

Changes in biomarkers of exposure and potential harm among adults who switch from cigarettes to the Ploom® Heated Tobacco System

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Agenda

Background

Overview of Study Design

Study Results

Discussion



PARTNERSHIP

Between JT Group and Altria

to Bring Ploom
System to U.S.
Adults (Age 21+)
Who Smoke



Portfolio Approach to Tobacco Harm Reduction Supports Greater Choice



**Smokeless
Tobacco
Products**



**Modern Oral
Tobacco
Products**



**Heated Tobacco
Products
(HTP)**



**E-Vapor
Products**

*PLOOM® is currently unavailable for sale in the United States.



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The Ploom® System

Ploom® Device

Heated Tobacco Sticks (HTS)



Generates aerosol without
burning of tobacco



Designed to provide
satisfying user experiences



Menthol-Flavored Variant



Tobacco-Flavored Variant



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Study Overview

STUDY DESIGN

A Multi-site, randomized, parallel-group study including:

HTP ARMS

2 HTS with
no combustion



-  Menthol Variant
-  Tobacco Variant

COMPARATOR ARMS

Continue to Smoke



Smoking
Abstinence



KEY OUTCOMES

Comparison of urinary and blood BOEs between HTP arms and the corresponding Continue Smoking arm following 5 days of *ad libitum* use of HTPs or cigarettes in a confinement setting.

✓	Biomarkers of Exposure (BOE)
✓	Daily Product Use
✓	Biomarkers of Potential Harm (BOPH)
✓	Modified Cigarette Evaluations Questionnaire (mCEQ; modified for HTP)

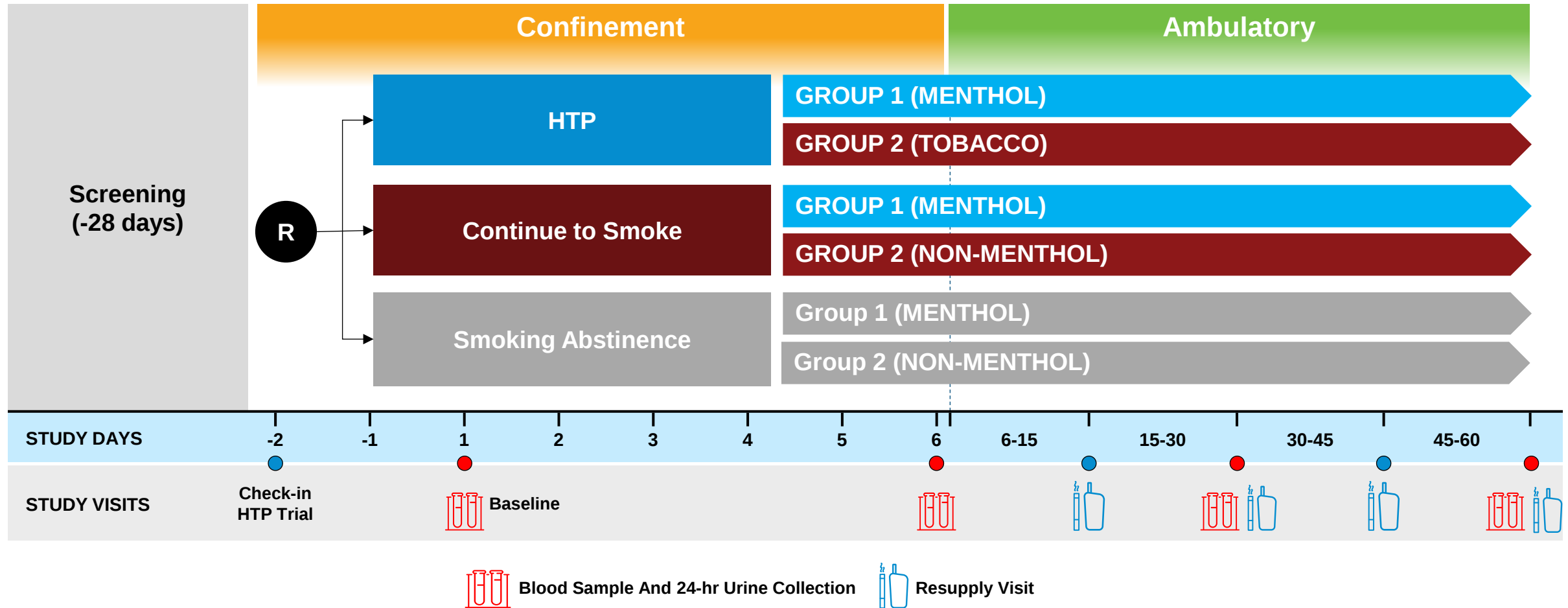
PARTICIPANTS



Adult Smokers of Combustible Cigarettes

- 10 – 30 cigarettes per day during last 12 months
- No plan to quit smoking in next 3 months

Study Overview



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Biomarkers of Exposure Endpoints

Biomarkers	Associated HPHC	Abbreviation	Classification
3-hydroxypropyl mercapturic acid	Acrolein	3-HPMA	RT, CT
2-cyanoethyl mercapturic acid	Acrylonitrile	CEMA	CA, RT
1-amino-naphthalene	1 amino-naphthalene	1-AN	CA
2-amino-naphthalene	2 amino-naphthalene	2-AN	CA
4-aminobiphenyl	4-aminobiphenyl	4-ABP	CA
S-phenyl mercapturic acid	Benzene	S-PMA (SPMA)	CA, CT, RDT
3-hydroxybenzo[a]pyrene	Benzo-a-pyrene	3-OH-B[a]P	CA
2-hydroxybutenyl mercapturic acid	1,3 butadiene	2-MHBMA	CA, RT, RDT
Carboxyhemoglobin	Carbon monoxide	COHb	RDT
3-hydroxy-1-methylpropyl mercapturic acid	Crotonaldehyde	HMPMA	CA
2 hydroxyethyl mercapturic acid	Ethylene oxide	HEMA	CA, RT, RDT
Total 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol	4-(methylnitrosoamino)-1-(3-pyridinyl)-1-butanone	NNAL	CA
Total N'-Nitrosonornicotine	N'-Nitrosonornicotine	NNN	CA
Nicotine equivalents* (nicotine, cotinine, 3-hydroxycotinine and their glucuronide conjugates)	Nicotine	NE	RDT, AD

Note: * Total Nicotine Equivalents (NE) was not one of the primary endpoints, AD: Addictive; CA: Carcinogen; RDT: Reproductive and Developmental Toxicant; RT: Respiratory Toxicant.



Study Population and Smoking History Summary

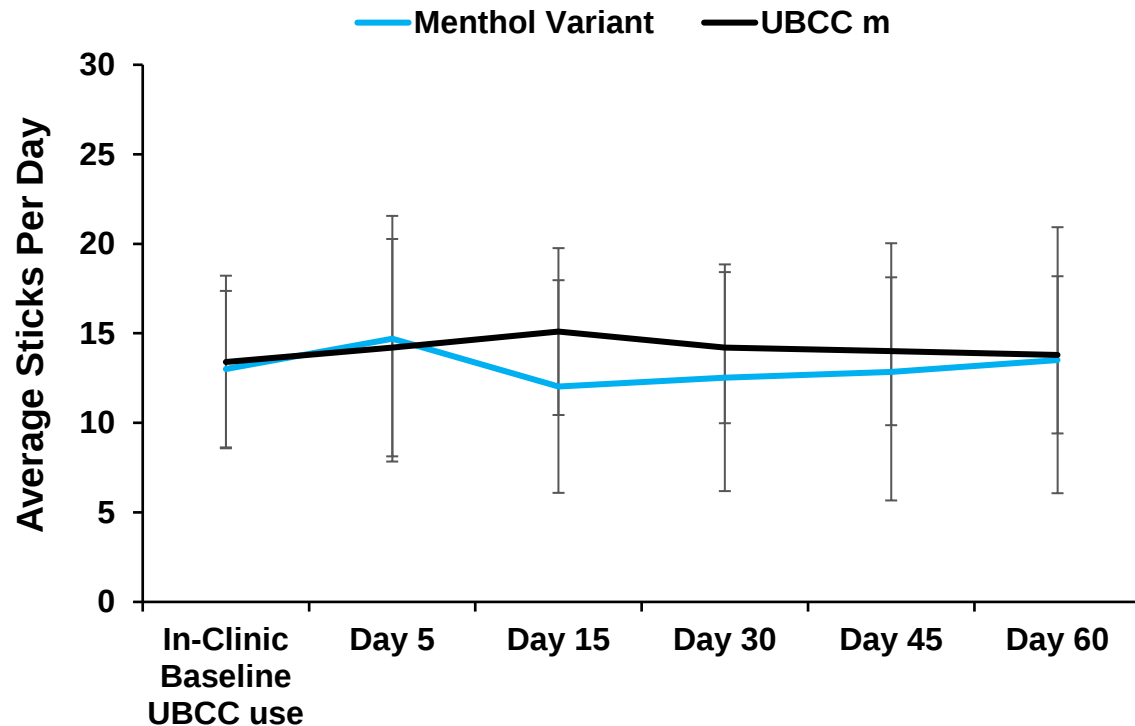
Data Category			Menthol Group (n=149)	Tobacco (Non-menthol) Group (n=147)	Total (n=296)
	Mean Age (SD)		37.5 (8.78)	39.3 (10.33)	38.4 (9.61)
	Body Mass Index (kg/m²) (SD)		28.8 (5.6)	29.1 (5.7)	28.9 (5.6)
	Race (%)	White	52 (35%)	122 (83%)	174 (59%)
		Black or African American	93 (62%)	19 (13%)	112 (38%)
		Other	4 (3%)	6 (4%)	10 (3%)
	Sex (%)	Male	86 (58%)	90 (61%)	176 (59%)
		Female	63 (42%)	57 (39%)	120 (41%)
	Cigarette per Day (SD)		15.5 (4.75)	16.9 (5.07)	16.2 (4.95)
	Years of Cigarette use (SD)		17.9 (9.30)	20.9 (11.14)	19.4 (10.34)

Note: Participants in each flavor group were randomized to one of 3 study arms: HTP arm, Continue to Smoke arm, and Smoking Abstinence arm based on 2:2:1 ratio.

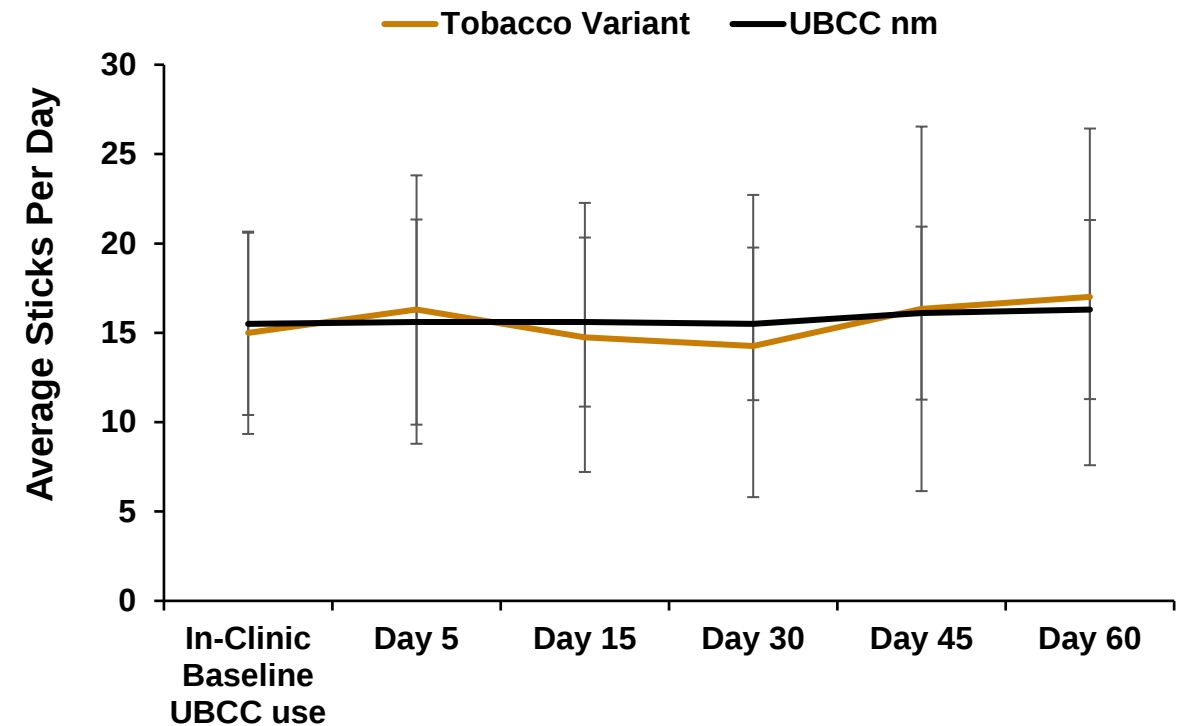


Ploom Use were Comparable to Baseline Cigarette Use

Menthol HTS Versus Menthol Cigarette Use



Tobacco HTS Versus Non-Menthol Cigarette Use



Note: Average sticks used per day shown with SD; Average HTS use were calculated at each follow-up visits (number of packs dispensed – number of packs used and residual HTS); Average number of cigarettes used per day were based on self report from participants in continue to smoke arms (menthol and non-menthol): UBCC m: Menthol Usual Brand Combustible Cigarettes; UBCC nm: Non-menthol Usual Brand Combustible Cigarettes.

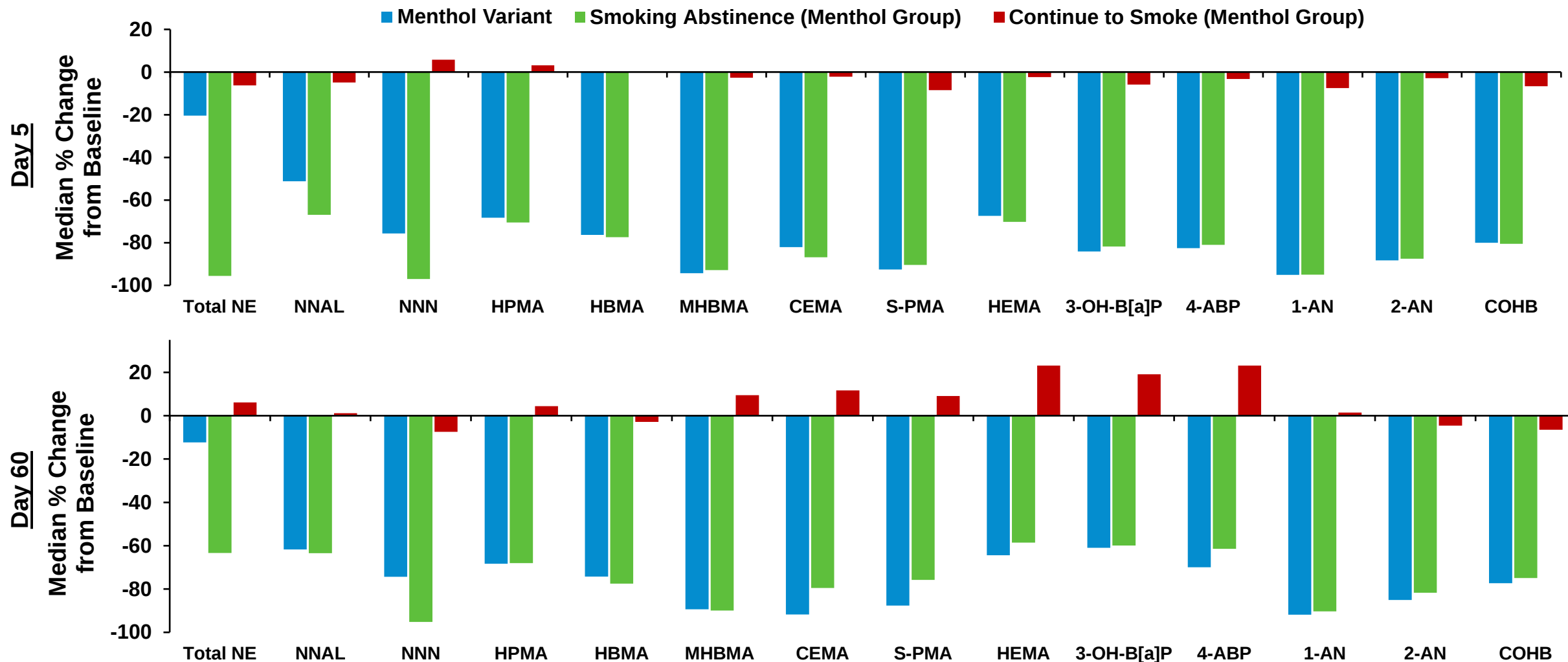


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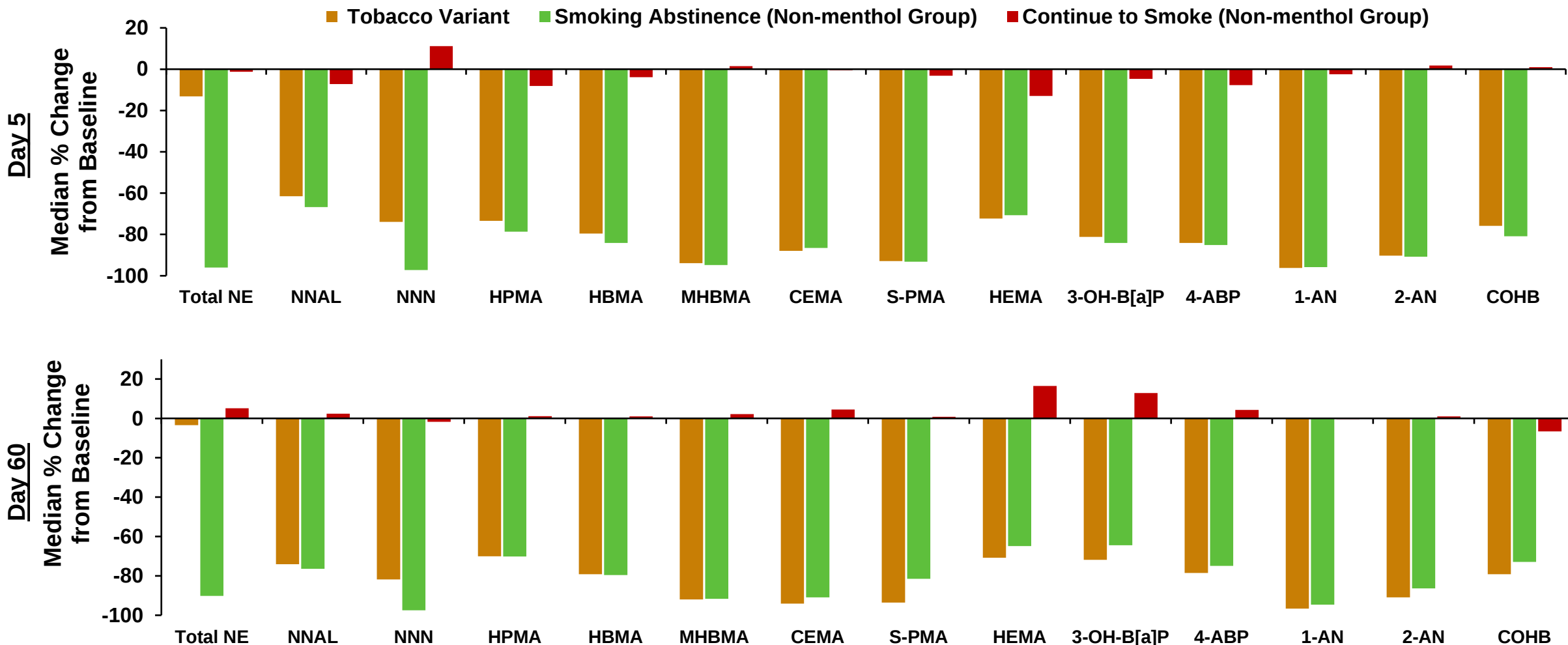
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Ploom Users Experienced Substantial Reductions in non-nicotine BoEs Similar to Smoking Abstinence



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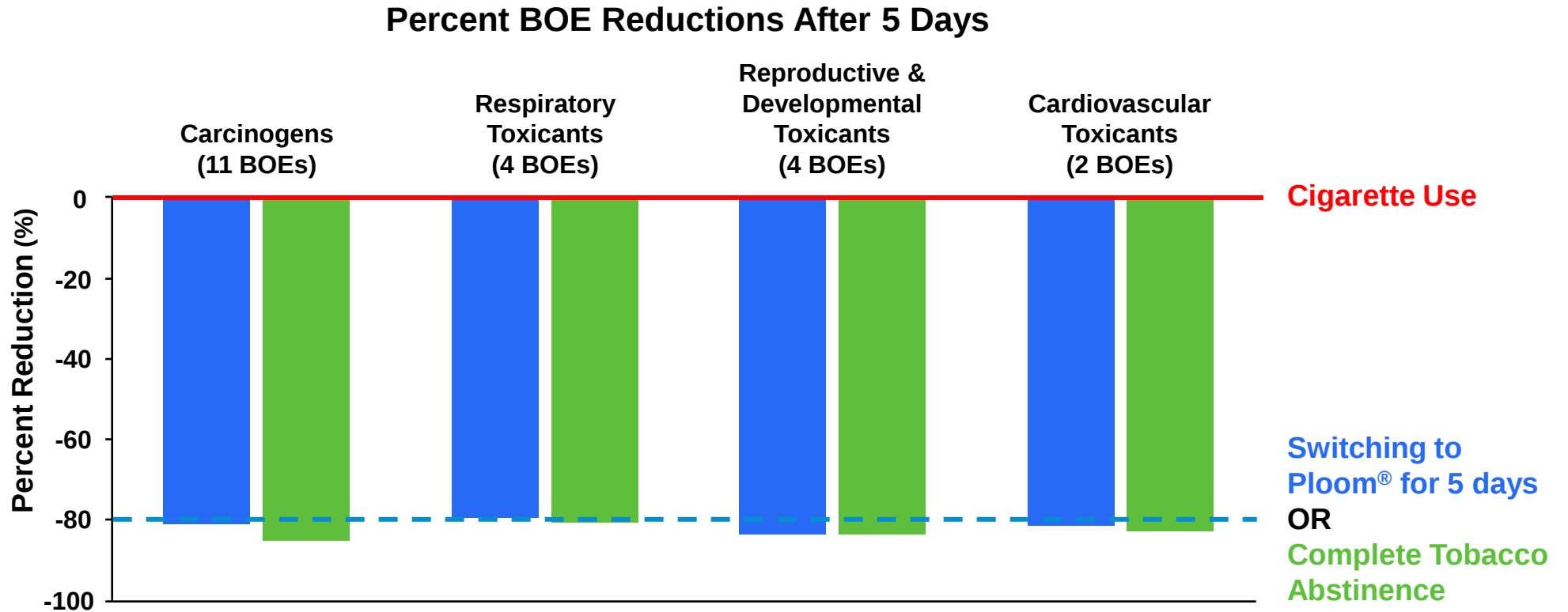
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Overall >80% Reduction in Exposure to Carcinogens and other Harmful Toxicants After Only 5 Days

>80%
Overall
average
reduction



Percent reductions in BOEs among adult smokers who **completely switched to Ploom®** were comparable to **complete tobacco abstinence**, excluding nicotine

Source: ALCS Clinical Study Report ALCS-REG-23-07-HT. Blue Bars represent median percent reductions in measured BOEs when adult smokers completely switched to Ploom for 5 days in our clinical study. Green Bars represent median percent reductions in measured BOEs when adult smokers abstained from all tobacco for 5 days in our clinical study. Some BOEs have more than one classification and are included for each of their classifications. Nicotine BOE is not included. BOE=Biomarkers of Exposure.

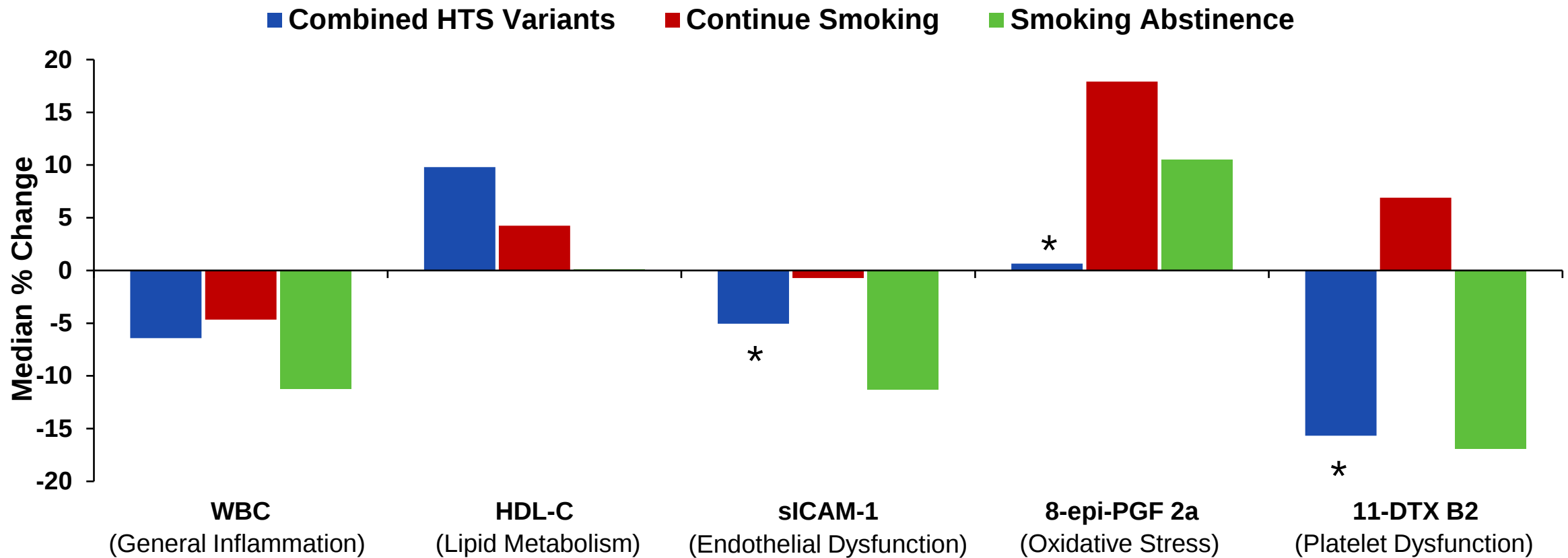


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Reductions in BoE led to Favorable Changes in BOPH Associated with Smoking-related Diseases



Note: HTS: Heated Tobacco Stick; CS: Continue Smoking; SA: Smoking Abstinence; sICAM-1: Soluble Intercellular adhesion molecule-1; WBC: White blood cell count; HDL-C: High density lipoprotein cholesterol; 11-DTX-B2: 11-Dehydrothromboxane B2; 8-epi-PGF2a: 8-epi-prostaglandin F2 alpha; * Statistically significant difference compared to Continued Smoking arm with significance level at $p < 0.05$.

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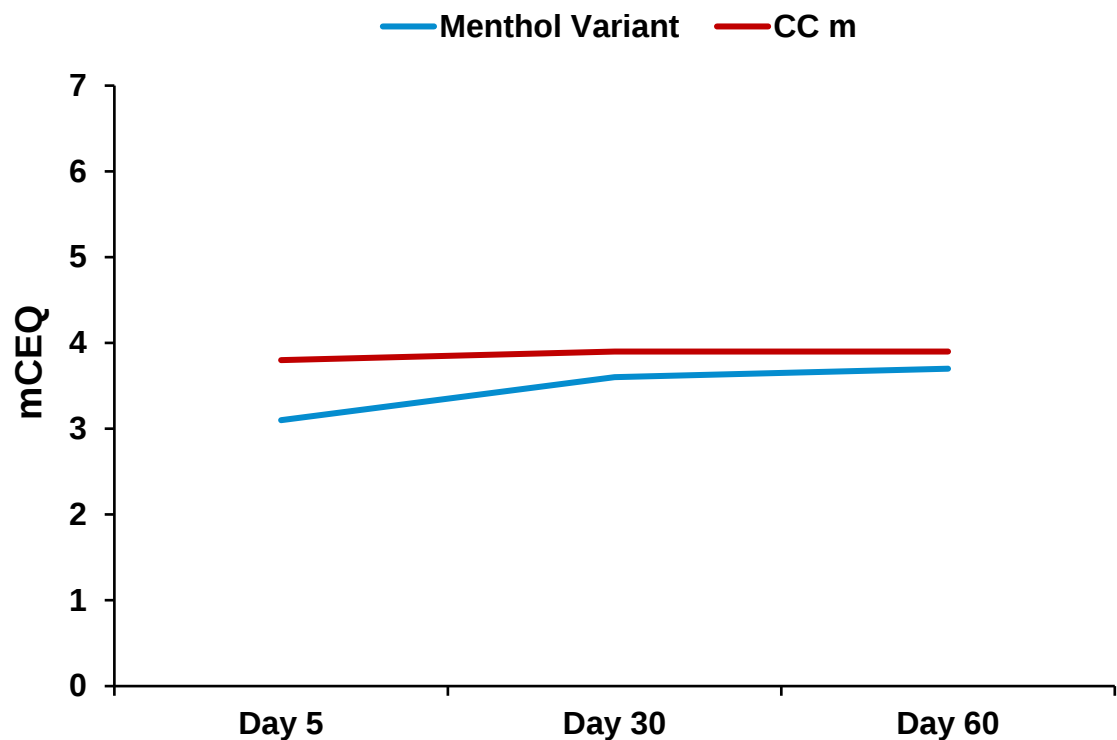


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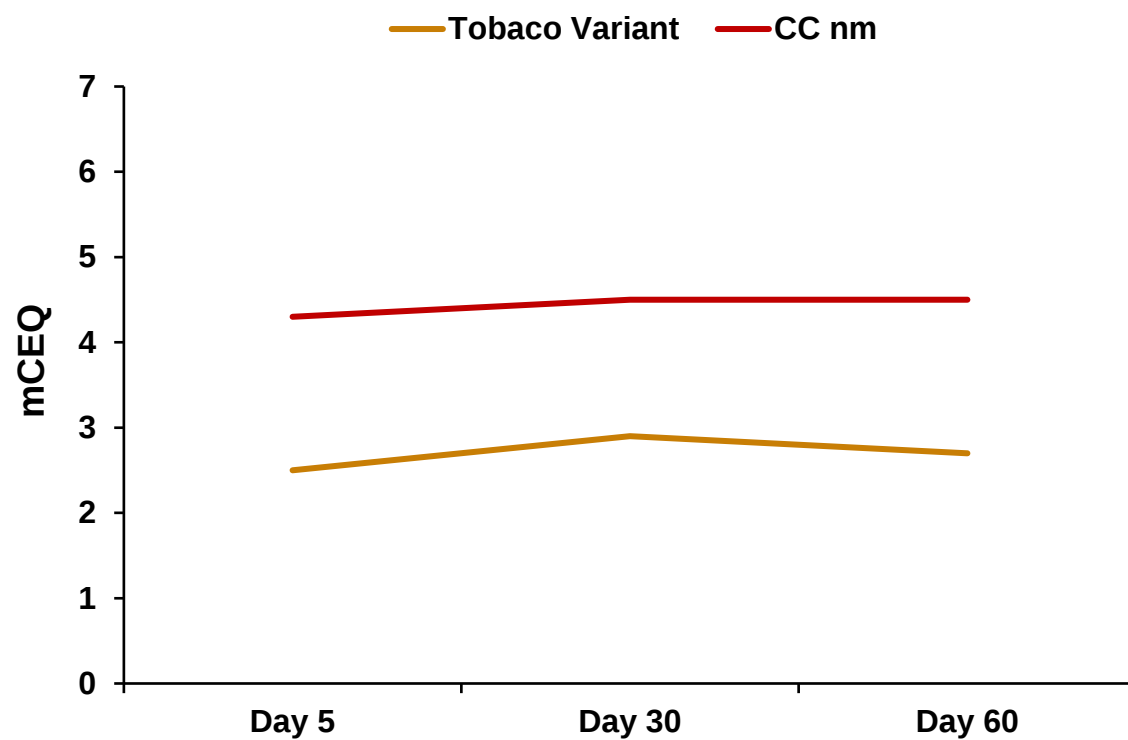
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Users Reported Ploom to be an Enjoyable Experience

Enjoyment



Enjoyment



mCEQ: Modified Cigarette Evaluations Questionnaire

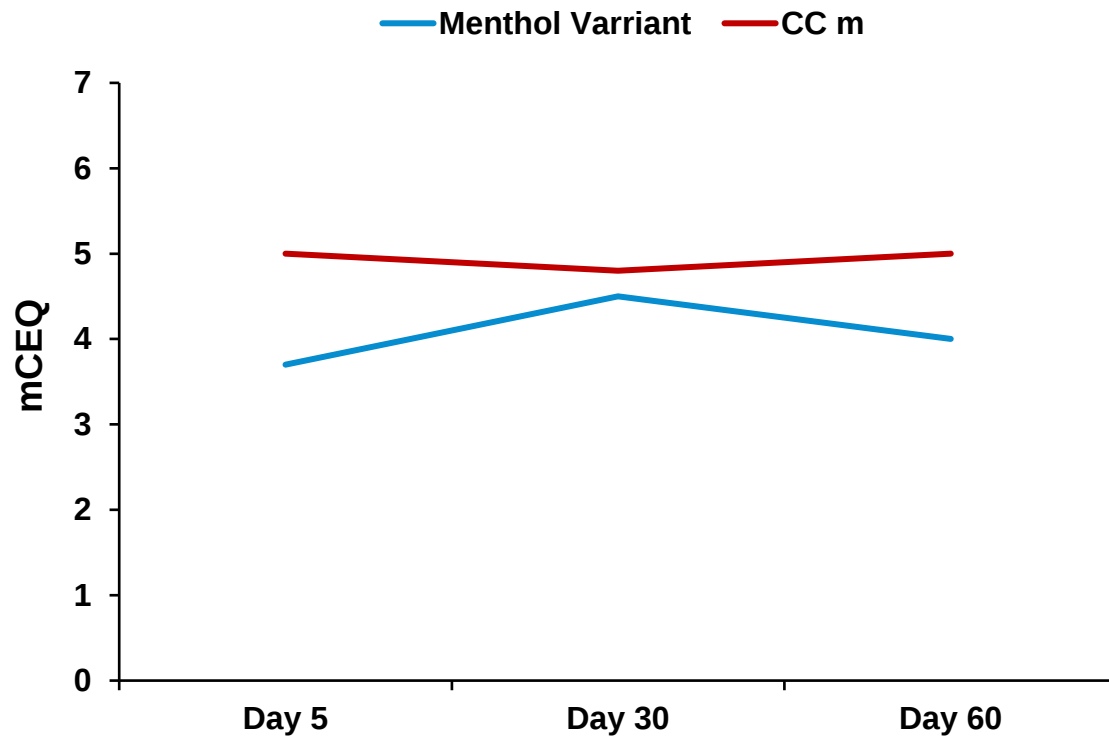


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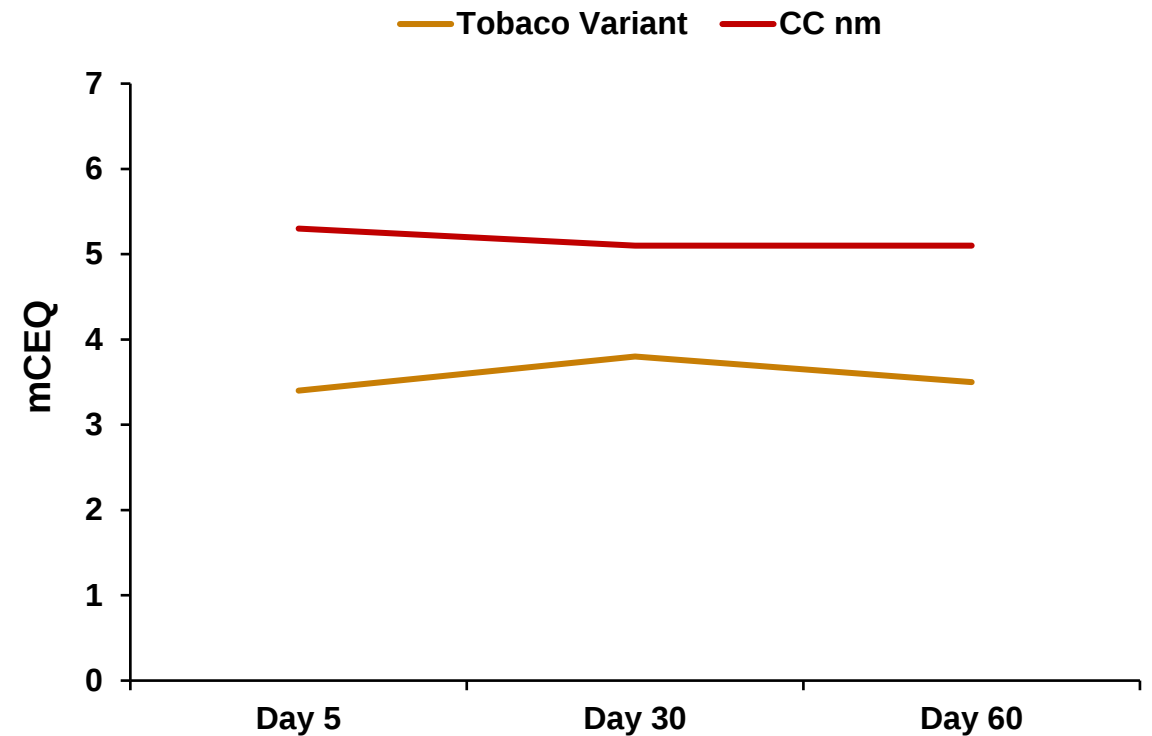
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Users Reported Ploom Reduced Cigarette Cravings

Cigarette Craving Reduction



Cigarette Craving Reduction



mCEQ: Modified Cigarette Evaluations Questionnaire



Summary and Conclusion

After 5 days of completely switching to the Ploom® System, adults 21+ who smoke experienced:



A SUBSTANTIAL REDUCTION

in BOEs to HPHCs

~80%

AVERAGE REDUCTION

of non-nicotine BOE across a range of toxicant classes, with reductions comparable to smoking abstinence



A SIMILAR EXPOSURE TO NICOTINE AS CIGARETTES

Reductions in exposure to HPHCs led to **favorable changes in BOPH associated with smoking-related diseases** after 60 days

Overall, this study demonstrates that:

Switching completely to the Ploom® system from combustible cigarettes substantially reduces exposure to harmful chemicals AFTER 5 DAYS and likely reduce the risk of smoking-related diseases in adults 21+ who smoke and choose to switch completely.



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Any Questions?



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