randomization List Format</b> * Note (Loaded in (b) (4)) <ul style="list-style-type: none"><li>• Per (b) (4) CT standards, only certain variables are required to be loaded into the (b) (4)</li><li>• Non-loaded variables (such as TrialID, StratDC, TrtDC, etc.) are already contained within the (b) (4) and hence can still be included in Live data transfers as required.</li><li>• Also note that BlockNo will only be loaded if required by the (b) (4) for dynamic allocation of blocks.</li></ul>			
Column No.	Column Header	Format	Description	* Loaded in (b) (4)
1	TrialID	Text	ZRHM-REXA-08-US	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2	RandNo	4 digits (numeric)	Randomization Number (unique) Randomization Numbers pre-allocated to Strata as displayed in Section 4.4	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3	Stratum	1 digit(s) (numeric)	Stratum Identifier; based on Stratum Definitions in Section 4.4	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4	StratDC	Text	Stratum Description; based on Stratum Definitions in Section 4.4	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
5	Treatment	1 digit(s) (numeric)	Treatment Identifier; based on Treatment Group Definitions in Section 4.2	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
6	TrtDC	Text	Treatment Description; based on Treatment Group Definitions in Section 4.2	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
7	BlockNo	3 digits (numeric)	Block Number Block Numbers pre-allocated to Strata as displayed in Section 4.4	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
File Example: To note, the sample below is for illustrative purposes and was not taken from the LIVE list.				
TrialID,RandNo,Stratum,StratDC,Treatment,TrtDC,BlockNo ZRHM-REXA-08-US,1001,1,Gender=Males; Smoking=10-19 mCC per day,3,SA,101 ZRHM-REXA-08-US,1002,1,Gender=Males; Smoking=10-19 mCC per day,1,THS 2.2 Menthol,101 ZRHM-REXA-08-US,1003,1,Gender=Males; Smoking=10-19 mCC per day,2,mCC,101 ZRHM-REXA-08-US,1004,1,Gender=Males; Smoking=10-19 mCC per day,1,THS 2.2 Menthol,101  ZRHM-REXA-08-US,1157,1,Gender=Males; Smoking=10-19 mCC per day,2,mCC,140 ZRHM-REXA-08-US,1158,1,Gender=Males; Smoking=10-19 mCC per day,1,THS 2.2 Menthol,140 ZRHM-REXA-08-US,1159,1,Gender=Males; Smoking=10-19 mCC per day,3,SA,140 ZRHM-REXA-08-US,1160,1,Gender=Males; Smoking=10-19 mCC per day,1,THS 2.2 Menthol,140  ZRHM-REXA-08-US,4001,4,Gender=Females; Smoking=> 19 mCC per day,1,THS 2.2 Menthol,221 ZRHM-REXA-08-US,4002,4,Gender=Females; Smoking=> 19 mCC per day,1,THS 2.2 Menthol,221 ZRHM-REXA-08-US,4003,4,Gender=Females; Smoking=> 19 mCC per day,2,mCC,221 ZRHM-REXA-08-US,4004,4,Gender=Females; Smoking=> 19 mCC per day,3,SA,221  ZRHM-REXA-08-US,4157,4,Gender=Females; Smoking=> 19 mCC per day,2,mCC,260 ZRHM-REXA-08-US,4158,4,Gender=Females; Smoking=> 19 mCC per day,3,SA,260 ZRHM-REXA-08-US,4159,4,Gender=Females; Smoking=> 19 mCC per day,1,THS 2.2 Menthol,260 ZRHM-REXA-08-US,4160,4,Gender=Females; Smoking=> 19 mCC per day,1,THS 2.2 Menthol,260				



(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client: PMI / Covance		Protocol Number: ZRHM-REXA-08-US
(b) : Project Code: COVNCREXA0801		Version: 2.0

## 5. Approval Requirements

List Delivery and Approval Information:	
(b) (4)	I generate (in parallel) both a LIVE and a DUMMY Subject Randomization List with each utilizing a different starting seed to ensure that the lists are identical in structure but non-identical with respect to Treatment Group ordering.
	<ul style="list-style-type: none"> <li><b>LIVE Subject Randomization List:</b> list to be loaded into the Live (b) (4); note this list can only be approved by an Unblinded Recipient (who is also privy to the file structure (e.g. treatment identifiers / block size)).</li> <li><b>DUMMY Subject Randomization List:</b> list used for (b) (4) development and for (b) (4) / Client User Acceptance Testing; note this list can be approved by any Blinded or Unblinded Recipient who is privy to the file structure (e.g. treatment identifiers / block size).</li> </ul>
Note:	
	<ul style="list-style-type: none"> <li>(b) (4) policy does not allow the sending of LIVE lists via Email.</li> <li>(b) (4) list generation standard fee covers 1xPre-Load Approval (Required) plus 1xPost-Load Approval (Optional). A cost of \$500 will be incurred for each additional Pre- or Post-Load Approval / Recipient.</li> </ul>
Approval Requirements – BA-S v1.0	
<b>Internal Note: Items in sections 5.1-5.3 are not to be resent; see below starting with Section 5.4 for Additional Recipient for BA-S v2.0</b>	
5.1	Pre-Load Approval of DUMMY and/or LIVE list (Required): Prior to the LIVE list(s) being loaded into (b) (4) (b) (4) policy requires a Client (or designee) to provide a Pre-Load Approval of the generated DUMMY or LIVE list.
1	A copy of the <u>pre-load</u> file(s) will be sent to the Client (or designee) for verification / approval: <input checked="" type="checkbox"/> Approval required
2	Version of the <u>pre-load</u> file(s) to be approved: DUMMY list(s) PMI_Covance_ZRHM-REXA-08-US_DUMMY_9XX.YYY_SRL.txt
3	Security Assessment: Password Protected .zip file: PMI_Covance_ZRHM-REXA-08-US_PreLoad_DUMMY_SRL_<YYYYMMDD>.zip
4	Route of Delivery: Email
5	Recipient Details: Name: Andrew Hedge Title: Principal Statistician Company: Covance Clinical Research Unit Address: Springfield House Hyde Street Leeds LS2 9LH Phone: 44 (0)113 237 3500 DDI: 44 (0)113 241 6716 Email: <a href="mailto:andrew.hedge@covance.com">andrew.hedge@covance.com</a>
6	The pre-load file must be approved in writing prior to the data being loaded into the (b) (4). Failure to do so can adversely affect the go-live date of the (b) (4).





(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
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(b) : Project Code: COVNCREXA0801		Version: 2.0

5.2	Additional Pre-Load Approval / Recipient of DUMMY and/or LIVE list(s) (Optional): each additional Pre-Load Approval / Recipient to Section 5.1 will incur a cost of \$500 per Recipient.	
1	A copy of the <u>pre-load</u> file(s) will also be sent to the Client (or designee):	<input type="checkbox"/> Not required <input checked="" type="checkbox"/> For Approval (additional to Section 5.1 above) <input type="checkbox"/> Recipient only (without approval)
2	Timing:	In parallel to Pre-Load Approval in Section 5.1
3	Version of the <u>pre-load</u> file(s) to be approved:	DUMMY list(s) PMI_Covance_ZRHM-REXA-08-US_DUMMY_9XX.YYY_SRL.txt
4	Security Assessment:	Password Protected .zip file: PMI_Covance_ZRHM-REXA-08-US_PreLoad_DUMMY_SRL <YYYYMMDD>.zip
5	Route of Delivery:	Email
6	Recipient Details:	Name: Guillaume de La Bourdonnaye Title: Staff Scientist – Expert Statistician Company: Philip Morris Products S.A. Address: Quai Jeanrenaud 3 2000 Neuchâtel, Switzerland Phone: +41 58 242 21 03 Mobile: +41 79 484 81 64 Email: <a href="mailto:Guillaume.deLaBourdonnaye@pmi.com">Guillaume.deLaBourdonnaye@pmi.com</a>
7	In the case of additional approval(s) being required, the pre-load file must be approved in writing (by each additional approver) prior to the data being loaded into (b) . Failure to do so can adversely affect the go-live date of (b) .	
5.3	<b>Post-Load Approval of LIVE list (Optional):</b> Following the required pre-load approval, the LIVE list(s) will be imported into the Live (b) : production environment and verified for accuracy; once complete, a Post-Load Approval may be required to verify the accuracy of the LIVE list loaded into the (b) . Note that: <ul style="list-style-type: none"> <li>- The LIVE Subject Randomization List is extracted directly from the (b) (post-load) and will only contain those variables that were required to be loaded into the (b) .</li> <li>- The file will be provided as ASCII text file only, using (b) (4) : filename convention.</li> <li>- (b) : policy does not allow the sending of LIVE lists via Email; Unblinded Recipient only.</li> </ul>	
1	A copy of the <u>post-load</u> file will be sent to the Client (or designee) for verification / approval:	<input checked="" type="checkbox"/> Client waives review (not required) <input type="checkbox"/> Approval required <input type="checkbox"/> Recipient only (without approval)



(b) (4)	Biostatistical Addendum-Subject Randomization List(BA-S)	Template v2.0 – SOP 30.7-8 Form 3b
Name of Client:	PMI / Covance	Protocol Number: ZRHM-REXA-08-US
(b) (4)	Code: COVNCREXA0801	Version: 2.0

Approval Requirements – BA-S v2.0		
5.4	Additional Approval / Recipient of DUMMY and/or LIVE list(s) (Optional): each additional Approval / Recipient to Section 5.1 will incur a cost of \$500 per Recipient.	
1	A copy of the <u>pre-load</u> file(s) will also be sent to the Client (or designee):	<input type="checkbox"/> Not required <input type="checkbox"/> For Approval (additional to Section 5.1 above) <input checked="" type="checkbox"/> Recipient only (without approval)
2	Version of the <u>pre-load</u> file(s) to be received:	LIVE list(s) PMI_Covance_ZRHM-REXA-08-US_LIVE_9.XX.YYY_SRL.txt
3	Security Assessment:	Password Protected .zip file: PMI_Covance_ZRHR_ZRHM_Studies_PreLoad_LIVE_SRL_<YYYYMMDD>.zip Note: zip file to contain all x8 LIVE lists relating to the below protocols: - ZRHR-PK-01-EU - ZRHR-PK-02-JP - ZRHR-REXC-03-EU - ZRHR-REXC-04-JP - ZRHM-PK-05-JP - ZRHM-PK-06-US - ZRHM-REXA-07-JP - ZRHM-REXA-08-US
4	Route of Delivery:	Covance sFTP / FTP (b) (4)
5	LIVE List Recipient Details:	Name: Andrew Hedge Title: Principal Statistician Company: Covance Clinical Research Unit Address: Springfield House Hyde Street Leeds LS2 9LH Phone: 44 (0)113 237 3500 DDI: 44 (0)113 301 3759 Email: <a href="mailto:andrew.hedge@covance.com">andrew.hedge@covance.com</a>