



PMI RESEARCH & DEVELOPMENT

Study ZRHR-REXC-03-EU Clinical Study Report Appendix 15.1 Figures

Study Title:	A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement
Study Number:	ZRHR-REXC-03-EU
Product Name:	Tobacco Heating System 2.2 (THS 2.2)
Study Initiated (first subject screened):	29 June 2013
Study Completed (last subject last visit):	26 September 2013
Principal Investigator and Affiliation:	Katarzyna Jarus-Dziedzic, MD, PhD BioVirtus Research Site Sp. z o.o., Mokra 7 05-830 Kajetany, Poland
Sponsor:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Sponsor Signatories:	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Andrea Donelli, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Kausar Aamir, MD, PhD, Medical Safety Officer
Version:	4.0
Date:	08 March 2016

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

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.



TABLE OF CONTENTS

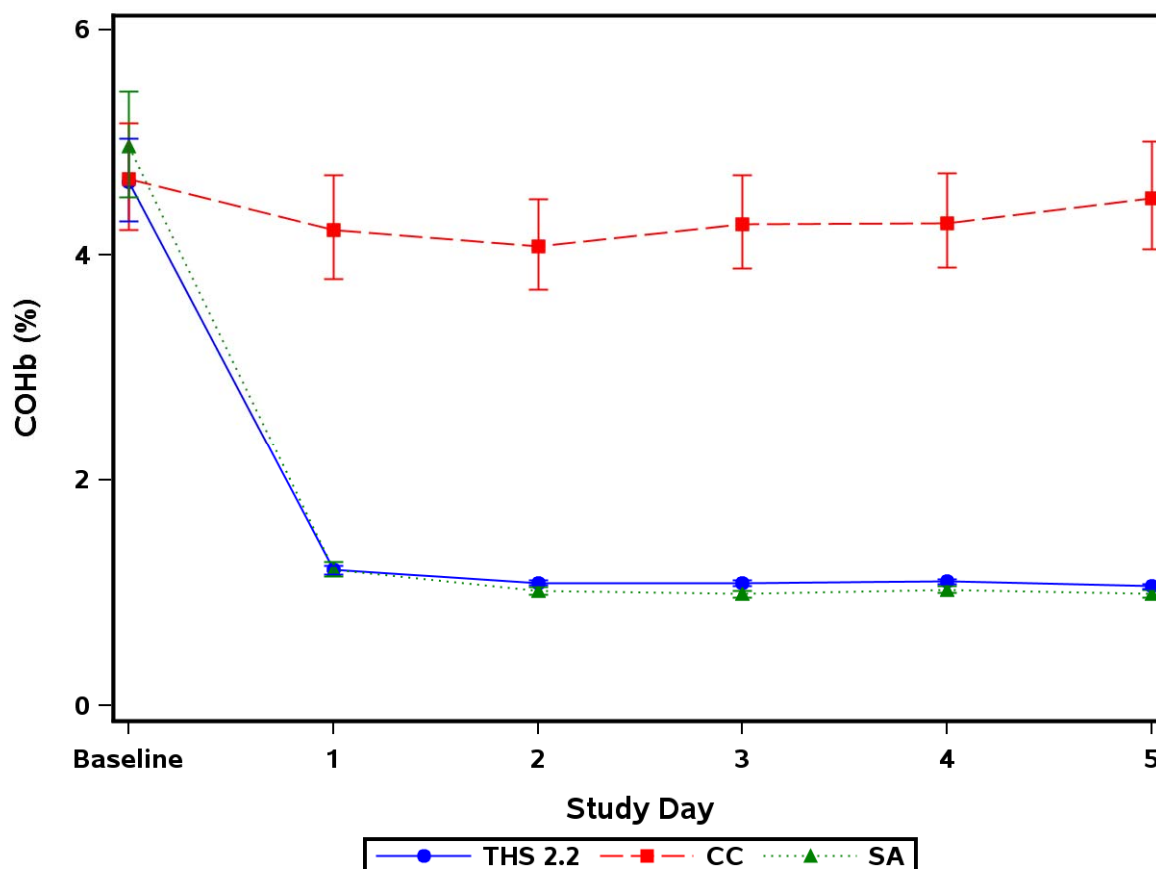
TABLE OF CONTENTS.....	2
15.1 FIGURES.....	3
15.1.1 PRIMARY ENDPOINTS	4
15.1.2 SECONDARY ENDPOINTS	13
15.1.3 OTHER ASSESSMENTS	99



15.1 FIGURES



15.1.1 Primary Endpoints

**Figure 15.1.1.1 Evening COHb (%) Geometric Mean and 95% CI - FAS**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.6

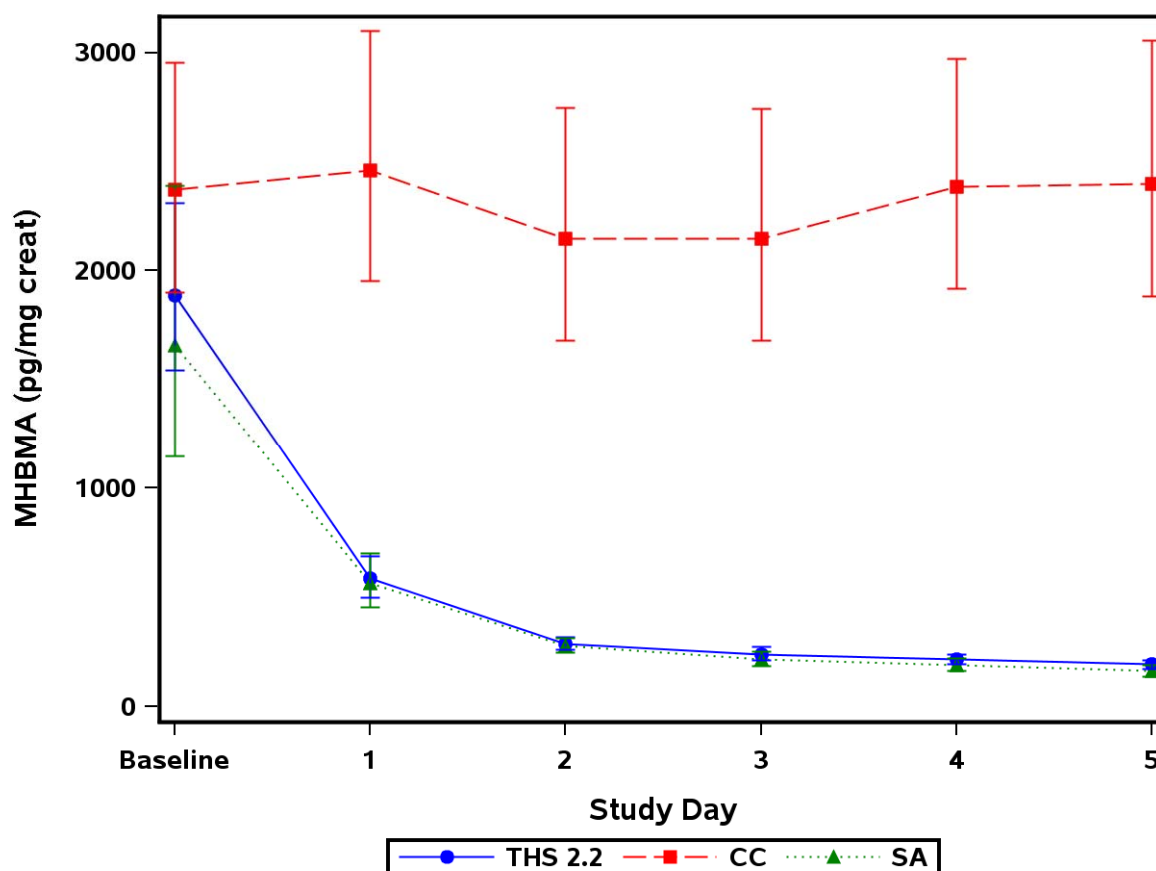
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(Page 1 of 1)

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Figure 15.1.1.2 MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.7

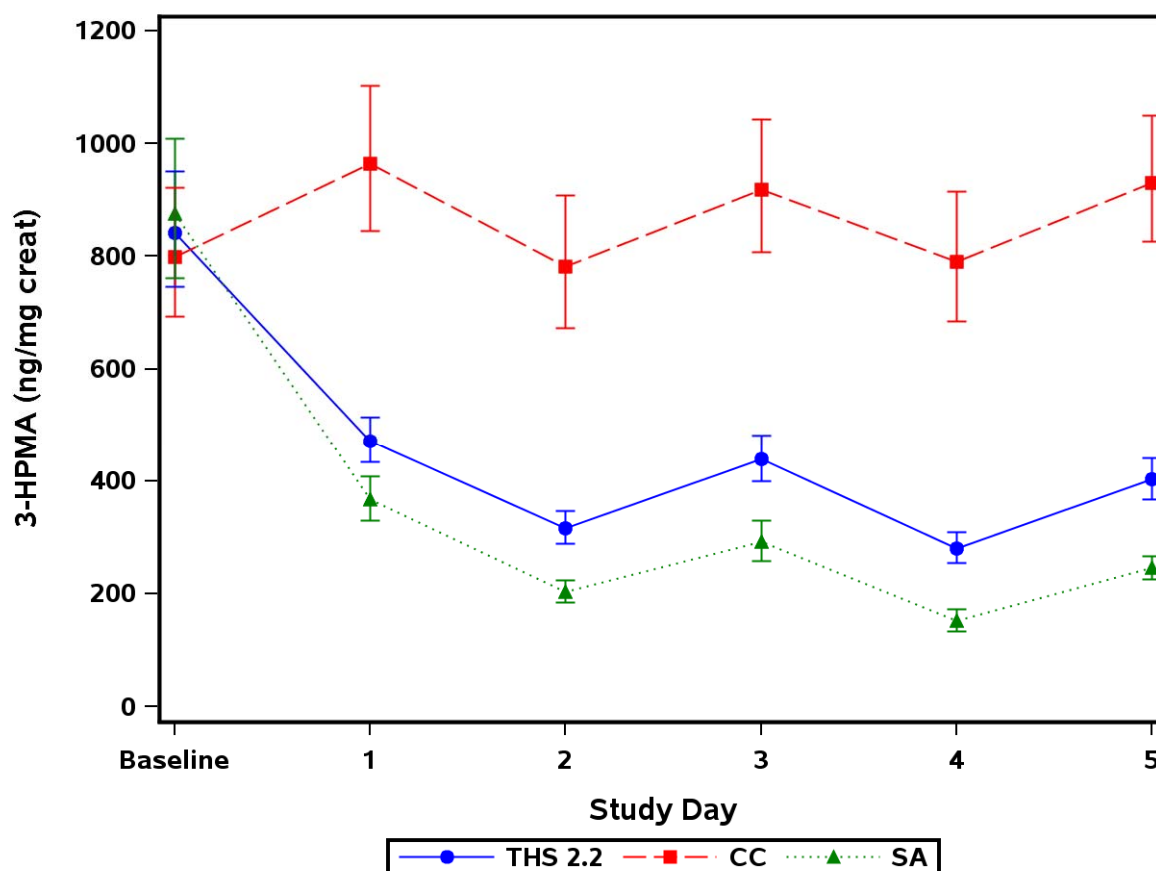
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(Page 1 of 1)

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Figure 15.1.1.3 3-HPMA Urinary Concentration Adjusted for Creatinine (ng/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.8

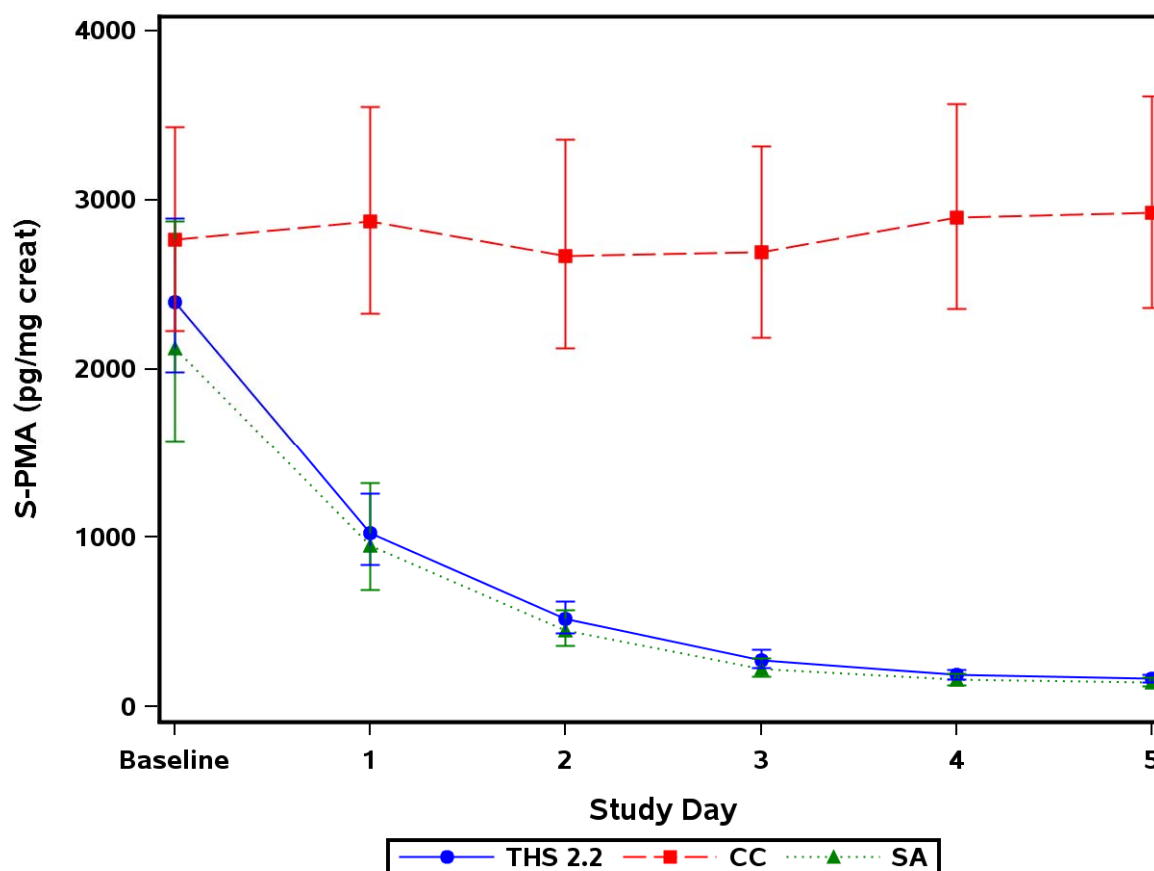
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(Page 1 of 1)

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Figure 15.1.1.4 S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

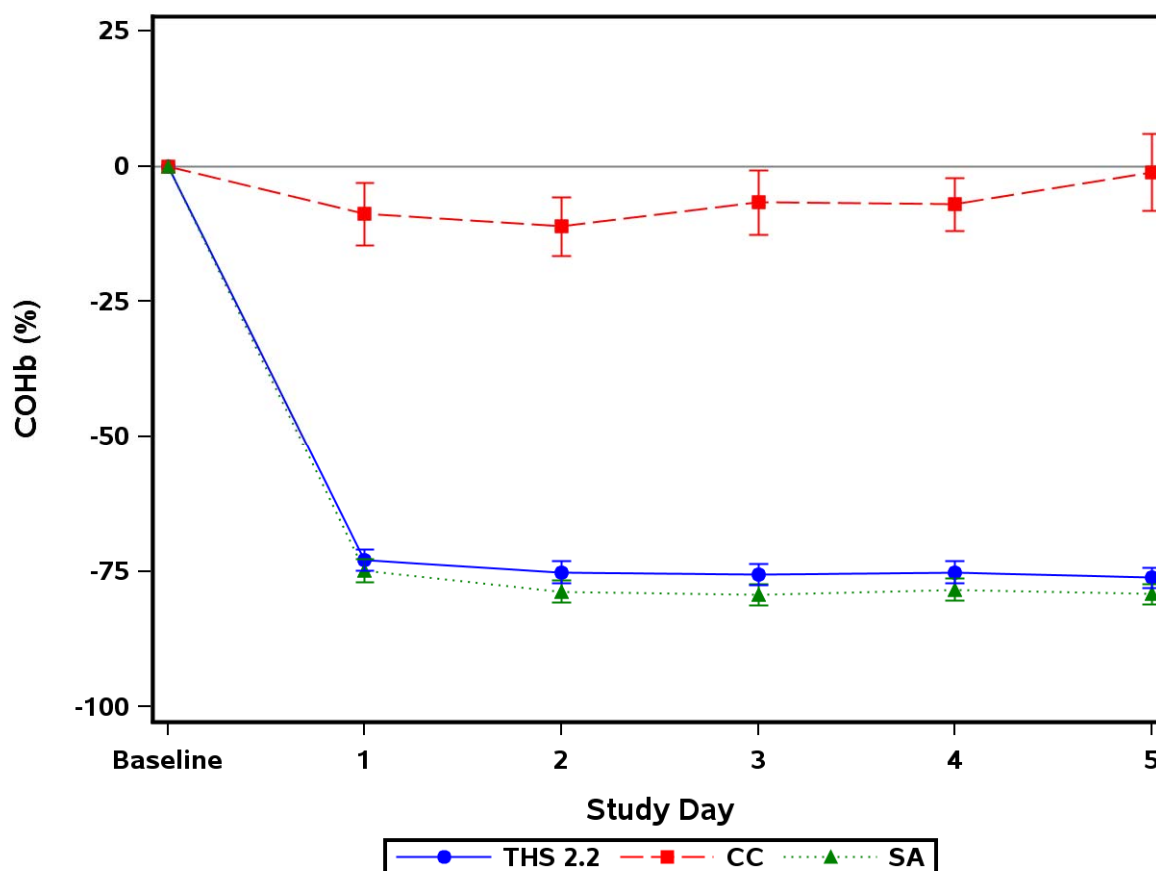
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.9

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_spma.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.1.5 Evening COHb % Change from Baseline Mean and 95% CI - FAS**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: % change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.6

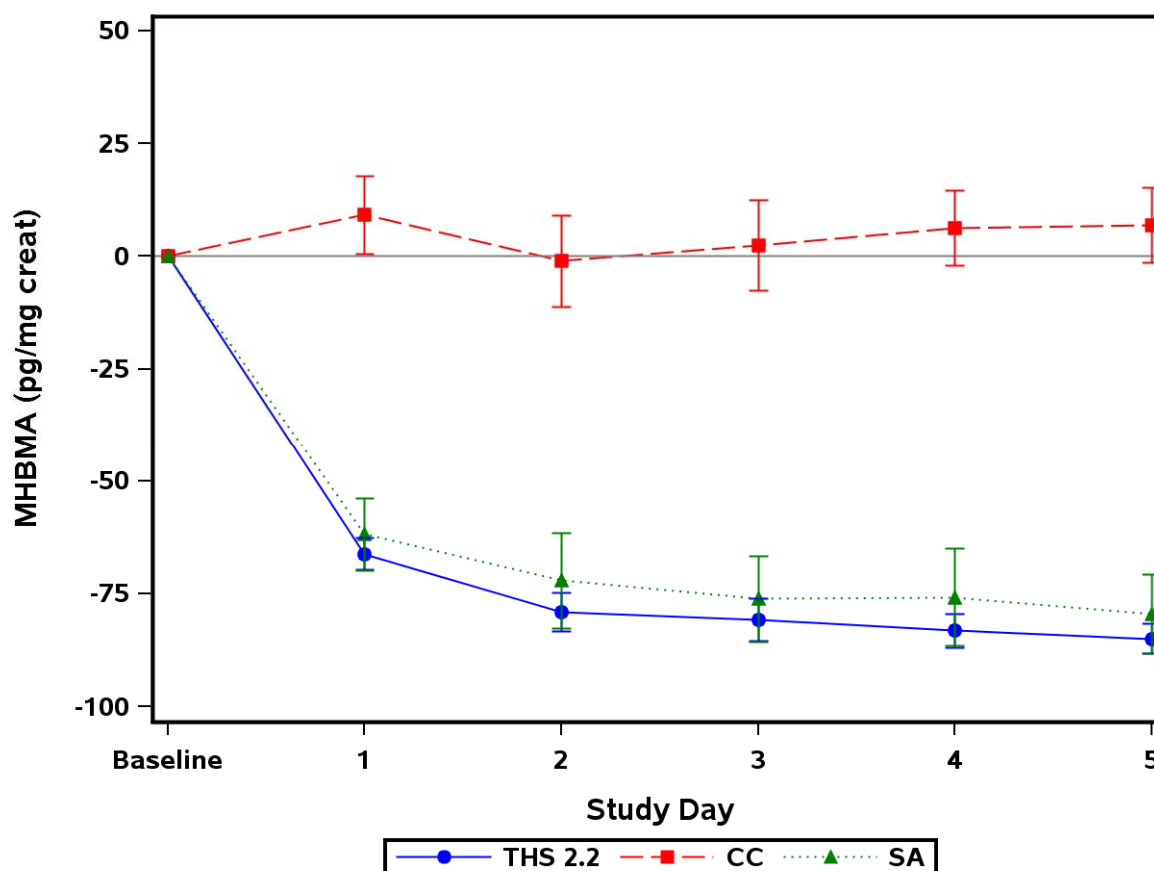
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Figure 15.1.1.6 MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) % Change from Baseline Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: % change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.7

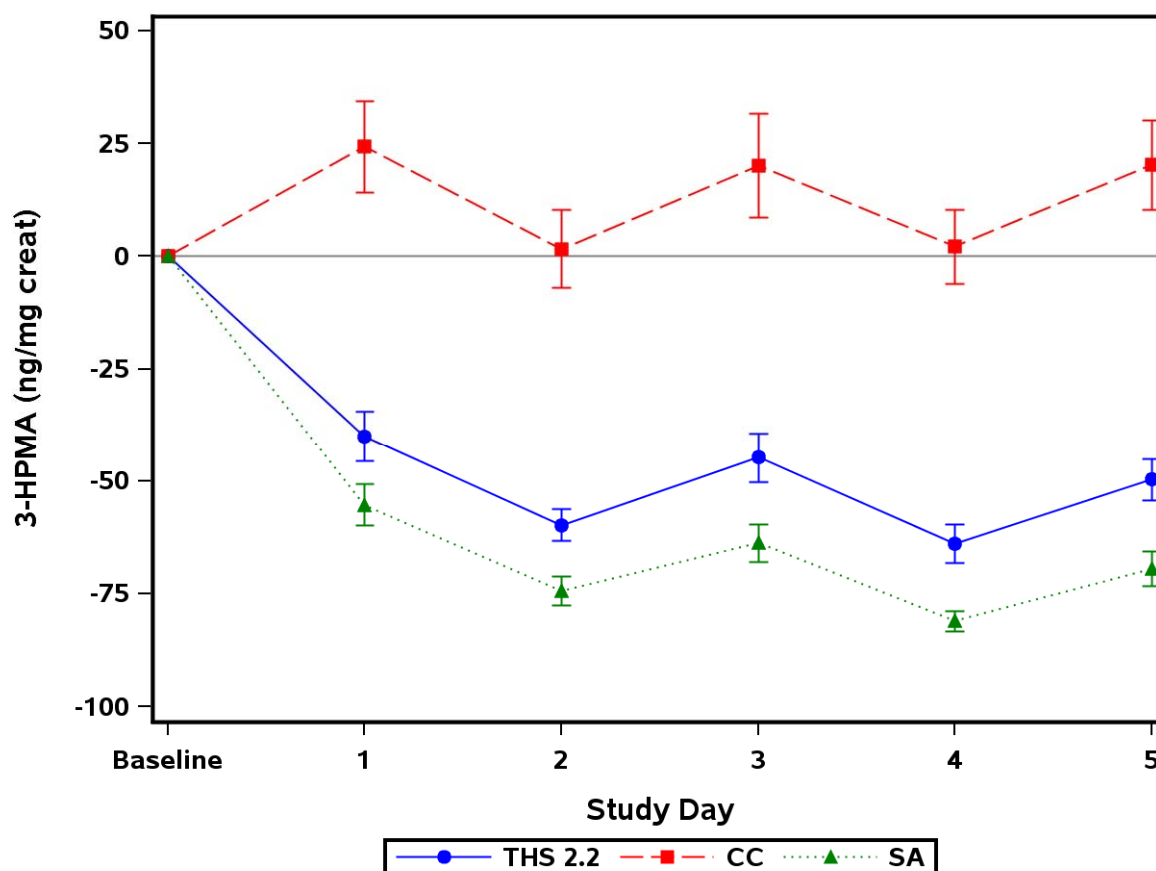
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(Page 1 of 1)

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Figure 15.1.1.7 3-HPMA Urinary Concentration Adjusted for Creatinine (ng/mg creat) % Change from Baseline Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: % change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.8

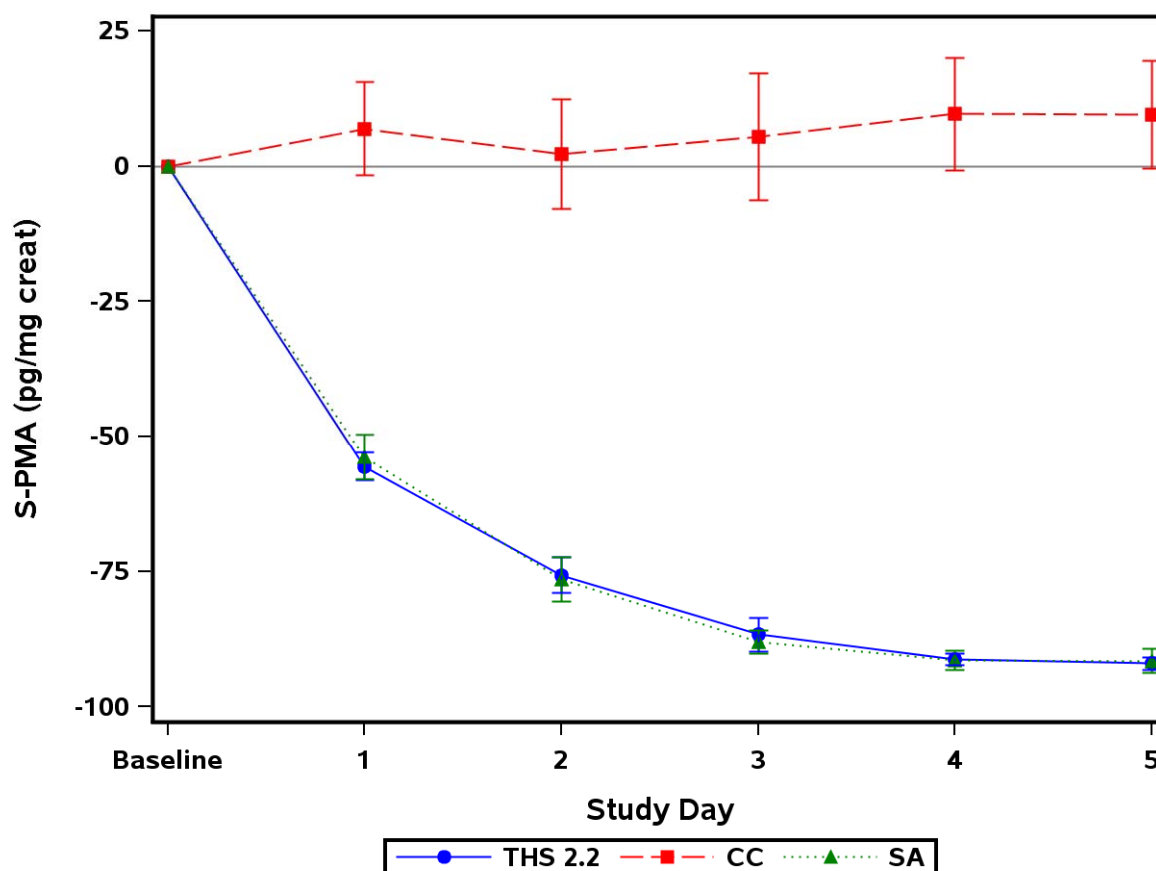
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(Page 1 of 1)

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Figure 15.1.1.8 S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) % Change from Baseline Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: % change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.3.9

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(Page 1 of 1)

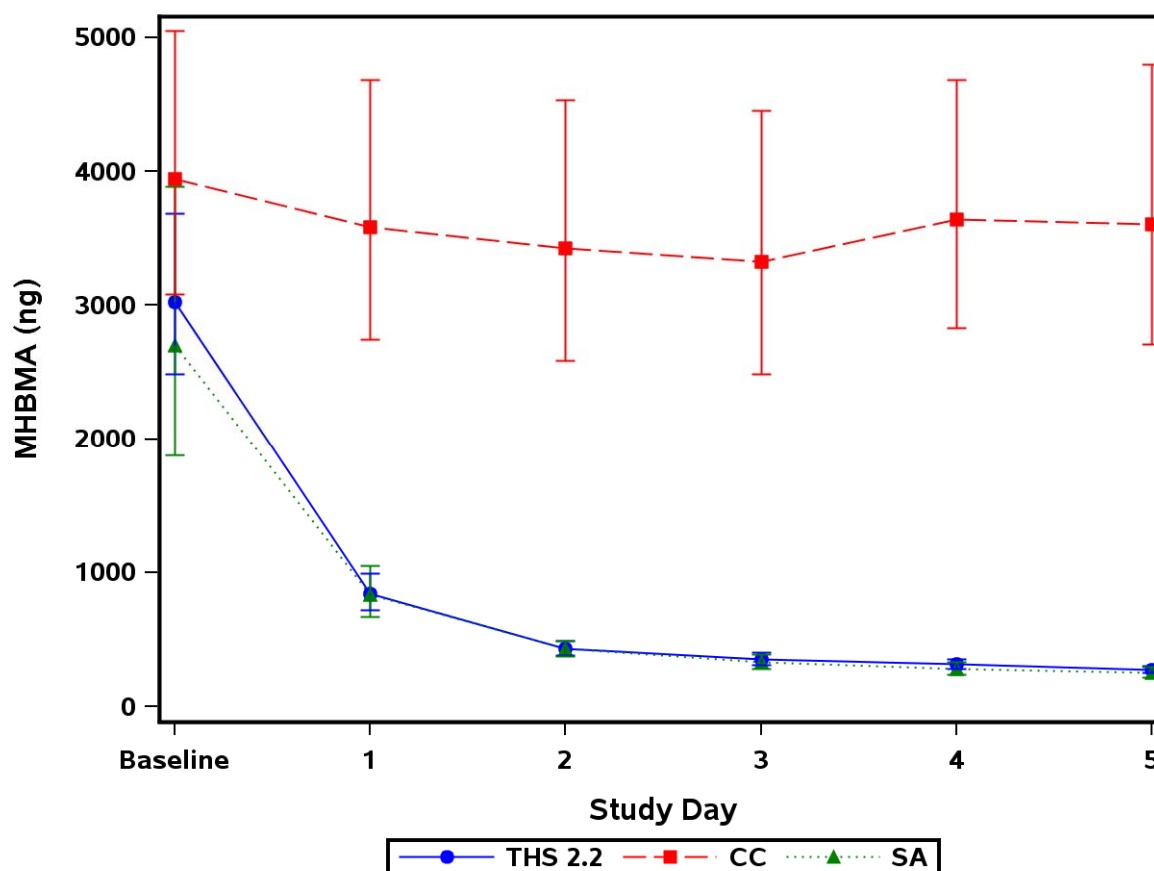
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15.1.2 Secondary Endpoints



**Figure 15.1.2.1 Urinary MHBMA Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.3

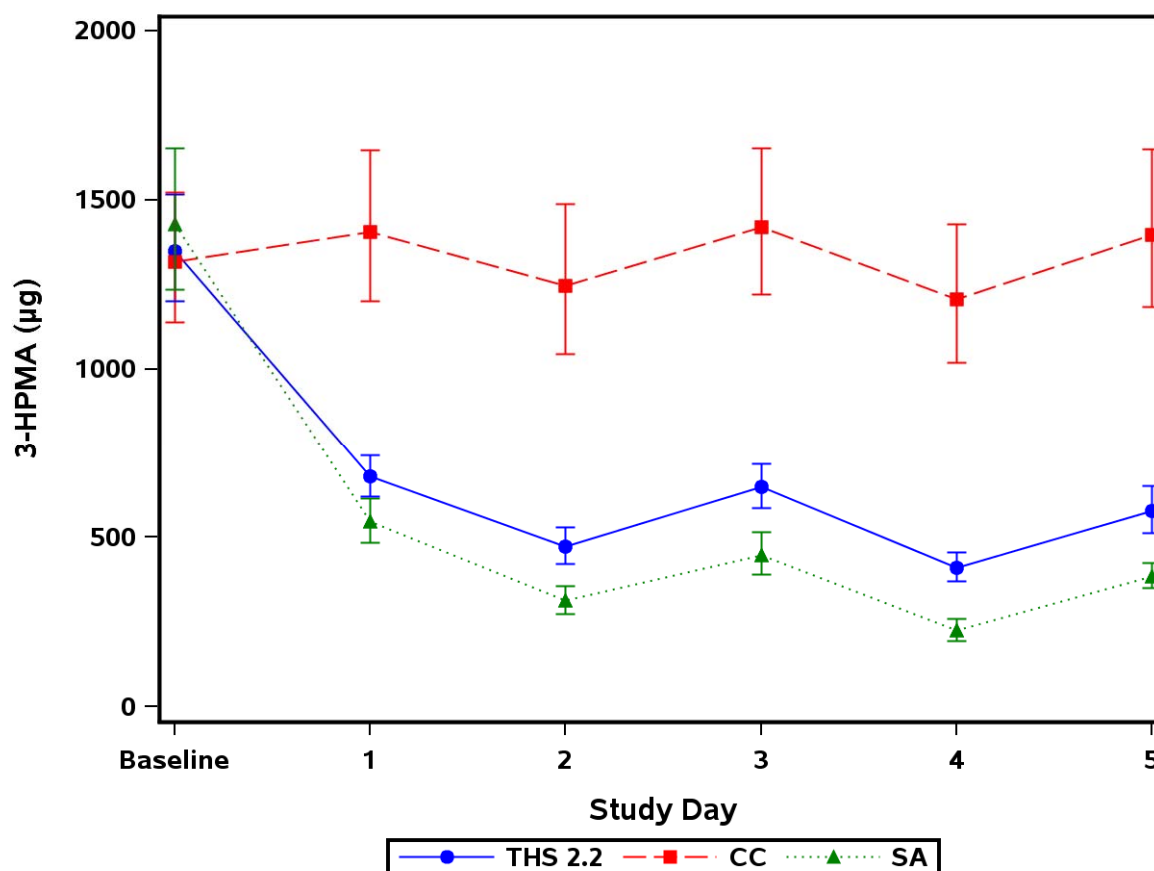
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(Page 1 of 1)

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**Figure 15.1.2.2 Urinary 3-HPMA Quantity Excreted over 24 hours (μg)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

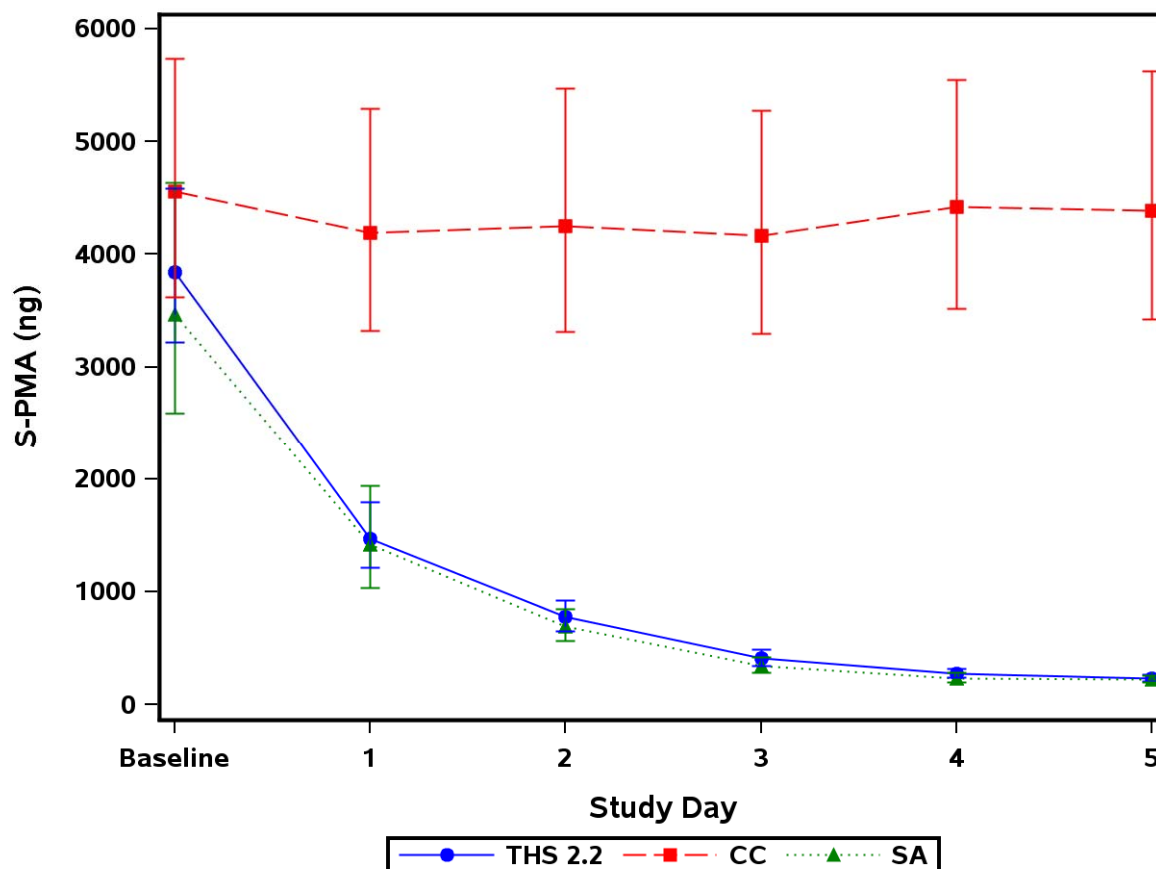
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.4

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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.3 Urinary S-PMA Quantity Excreted over 24 hours (ng) Geometric Mean and 95% CI - FAS**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

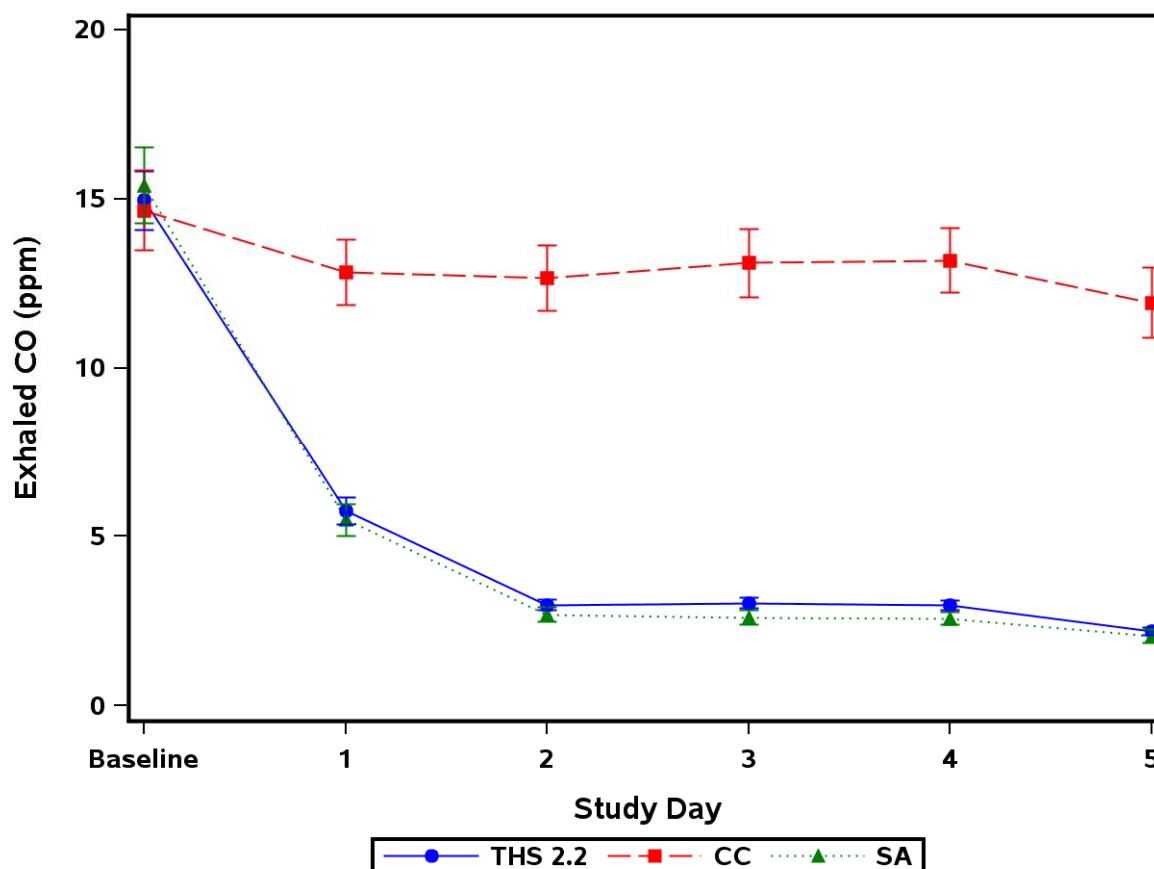
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.5

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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.4 Exhaled CO Arithmetic Mean and 95% CI - FAS**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.7

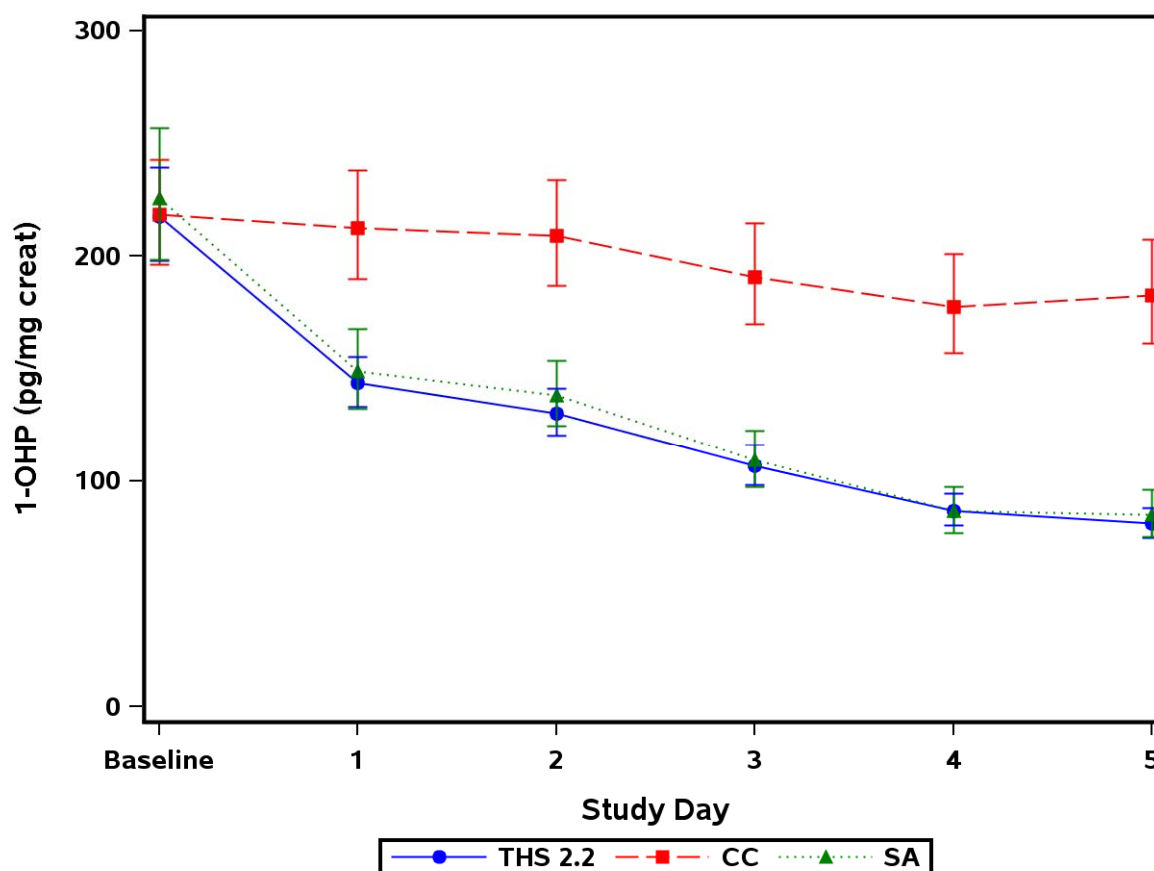
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(Page 1 of 1)

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Figure 15.1.2.5 1-OHP Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.10

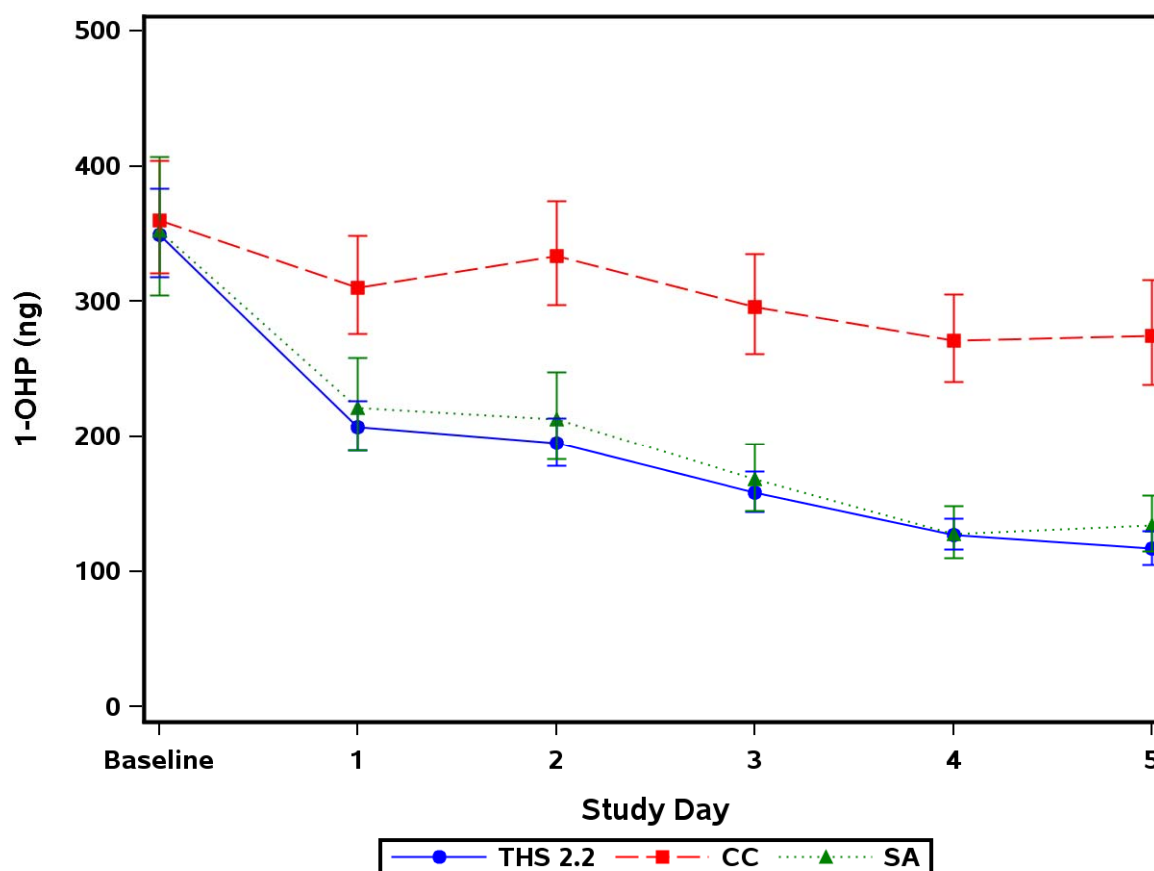
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(Page 1 of 1)

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Figure 15.1.2.6 Urinary 1-OHP Quantity Excreted over 24 hours (ng) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.10

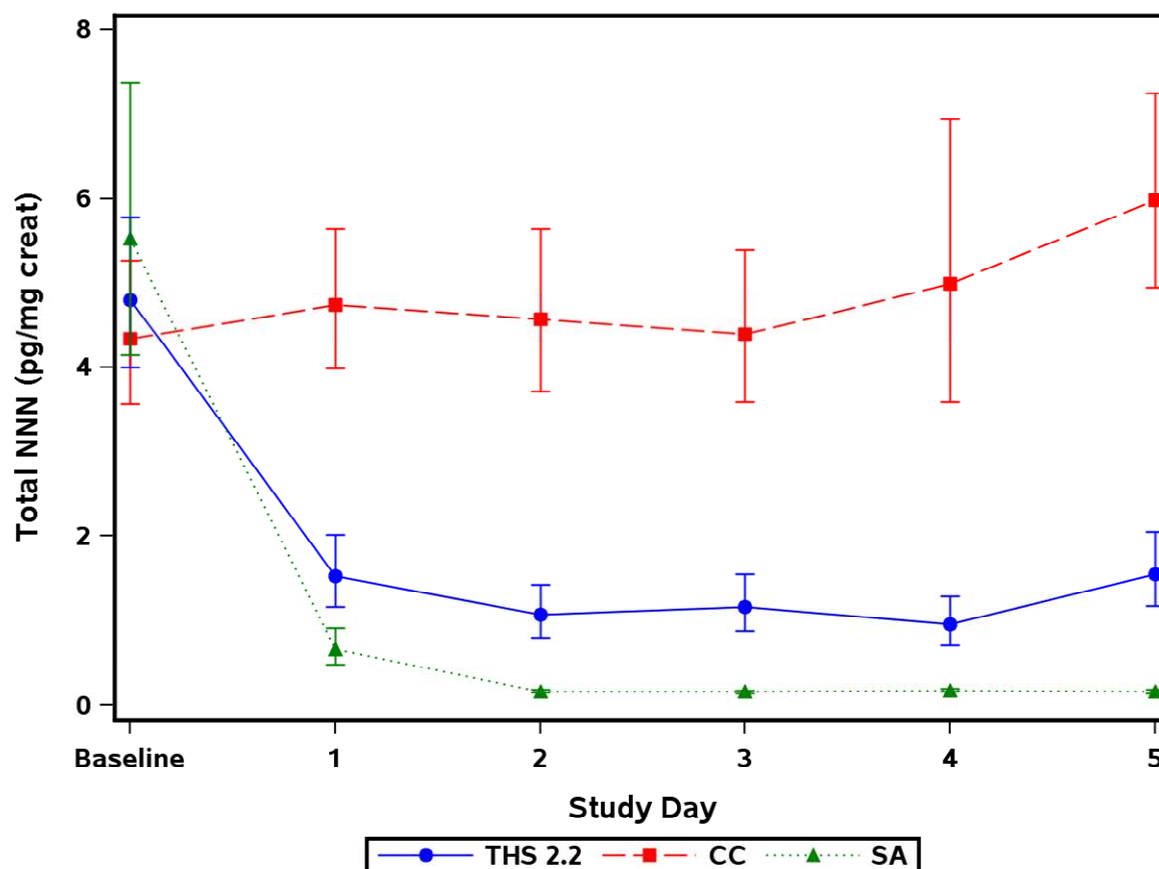
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(Page 1 of 1)

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Figure 15.1.2.7 Total NNN Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.12

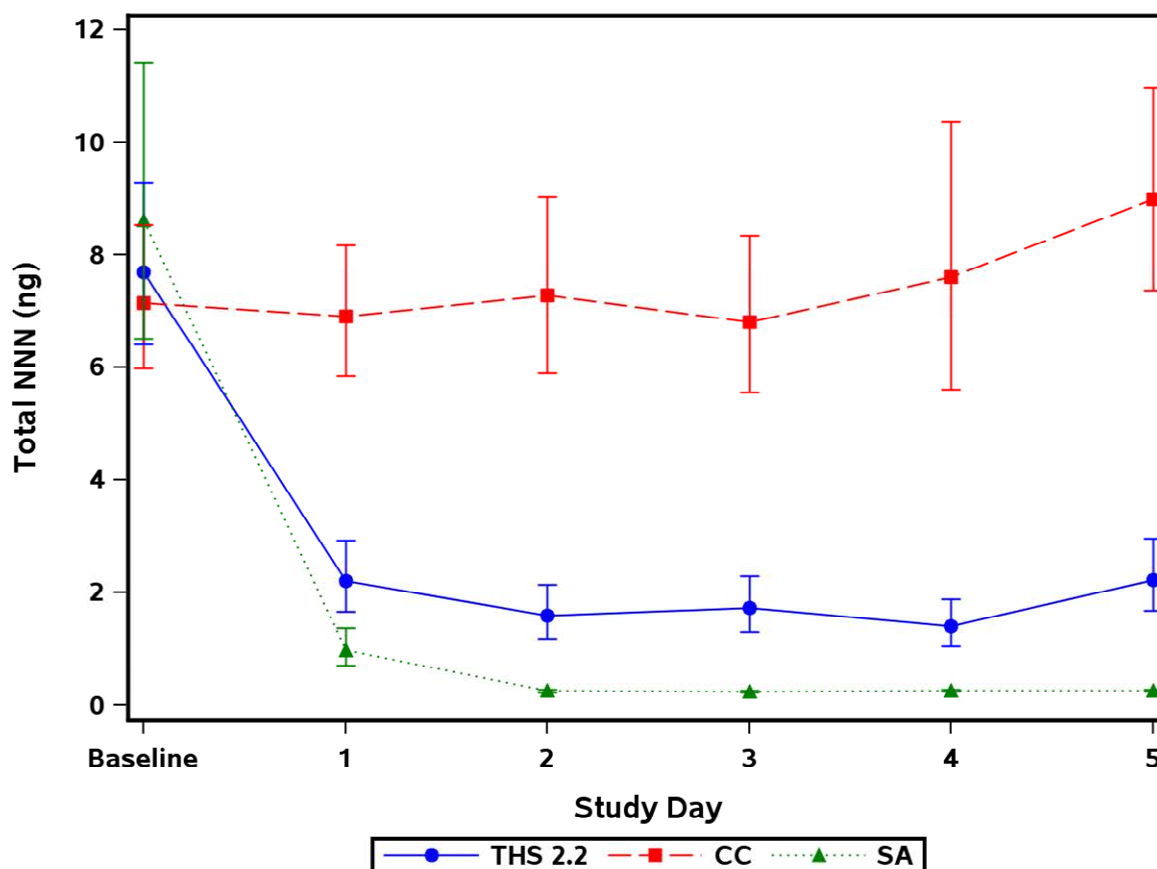
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(Page 1 of 1)

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**Figure 15.1.2.8 Urinary Total NNN Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.12

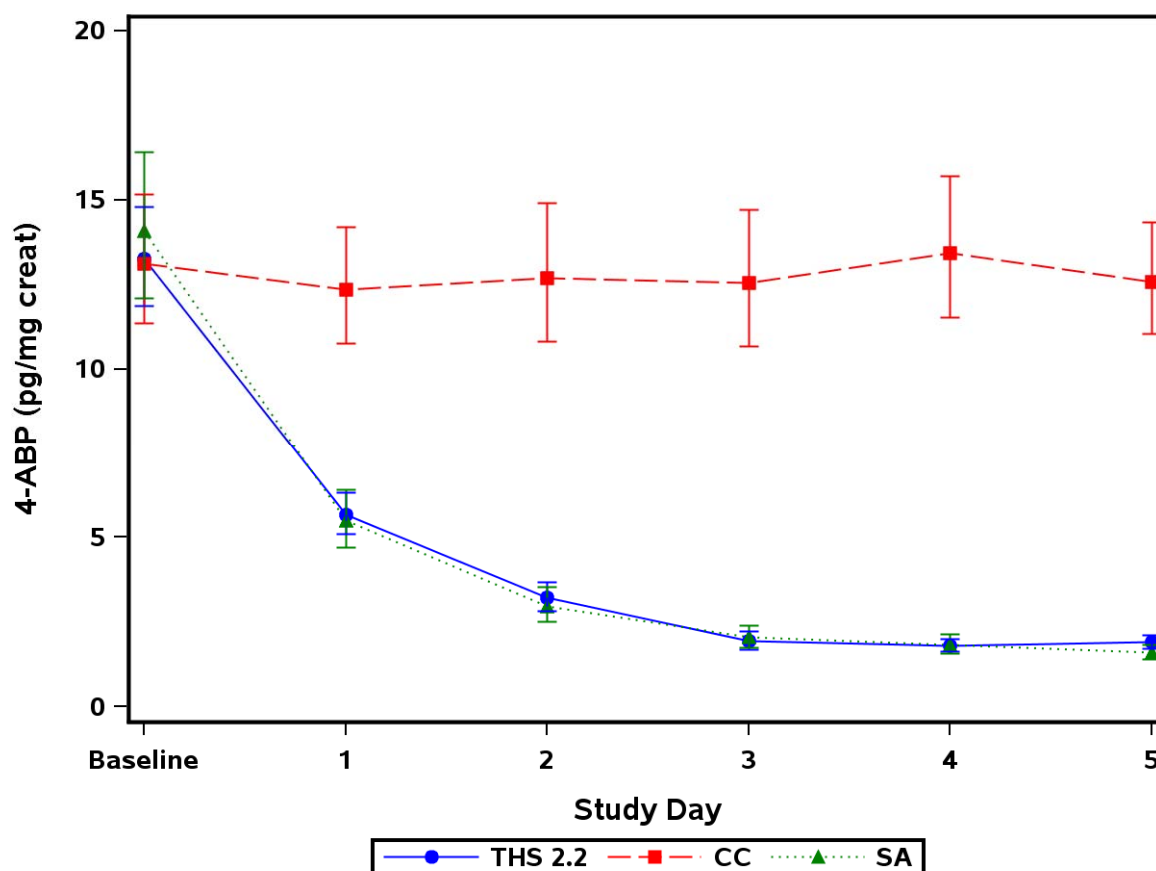
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Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.9 4-ABP Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.14

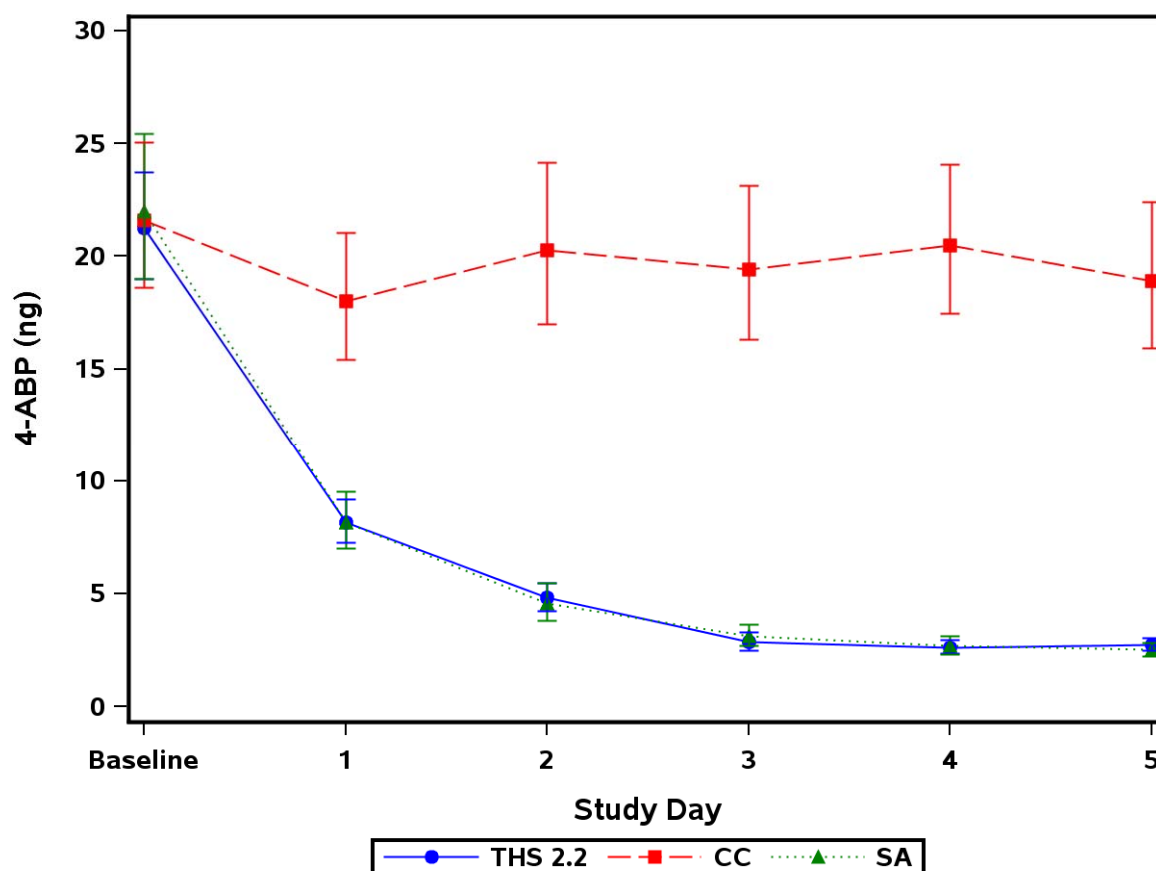
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(Page 1 of 1)

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**Figure 15.1.2.10 Urinary 4-ABP Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.14

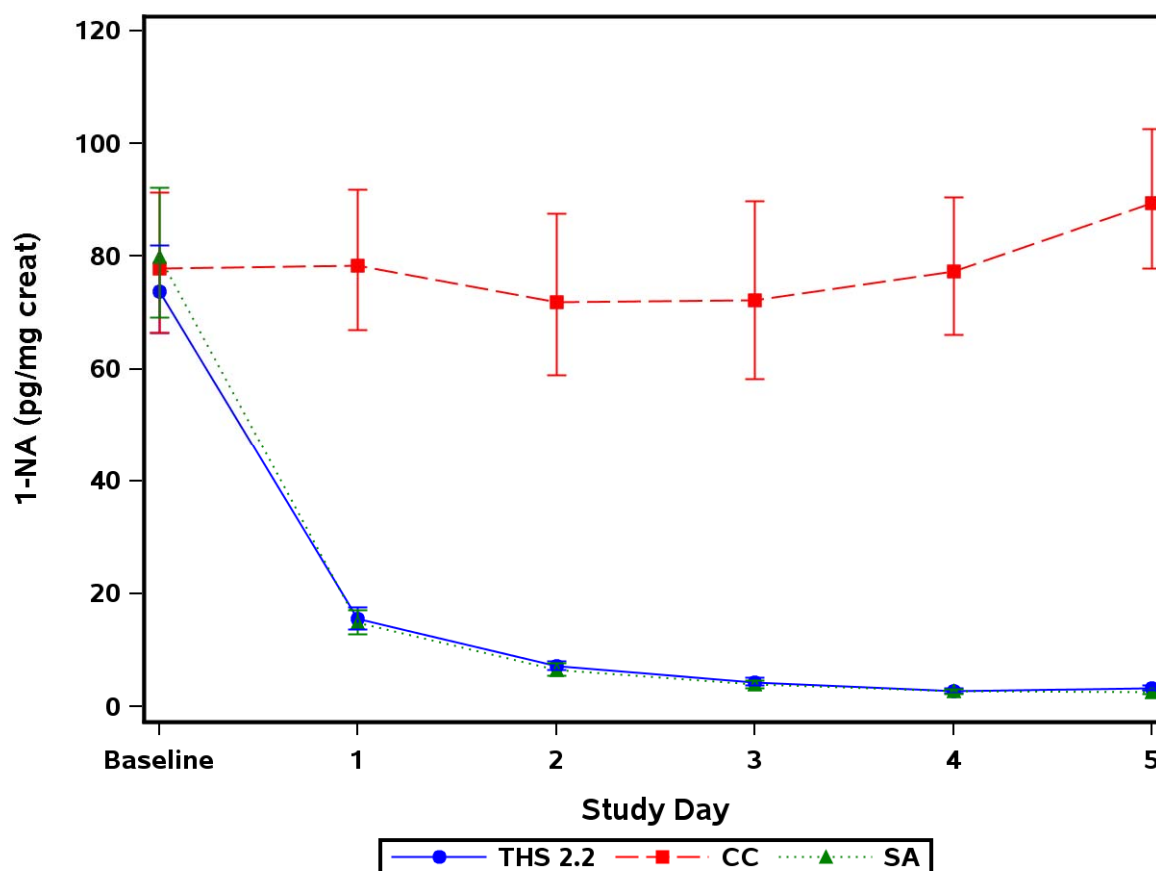
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.11 1-NA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.16

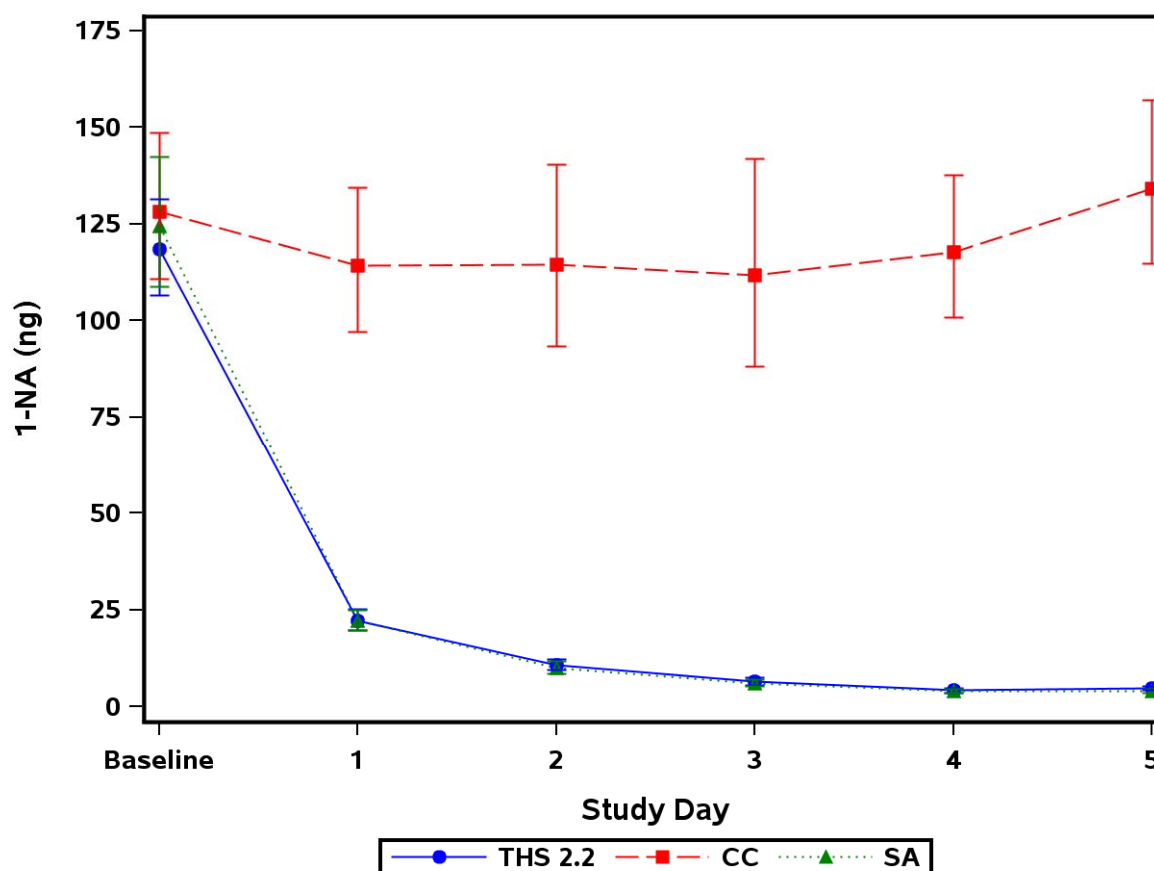
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.12 Urinary 1-NA Quantity Excreted over 24 hours (ng) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.16

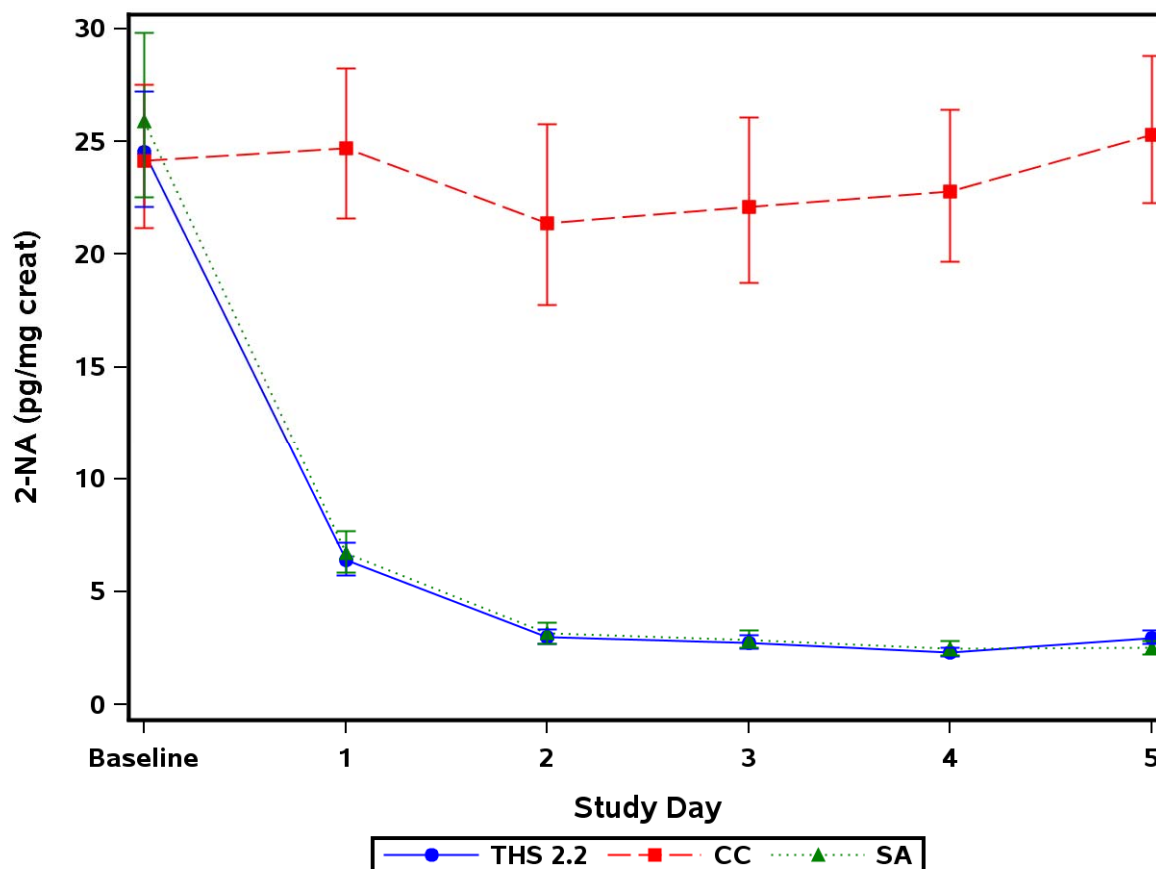
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(Page 1 of 1)

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Figure 15.1.2.13 2-NA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.18

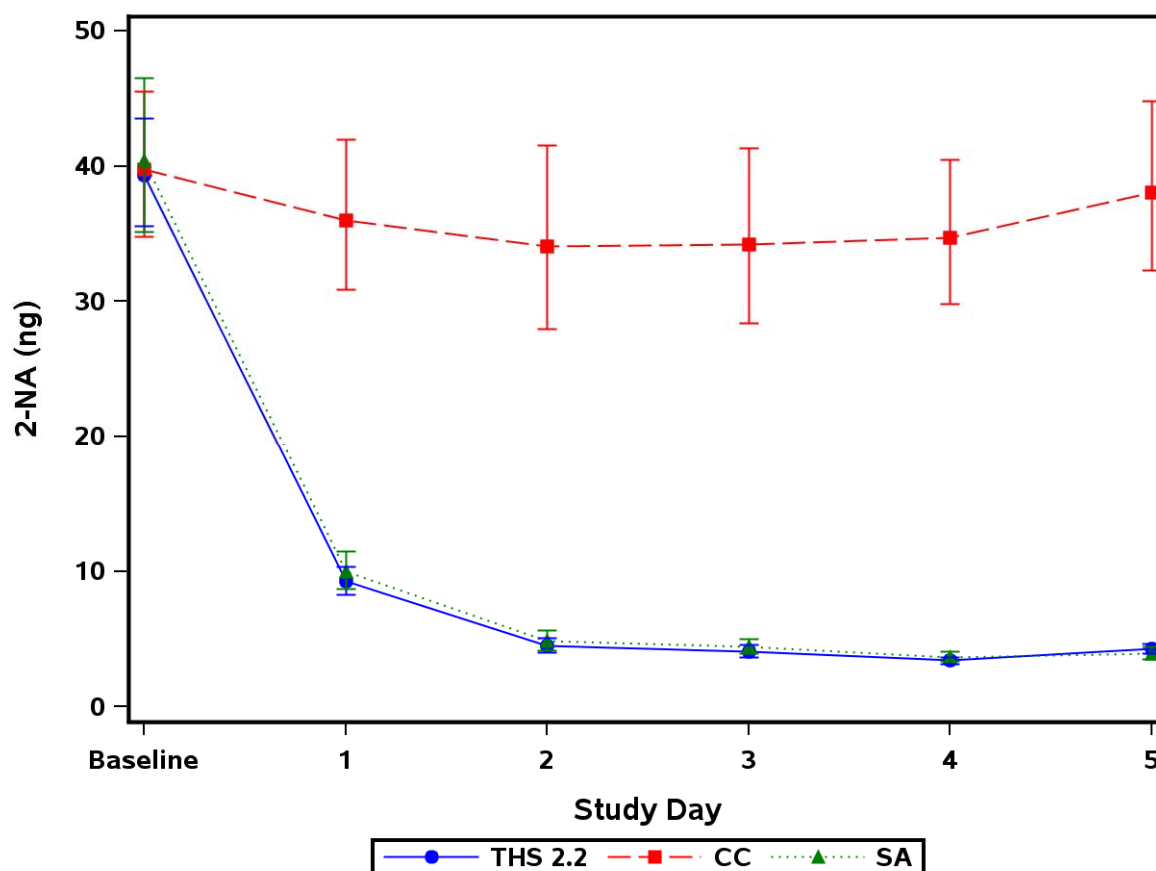
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(Page 1 of 1)

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Figure 15.1.2.14 Urinary 2-NA Quantity Excreted over 24 hours (ng) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.18

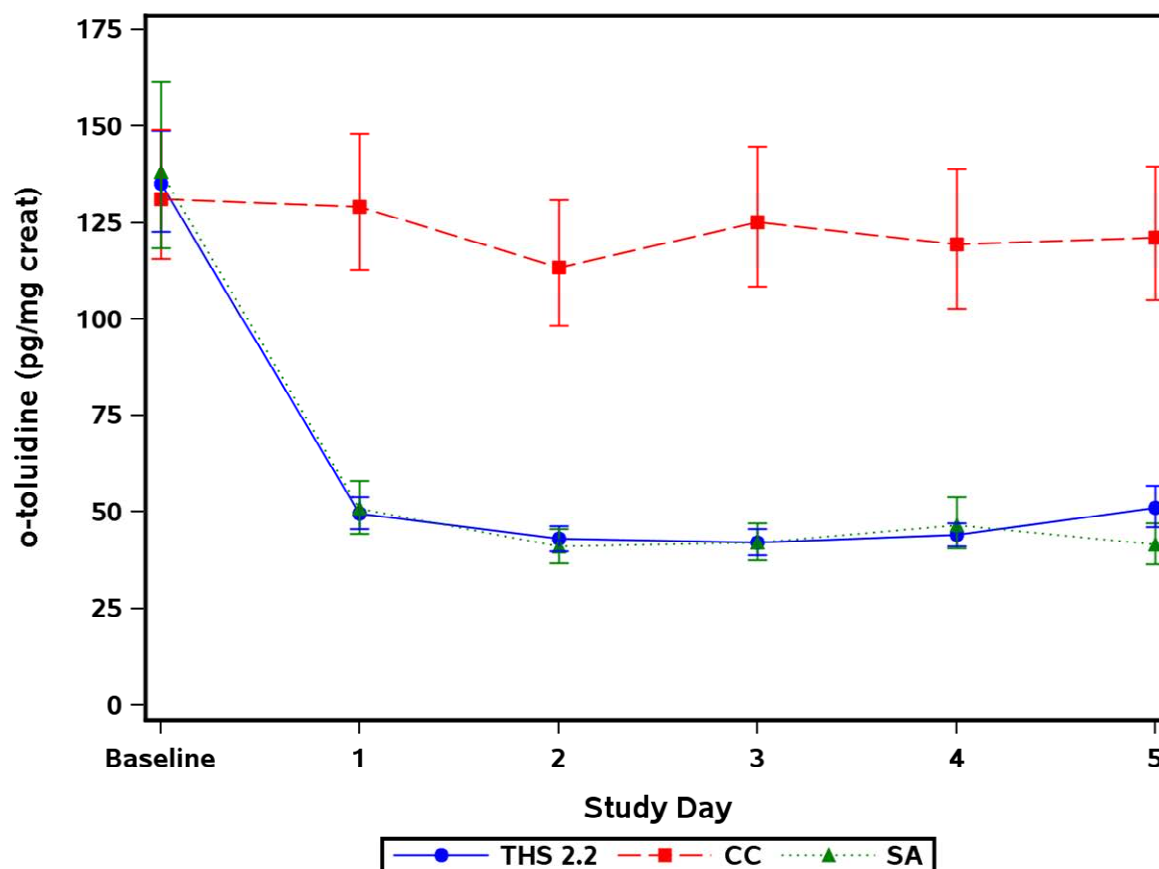
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.15 o-toluidine Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.20

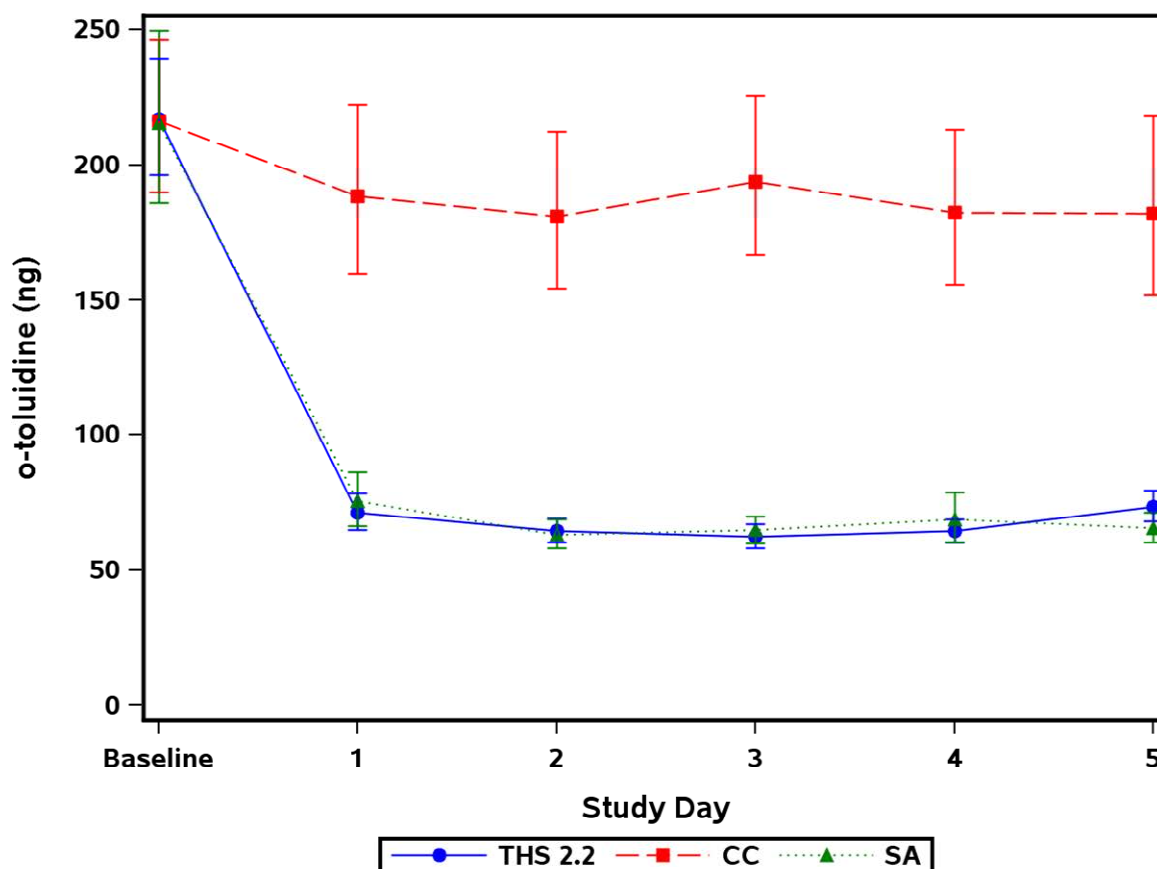
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(Page 1 of 1)

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**Figure 15.1.2.16 Urinary o-toluidine Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.20

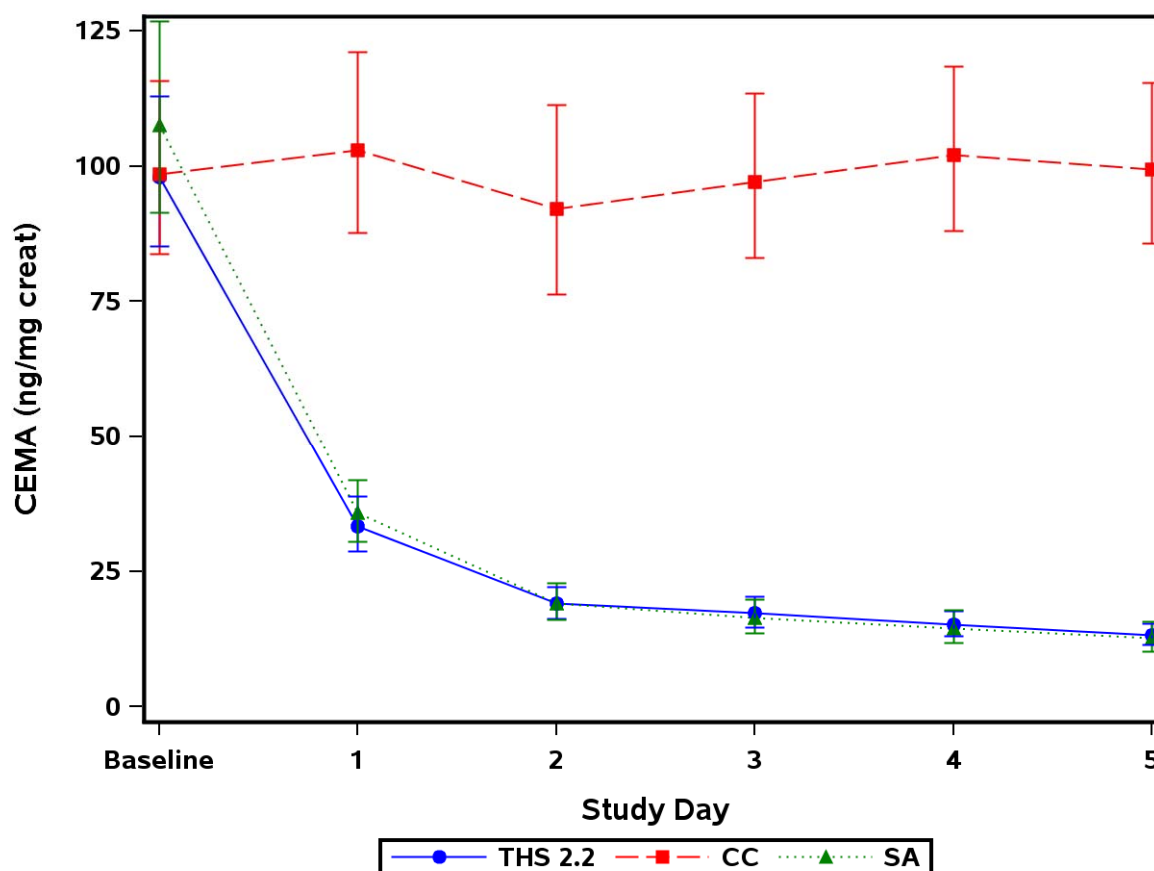
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.17 CEMA Urinary Concentration Adjusted for Creatinine (ng/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.22

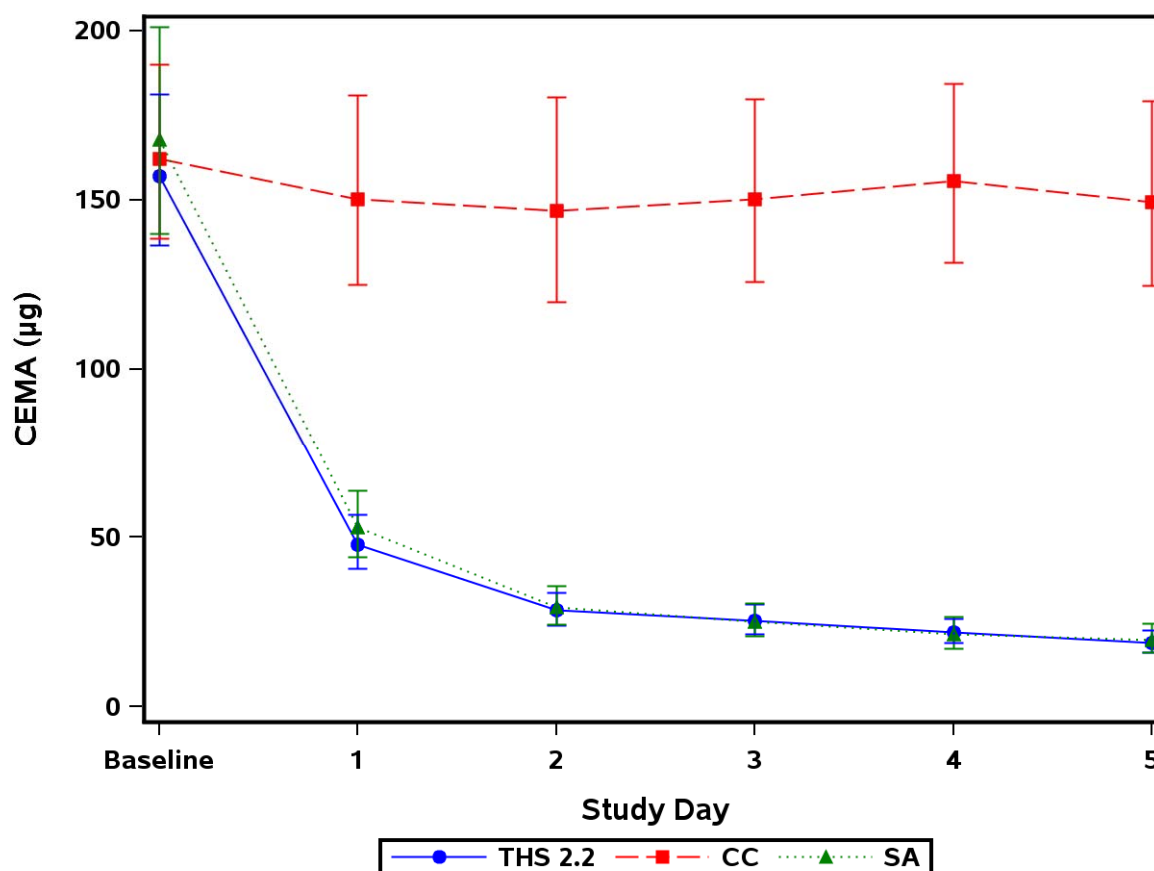
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**Figure 15.1.2.18 Urinary CEMA Quantity Excreted over 24 hours (μg)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.22

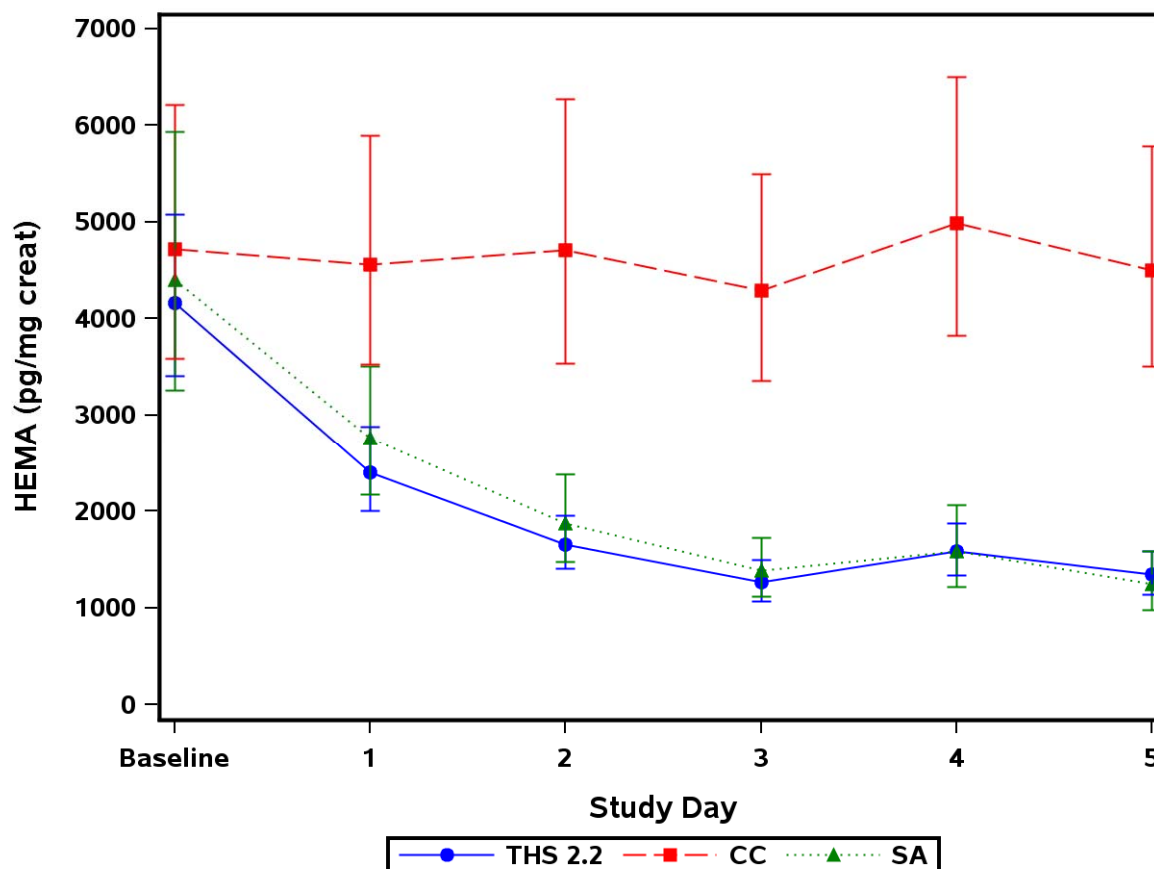
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.19 HEMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.24

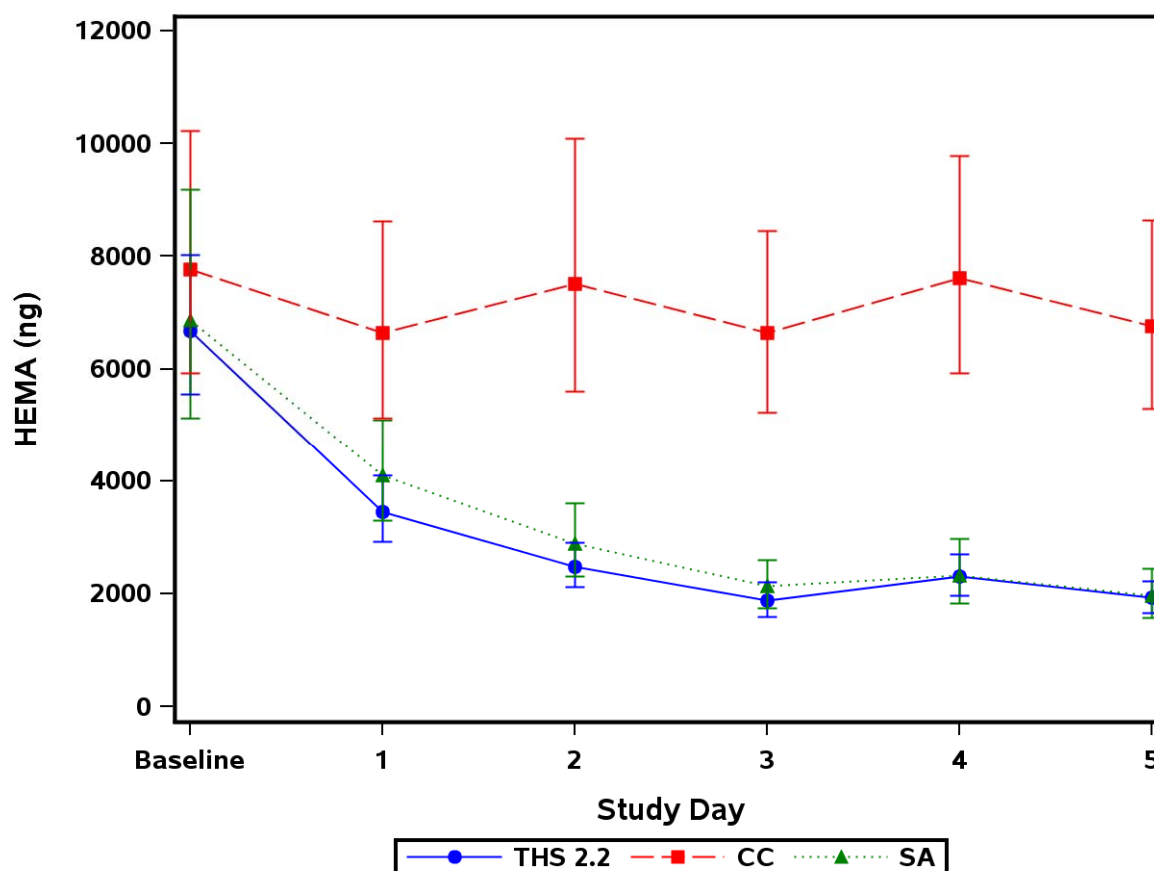
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(Page 1 of 1)

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**Figure 15.1.2.20 Urinary HEMA Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.24

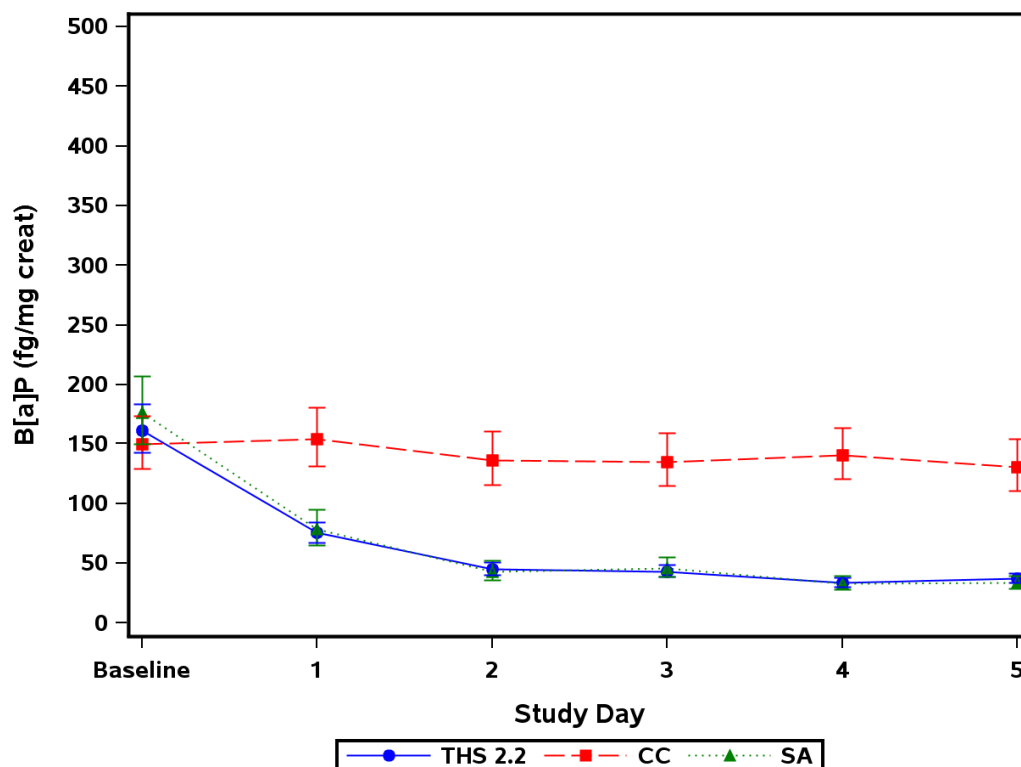
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(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.21 B[a]P Urinary Concentration Adjusted for Creatinine (fg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.26

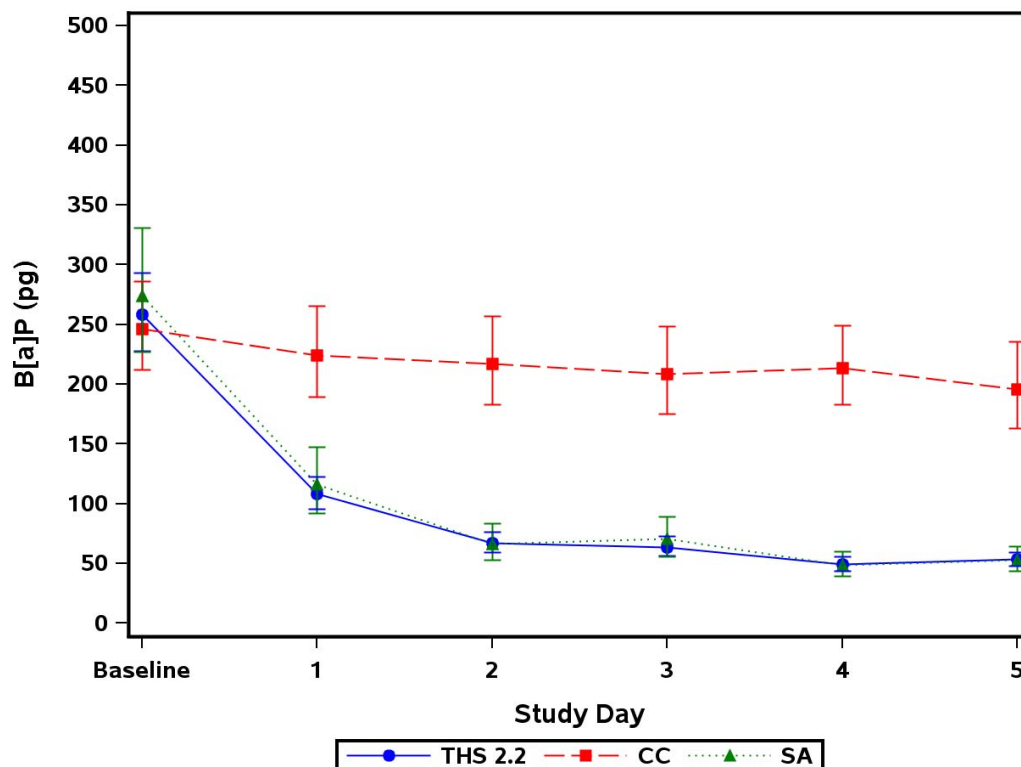
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(Page 1 of 1)

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Figure 15.1.2.22 Urinary B[a]P Quantity Excreted over 24 hours (pg) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.26

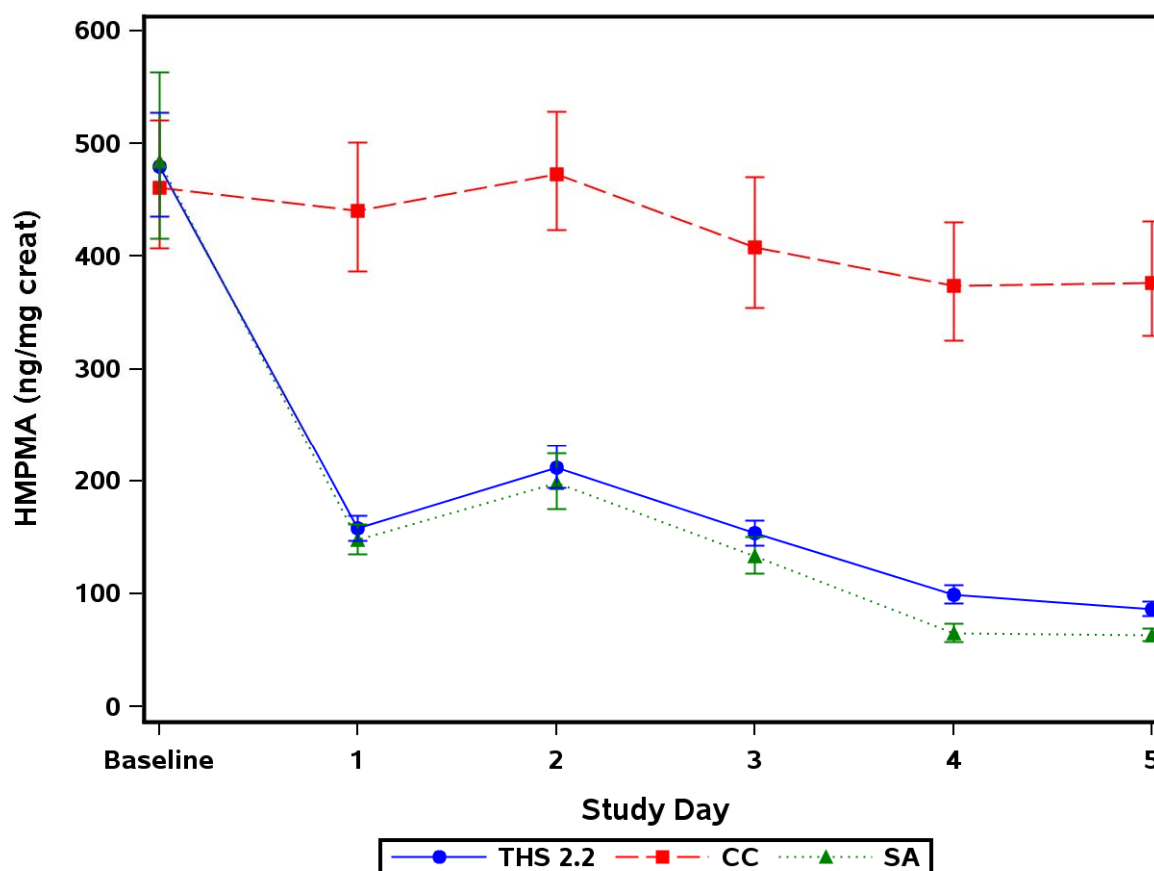
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(Page 1 of 1)

Program Run: 05NOV15 cvn_kbooth Program Status: FINAL



Figure 15.1.2.23 HMPMA Urinary Concentration Adjusted for Creatinine (ng/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.28

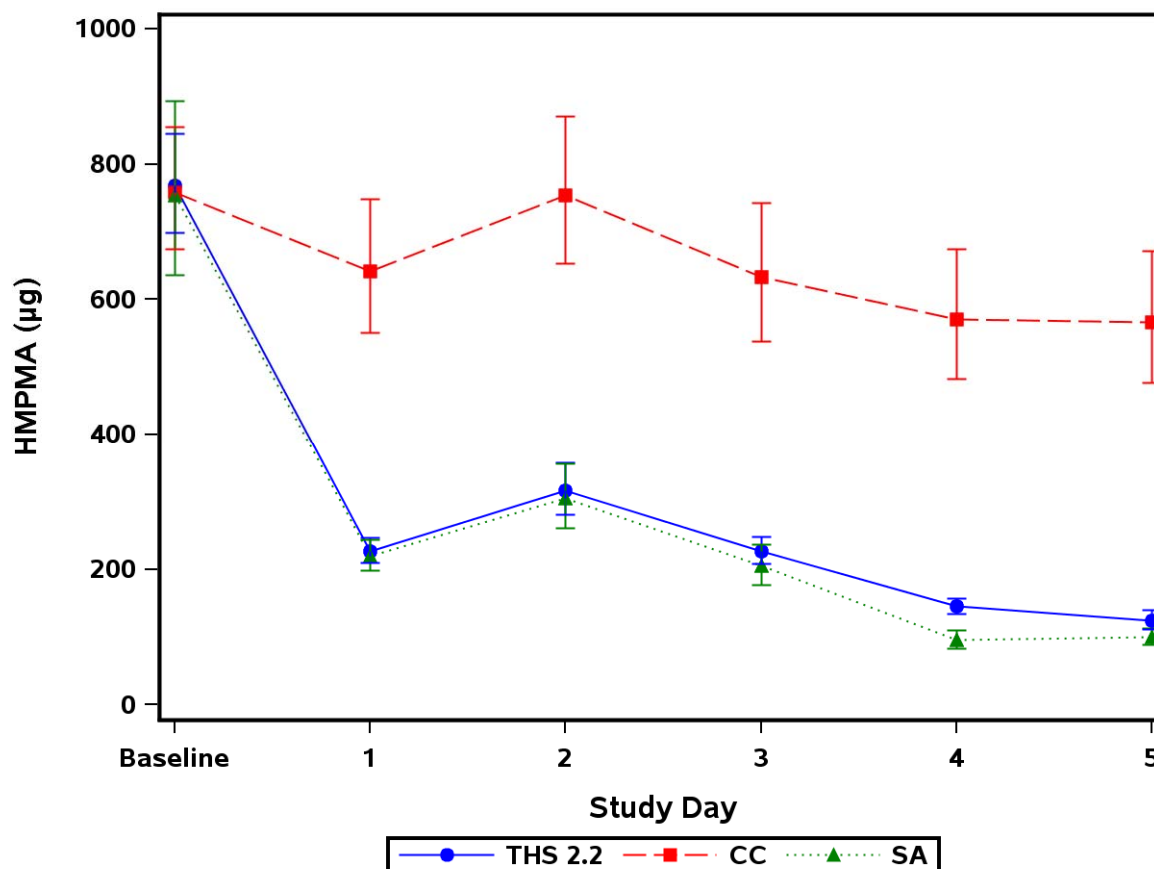
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hmpma.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



**Figure 15.1.2.24 Urinary HMPMA Quantity Excreted over 24 hours (μg)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.28

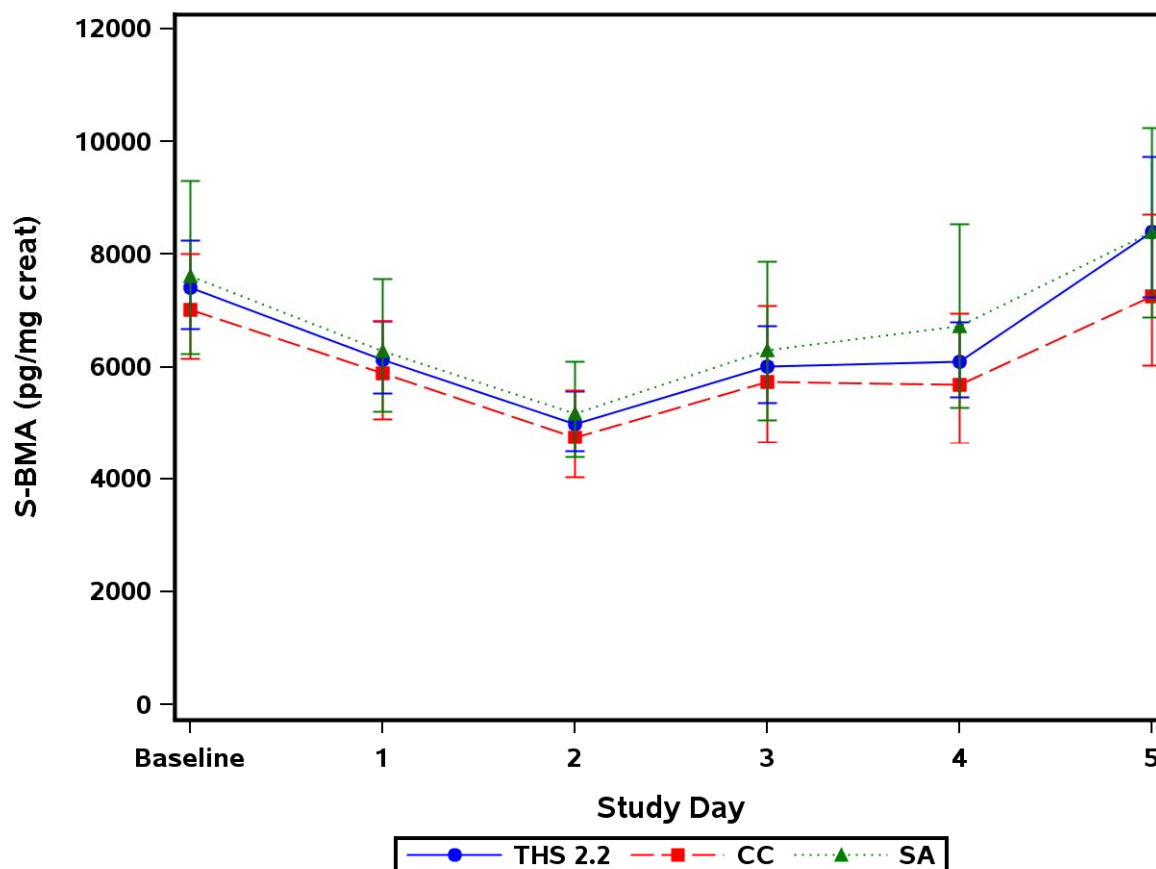
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hmpma24.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.25 S-BMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.30

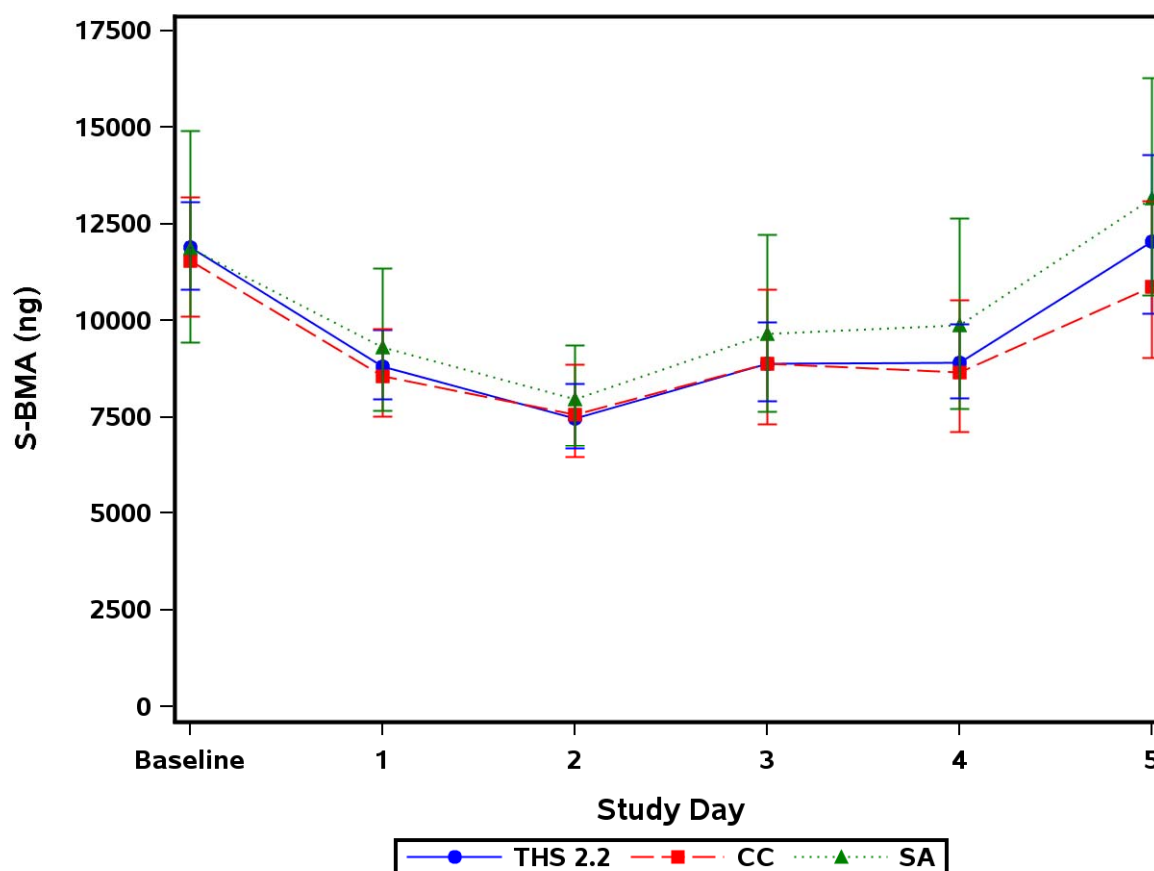
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_sbma.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



**Figure 15.1.2.26 Urinary S-BMA Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.30

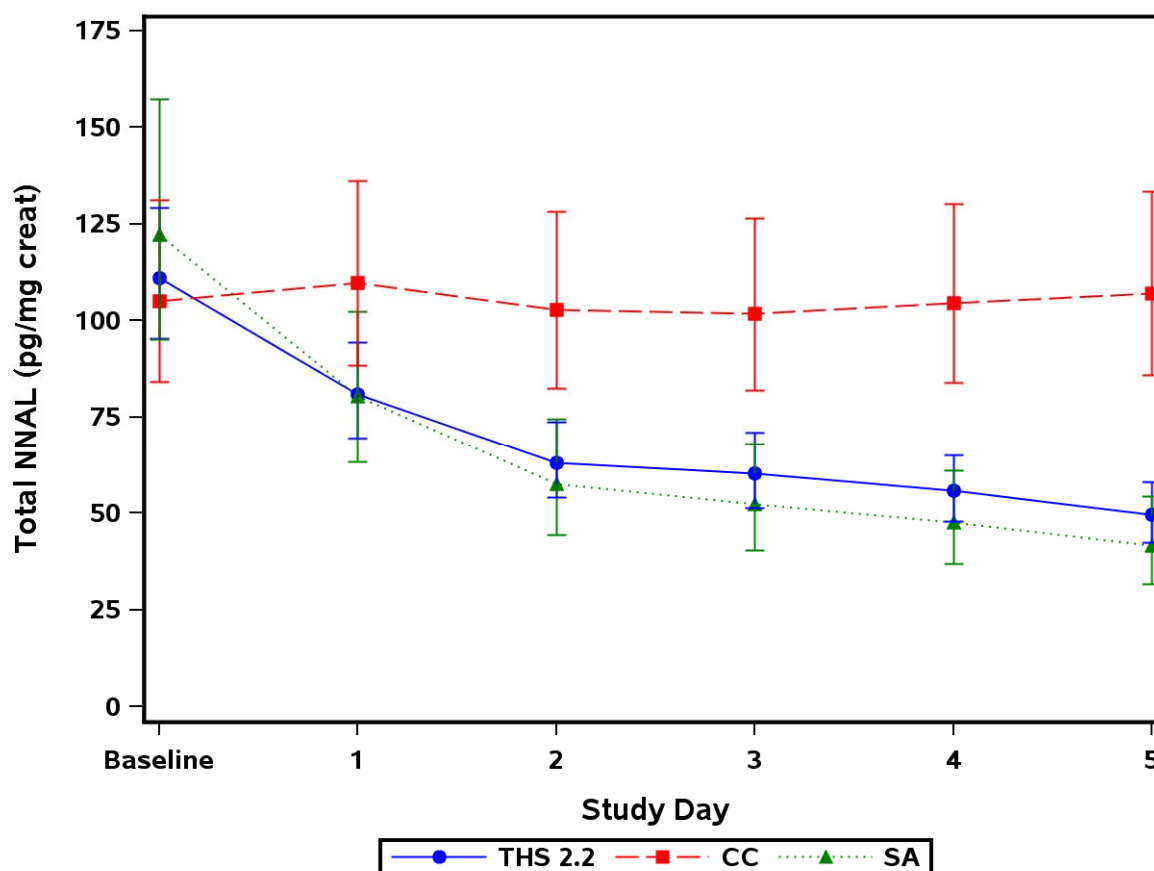
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_sbma24.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.27 Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.32

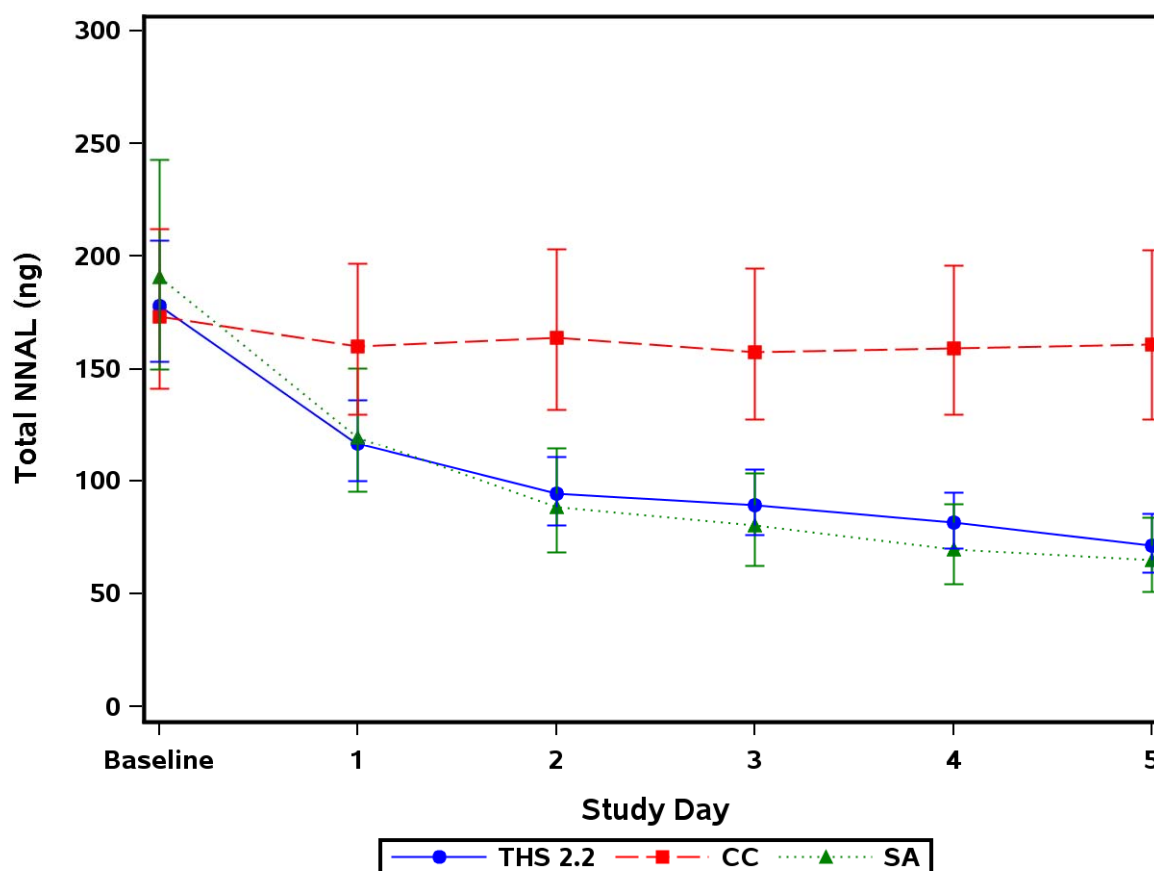
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_nnal.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



**Figure 15.1.2.28 Urinary Total NNAL Quantity Excreted over 24 hours (ng)
Geometric Mean and 95% CI - FAS**



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.32

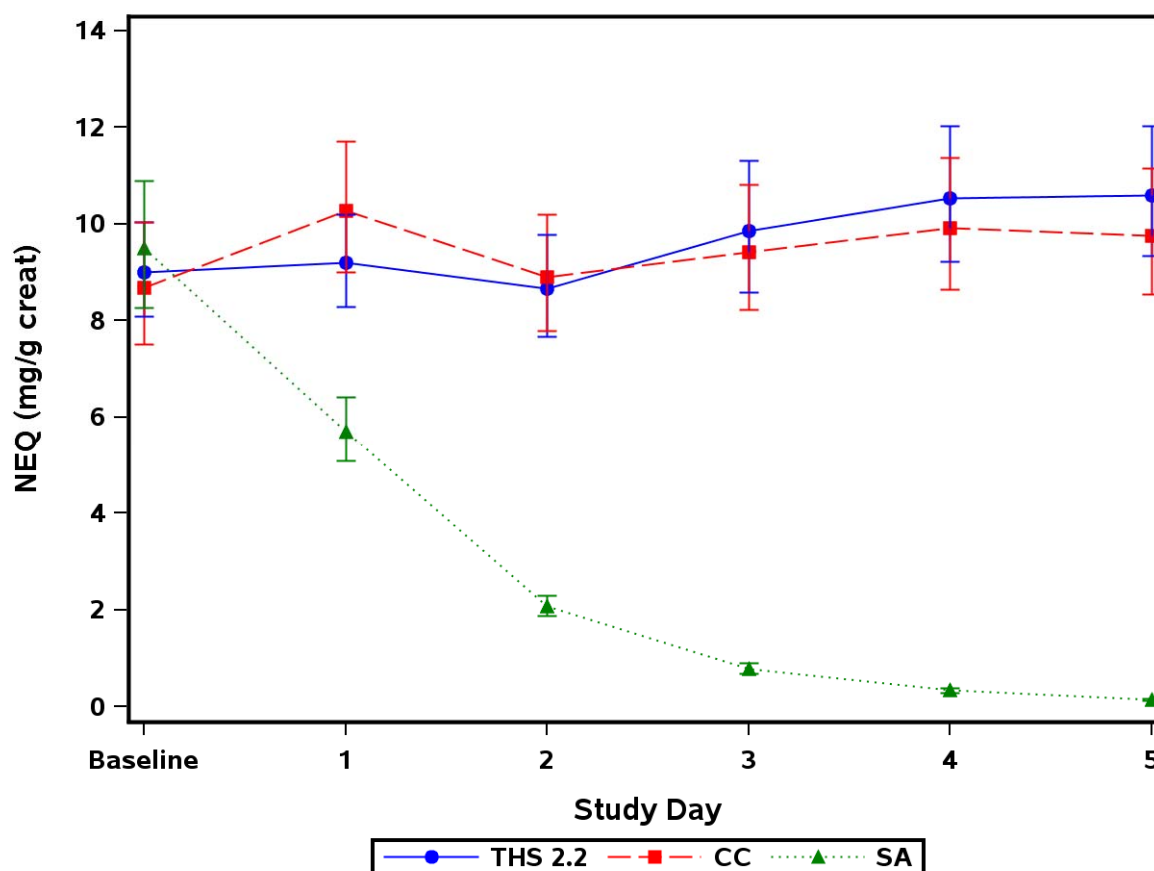
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_nnal24.sas

(Page 1 of 1)

Program Run: 31OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.29 NEQ Urinary Concentration Adjusted for Creatinine (mg/g creat) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.34

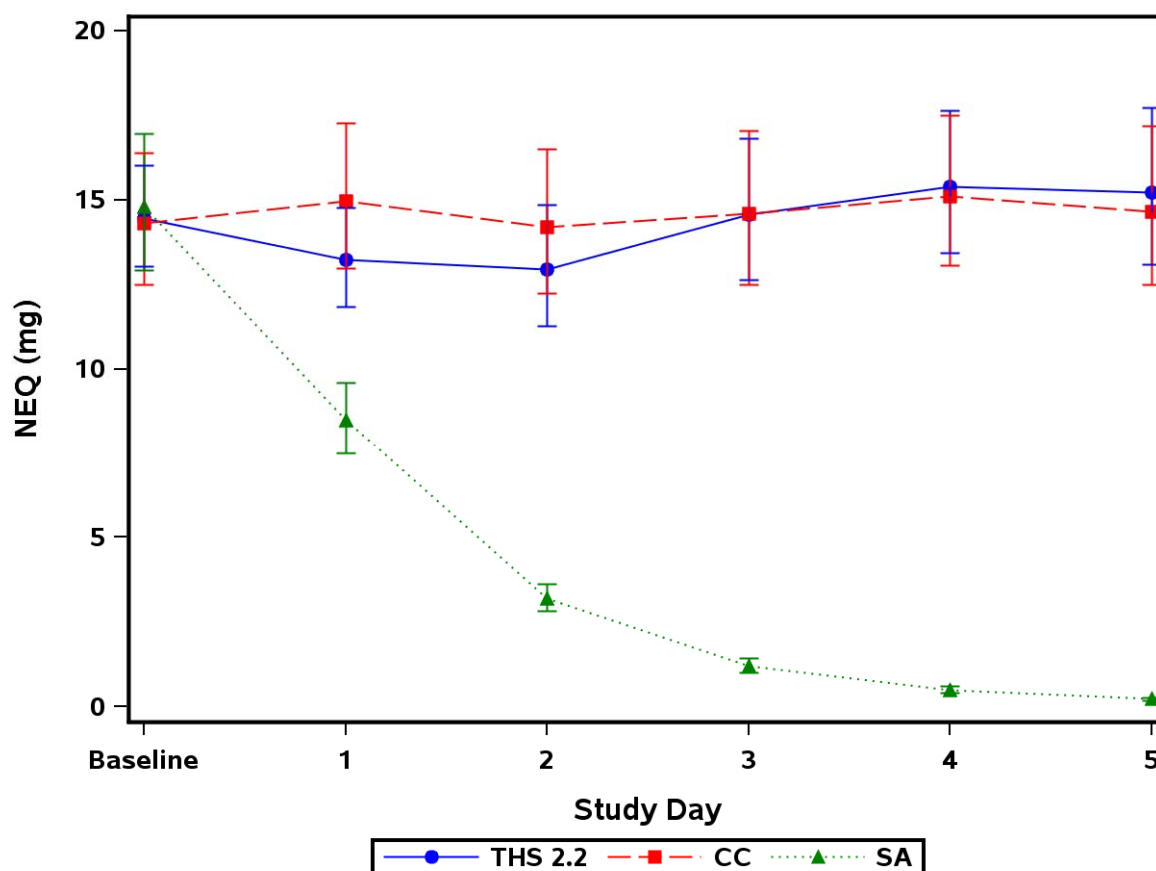
Path: /cvn/projects/prj/development/000000106324/dev/figures/f_neq.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.30 Urinary NEQ Quantity Excreted over 24 hours (mg) Geometric Mean and 95% CI - FAS



Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

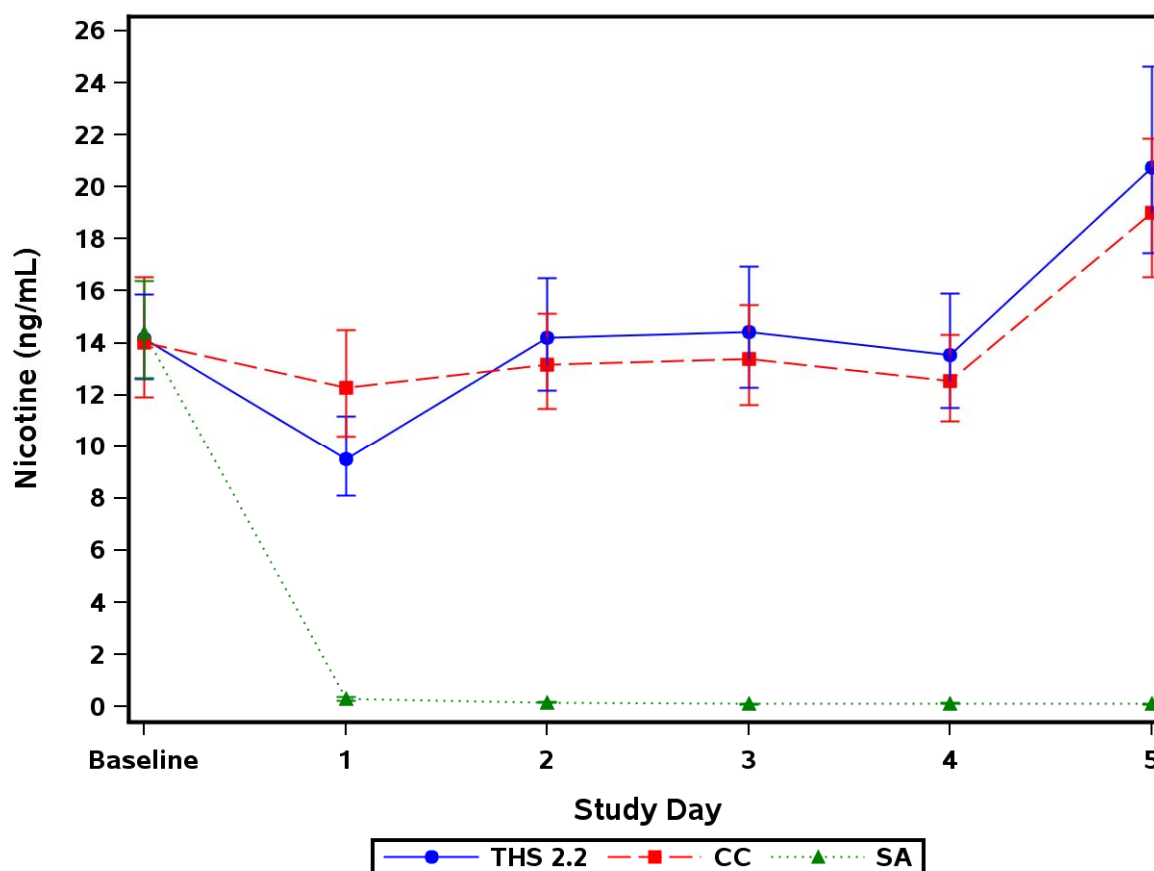
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.34

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_neq24.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.31 Plasma Nicotine Concentrations (ng/mL) Geometric Mean and 95% CI - FAS**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

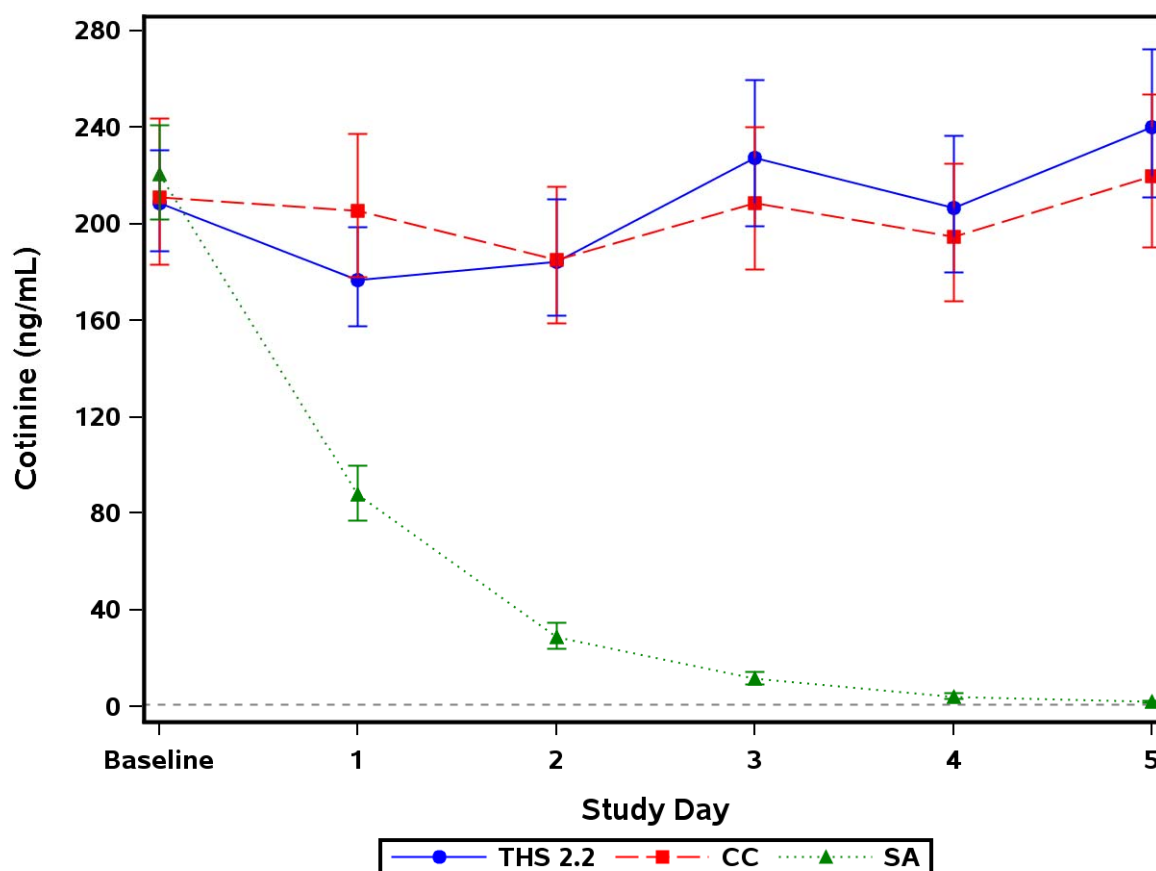
Note: Evening result is presented for Day 5.

Appendix 15.2.4.35

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_pkconc.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.32 Plasma Cotinine Concentrations (ng/mL) Geometric Mean and 95% CI - FAS**

----- Lower limit of quantification (1 ng/mL).

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

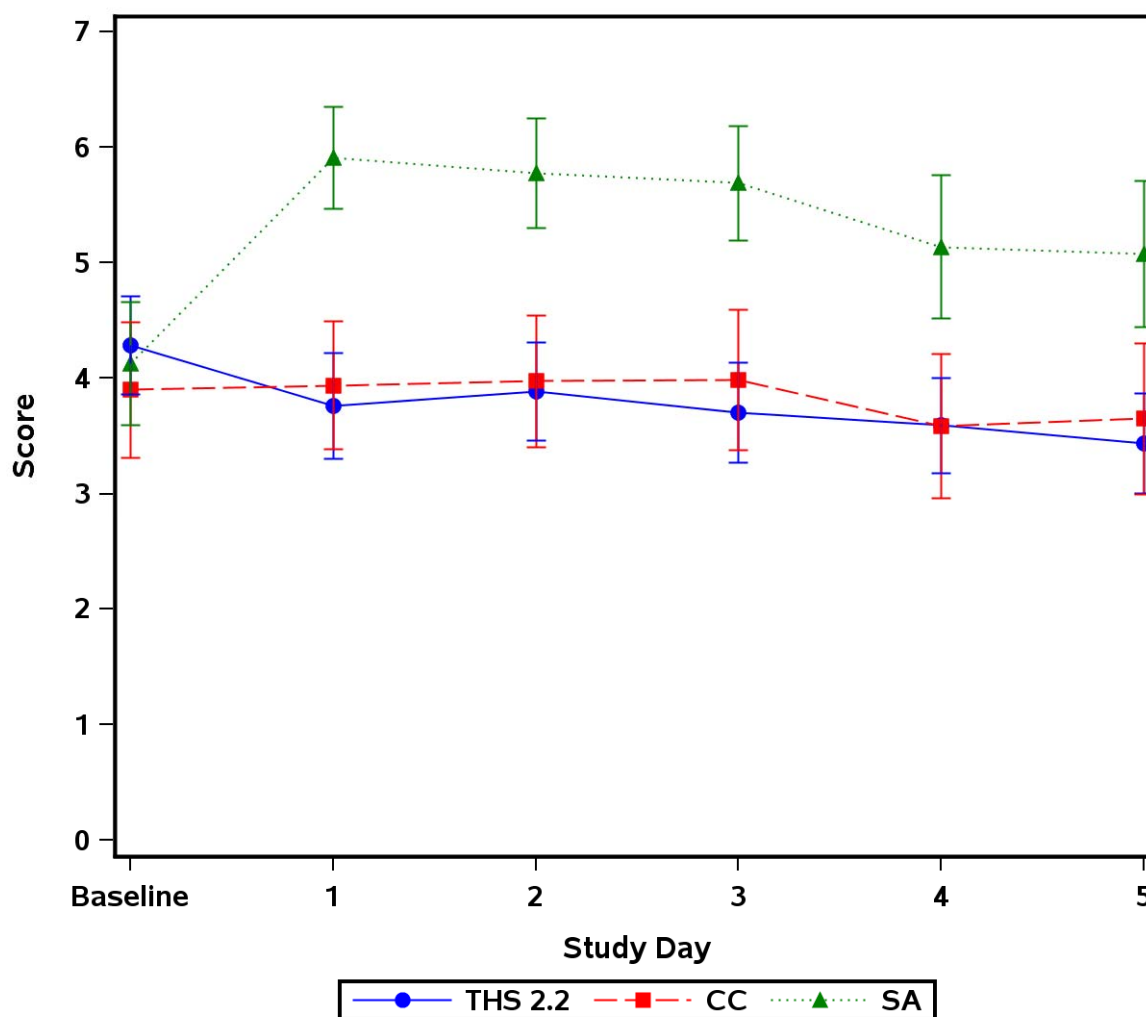
Note: Evening result is presented for Day 5.

Appendix 15.2.4.36

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_pkconc2.sas

(Page 1 of 1)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.33 QSU-brief Factors and Total Scores Arithmetic Mean and 95% CI – FAS****Factor 1 - Reward**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

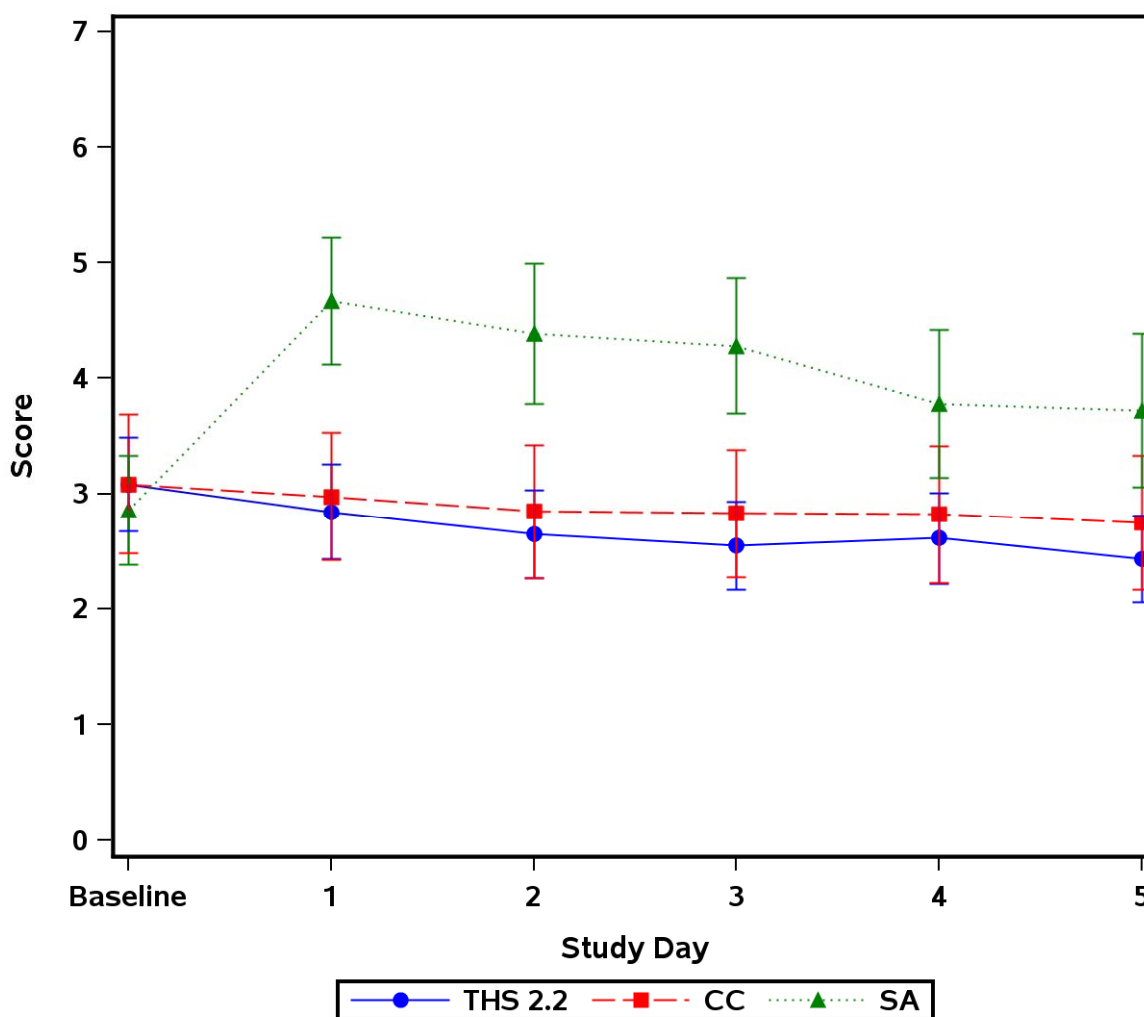
Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

Appendix 15.2.4.43

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_qsu.sas

(Page 1 of 3)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.33 QSU-brief Factors and Total Scores Arithmetic Mean and 95% CI – FAS****Factor 2 - Relief**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

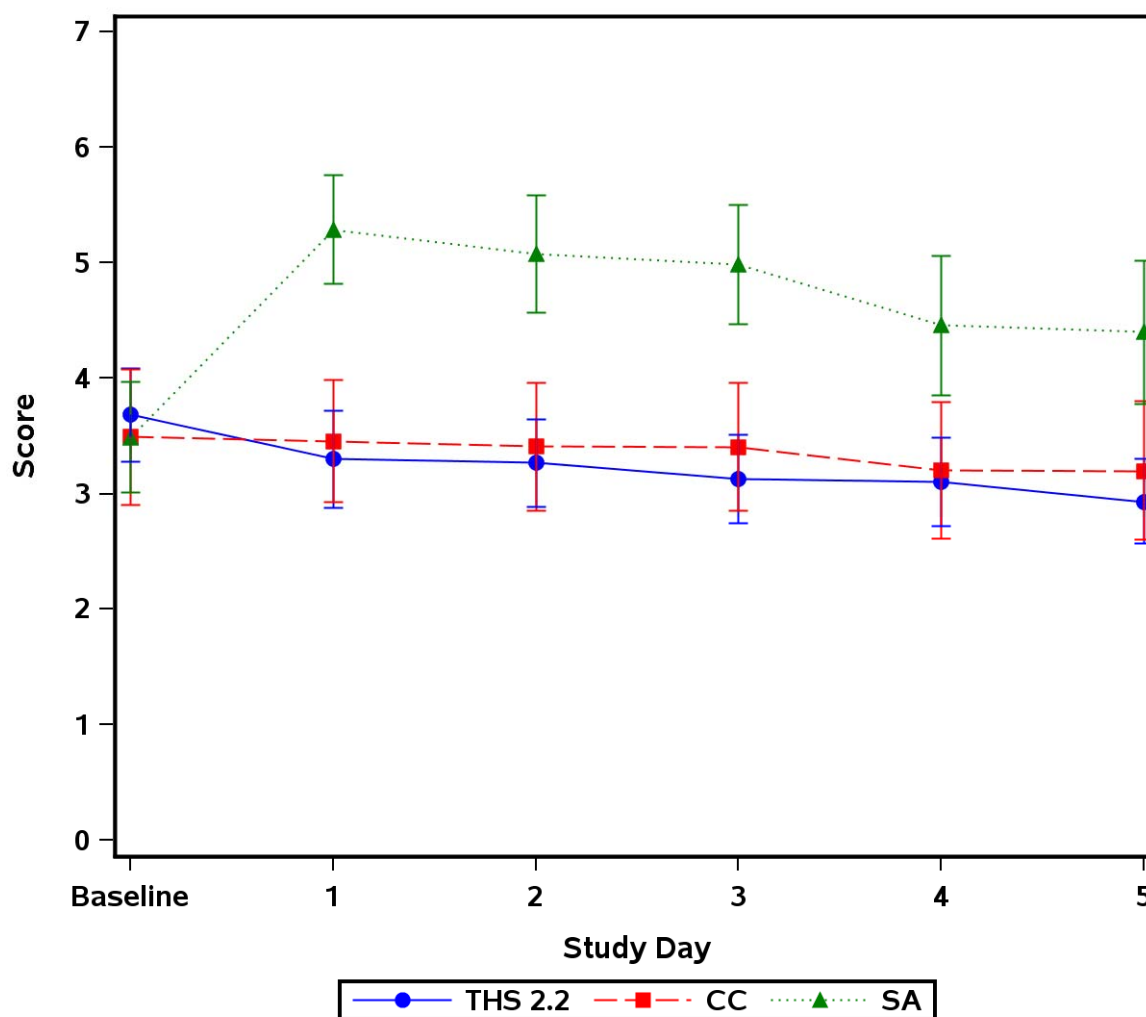
Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

Appendix 15.2.4.43

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_qsu.sas

(Page 2 of 3)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.33 QSU-brief Factors and Total Scores Arithmetic Mean and 95% CI – FAS****Total Score**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

Appendix 15.2.4.43

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_qsu.sas

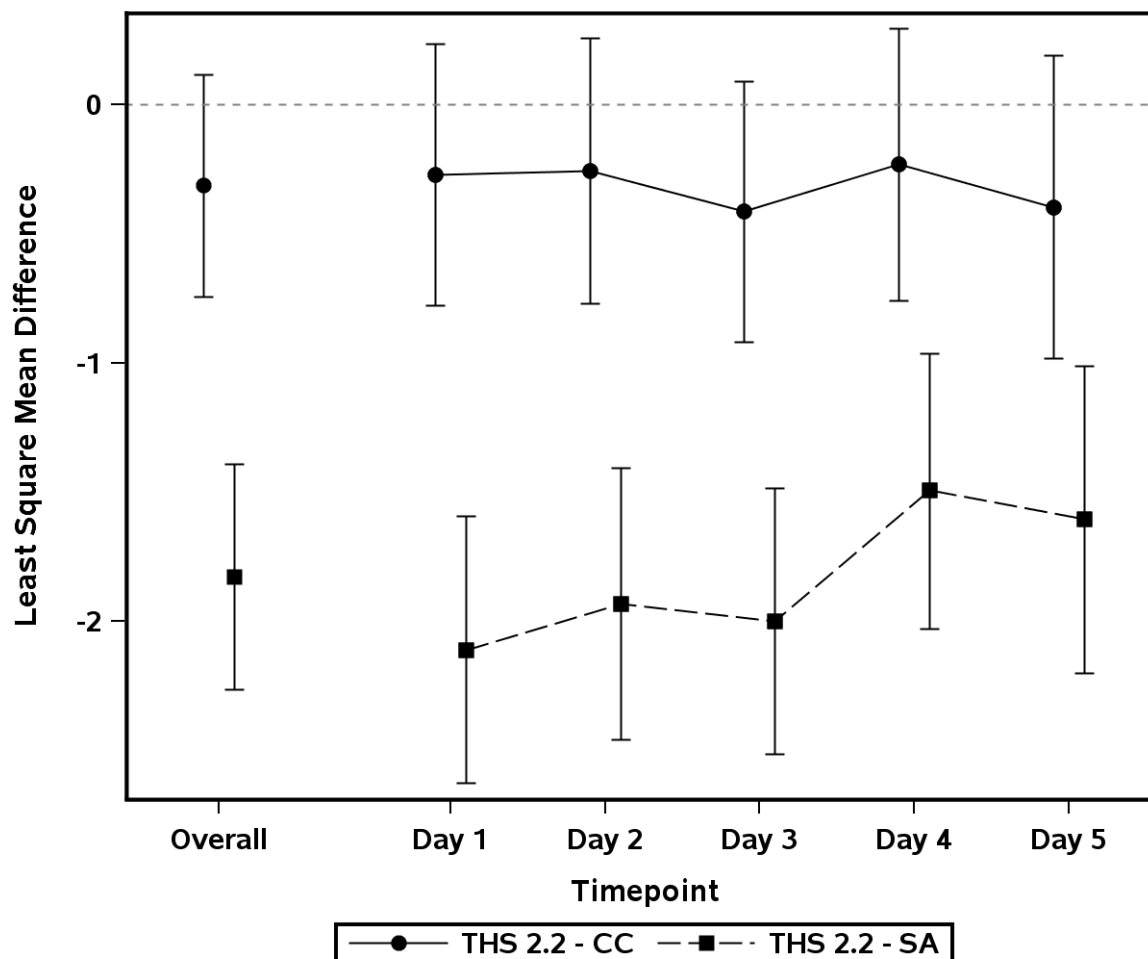
(Page 3 of 3)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



**Figure 15.1.2.34 QSU-brief Factors and Total Scores Change from Baseline
Least Squares Mean Differences and 95% CI - FAS**

Variable: Total Score



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

15.4.4.44 and 15.3.6.11

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlqsu.sas

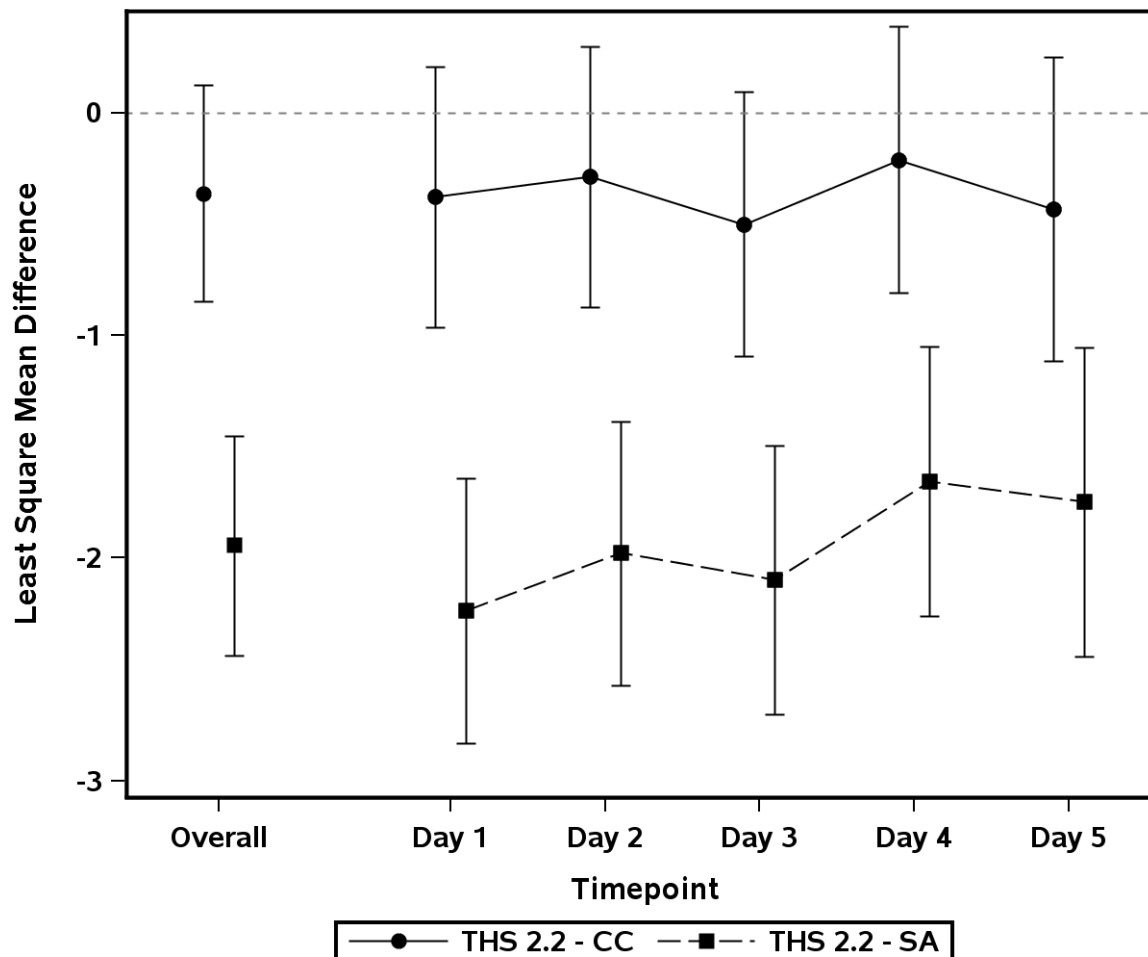
(Page 1 of 3)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL



**Figure 15.1.2.34 QSU-brief Factors and Total Scores Change from Baseline
Least Square Mean Differences and 95% CI - FAS**

Variable: Factor 1 - Reward



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

15.4.4.44 and 15.3.6.11

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlqsu.sas

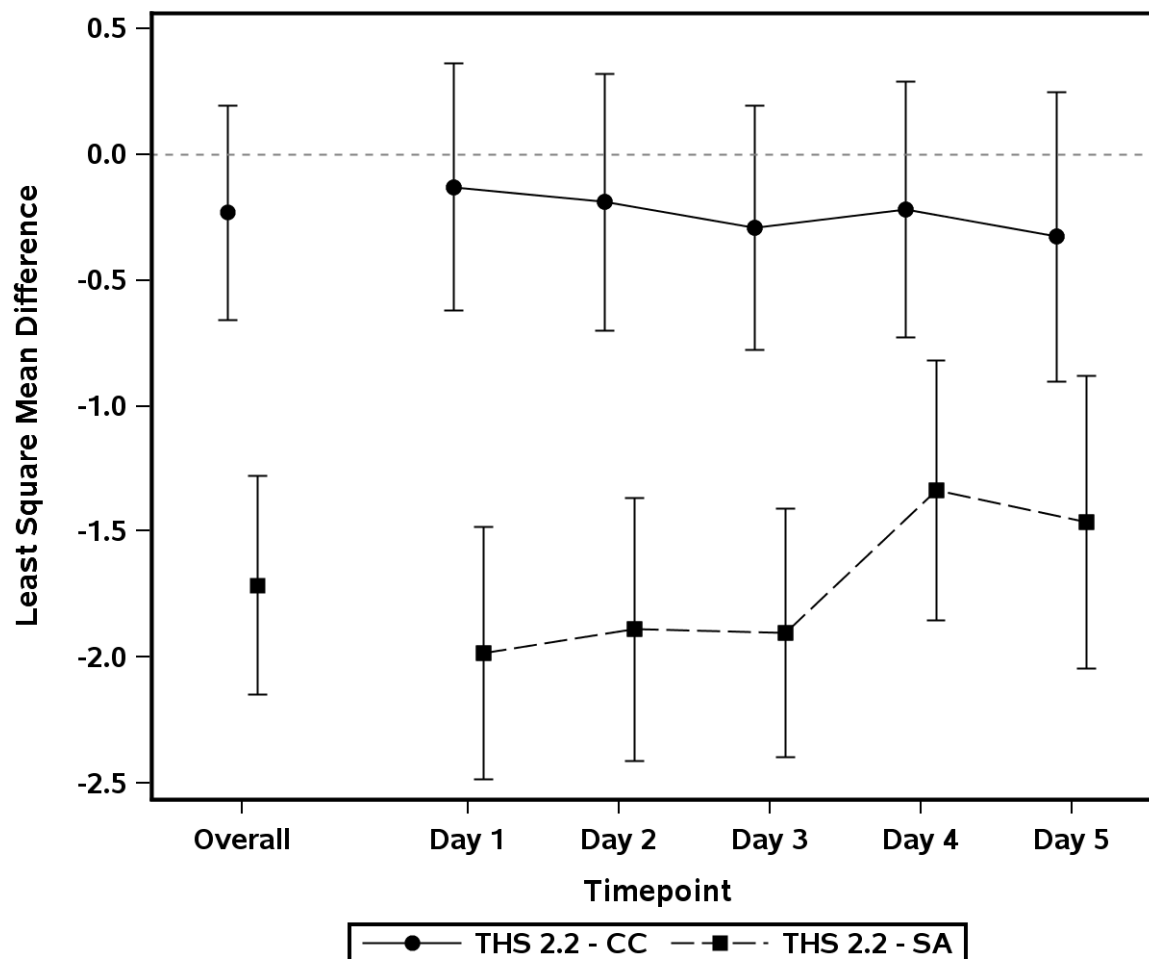
(Page 2 of 3)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL



**Figure 15.1.2.34 QSU-brief Factors and Total Scores Change from Baseline
Least Squares Mean Differences and 95% CI - FAS**

Variable: Factor 2 - Relief



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

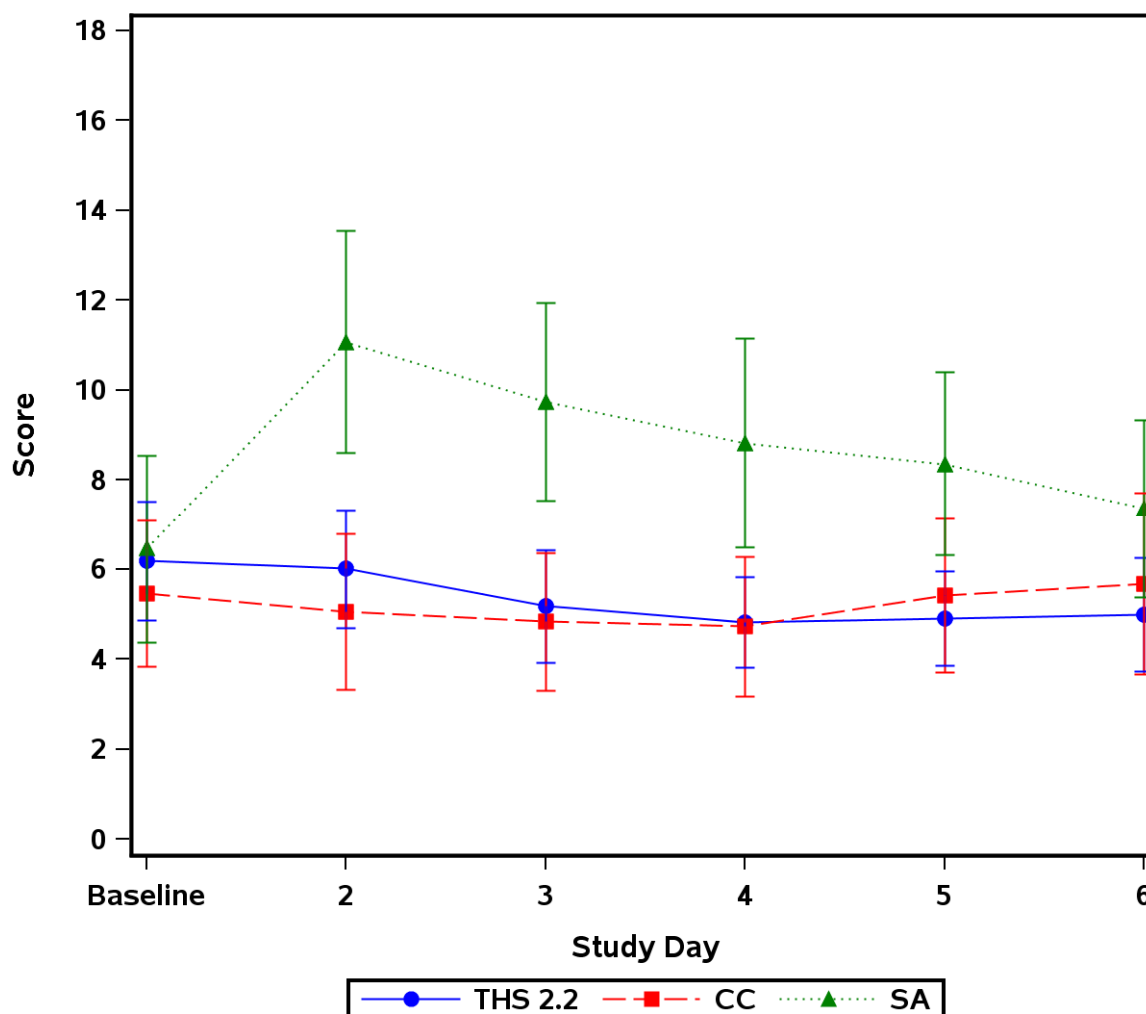
Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

15.4.4.44 and 15.3.6.11

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlqsu.sas

(Page 3 of 3)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.35 MNWS Total Scores Arithmetic Mean and 95% CI – FAS****Total Score 1**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

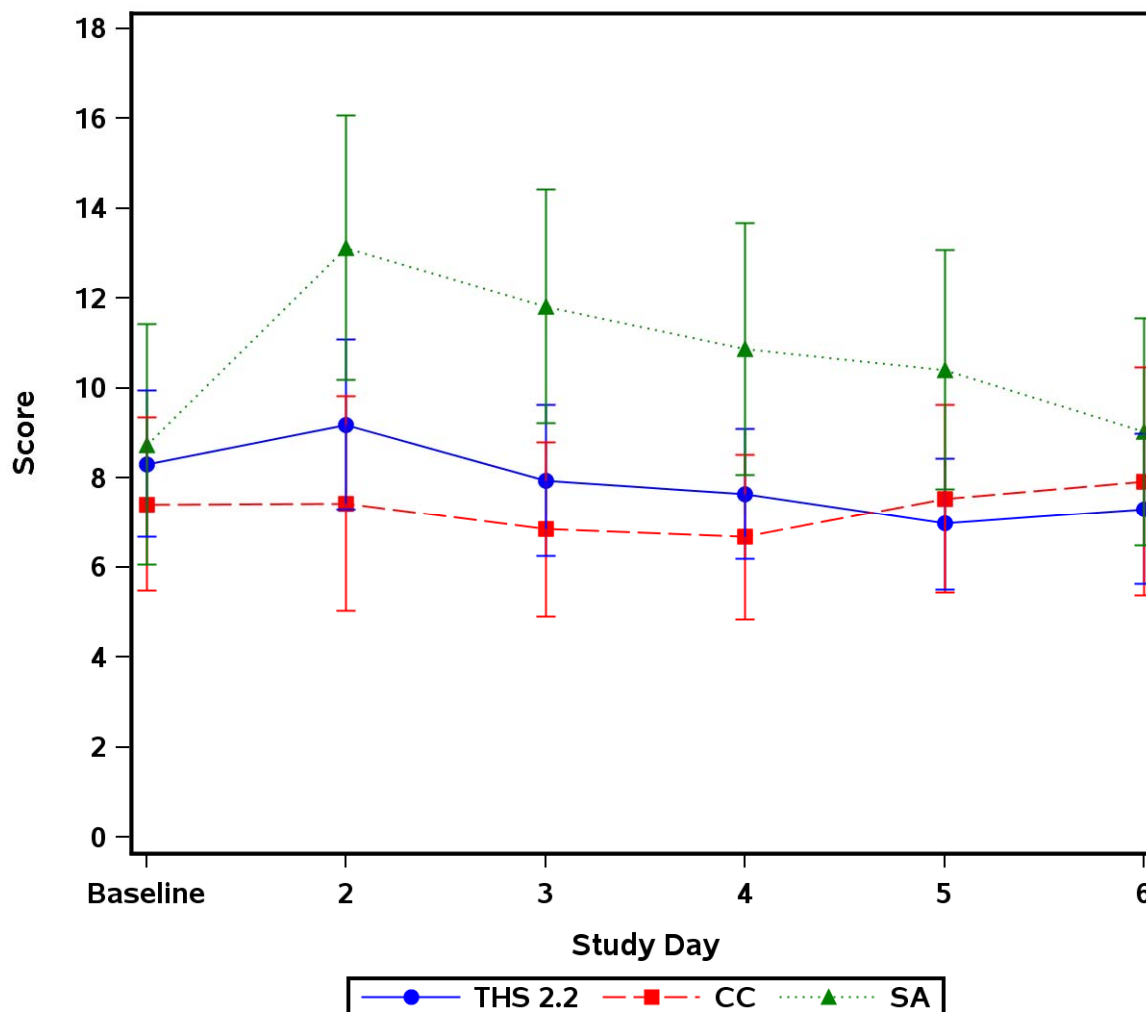
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.45

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mnws.sas

(Page 1 of 2)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.35 MNWS Total Scores Arithmetic Mean and 95% CI – FAS****Total Score 2**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.45

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mnws.sas

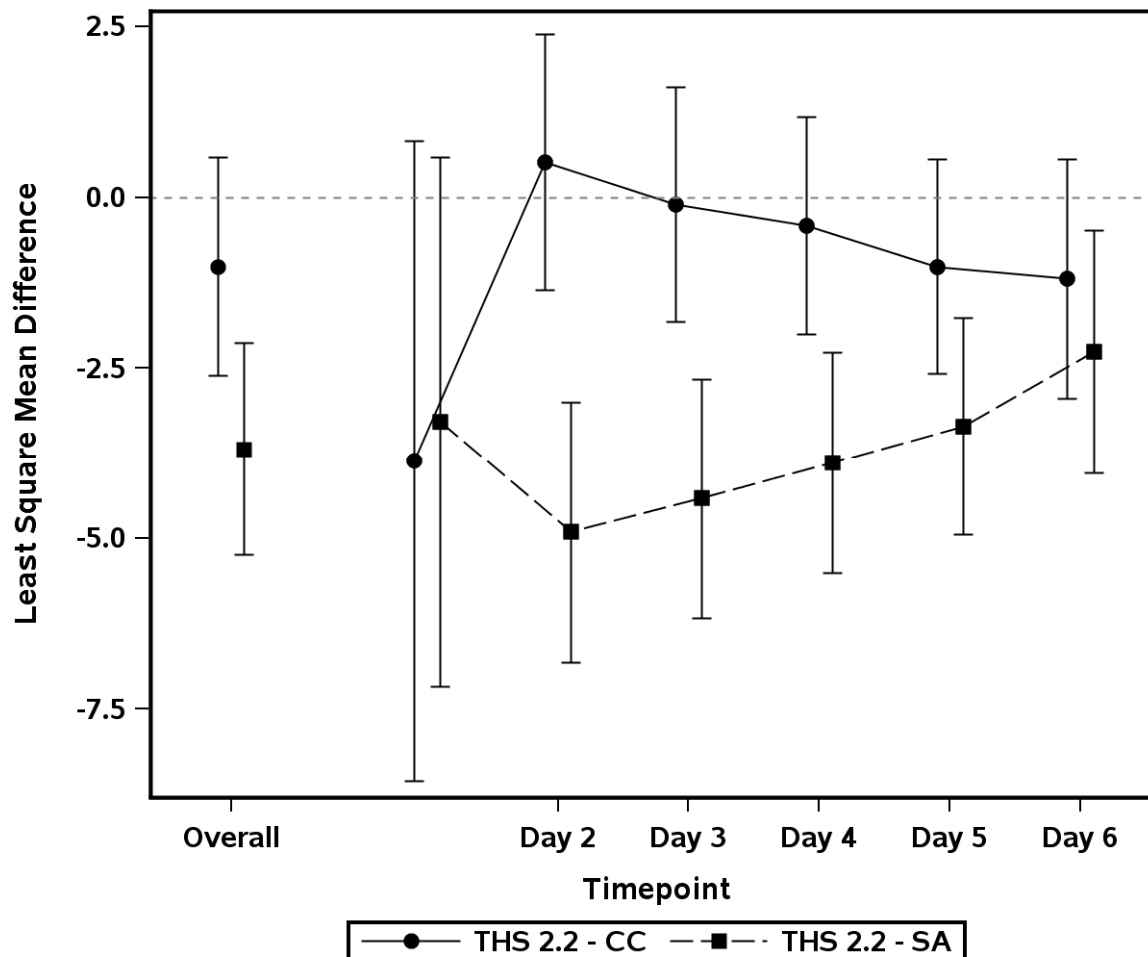
(Page 2 of 2)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.36 MNWS Total Scores Change from Baseline Least Squares Mean Differences and 95% CI - FAS

Variable: Total Score 1



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MNWS scores reported on a 5-point scale (0-4). Higher scores indicate greater intensity on that scale.

15.4.4.46 and 15.3.6.12)

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmnws.sas

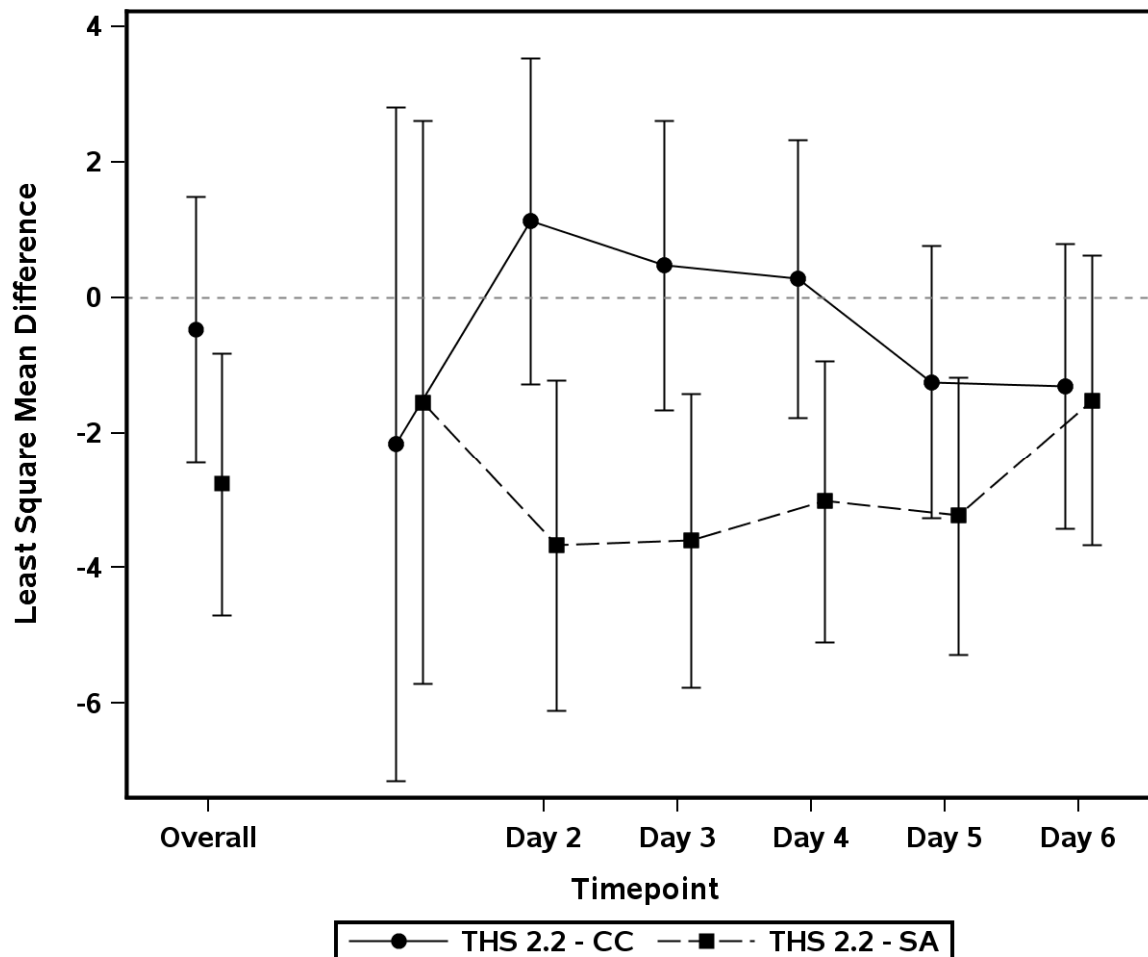
(Page 1 of 2)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.36 MNWS Total Scores Change from Baseline Least Squares Mean Differences and 95% CI - FAS

Variable: Total Score 2



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

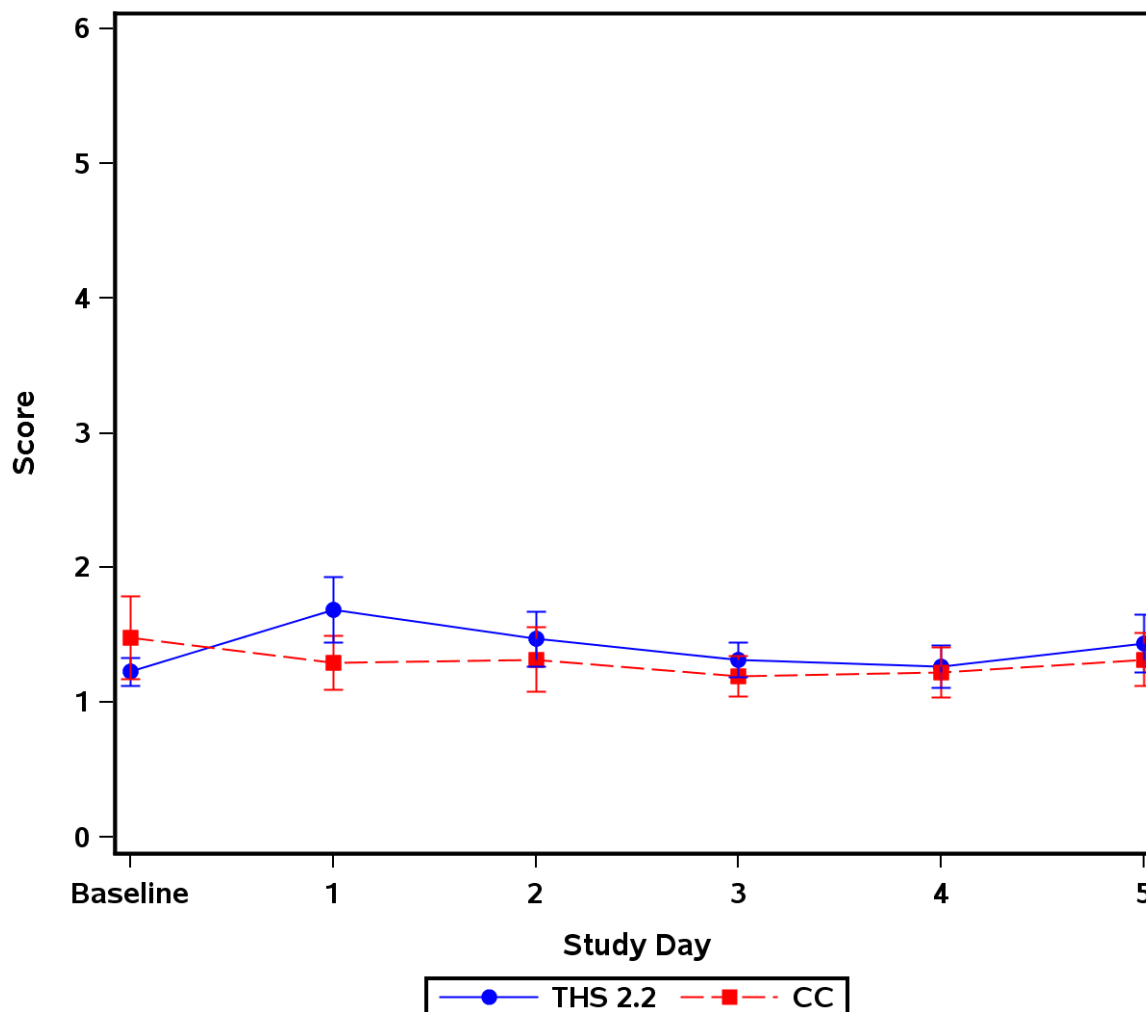
Note: MNWS scores reported on a 5-point scale (0-4). Higher scores indicate greater intensity on that scale.

15.4.4.46 and 15.3.6.12)

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmnws.sas

(Page 2 of 2)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.37 MCEQ Subscales Arithmetic Mean and 95% CI – FAS****Aversion Subscale**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

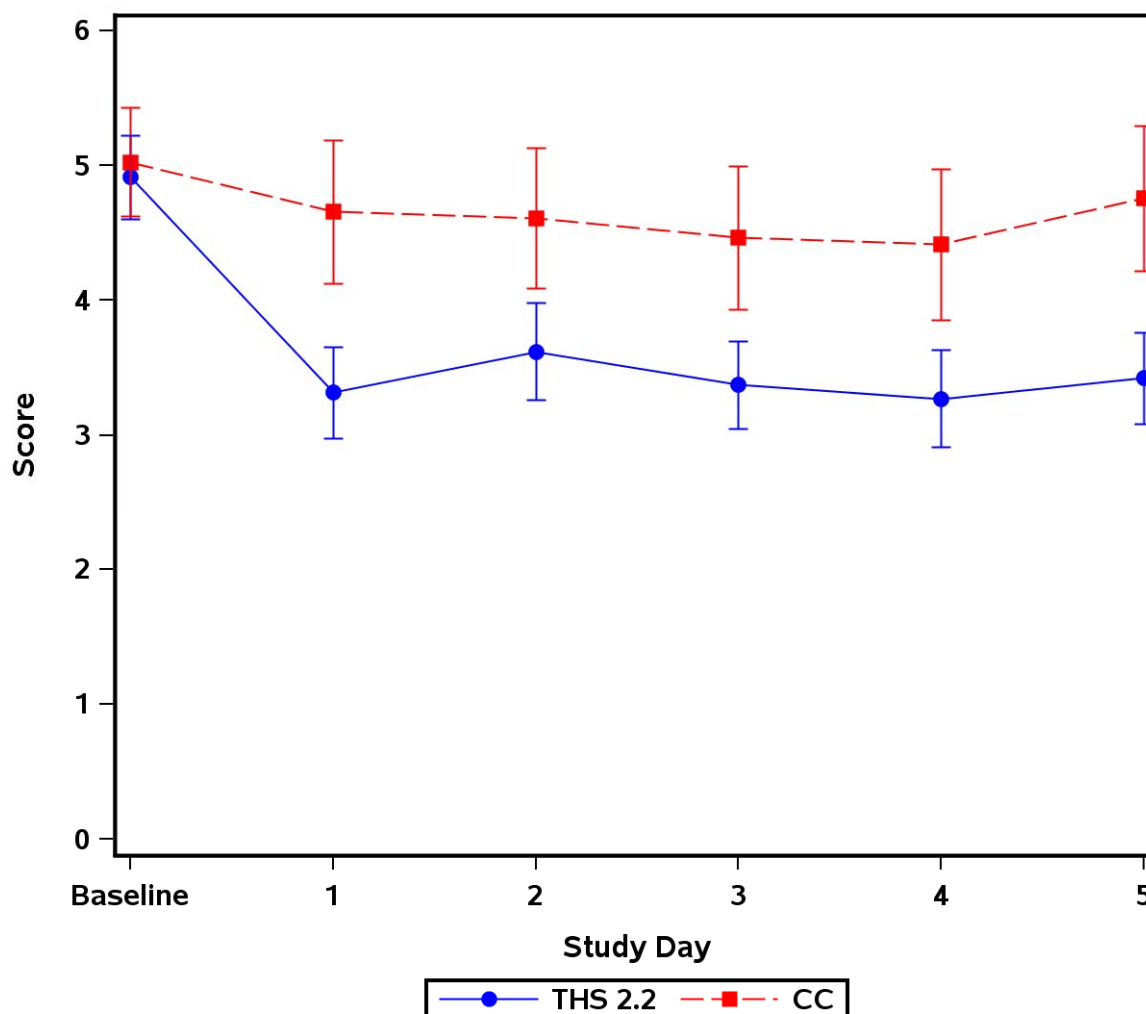
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.47

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mceq.sas

(Page 1 of 5)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.37 MCEQ Subscales Arithmetic Mean and 95% CI – FAS****Craving Reduction Subscale**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

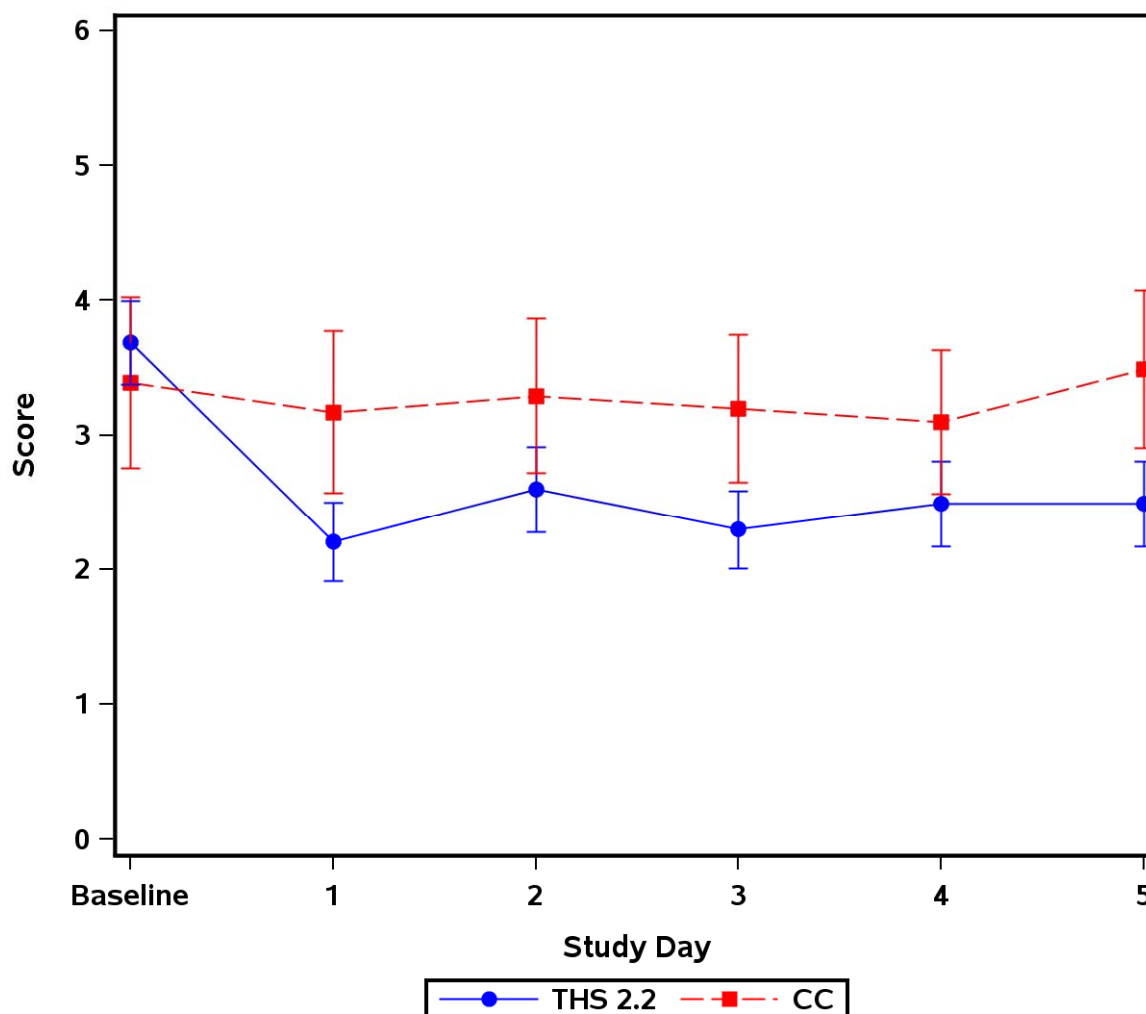
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.47

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mceq.sas

(Page 2 of 5)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.37 MCEQ Subscales Arithmetic Mean and 95% CI – FAS****Enjoyment of Respiratory Tract Sensation Subscale**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

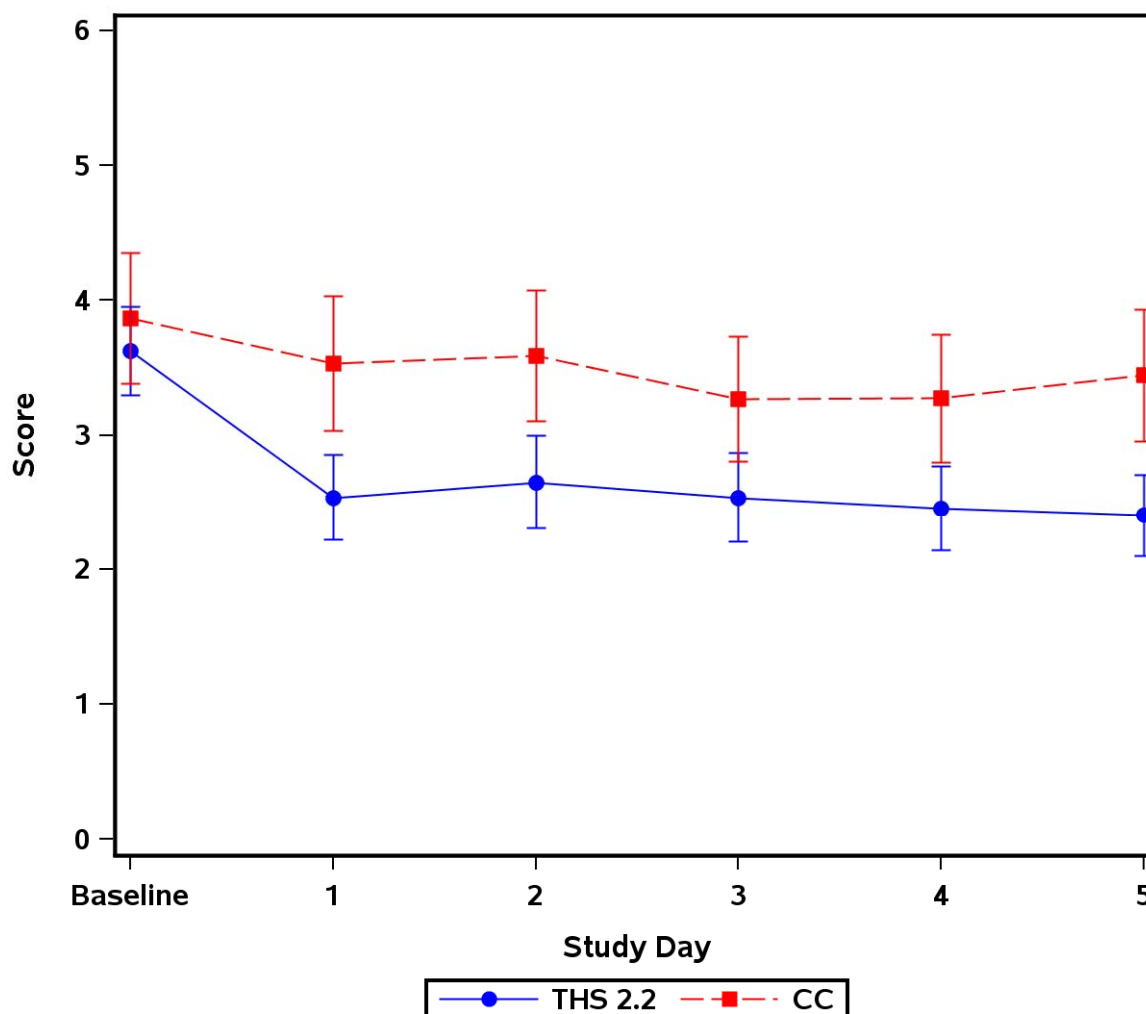
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.47

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mceq.sas

(Page 3 of 5)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.37 MCEQ Subscales Arithmetic Mean and 95% CI – FAS****Psychological Reward Subscale**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

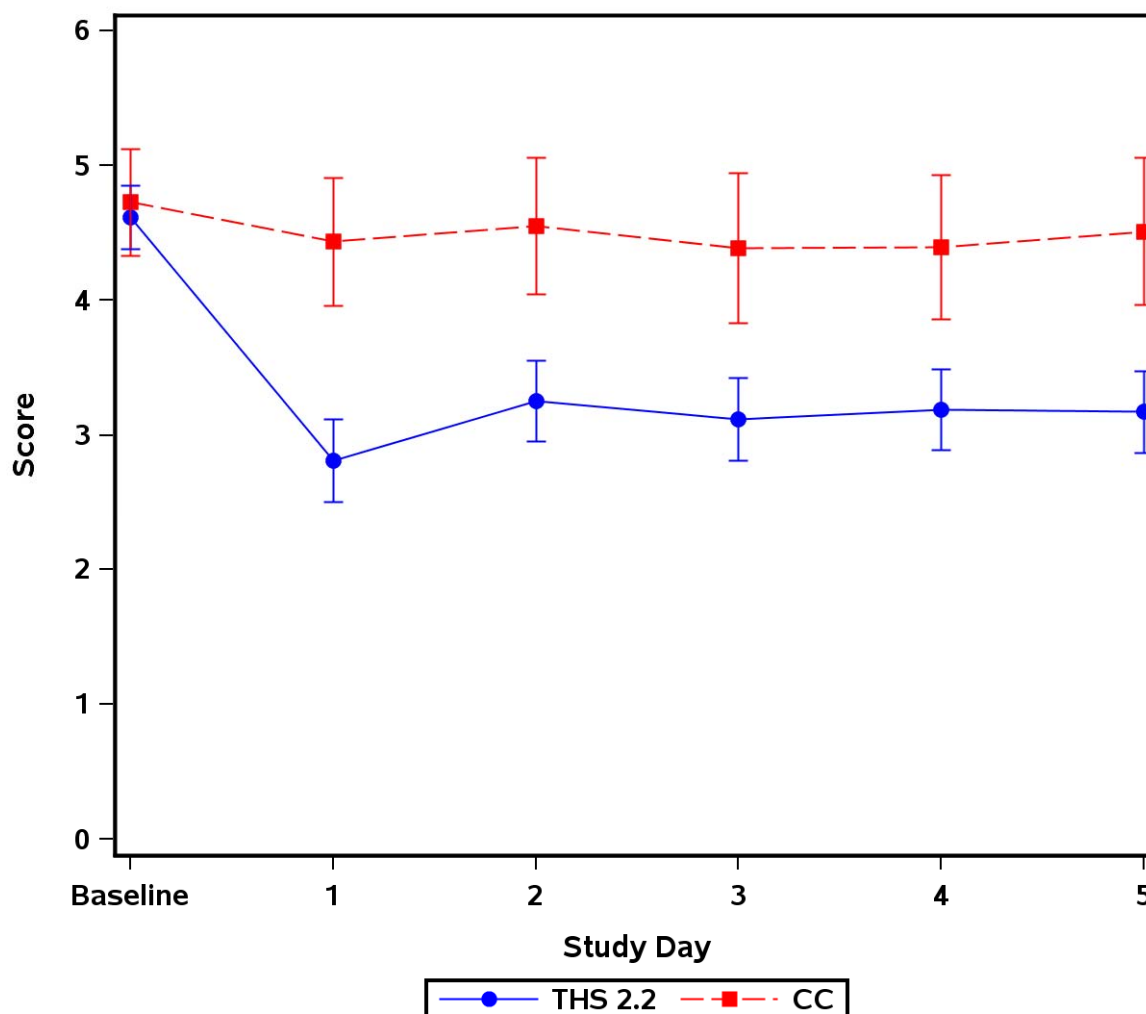
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.47

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mceq.sas

(Page 4 of 5)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.37 MCEQ Subscales Arithmetic Mean and 95% CI – FAS****Smoking Satisfaction Subscale**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

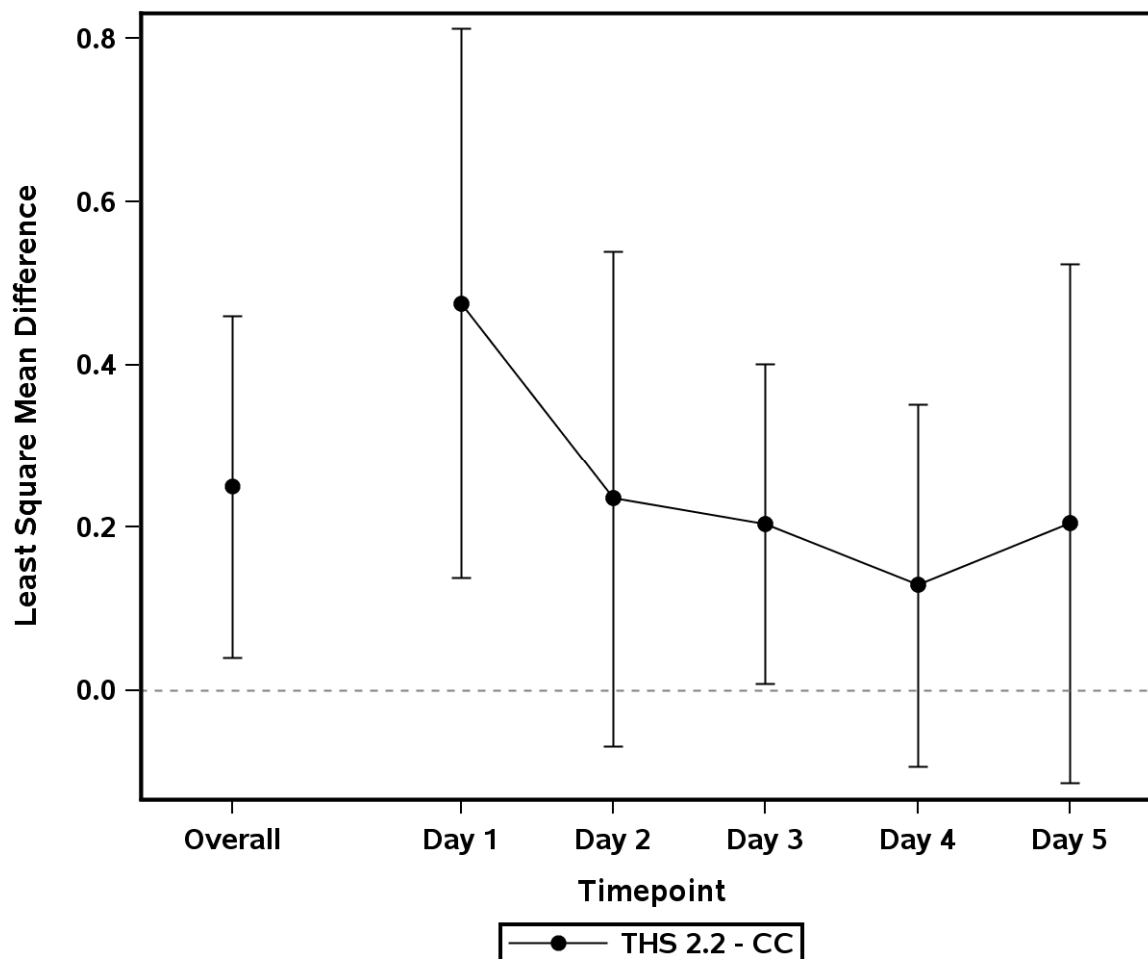
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.47

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_mceq.sas

(Page 5 of 5)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.38 MCEQ Subscales Change from Baseline Least Squares Mean Differences and 95% CI - FAS****Variable: Aversion Subscale**

Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

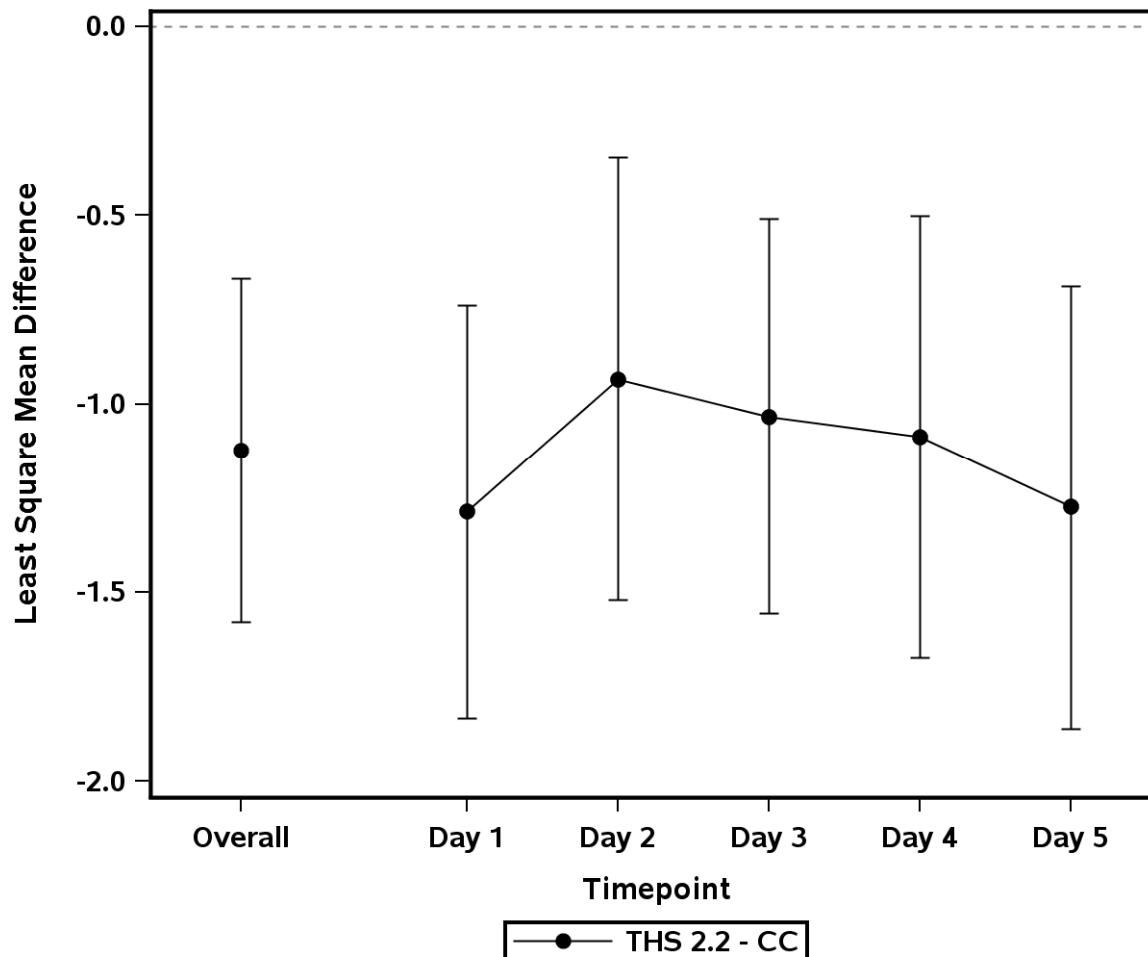
Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MCEQ subscales reported on a 7-point scale (1-7). Higher scores indicate greater intensity on that scale. 15.4.4.48 and 15.3.6.13

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmceq.sas

(Page 1 of 5)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.38 MCEQ Subscales Change from Baseline Least Squares Mean Differences and 95% CI - FAS****Variable: Craving Reduction Subscale**

Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

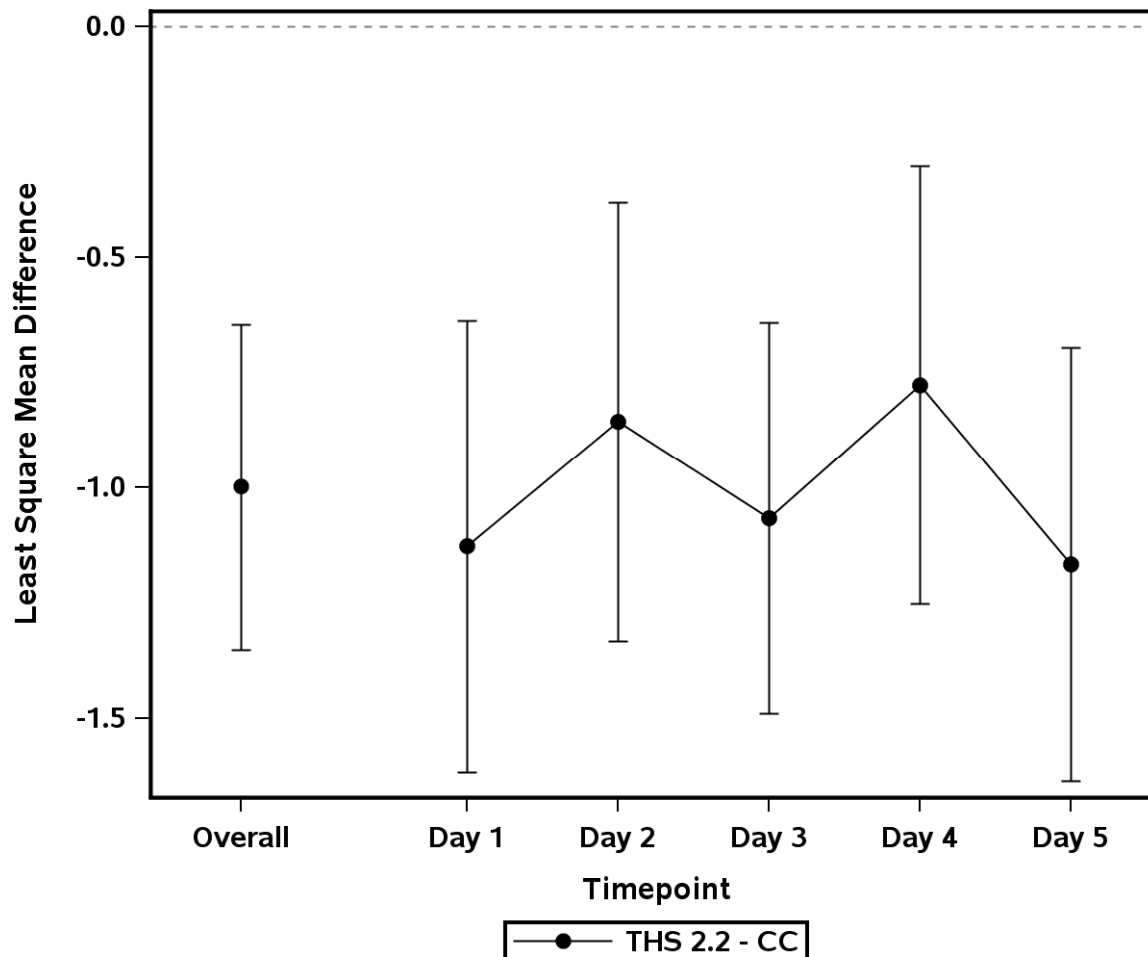
Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MCEQ subscales reported on a 7-point scale (1-7). Higher scores indicate greater intensity on that scale. 15.4.4.48 and 15.3.6.13

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmceq.sas

(Page 2 of 5)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.38 MCEQ Subscales Change from Baseline Least Squares Mean Differences and 95% CI - FAS****Variable: Enjoyment of Respiratory Tract Sensation Subscale**

Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MCEQ subscales reported on a 7-point scale (1-7). Higher scores indicate greater intensity on that scale. 15.4.4.48 and 15.3.6.13

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmceq.sas

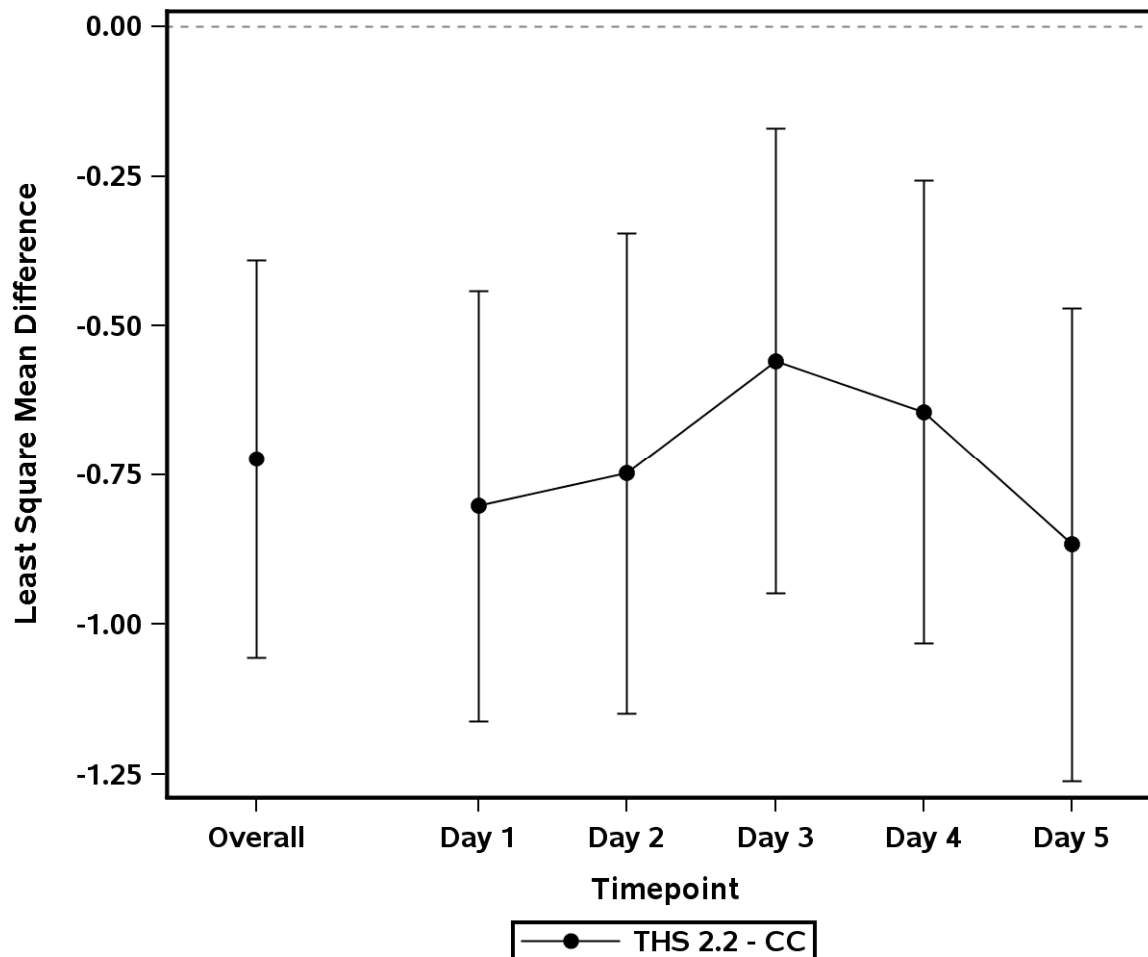
(Page 3 of 5)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.38 MCEQ Subscales Change from Baseline Least Squares Mean Differences and 95% CI - FAS

Variable: Psychological Reward Subscale



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

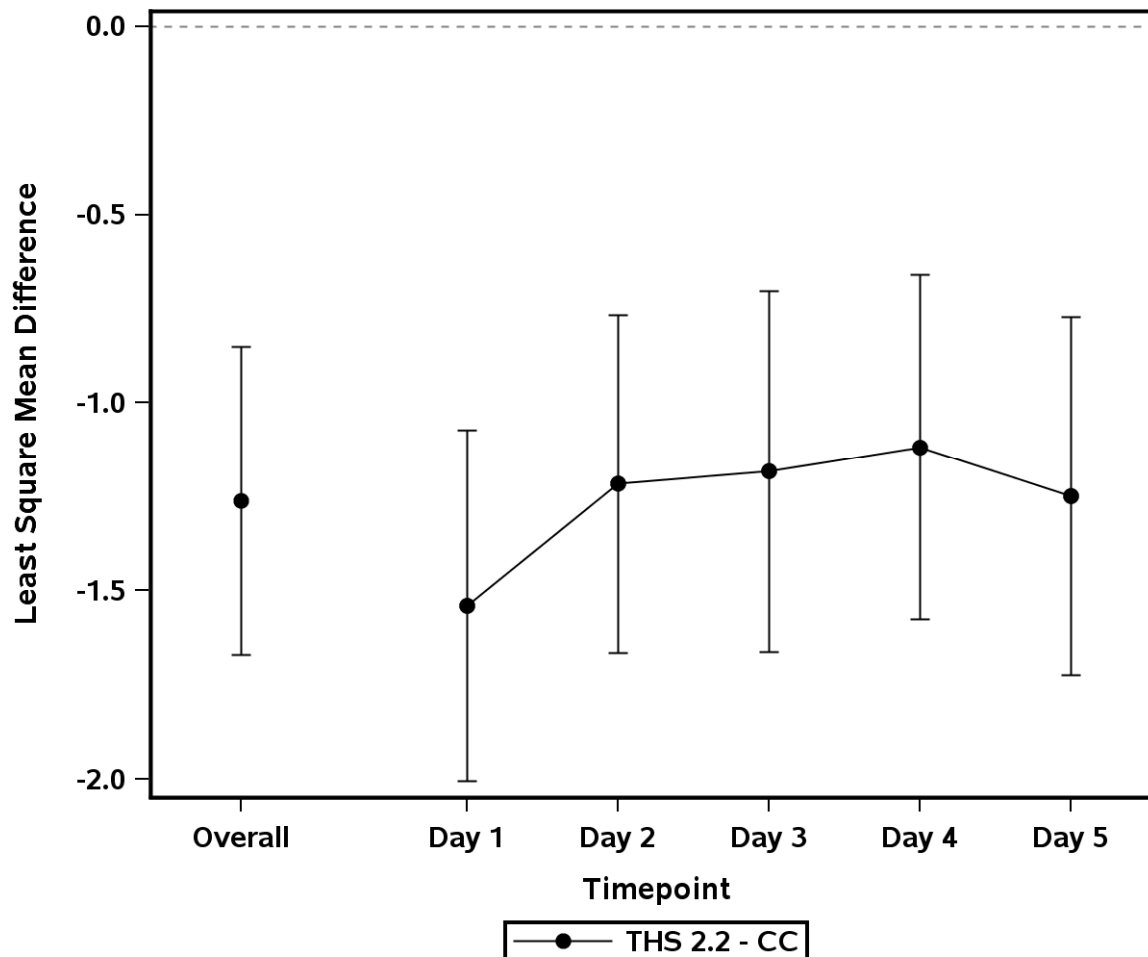
Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MCEQ subscales reported on a 7-point scale (1-7). Higher scores indicate greater intensity on that scale. 15.4.4.48 and 15.3.6.13

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmceq.sas

(Page 4 of 5)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.38 MCEQ Subscales Change from Baseline Least Squares Mean Differences and 95% CI - FAS****Variable: Smoking Satisfaction Subscale**

Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

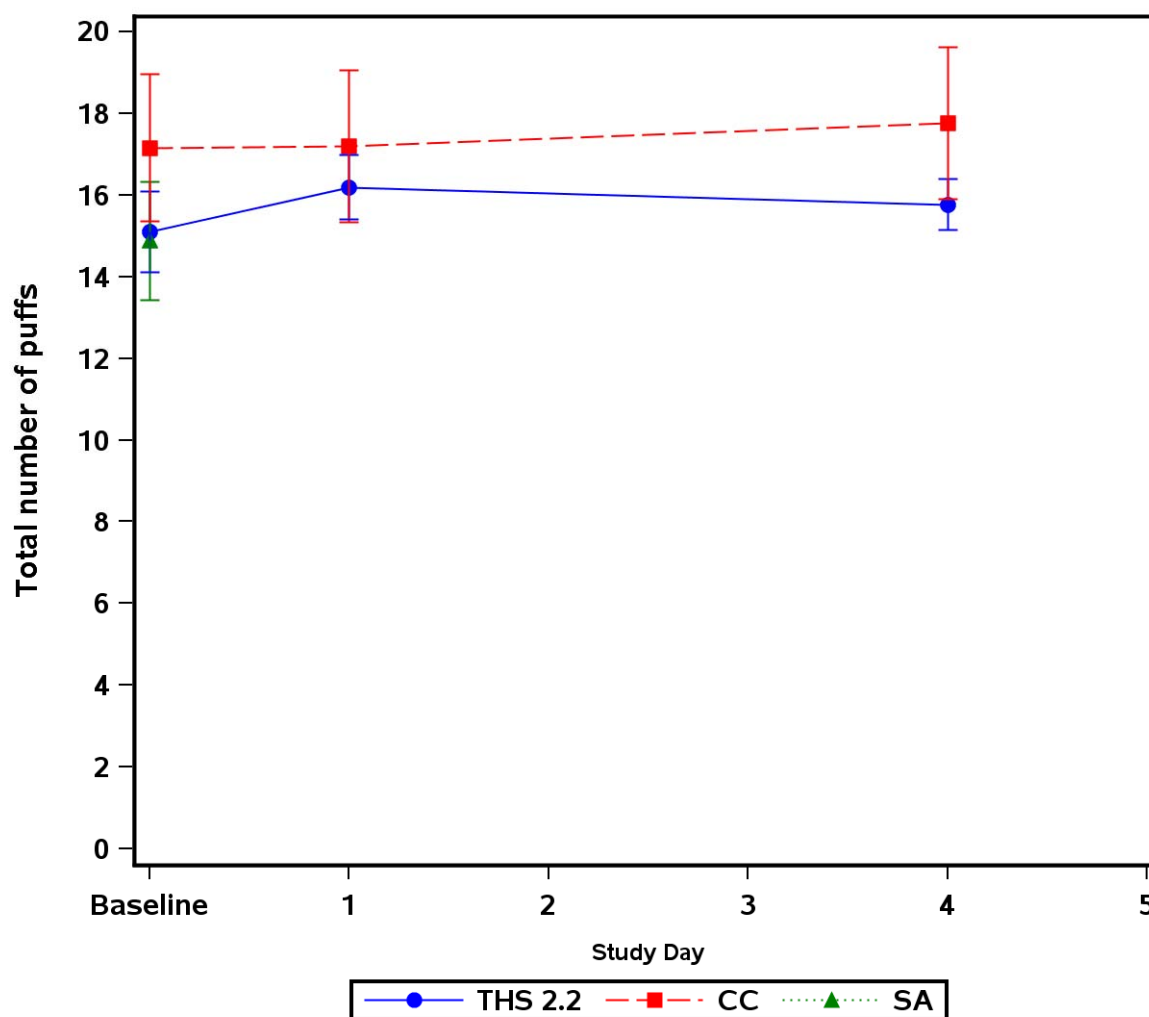
Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model with study arm, sex, CC consumption reported at screening, day and study arm*day fitted as fixed effect factors with baseline fitted as a covariate. Day fitted as a repeated factor.

Note: MCEQ subscales reported on a 7-point scale (1-7). Higher scores indicate greater intensity on that scale. 15.4.4.48 and 15.3.6.13

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlmceq.sas

(Page 5 of 5)

Program Run: 27OCT14 cvn_ahedge Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total number of puffs (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

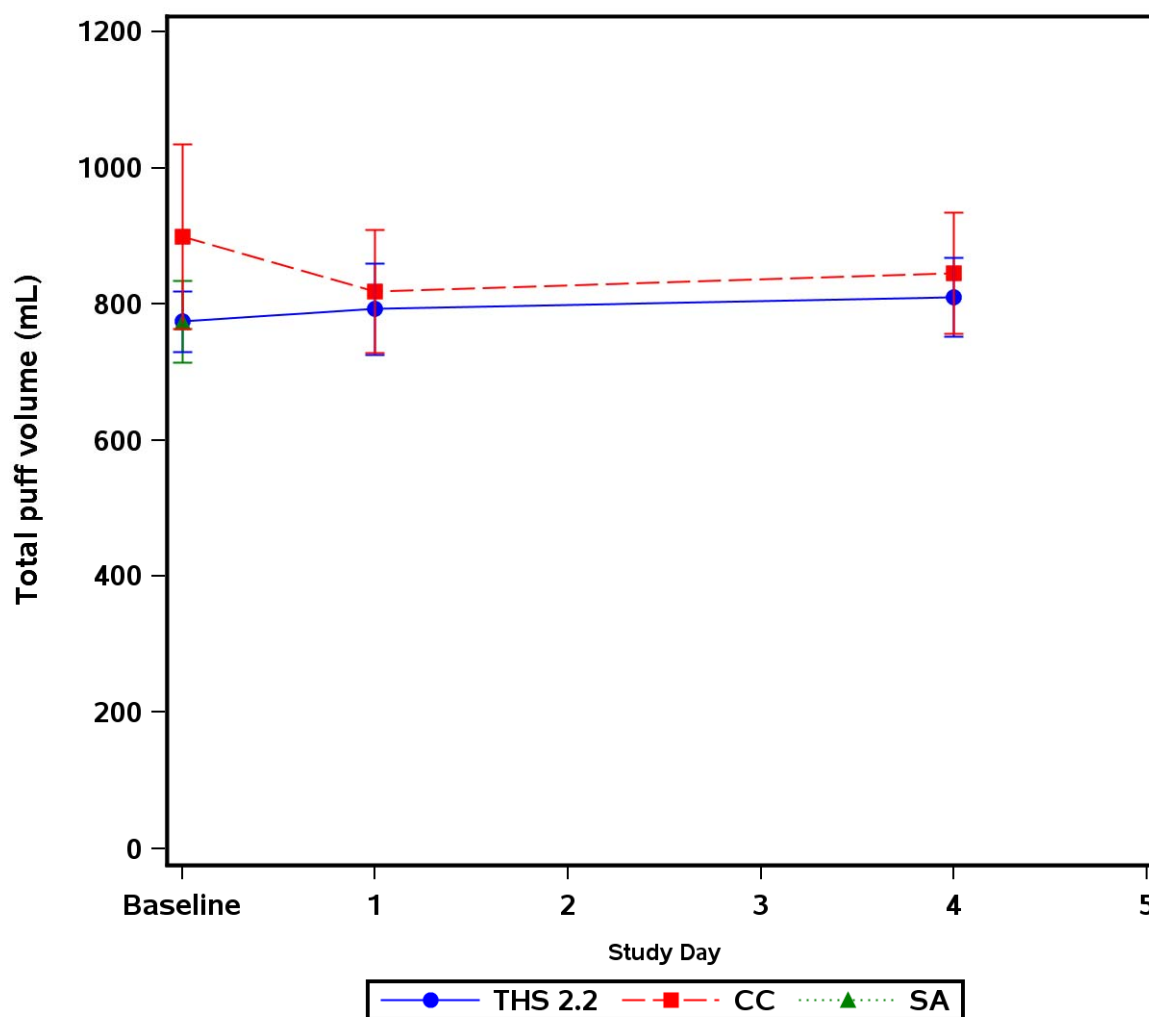
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 1 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total puff volume (mL) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

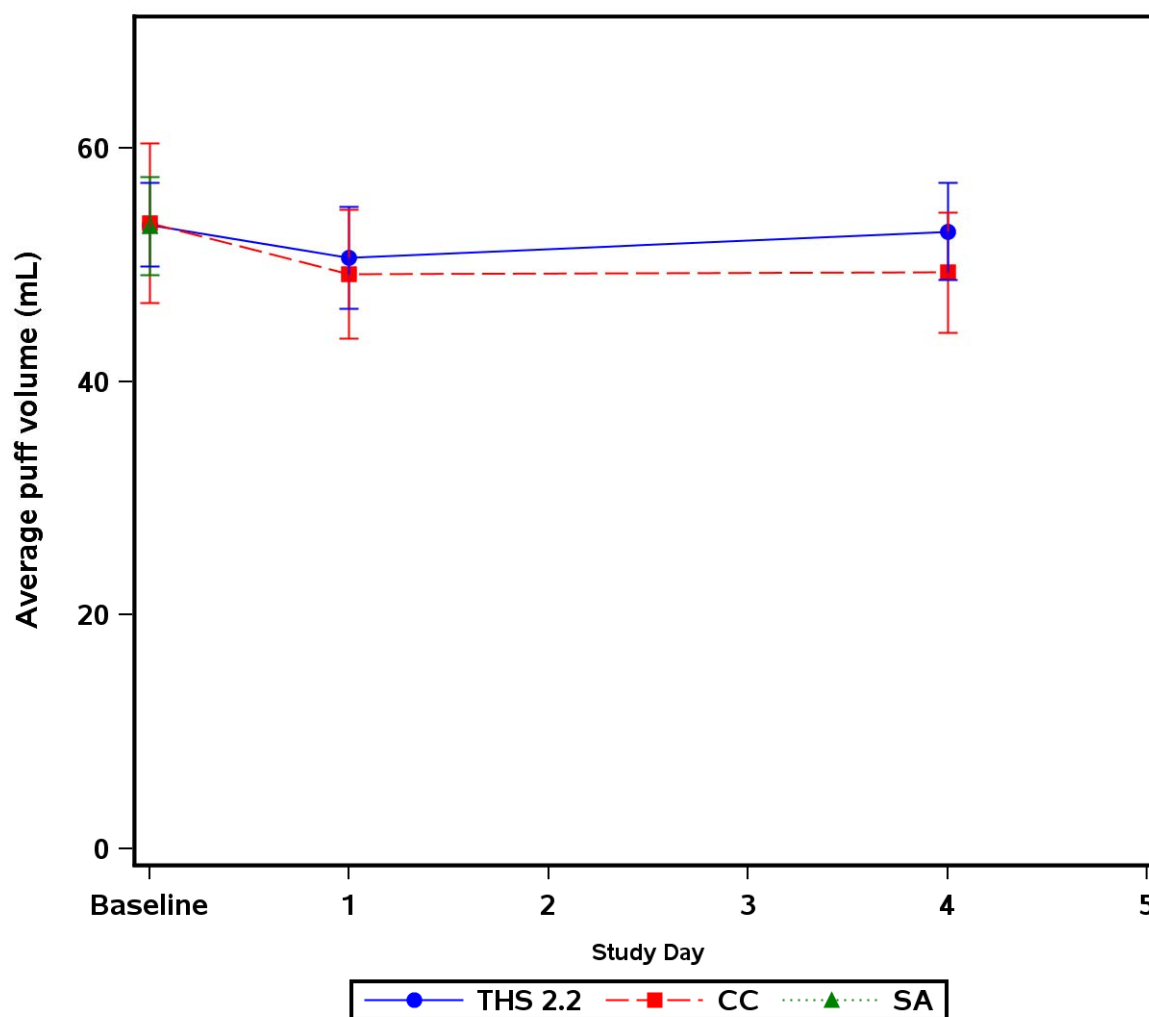
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 2 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average puff volume (mL) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

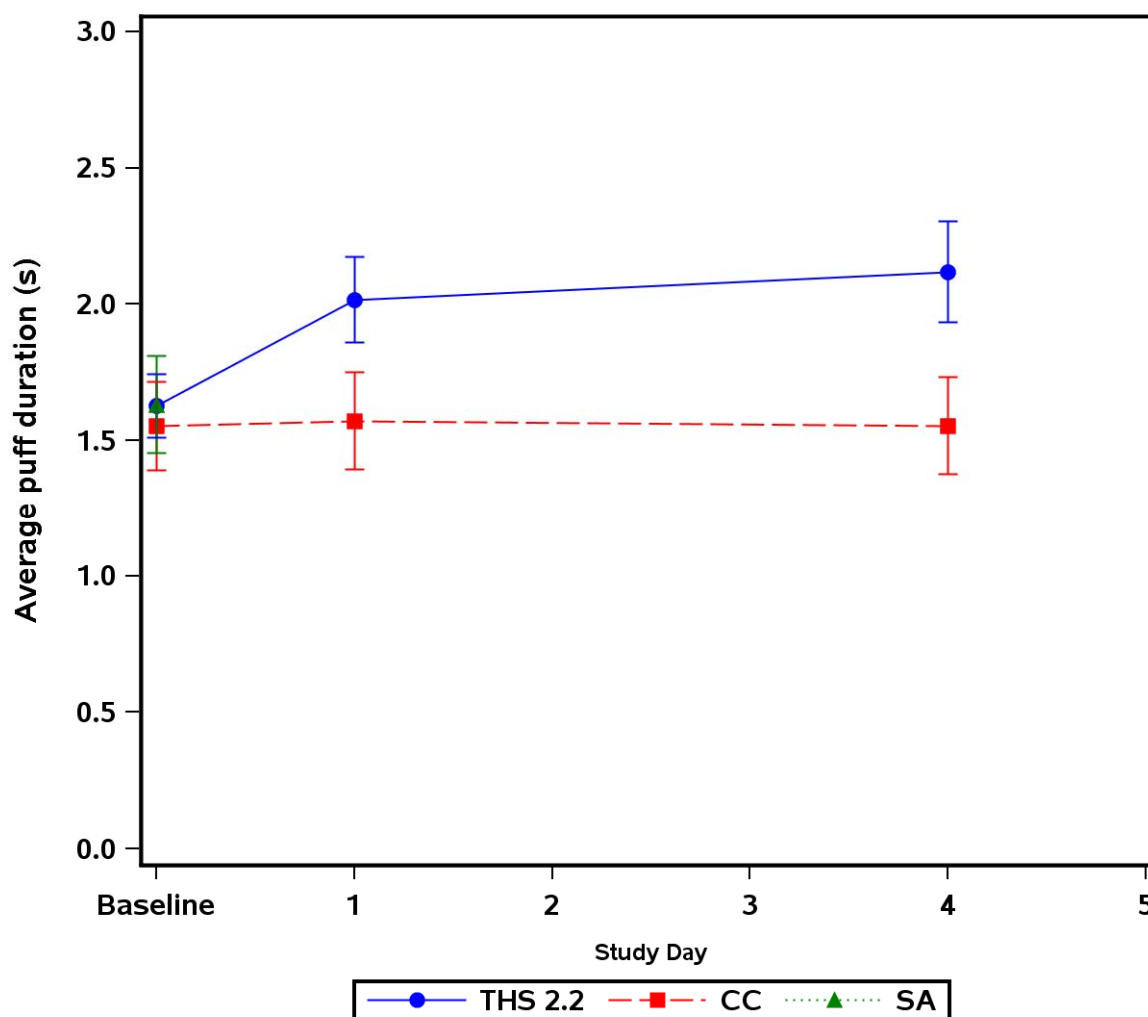
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 3 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average puff duration (s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

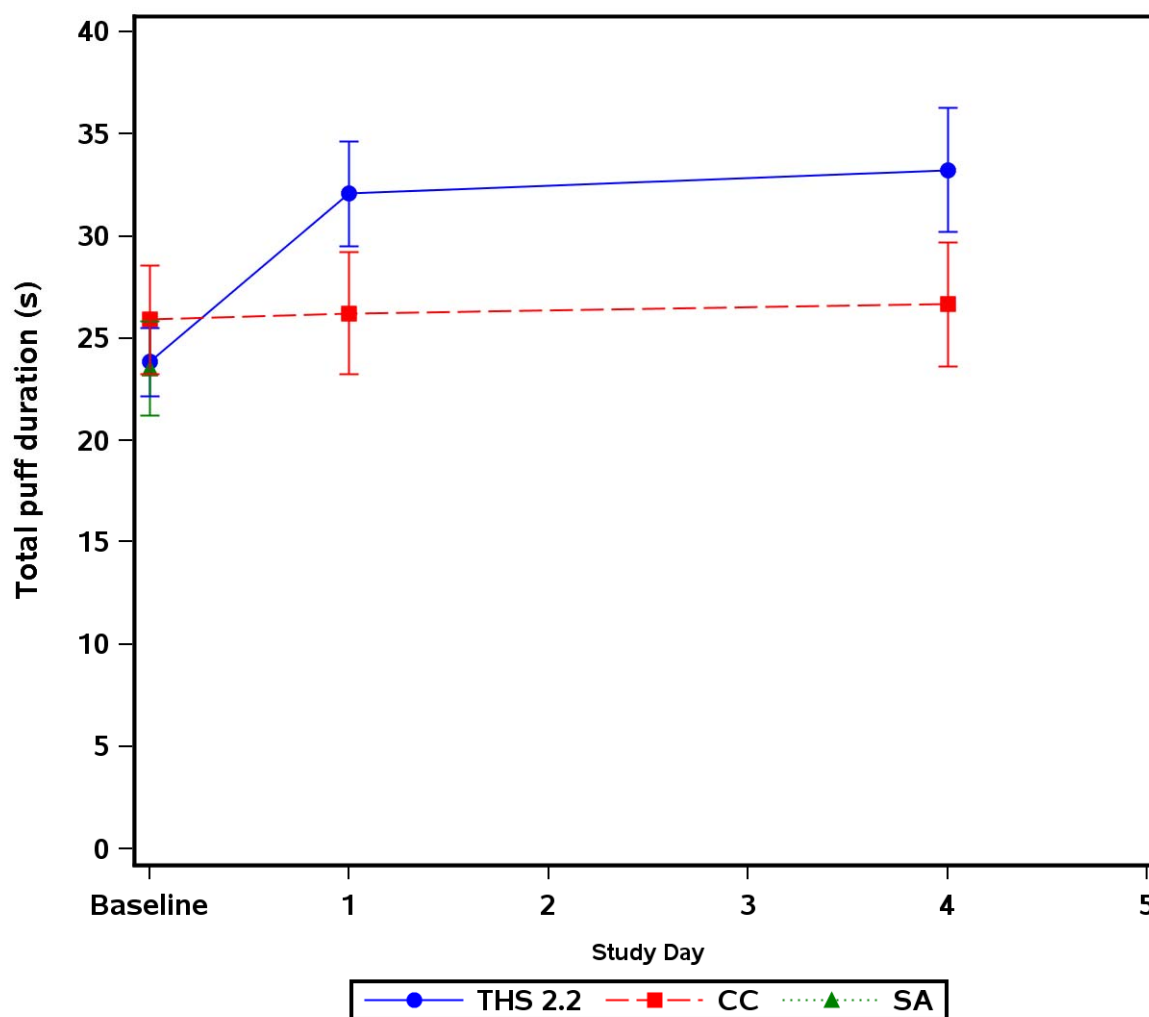
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 4 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total puff duration (s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

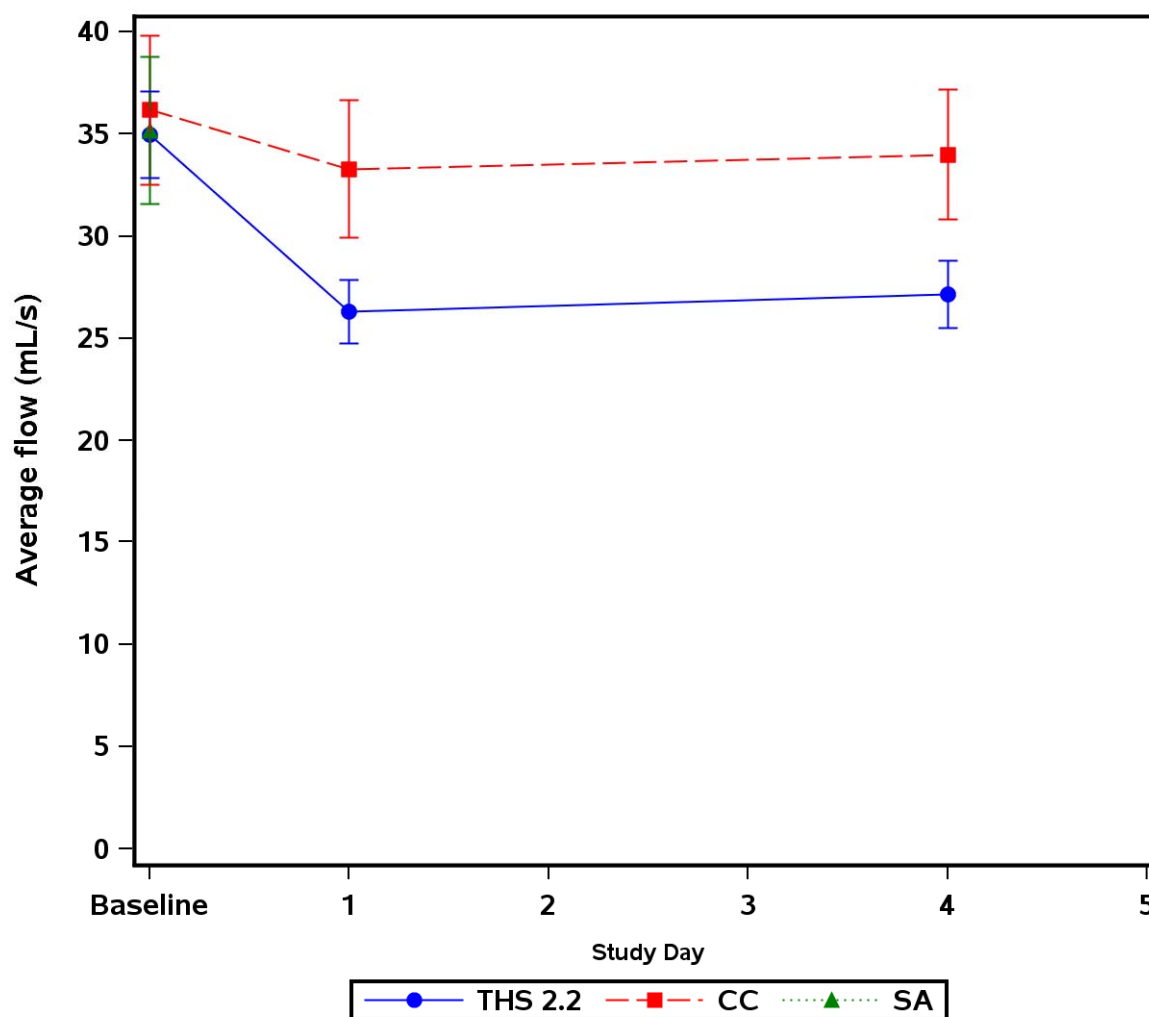
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 5 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average flow (mL/s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

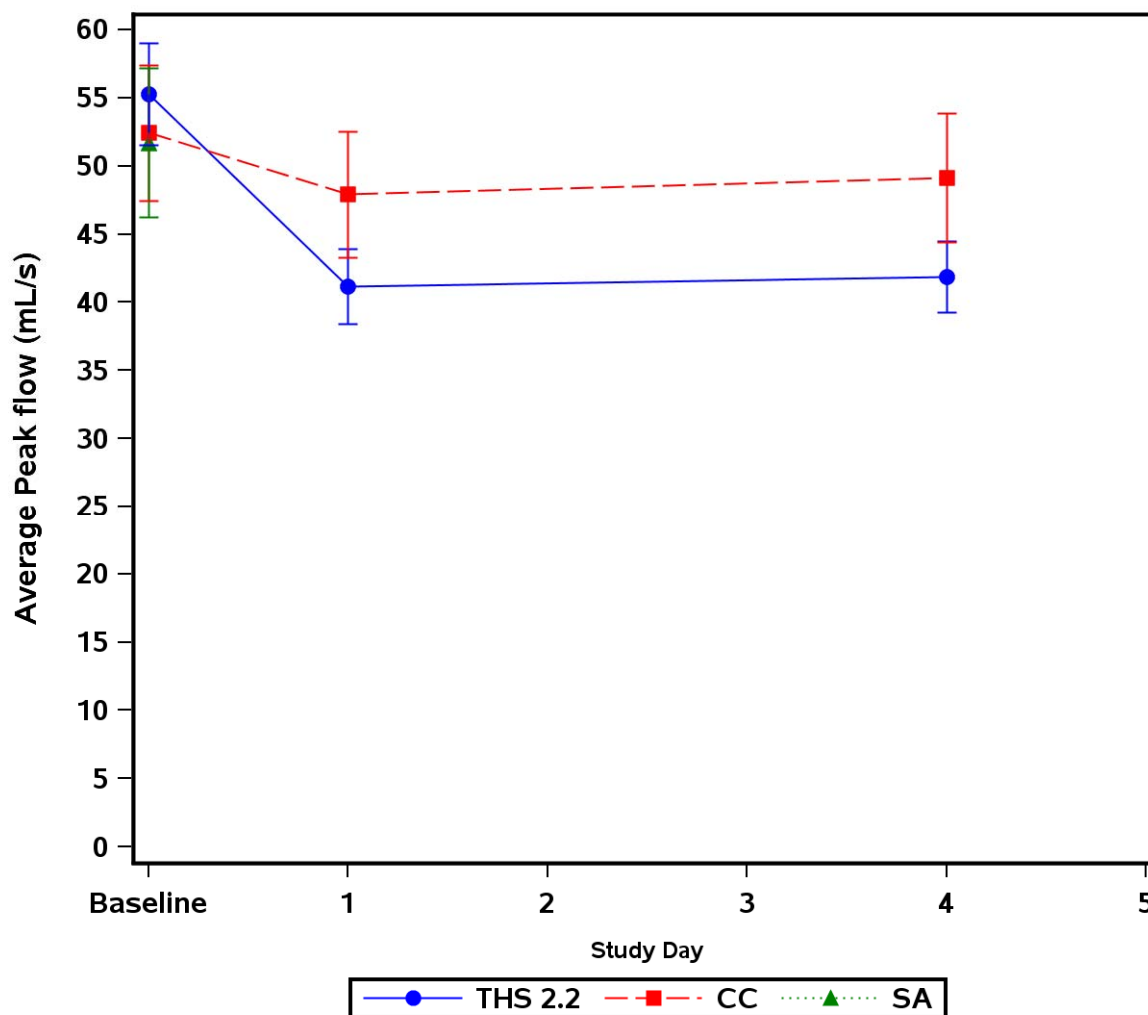
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 6 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average peak flow (mL/s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

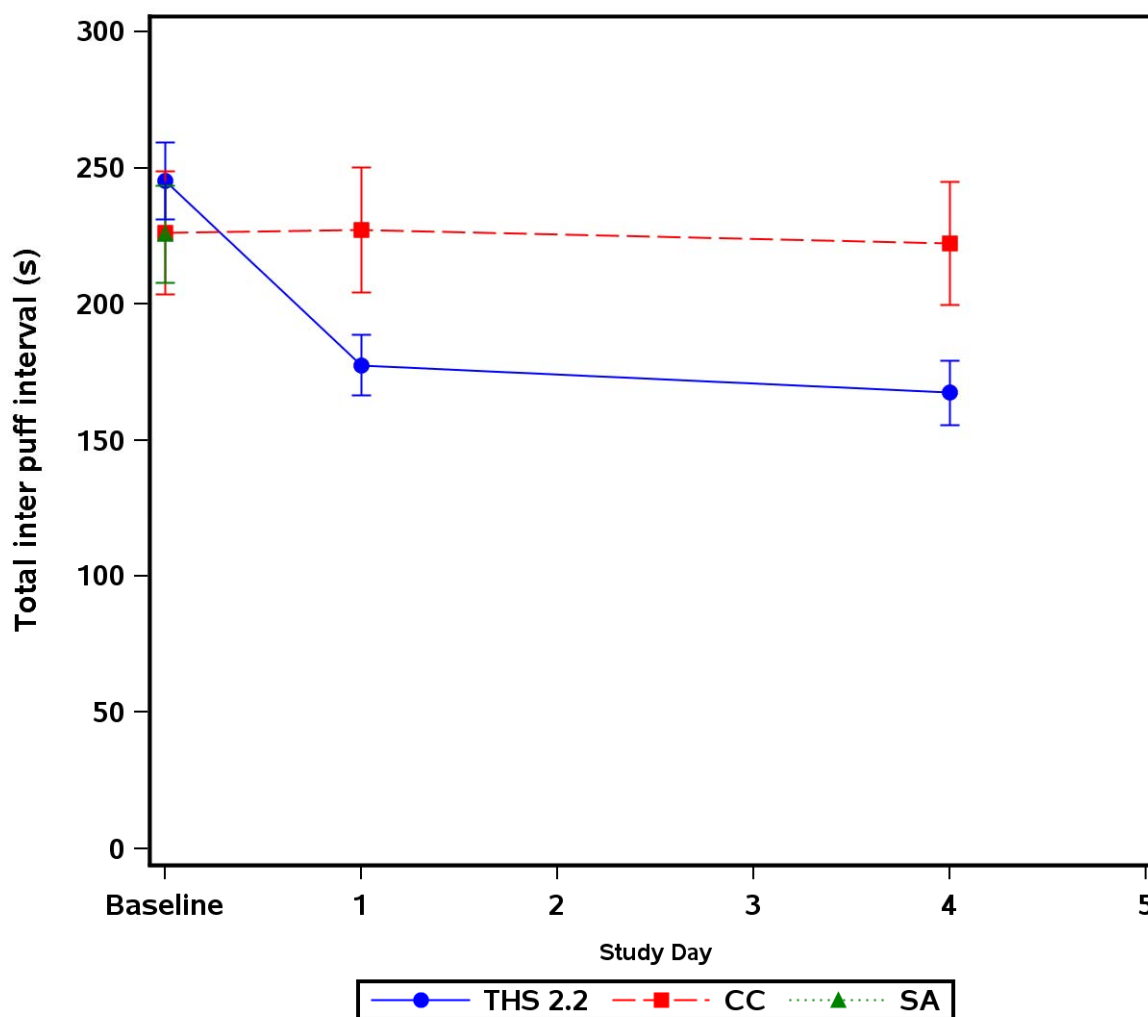
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 7 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total inter puff interval (s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

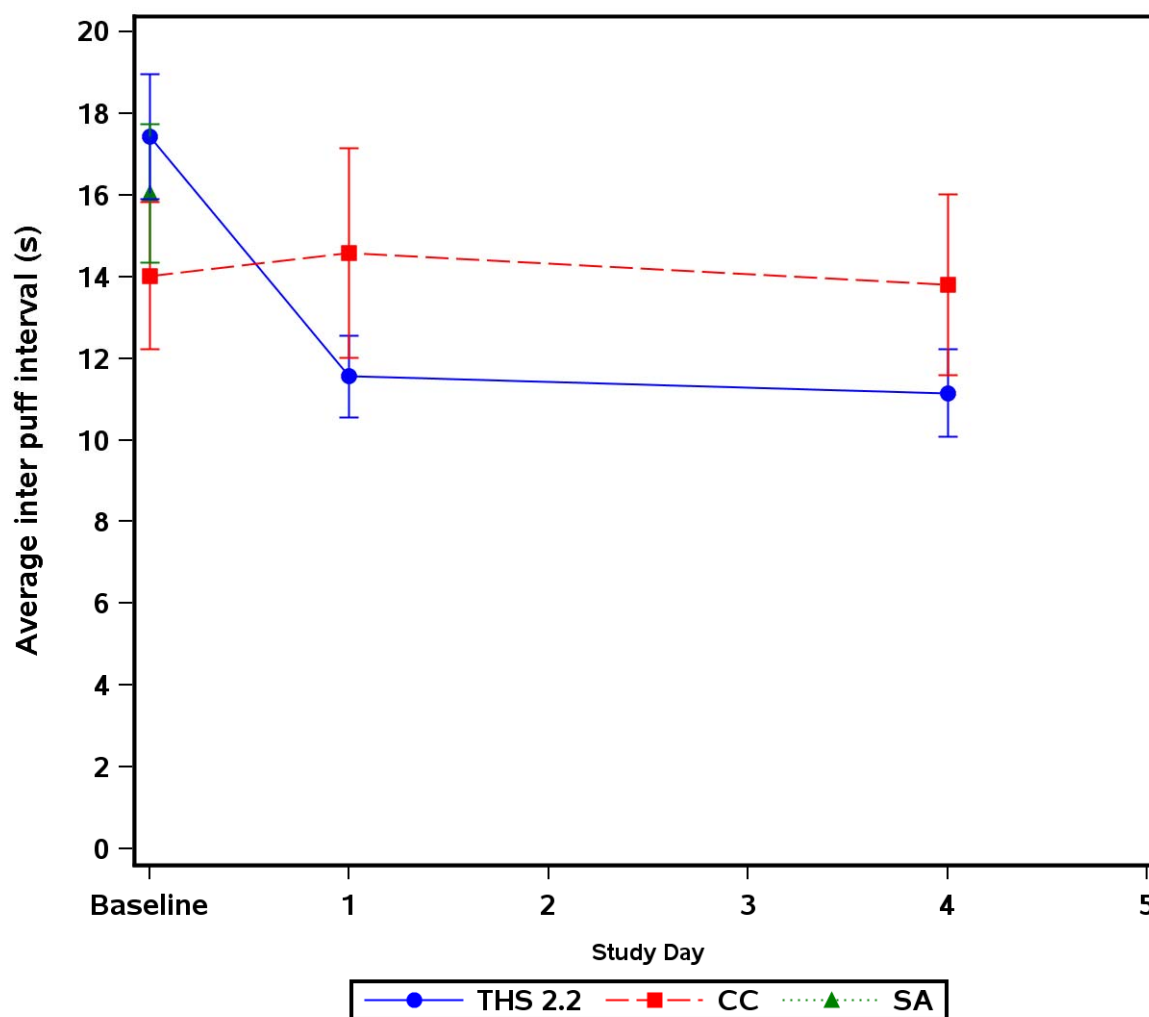
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 8 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average inter puff interval (s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

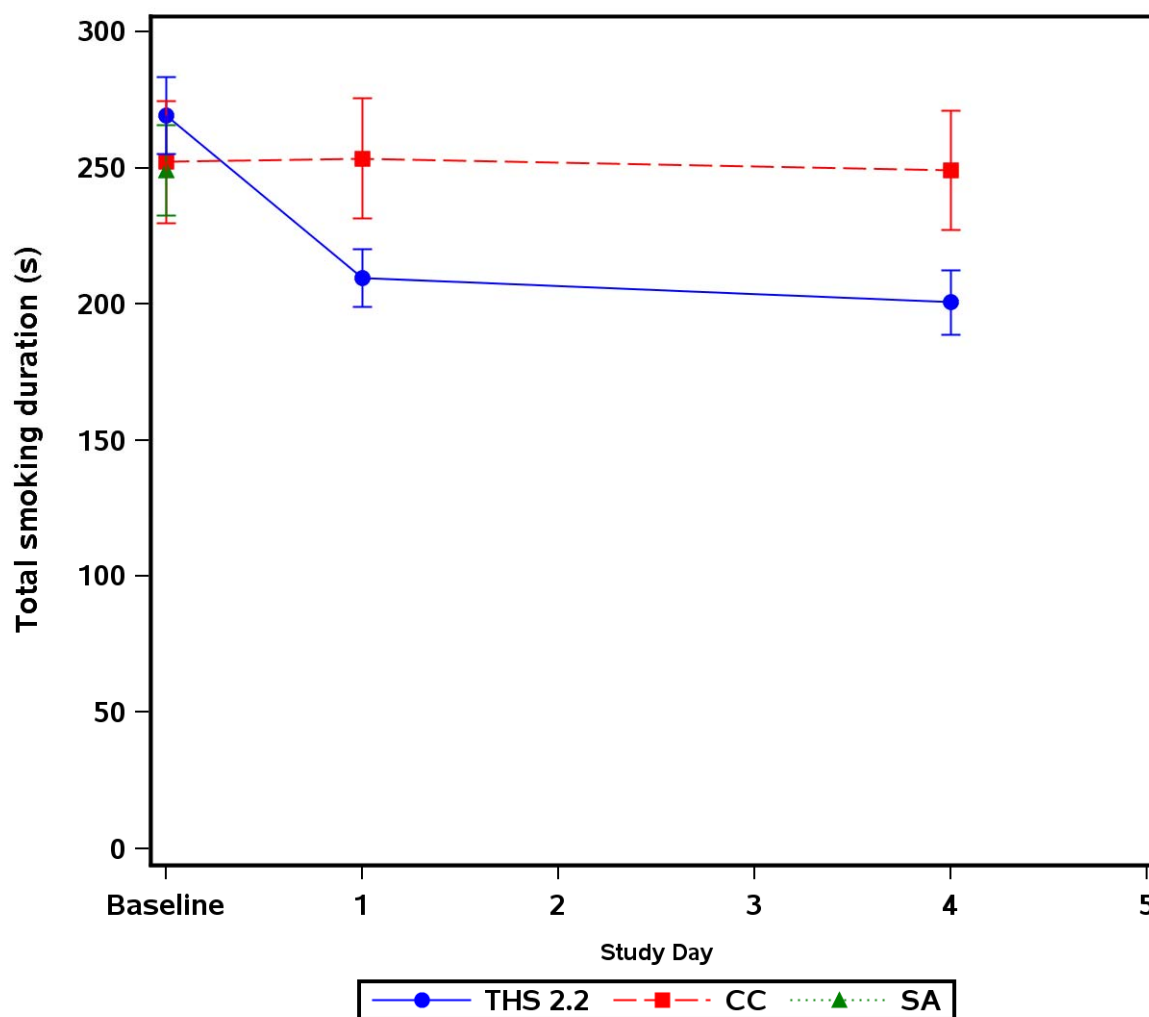
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 9 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total smoking duration (s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

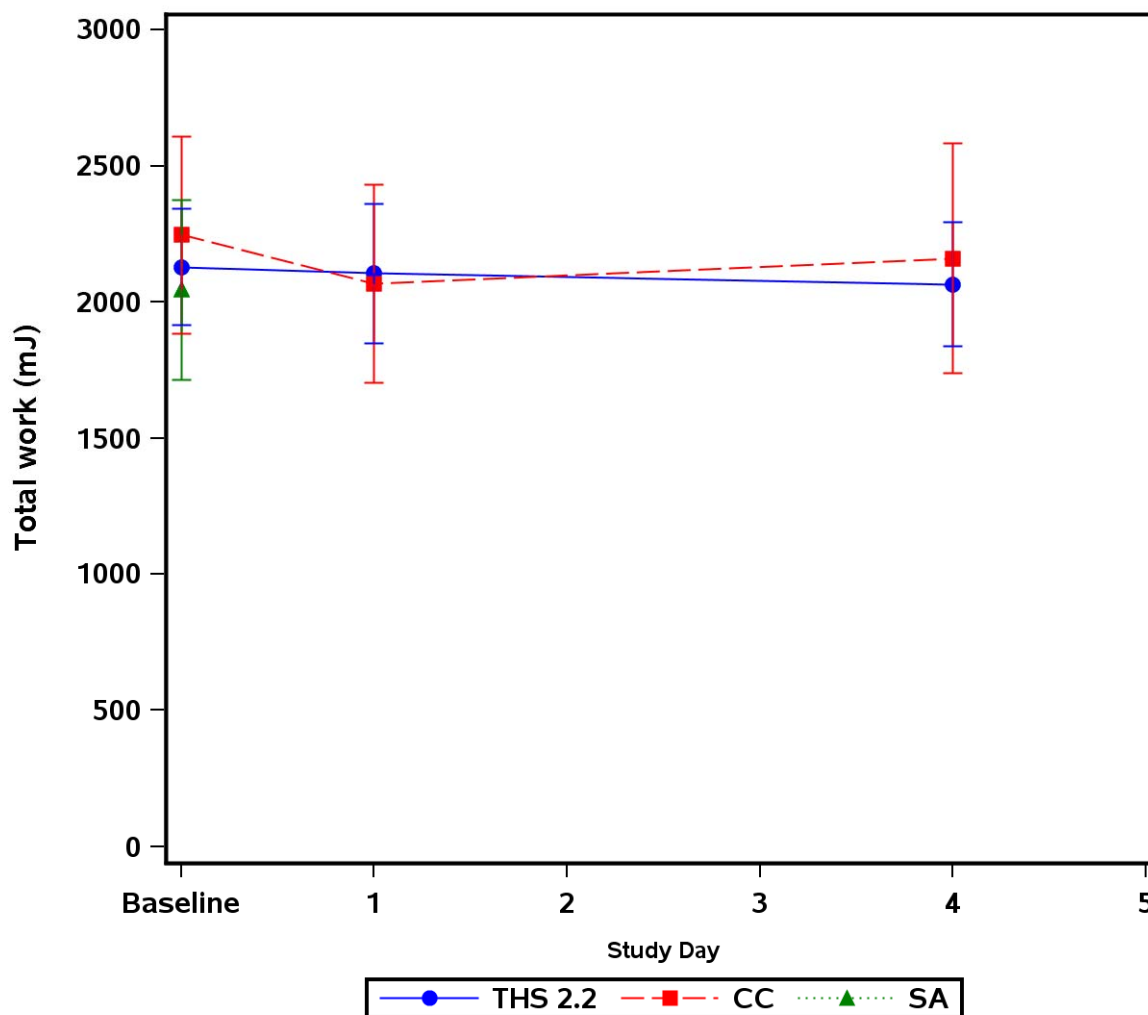
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 10 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Total work (mJ) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

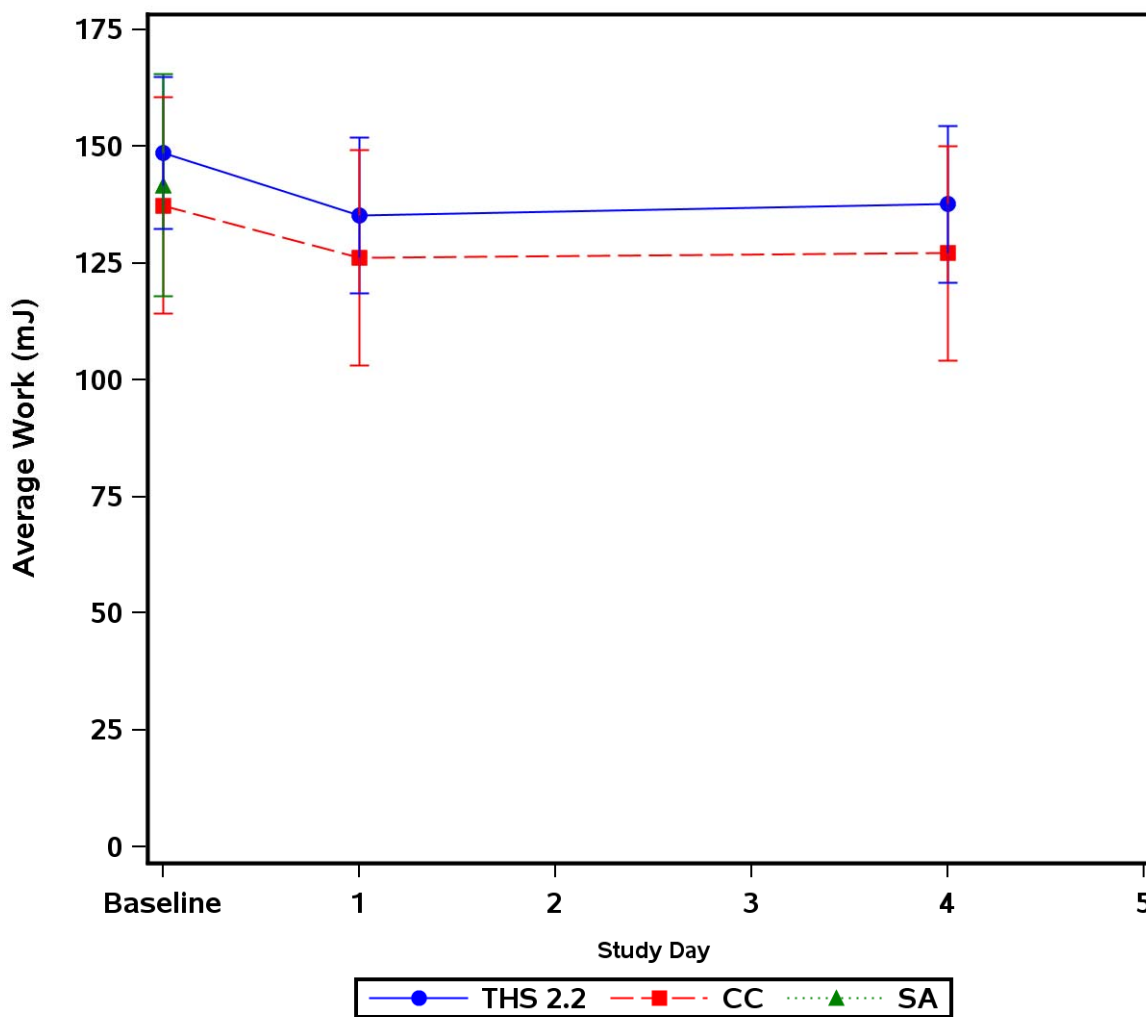
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 11 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average work (mJ) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

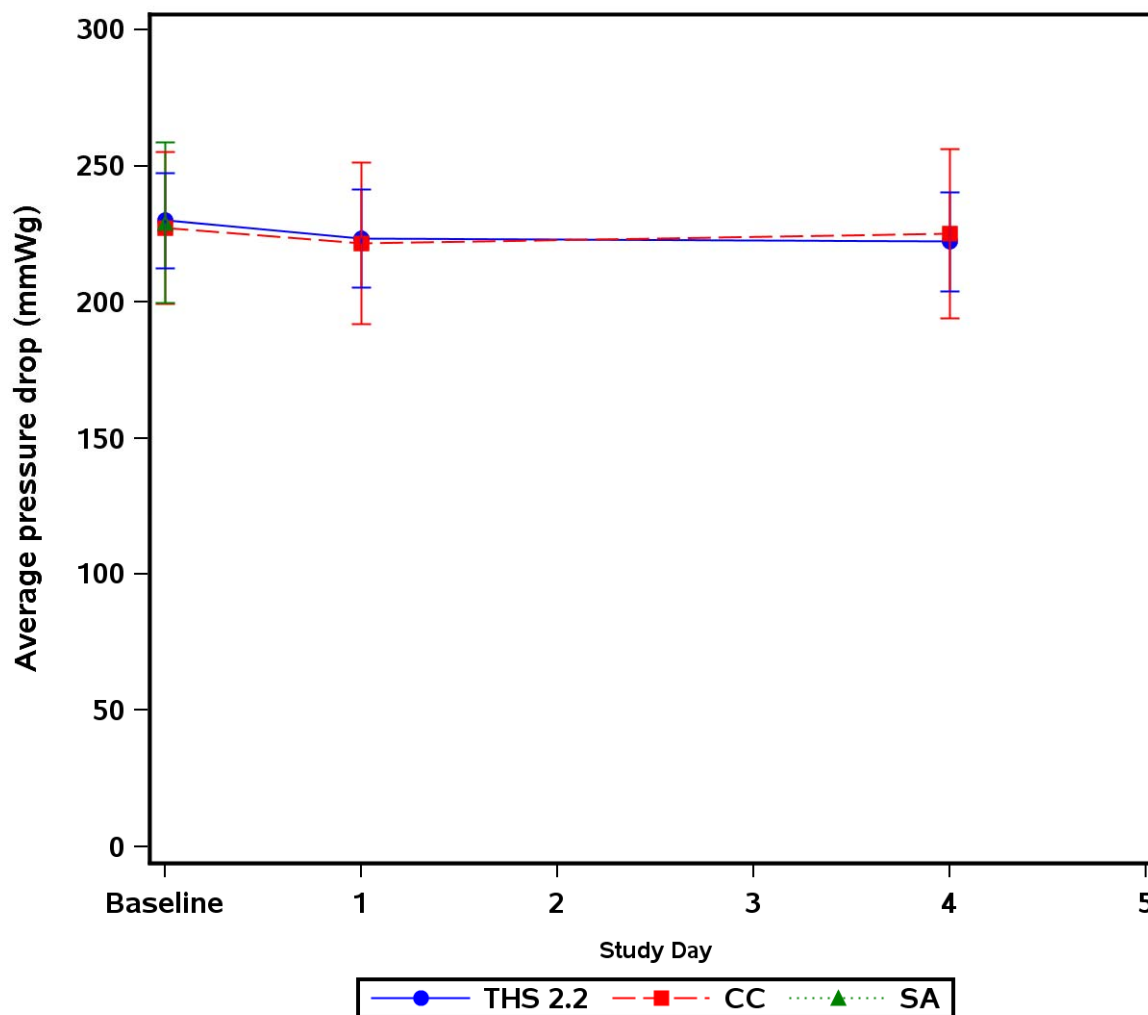
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 12 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average pressure drop (mmWg) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

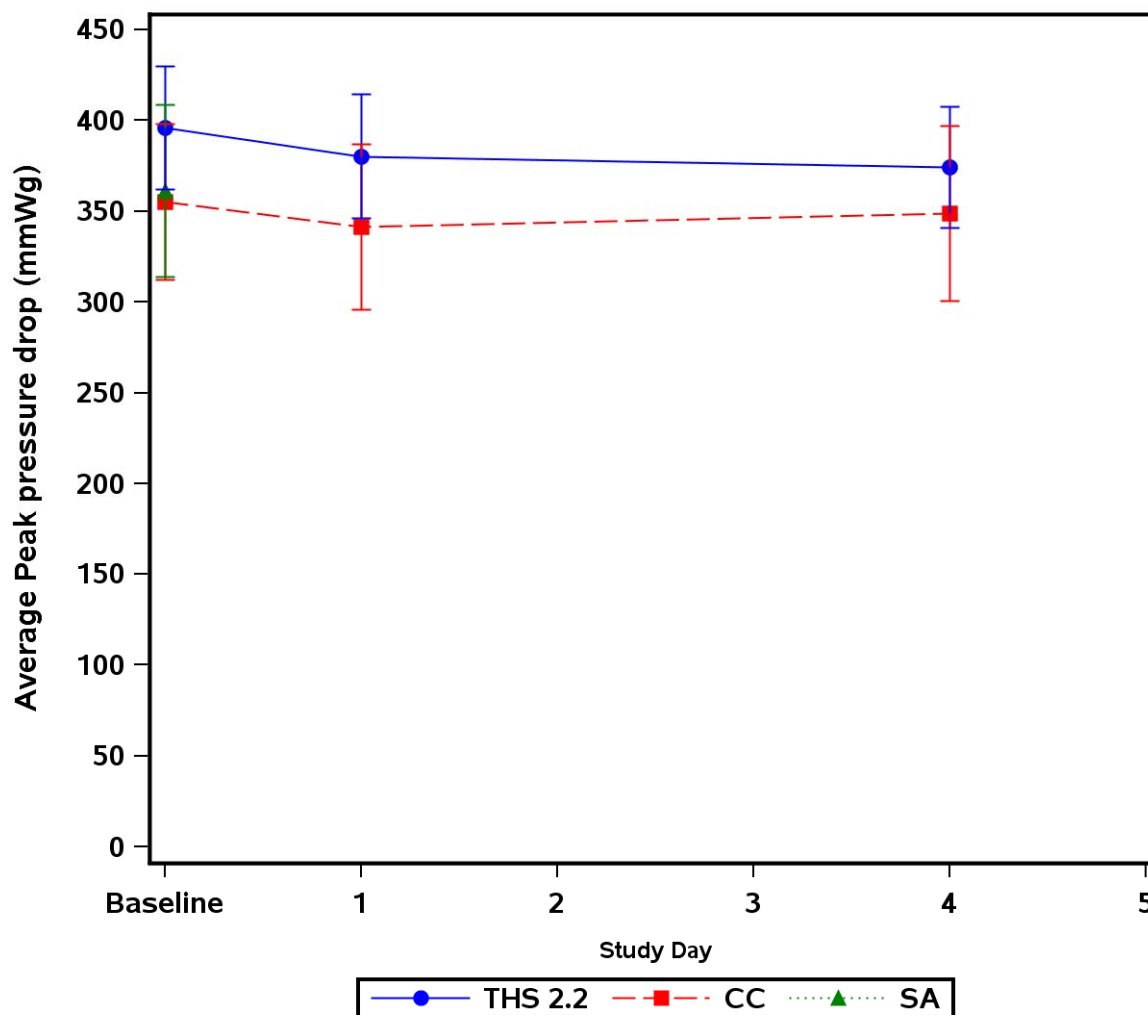
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 13 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Average peak pressure drop (mmWg) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

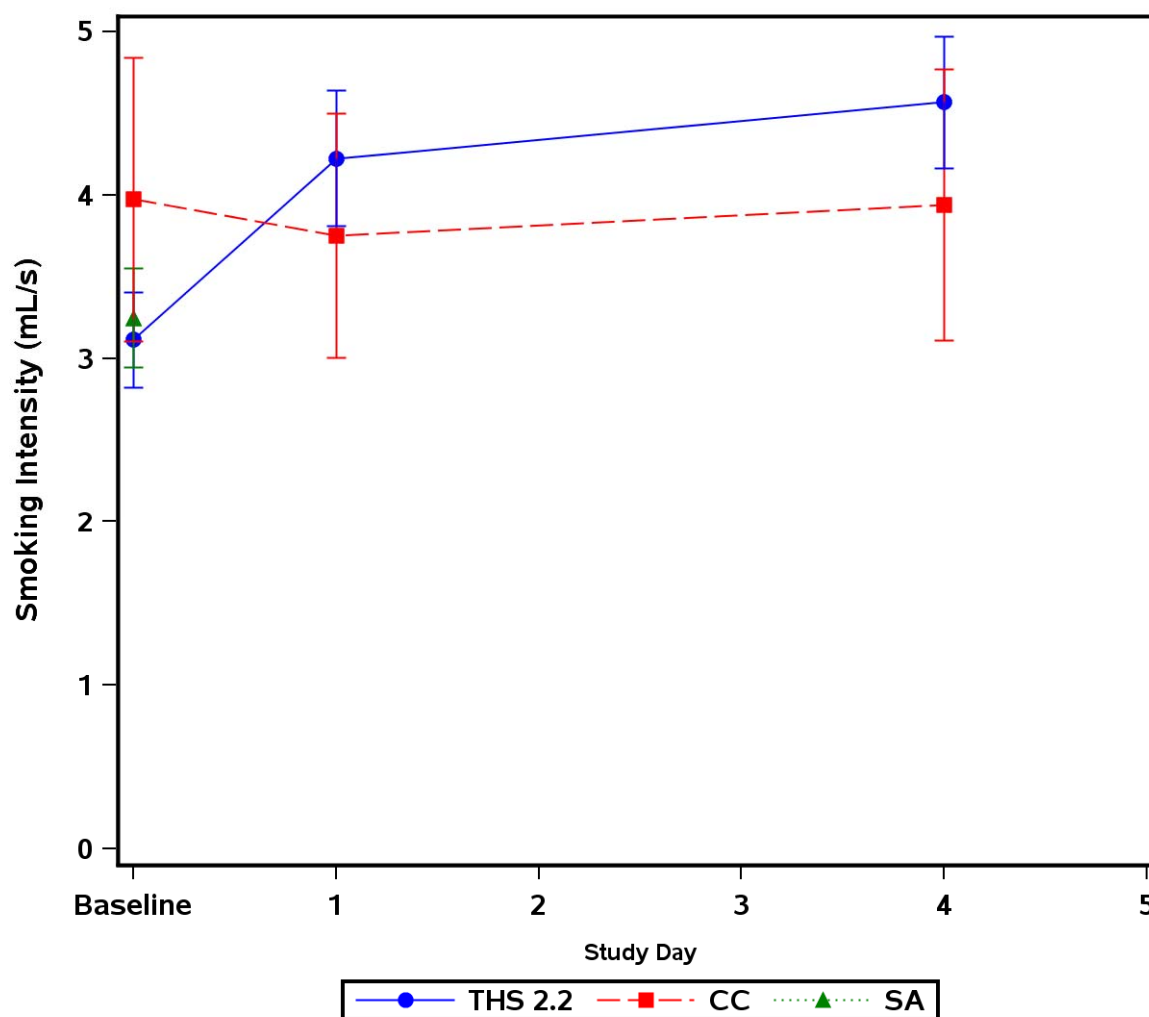
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 14 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Smoking intensity (mL/s) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

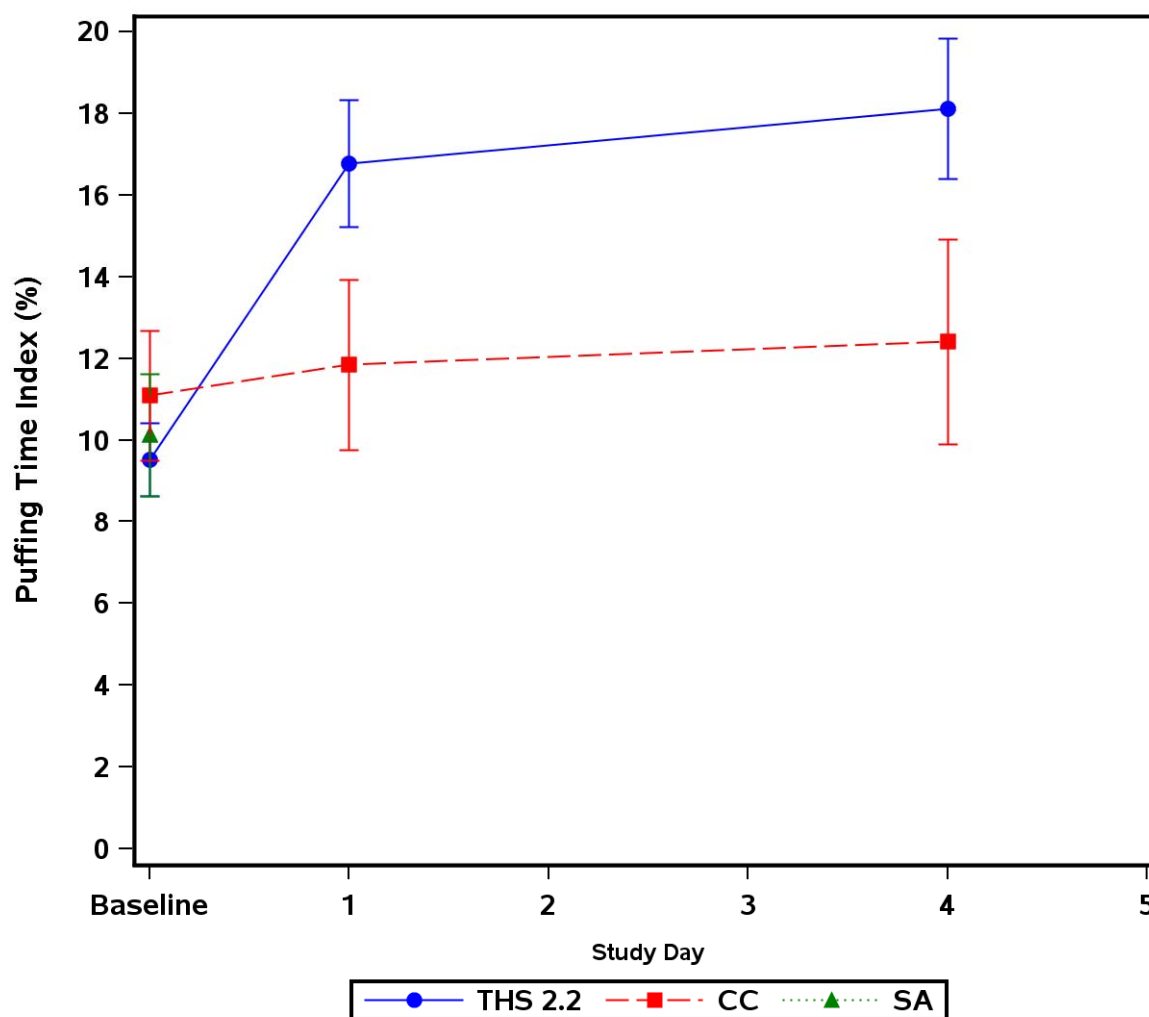
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 15 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Puffing time index (%) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

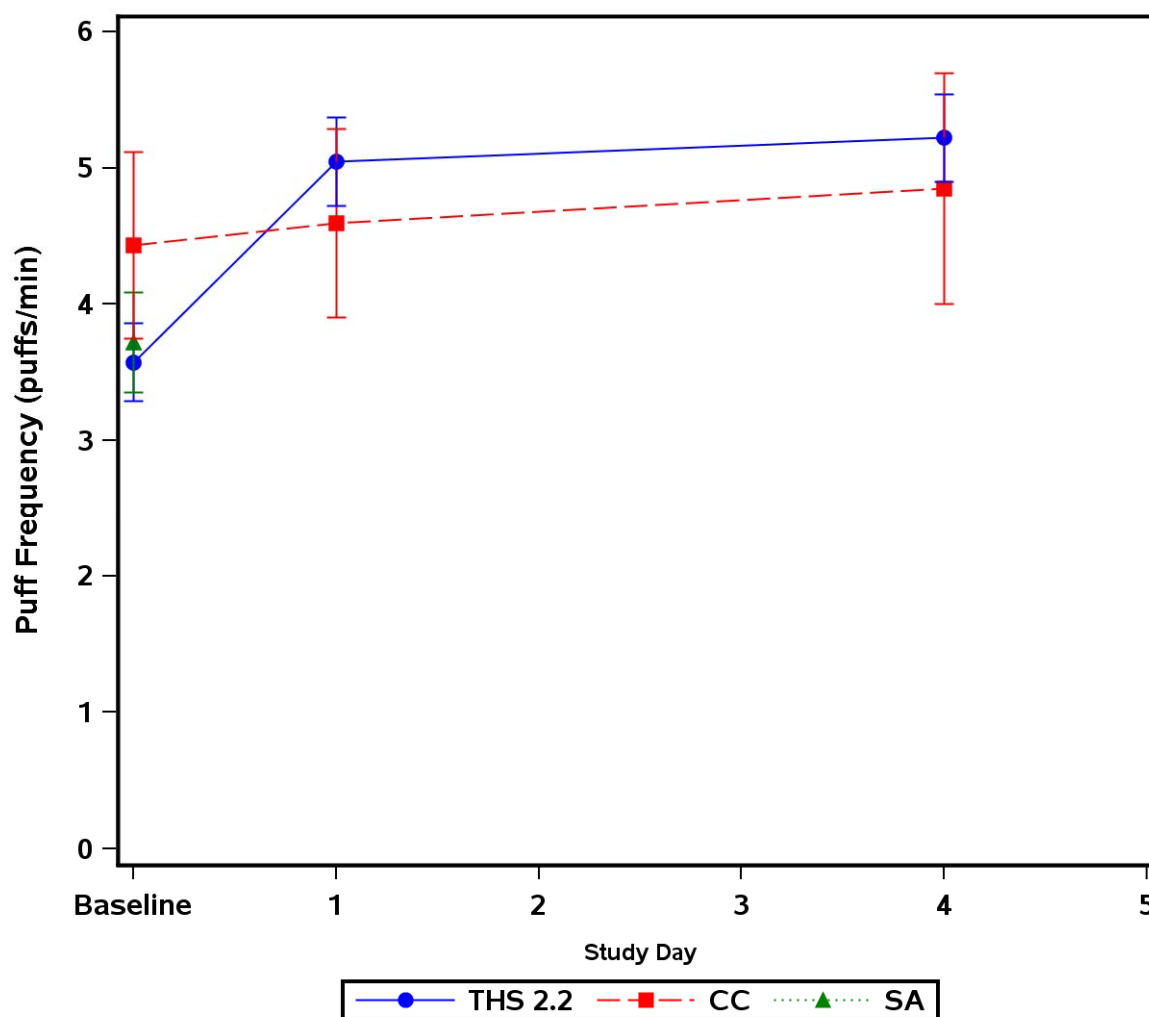
Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

(Page 16 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL

**Figure 15.1.2.39 HST per Cigarette Parameters Arithmetic Mean and 95% CI – FAS****Puff frequency (puffs/min) (average over visit)**

Note: CC = Conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: Baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29 AM in SA arm on Day 1.

Appendix 15.2.4.58

Path: /cvn/projects/prj/development/000000106324/dev/figures/f_hst.sas

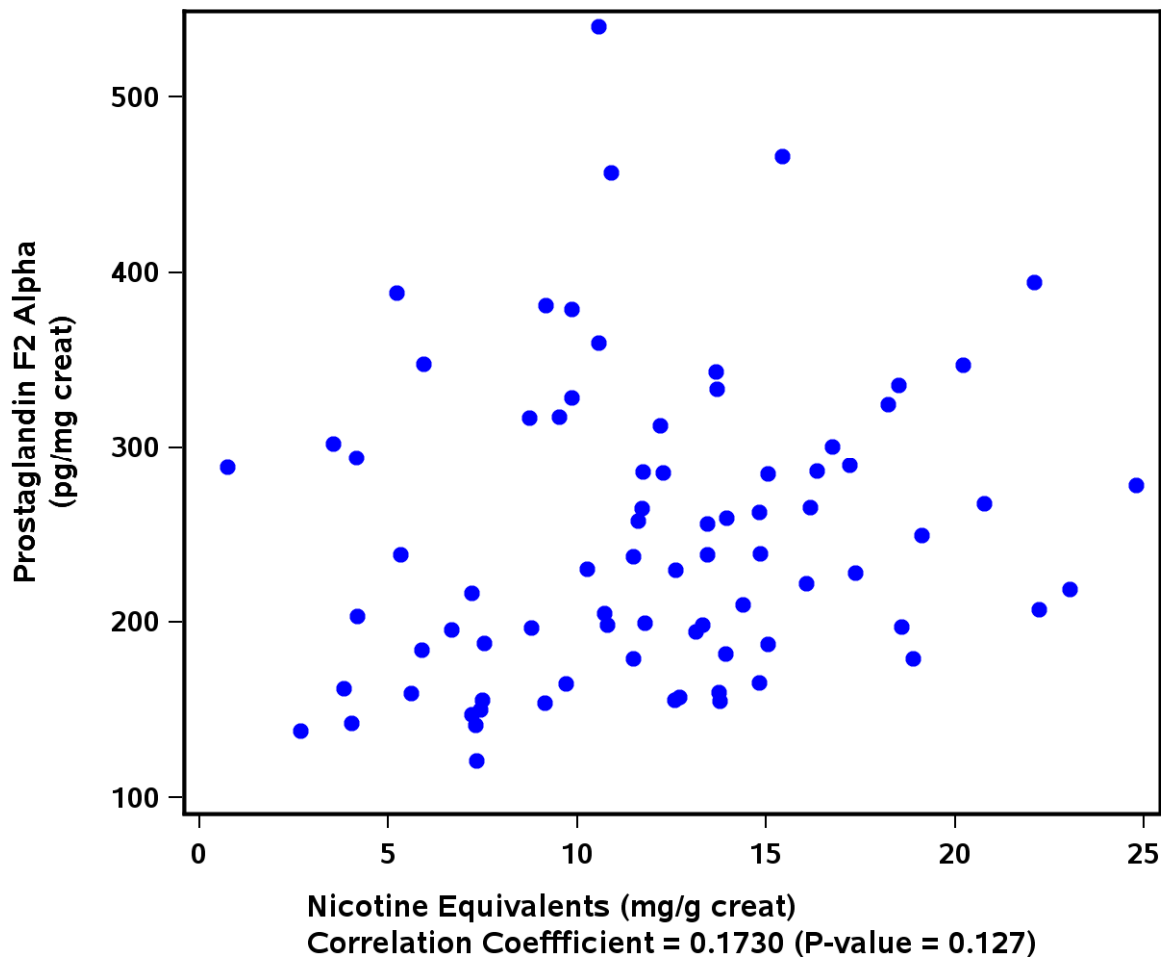
(Page 17 of 17)

Program Run: 27OCT14 cvn_kbooth Program Status: FINAL



Figure 15.1.2.40 Scatterplot of 8-epi-PGF2 α Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: THS 2.2



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

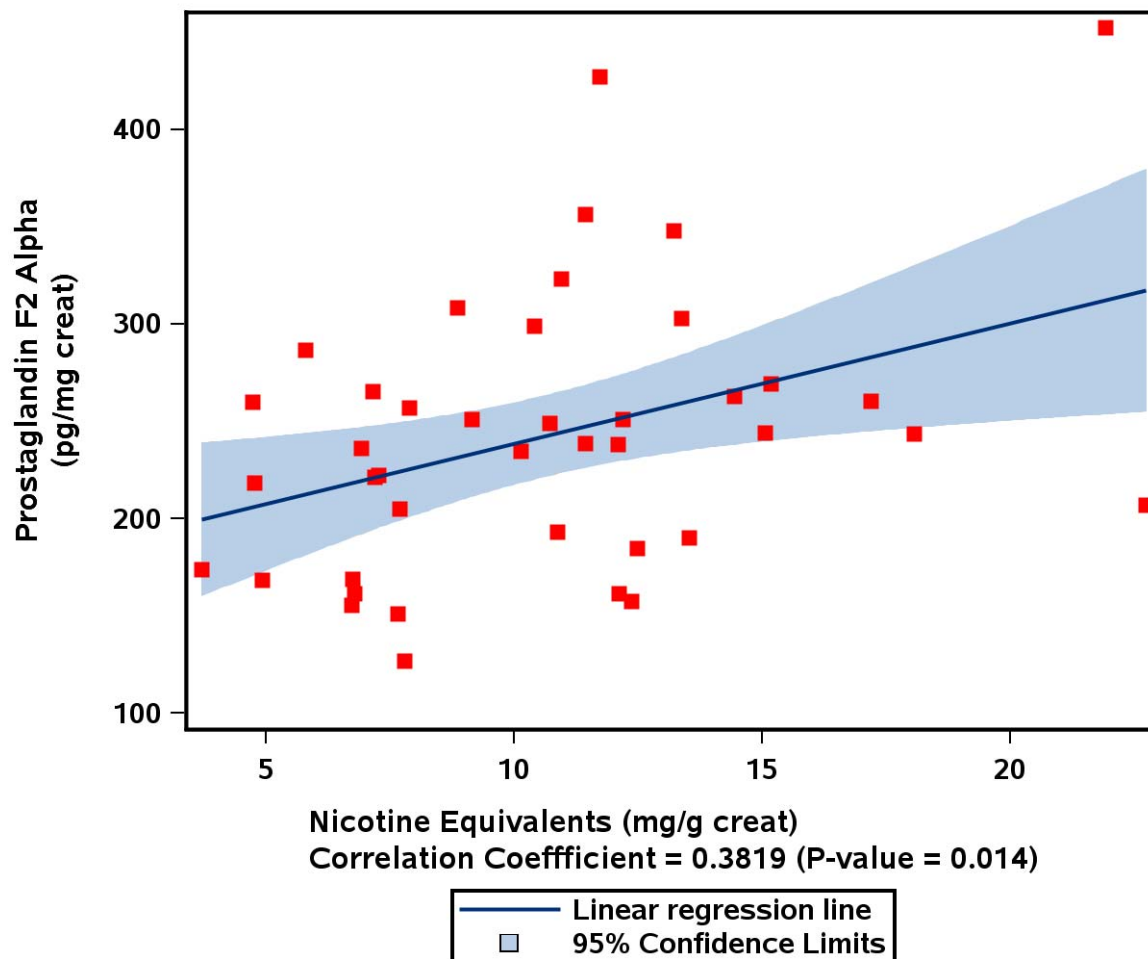
(Page 1 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.40 Scatterplot of 8-epi-PGF2 α Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: CC



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

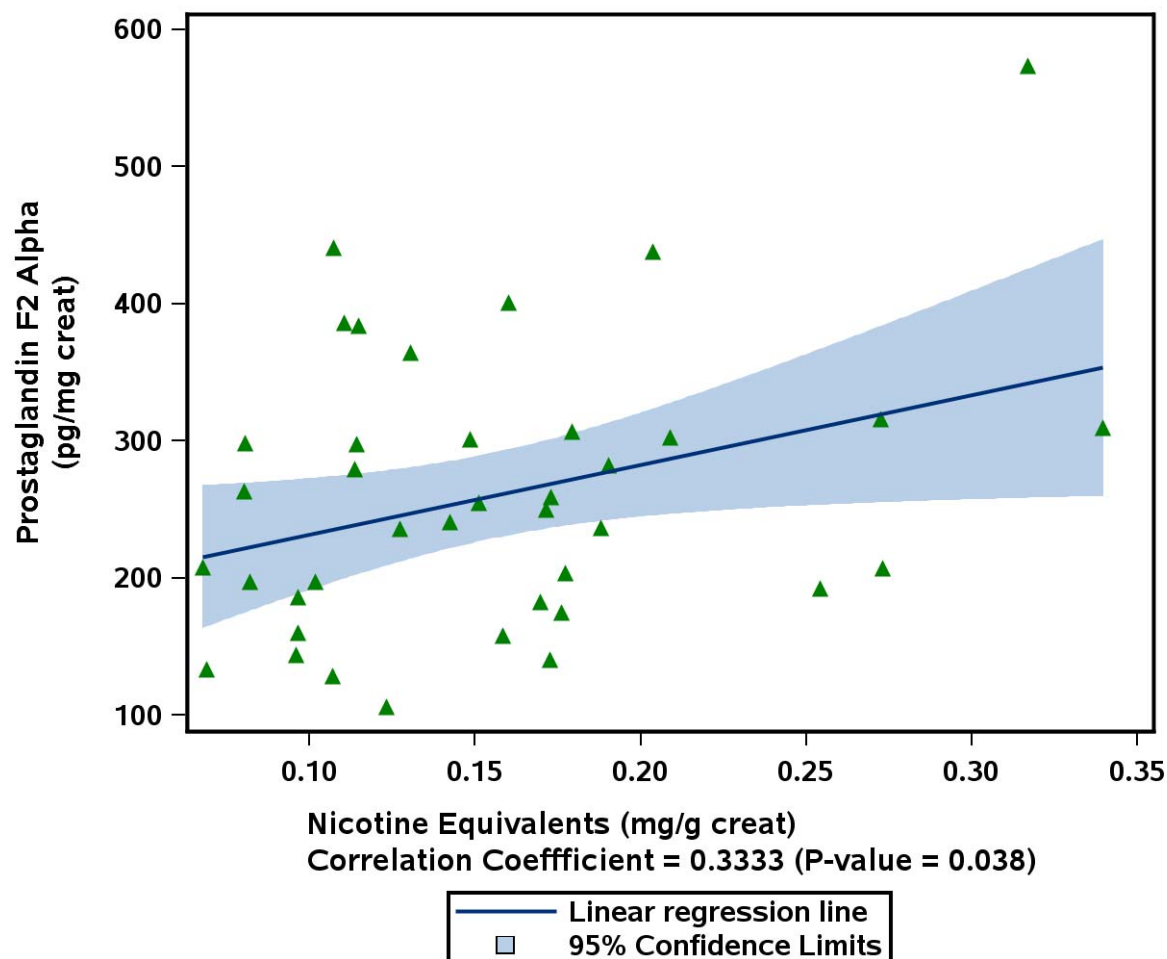
(Page 2 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.40 Scatterplot of 8-epi-PGF2 α Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: SA



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

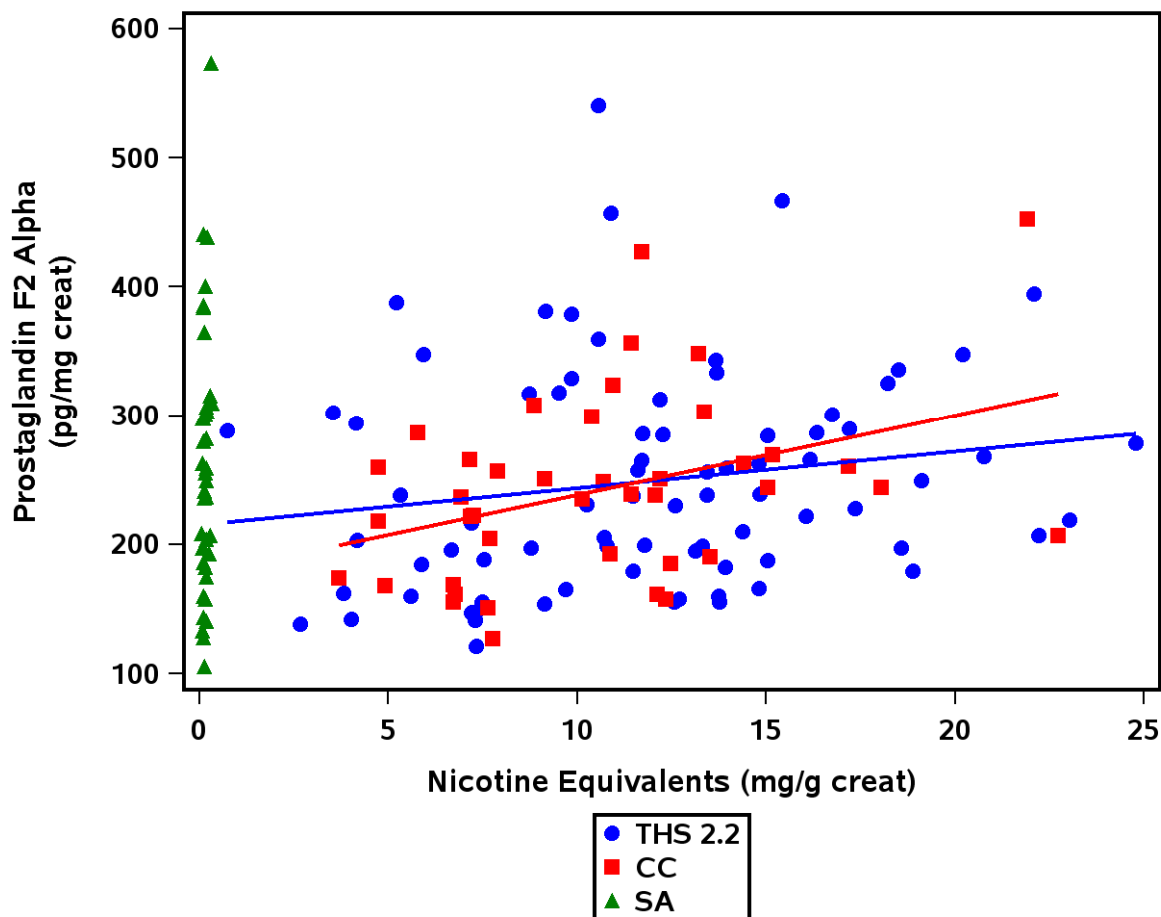
(Page 3 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.40 Scatterplot of 8-epi-PGF2 α Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: Overall. (P-value for comparison of slopes between THS 2.2 and CC = 0.314)



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

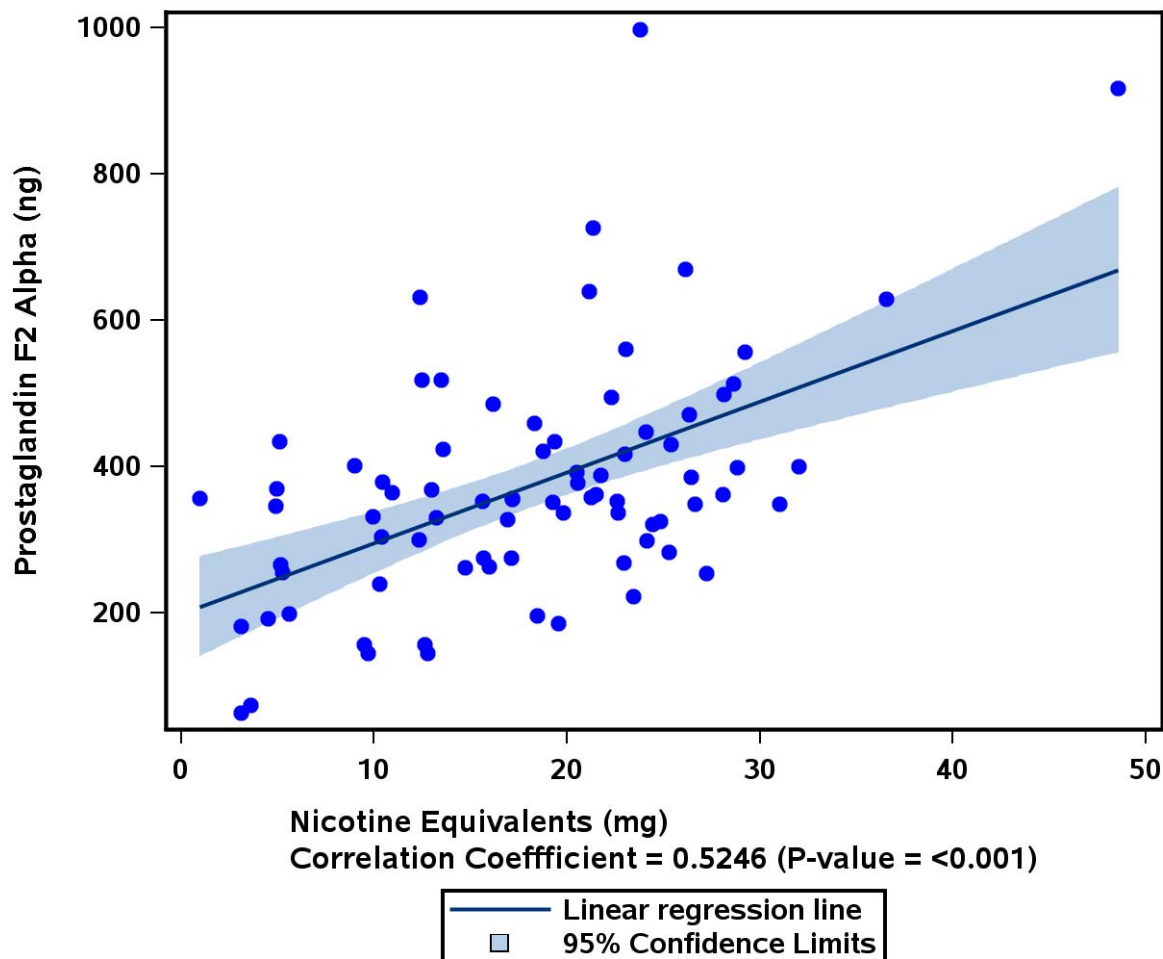
(Page 4 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.41 Scatterplot of Urinary 8-epi-PGF2 α Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: THS 2.2



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

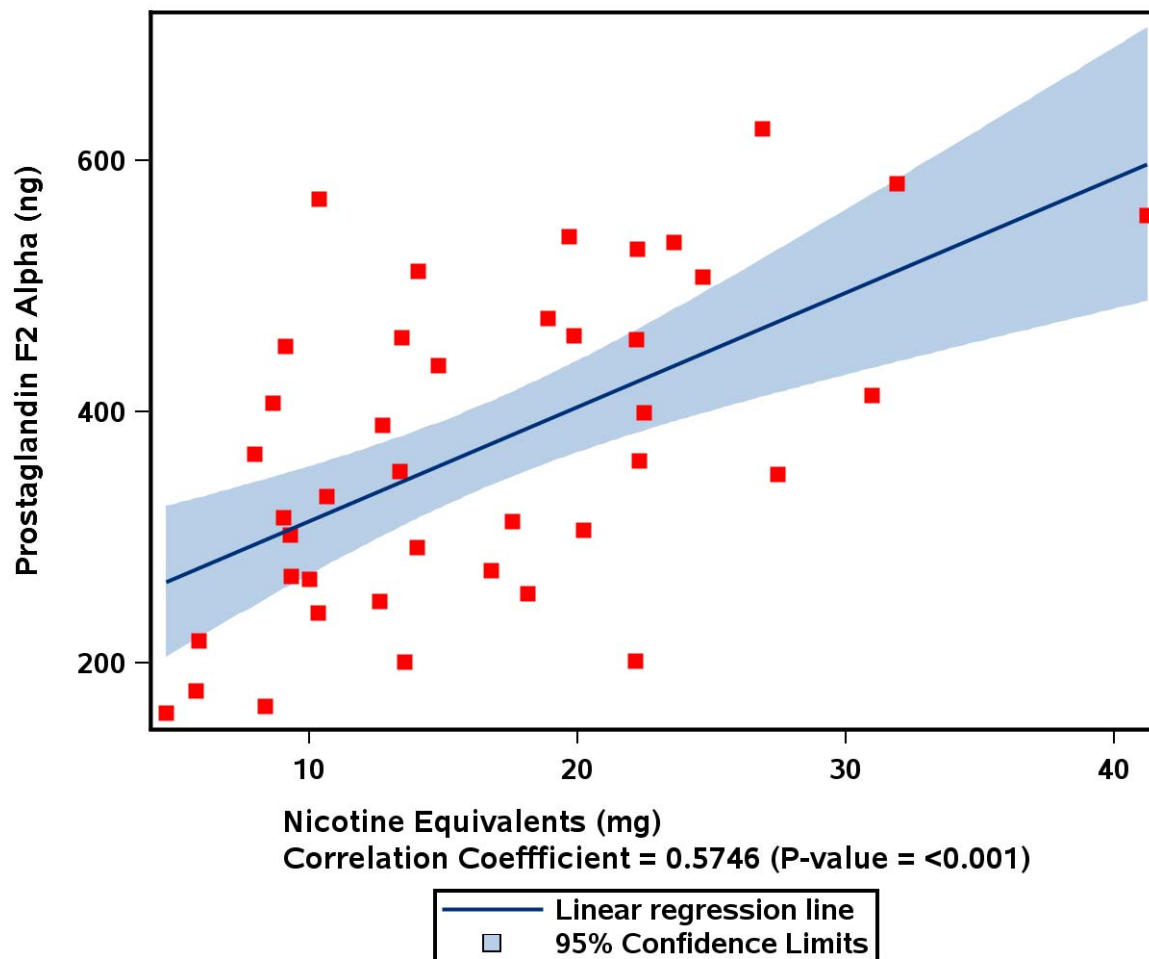
(Page 1 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.41 Scatterplot of Urinary 8-epi-PGF2 α Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: CC



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

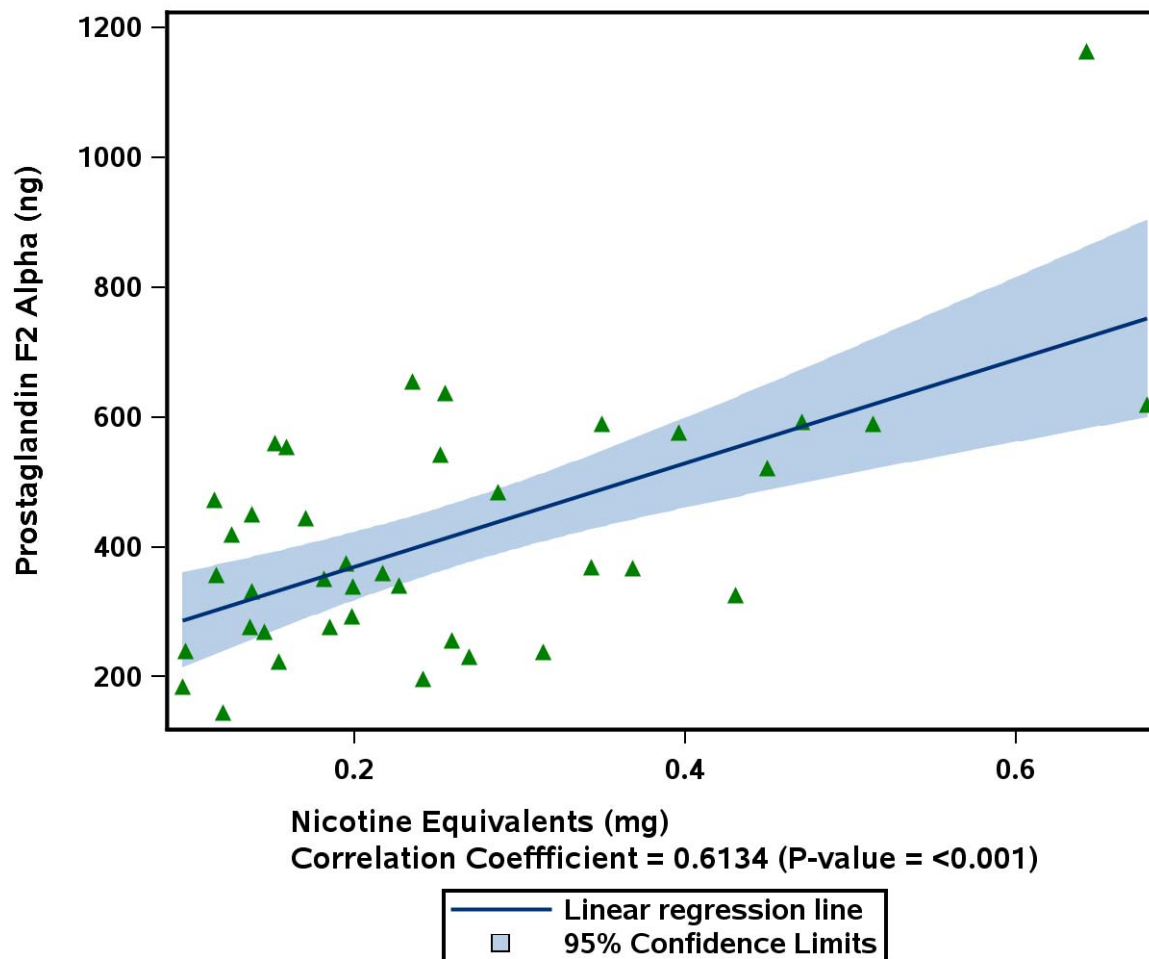
(Page 2 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.41 Scatterplot of Urinary 8-epi-PGF2 α Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: SA



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

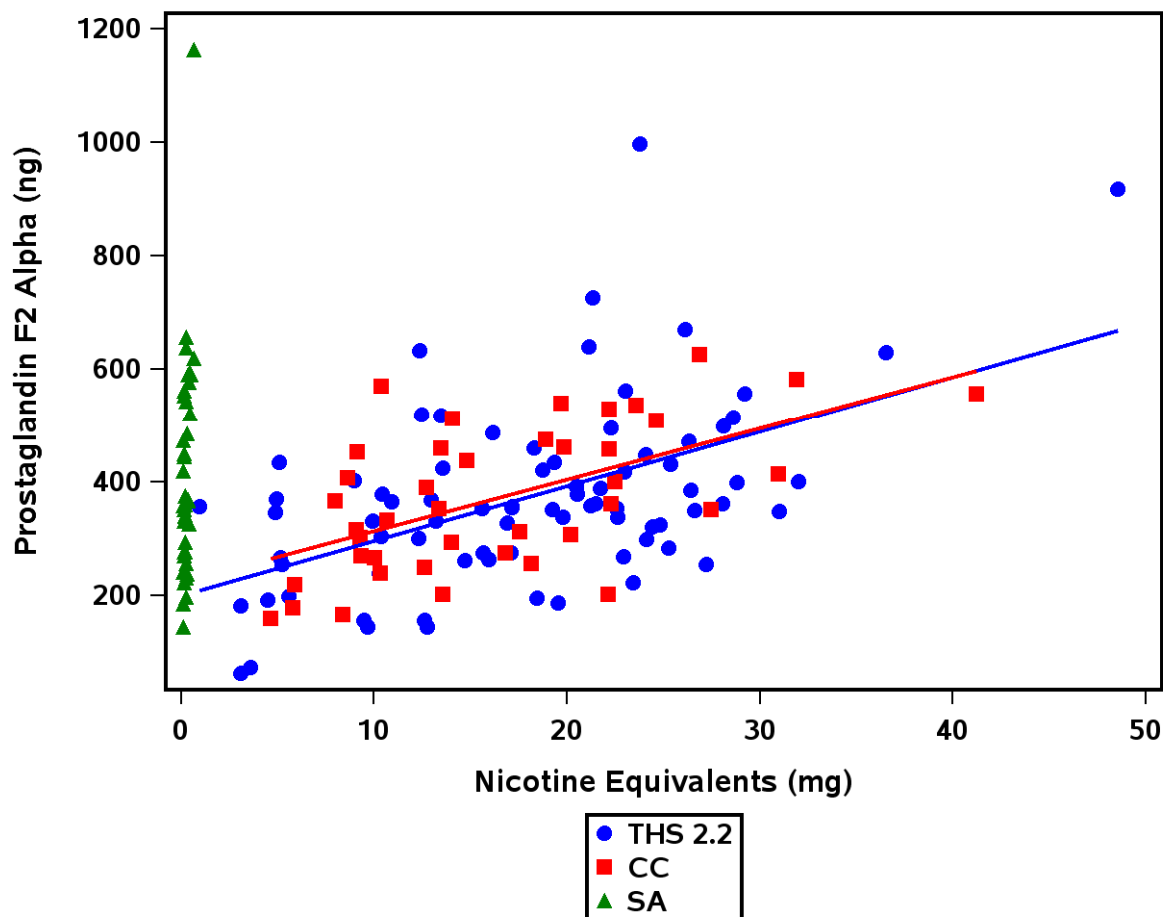
(Page 3 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.41 Scatterplot of Urinary 8-epi-PGF2 α Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: Overall. (P-value for comparison of slopes between THS 2.2 and CC = 0.848)



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

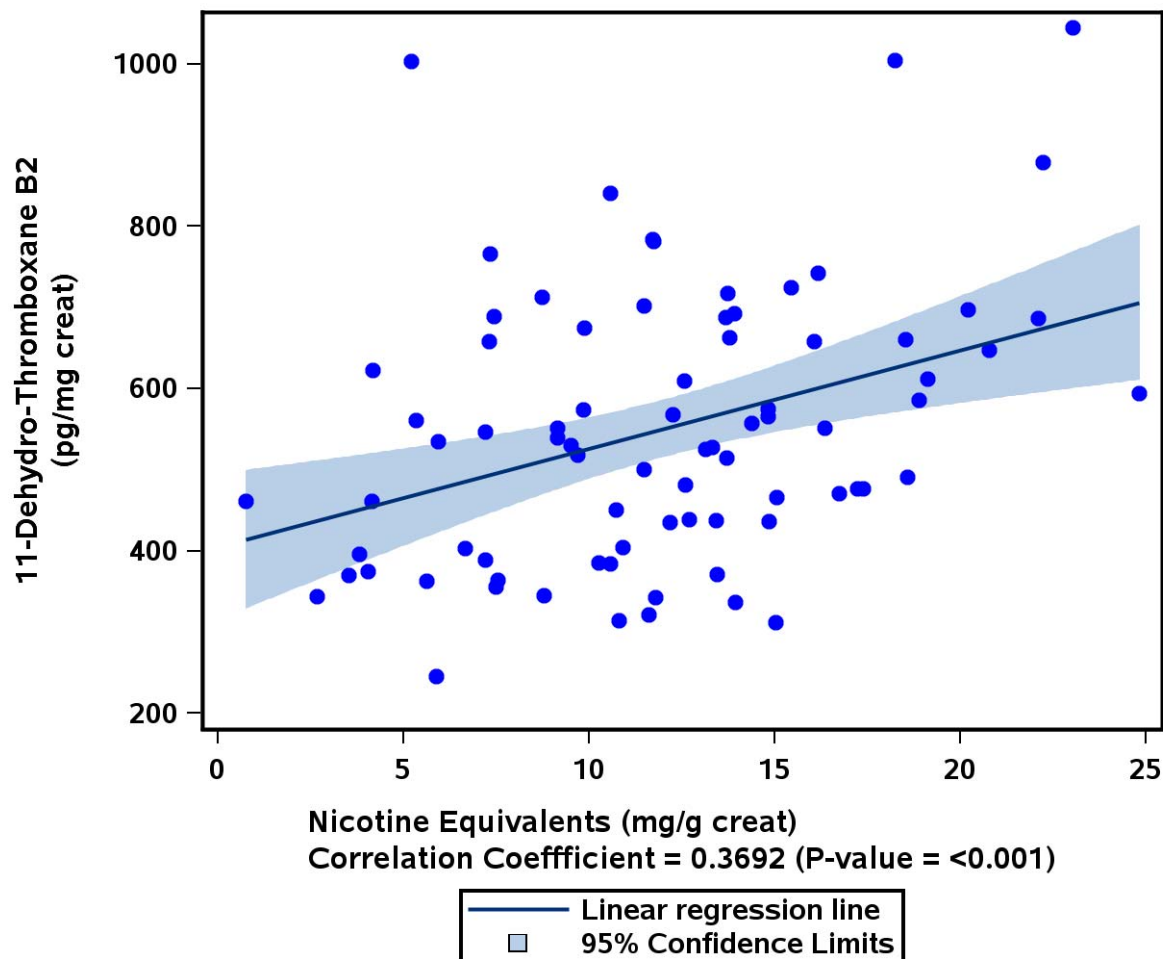
(Page 4 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.42 Scatterplot of 11-DTX-B2 Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: THS 2.2



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

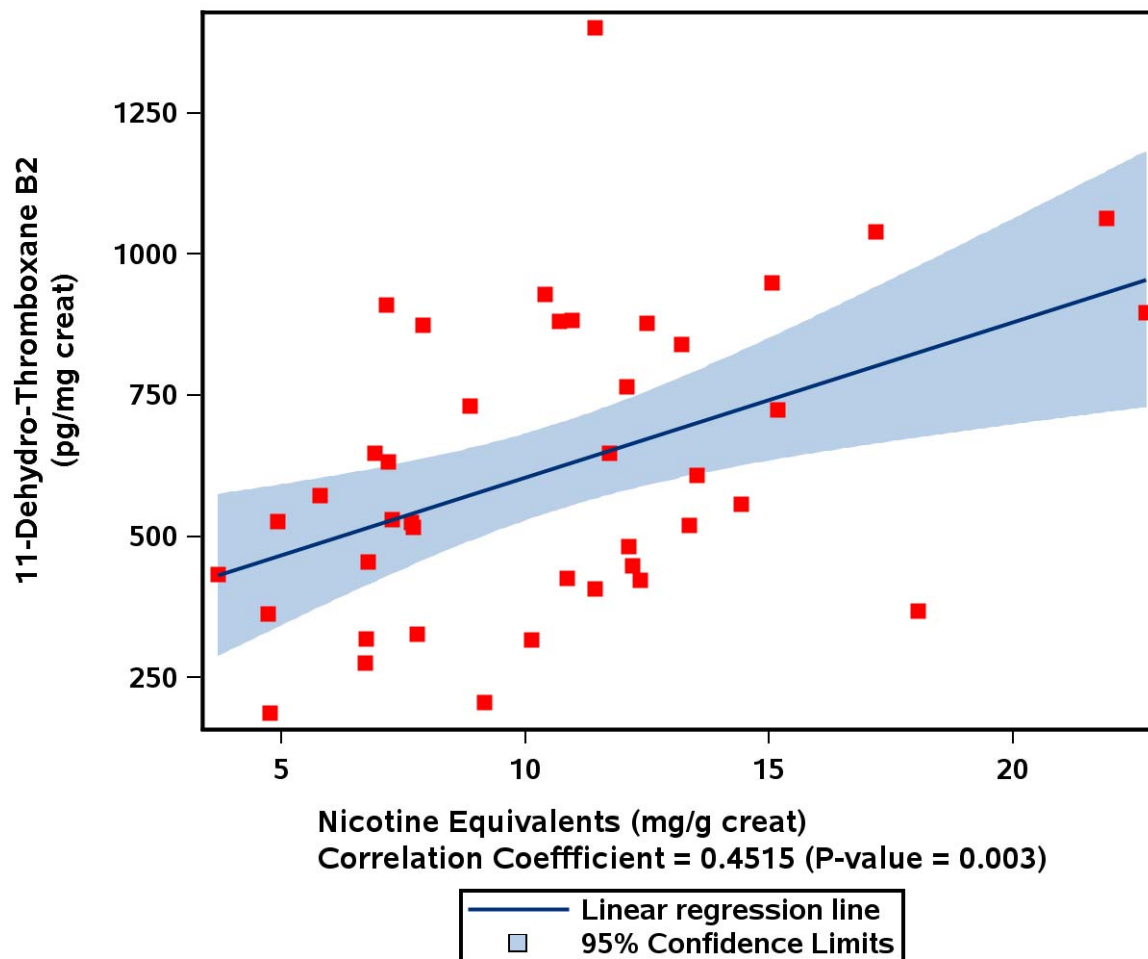
(Page 1 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.42 Scatterplot of 11-DTX-B2 Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: CC



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

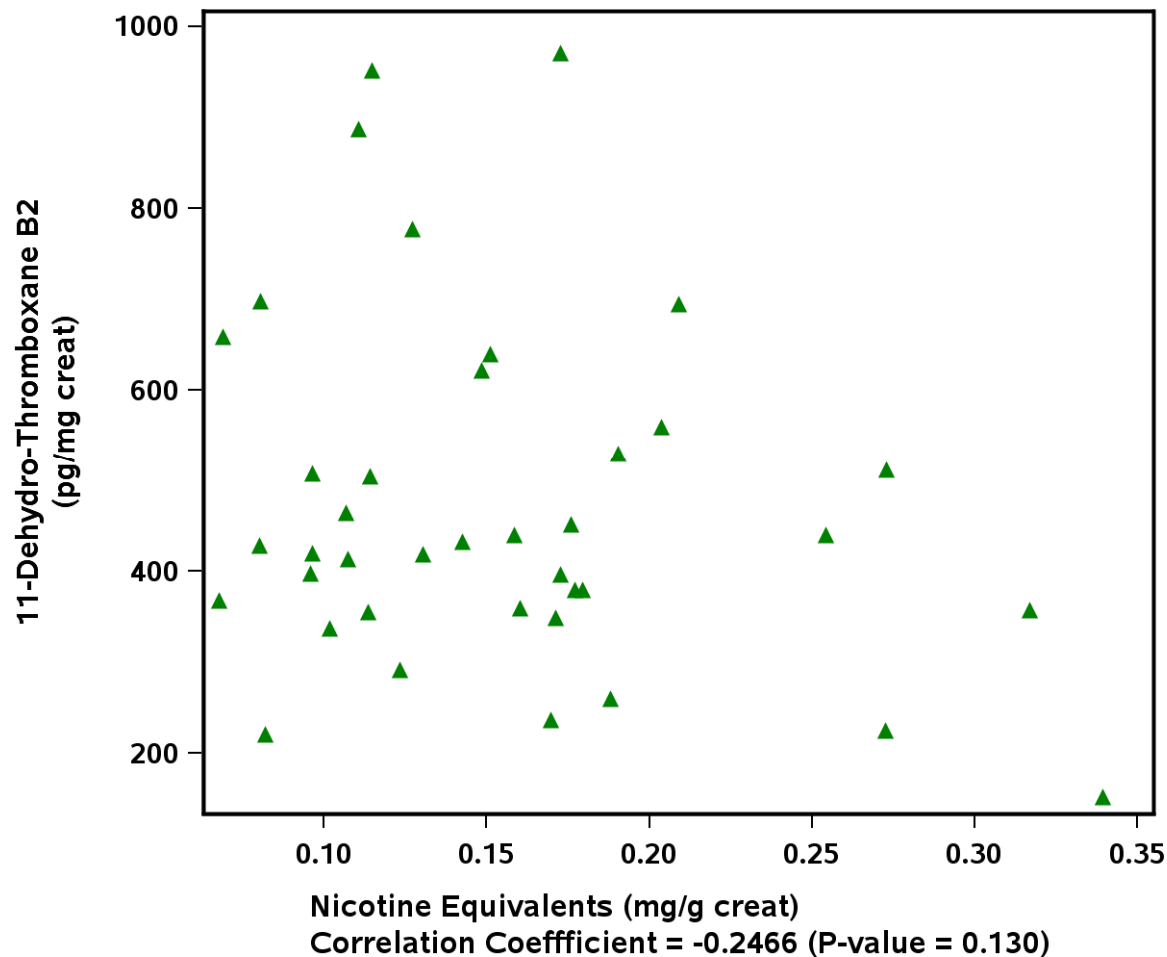
(Page 2 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.42 Scatterplot of 11-DTX-B2 Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: SA



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

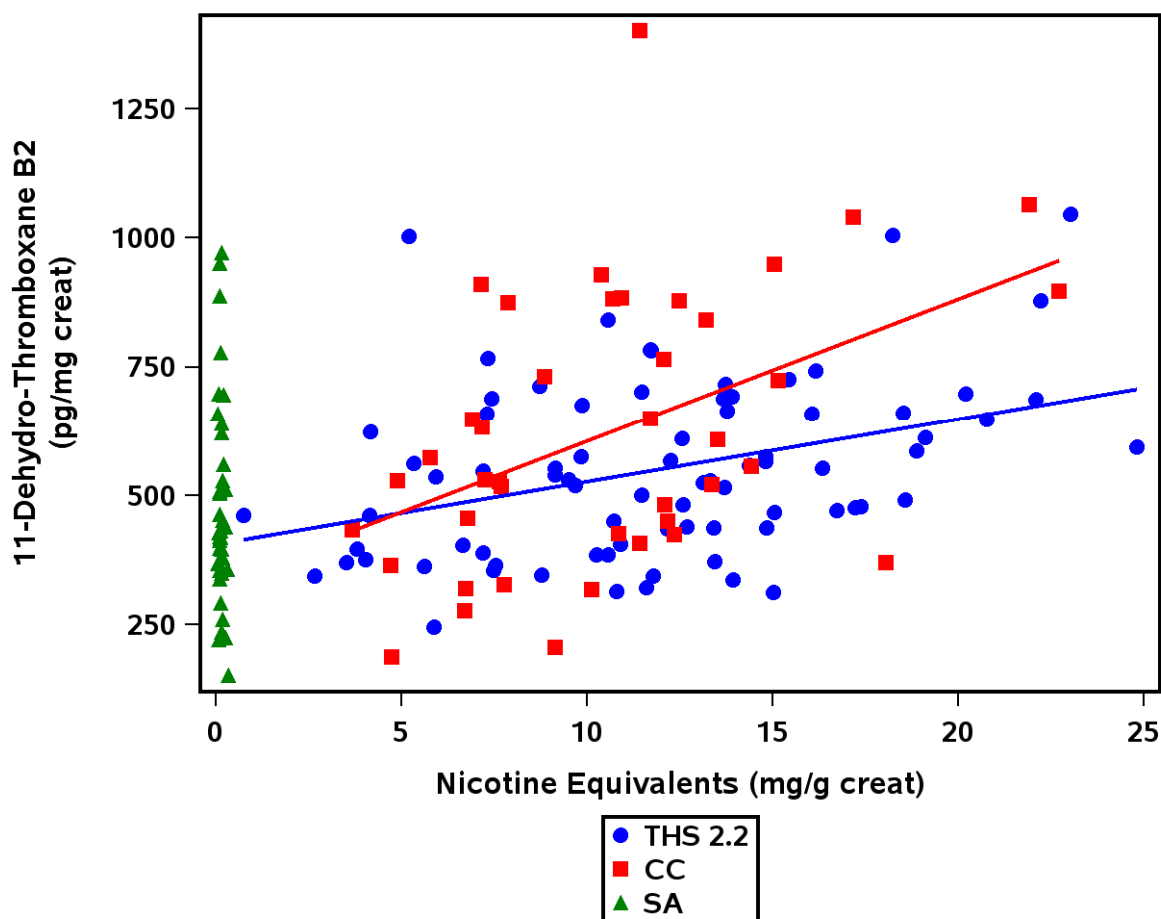
(Page 3 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.42 Scatterplot of 11-DTX-B2 Urinary Concentration Adjusted for Creatinine vs. NEQ Urinary Concentration Adjusted for Creatinine - FAS

Study Arm: Overall. (P-value for comparison of slopes between THS 2.2 and CC = 0.058)



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

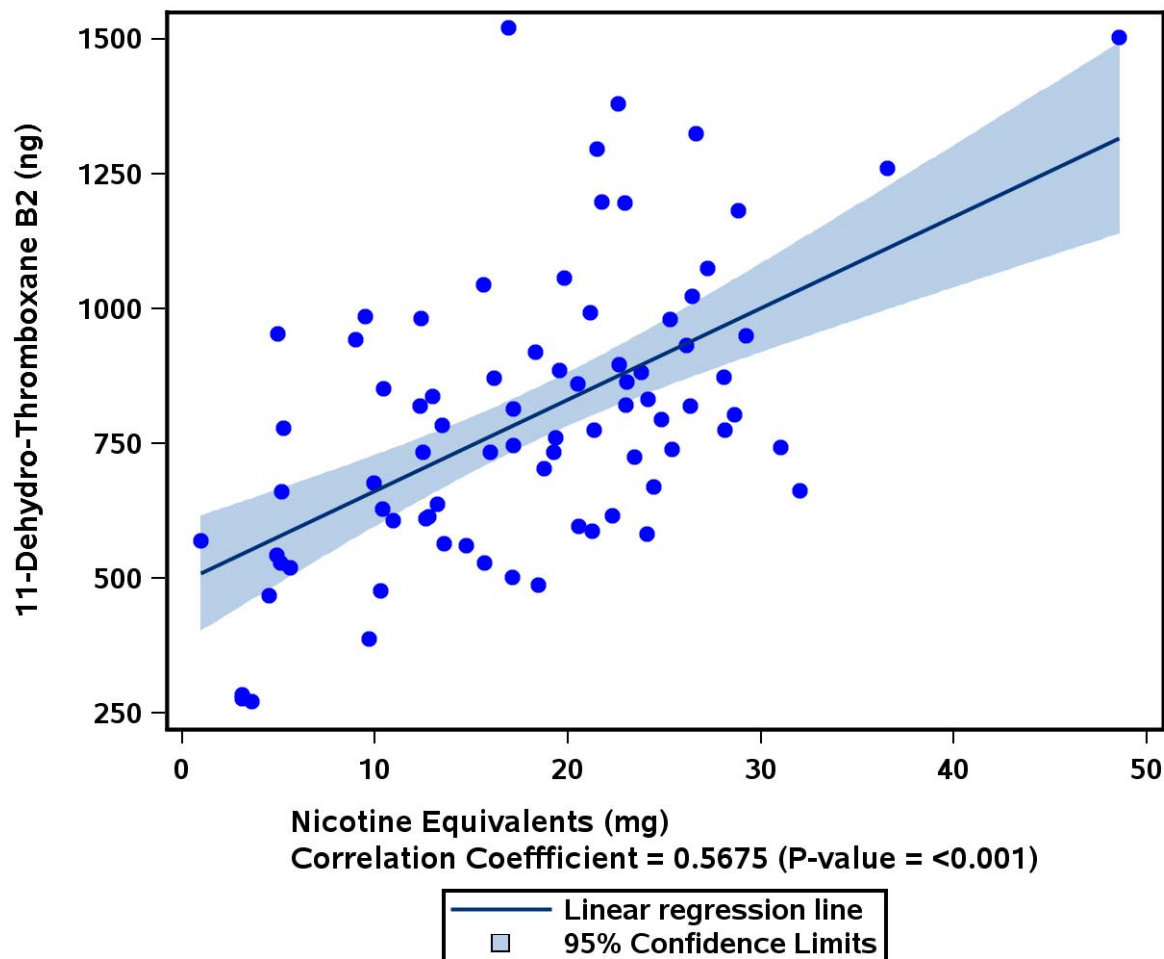
(Page 4 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.43 Scatterplot of Urinary 11-DTX-B2 Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: THS 2.2



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

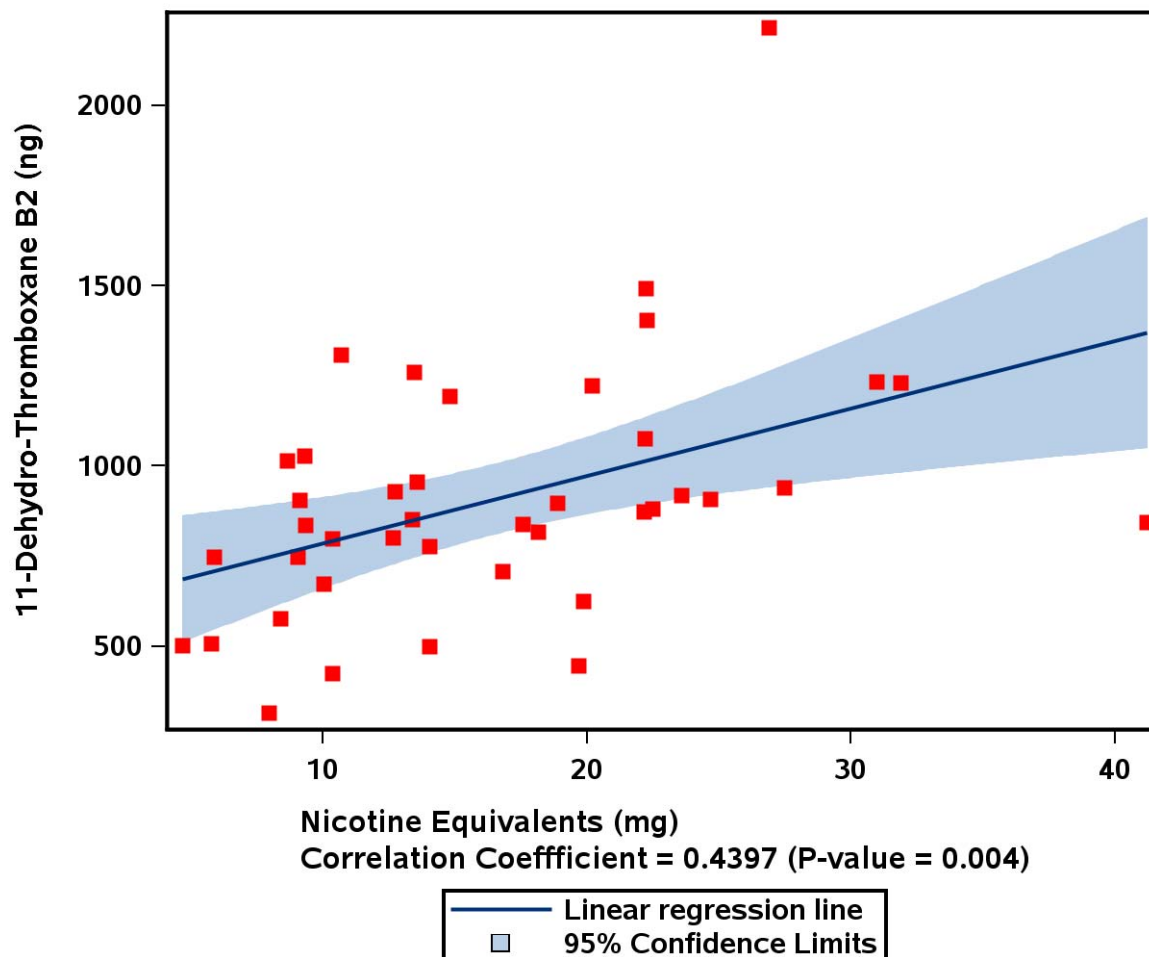
(Page 1 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.43 Scatterplot of Urinary 11-DTX-B2 Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: CC



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

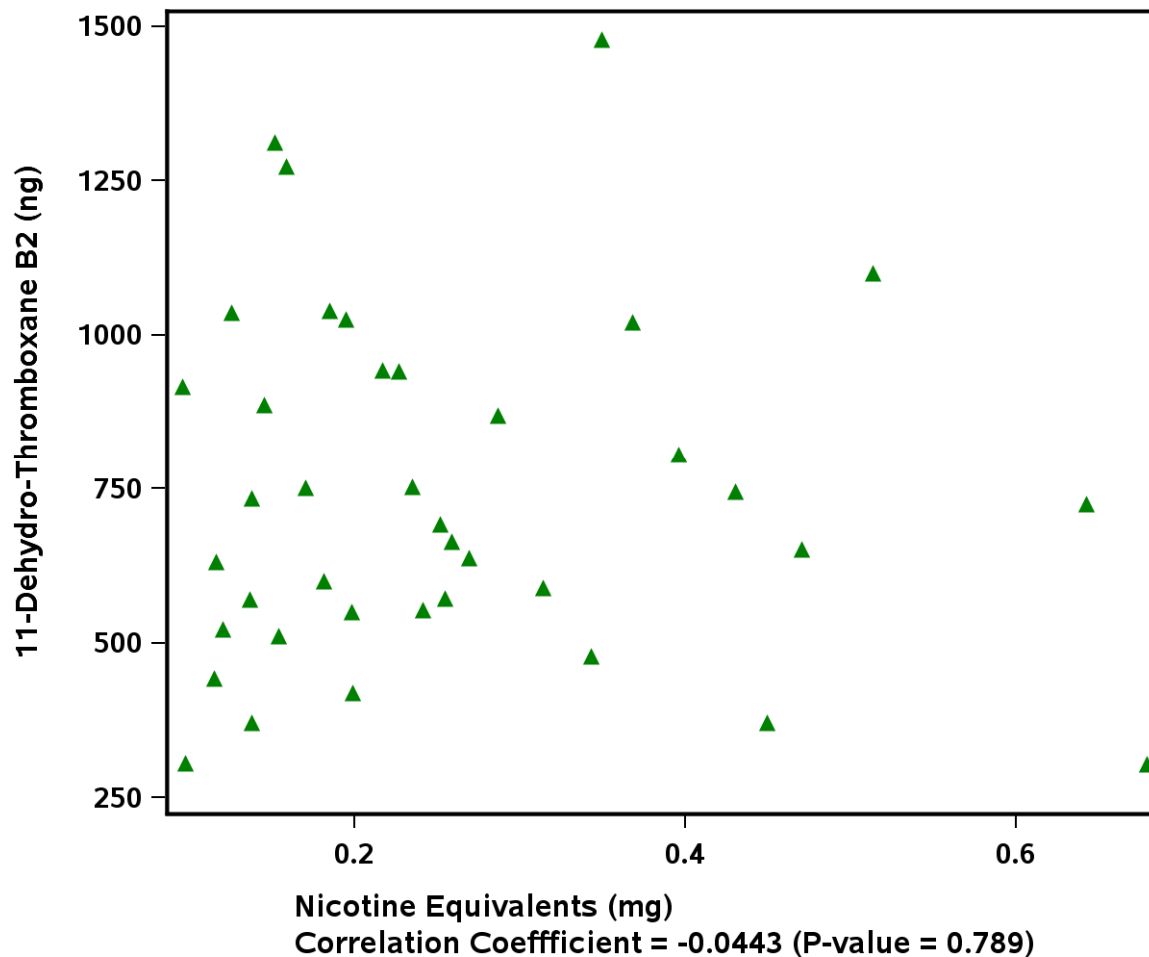
(Page 2 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.43 Scatterplot of Urinary 11-DTX-B2 Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: SA



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

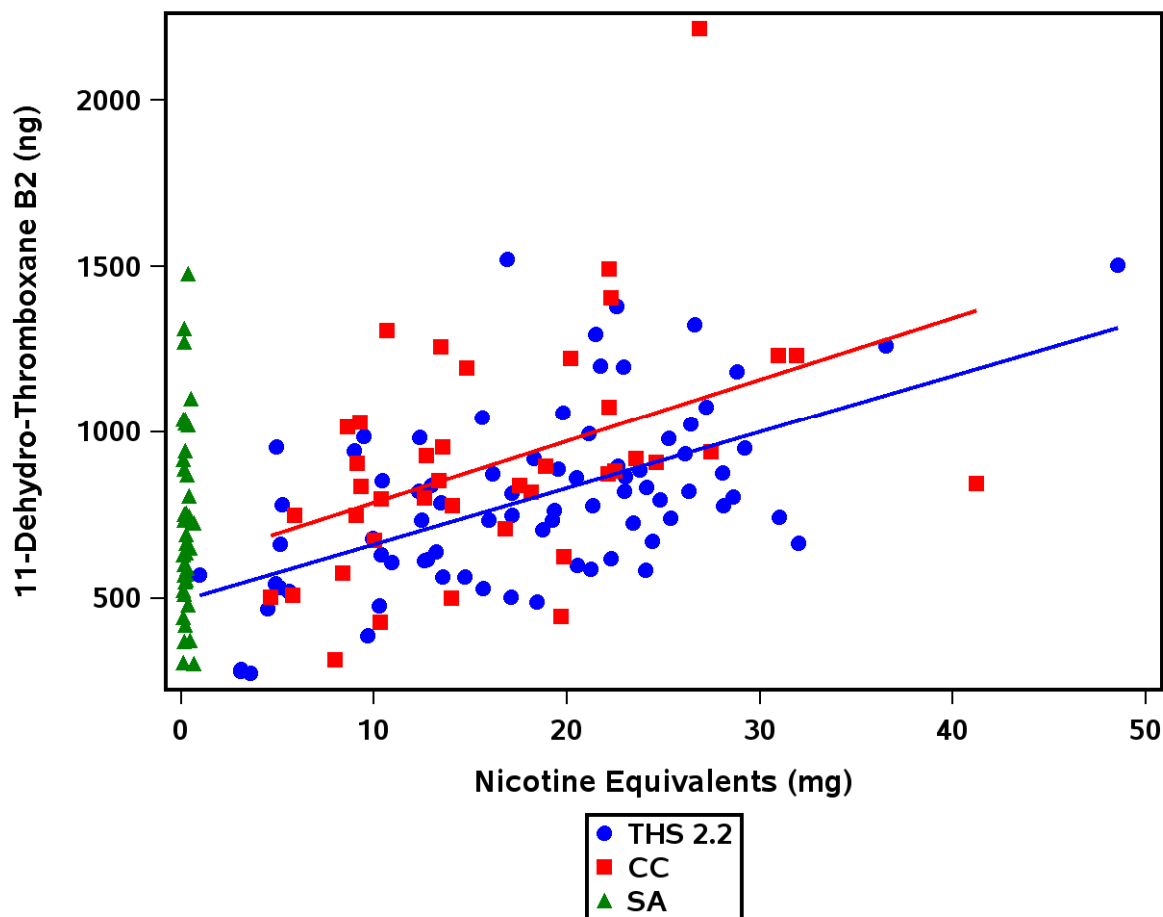
(Page 3 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



Figure 15.1.2.43 Scatterplot of Urinary 11-DTX-B2 Quantity Excreted over 24 hours vs. Urinary NEQ Quantity Excreted over 24 hours - FAS

Study Arm: Overall. (P-value for comparison of slopes between THS 2.2 and CC = 0.771)



Note: CC = Conventional cigarettes; THS = Tobacco Heating System.

Note: Regression lines only shown on separate study arm plots where a significant result was found for the slope (see Table 15.2.4.57).

15.4.4.57

Path: /cvn/projects/prj/development/000000106324/dev/tables/tlf_anlneqrisk.sas

(Page 4 of 4)

Program Run: 31OCT14 cvn_ahedge Program Status: FINAL



15.1.3 Other Assessments

Not applicable.