

# Nicotine Pharmacokinetics and Subjective Effects During Use of Ploom Heated Tobacco Products Compared to Combustible Cigarettes and Nicotine Gum Among Adults Who Smoke

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Senior Principal Scientist, Altria Client Services



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— FAMILY OF COMPANIES —



# Presentation Agenda



## **01 Background**

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## **02 Overview of Study Design**

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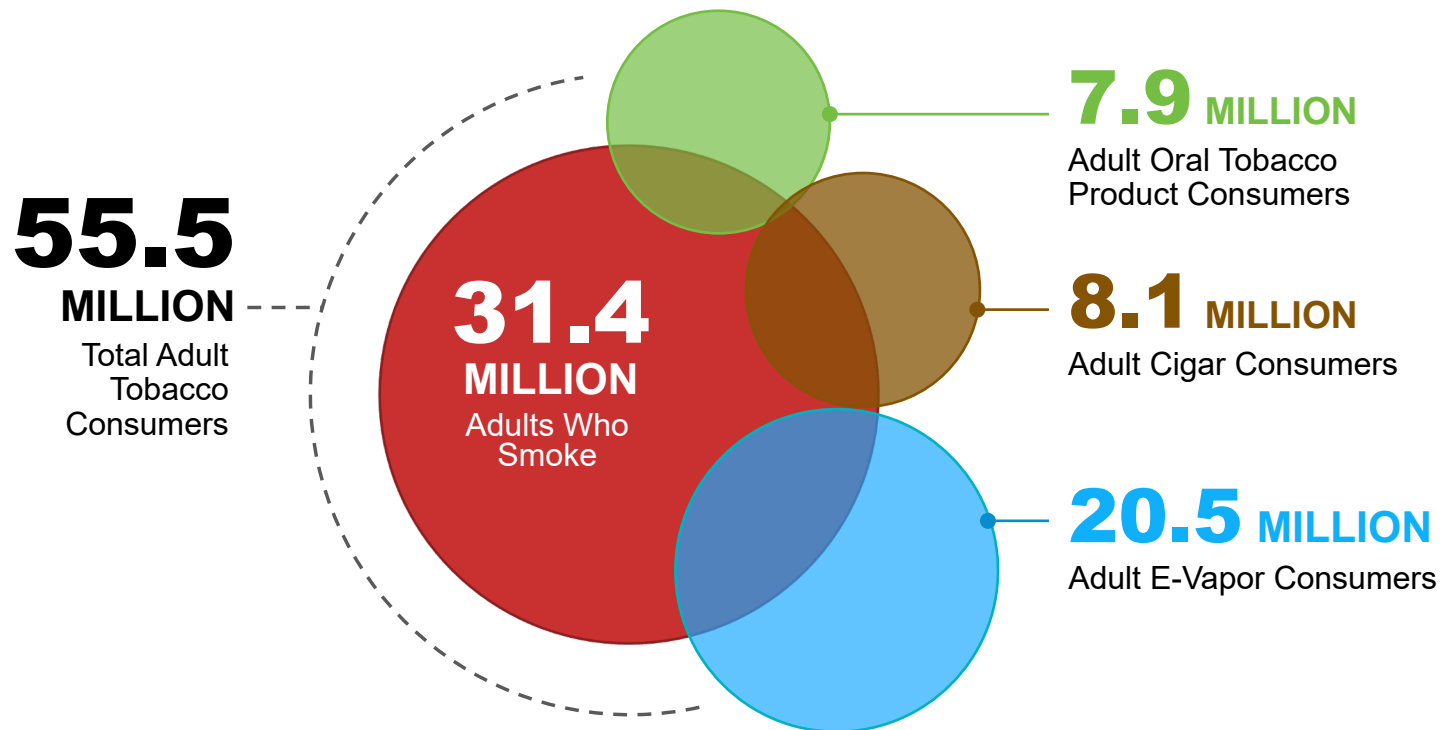
## **03 Study Results**

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## **04 Discussion**



# Population of Adults Who Smoke in The U.S. is Still Sizeable



Altria Client Services LLC. (2025). Adult Tobacco Consumer Tracker (ATCT) – Q2, 2025.

Proprietary analysis based on survey data from adult tobacco consumers in the United States. Note: Overlaps do not represent the actual number of dual users.



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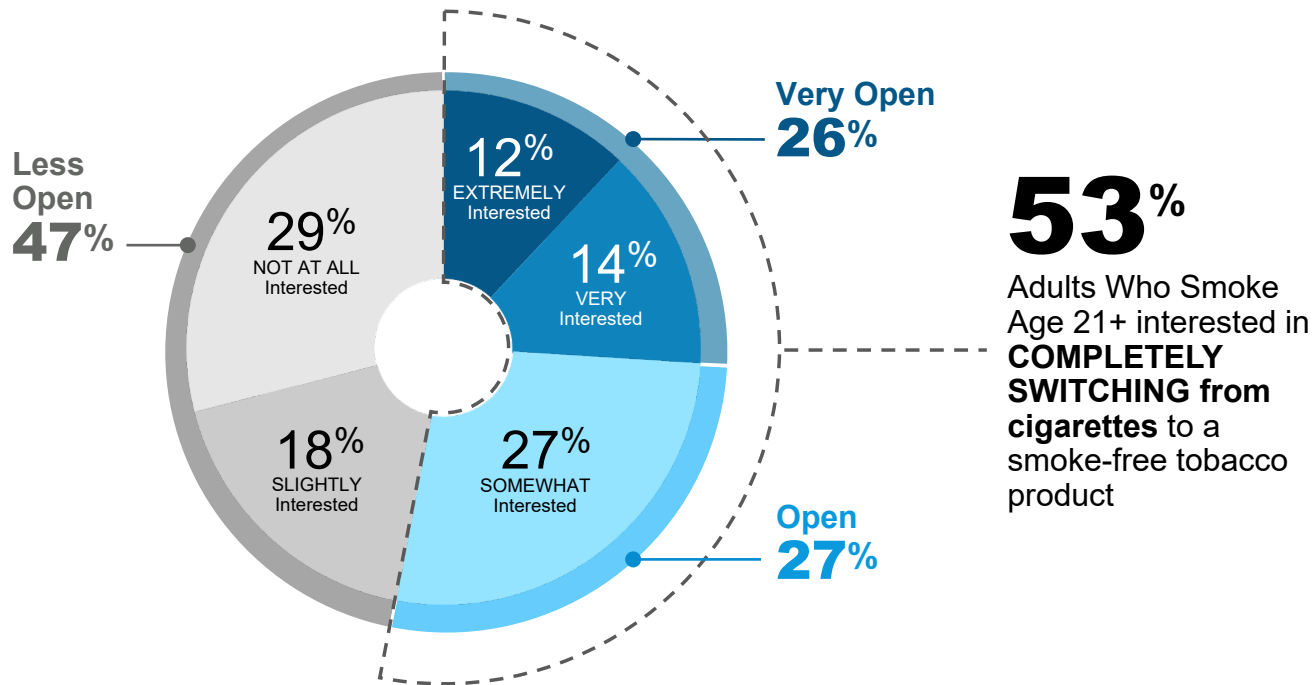
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# There is Interest Among U.S. Adults Who Smoke in Completely Switching to Smoke-free Products

**?** ADULTS WHO  
SMOKE 21-54  
n=4037

In the next 6 months, how interested are you in **completely switching** all of your current cigarette usage occasions to a different tobacco product (such as e-vapor, smokeless tobacco, snus, or nicotine pouches)?



ALCS Consumer Market Insights Data.



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# The Ploom® System

## Ploom® Device



Generates aerosol without  
burning of tobacco



Designed to provide  
satisfying user experiences



## Heated Tobacco Sticks

### Menthol-Flavored

Menthol 1

Menthol 2

### Tobacco-Flavored

Tobacco 1

Tobacco 2



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# FDA Regulation of Tobacco Products

## Product Pathways

### Premarket Tobacco Application (PMTA)

“

...the finding as to whether the marketing of a tobacco product for which an application has been submitted is **appropriate for the protection of the public health (APPH)** shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product...

”



# Scientific Framework for New Tobacco Products

## CONSTITUENT REDUCTION

Product  
Design and  
Control

Chemical  
and Physical  
Characterization



### THE PRODUCT

- Chemistry Manufacturing and Controls
- Product Stability
- Chemical characterization

## INDIVIDUAL RISK REDUCTION

Toxicology  
and Risk  
Assessment

Studies in  
Adult Human  
Subjects



### EXPOSURE and HEALTH RISK

- Toxicology & Risk Assessment
- Health risk assessment (absolute and relative)
- Human Studies
- Human Factors Assessment

## POPULATION HARM REDUCTION

Perception  
and Behavior  
Assessment

Risks and  
Benefits to  
Health of the  
Population



### IMPACT on the POPULATION

- Risk perceptions (absolute and relative)
- Impact of product on users
- Impact on non-users
- Overall impact on the population
- Environmental Assessment



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# Ploom® System Aerosol is Chemically Less Complex with Lower Levels of Emissions Compared to Cigarette Smoke



**Smoke and aerosol were collected on a Cambridge filter pad using Health Canada Intense Puffing Regime**



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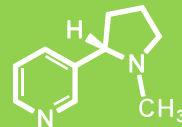
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# Abuse Liability Assessment (ALA) of The Ploom® System

**ALA relies on nicotine exposure and subjective effects**

## **NICOTINE EXPOSURE**

Pharmacokinetics (PK)



## **SUBJECTIVE EFFECTS**

Pharmacodynamics (PD)  
Product Liking, Satisfaction, Craving,  
and Withdrawal



**ALA is also informed by switching potential and potential health risks**

## **USE PATTERNS**

Topography, Actual Use/Switching,  
Use Not as Intended



## **HEALTH RISK ASSESSMENT**

Chemical Analyses,  
In Vitro Assessment, Human Exposure.





# Study Overview

## STUDY DESIGN

Randomized, six-way cross-over study including:

### PLOOM® SYSTEM

4 Heated Tobacco Products with no combustion



### COMPARATOR PRODUCTS

Usual Brand Combustible Cigarette



Nicorette® Nicotine Gum



## KEY OUTCOMES

Plasma nicotine pharmacokinetics of study products assessment of subjective effects:

- |   |   |
|---|---|
| ✓ | Nicotine /Tobacco Withdrawal Symptoms                           |
| ✓ | Direct Effect of the Product                                    |
| ✓ | Product Liking  |
| ✓ | Modified Cigarette Evaluations Questionnaire (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



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# Study Population and Smoking History Summary

## DATA CATEGORY

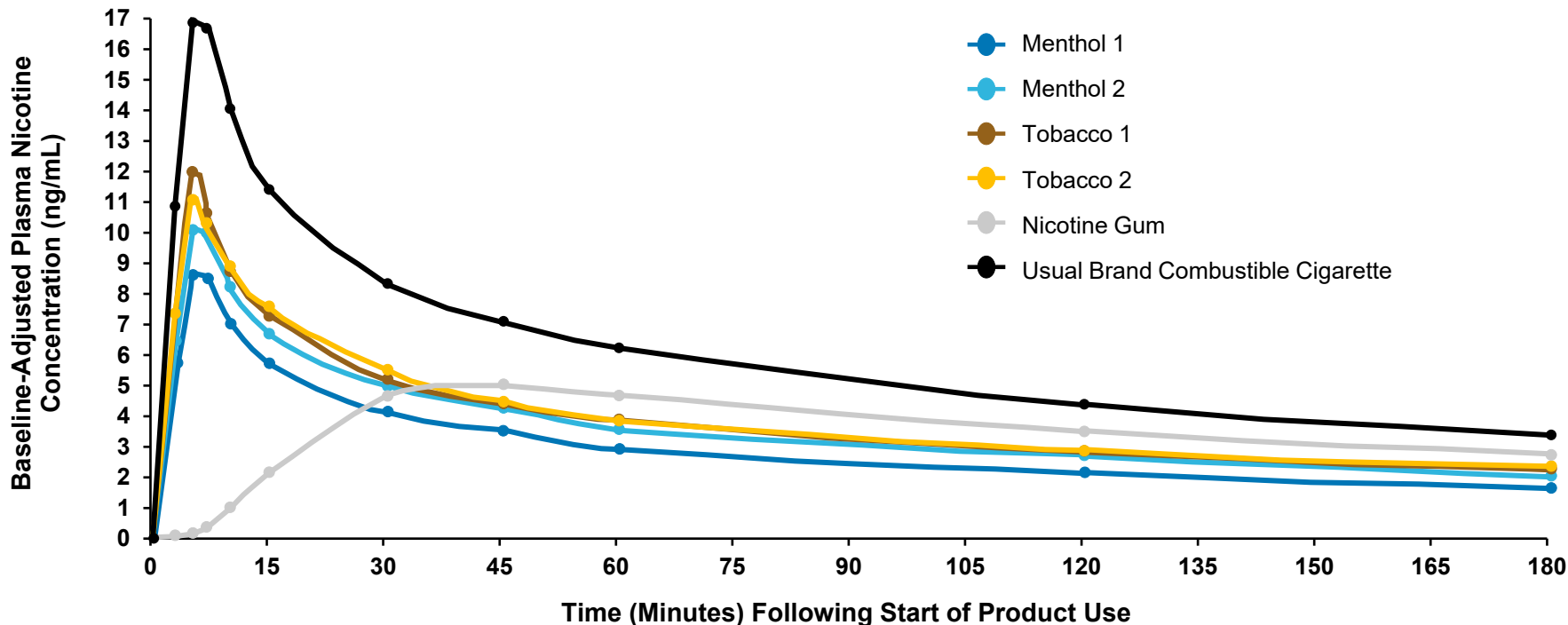
## OVERALL

Mean (SD)/ Range (min/max)

 <b>Mean Age (SD)</b>	<b>39 (7.63)</b>
 <b>Body Mass Index (kg/m<sup>2</sup>) (SD)</b>	<b>30.62 (5.63)</b>
 <b>Usual Brand Cigarette Flavor Category (%)</b>	<b>Menthol</b> <b>30 (50%)</b>
	<b>Non-Menthol</b> <b>30 (50%)</b>
 <b>Cigarette per Day (min/max)</b>	<b>15.7 (10/30)</b>
 <b>Years of Cigarette use (min/max)</b>	<b>21.1 (2/40)</b>



# Maximum Nicotine Concentration During Use of Ploom® System Was Lower than Cigarettes but Higher than Nicotine Gum



Source: ALCS Clinical Study Report ALCS-REG-23-08-HT. Graph generated using baseline adjusted arithmetic values of plasma nicotine concentrations at each time point;



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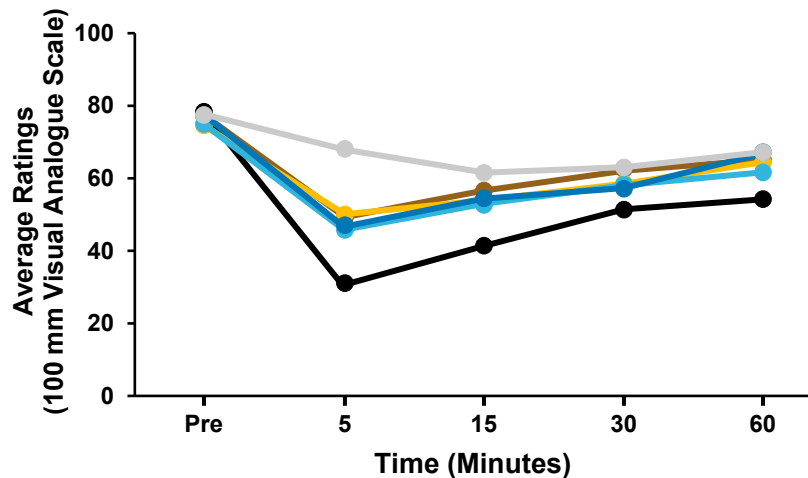
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# Ploom® System Reduced Nicotine Withdrawal Symptoms More than Nicotine Gum and Similar in Profile to Cigarettes

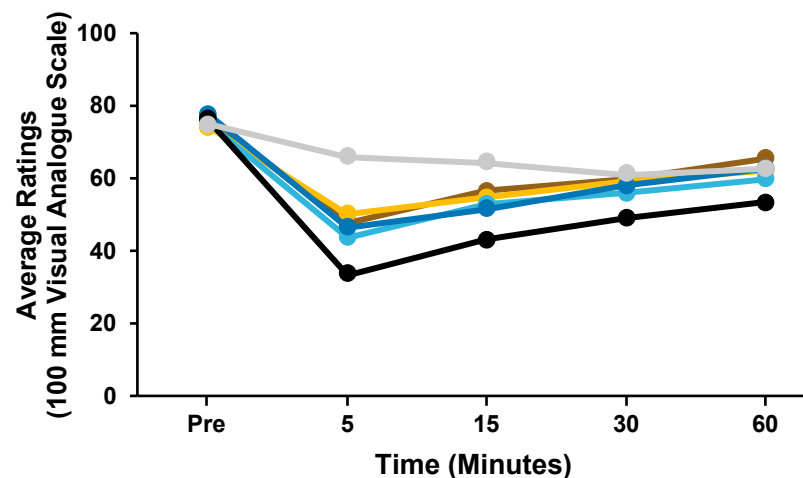


INDIVIDUAL RISK REDUCTION

## Cigarette Craving



## Urge to Smoke



● Menthol 1    ● Menthol 2    ● Nicotine Gum  
● Tobacco 1    ● Tobacco 2    ● Usual Brand Combustible Cigarette

Source: ALCS Clinical Study Report ALCS-REG-23-08-HT.



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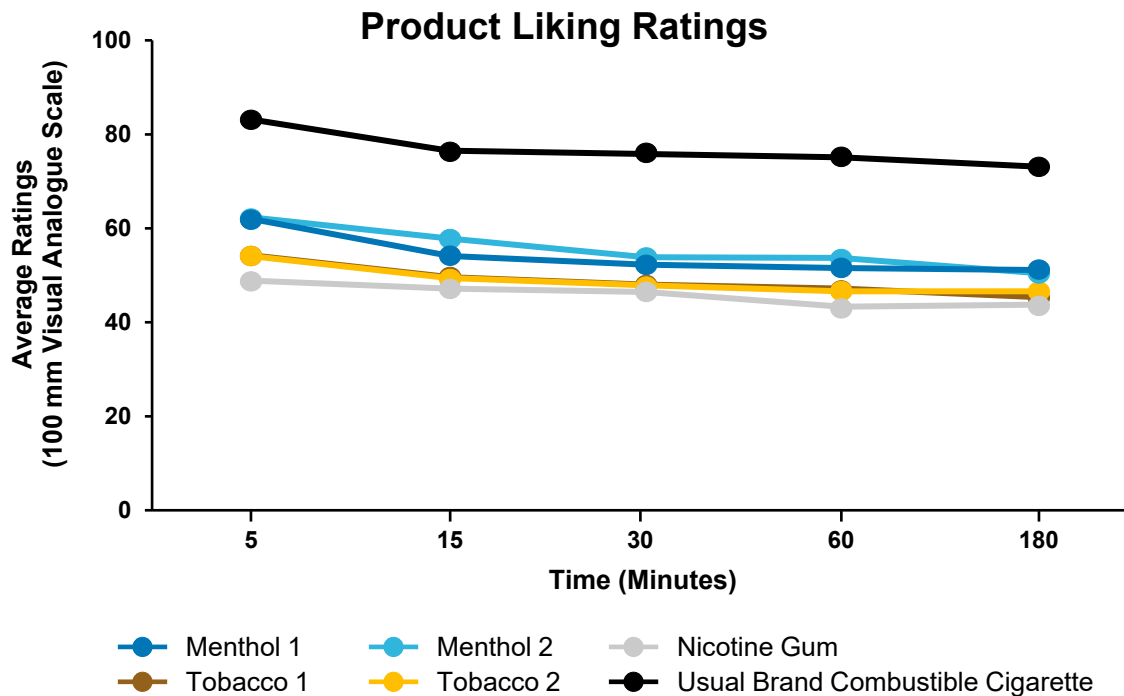
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# Product Liking Ratings were Lower than Cigarettes and Similar to Nicotine Gum



INDIVIDUAL RISK REDUCTION



Source: ALCS Clinical Study Report ALCS-REG-23-08-HT.



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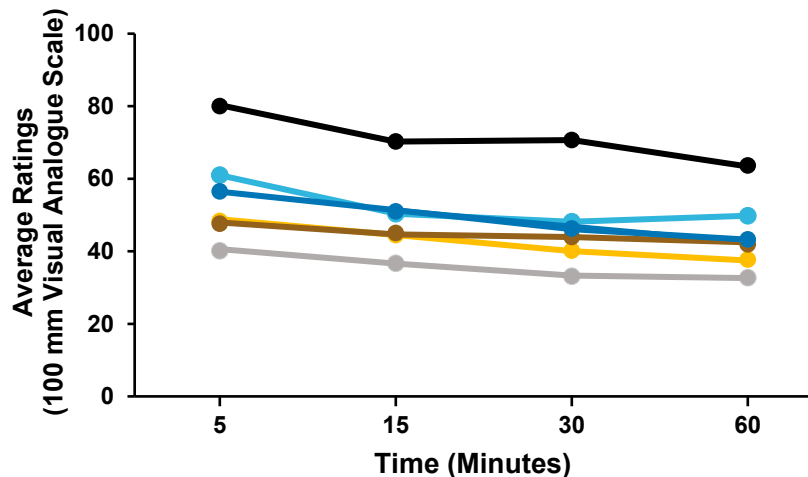
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# Ploom® System is Pleasant and Satisfying, Lower than Cigarettes but Similar to Nicotine Gum

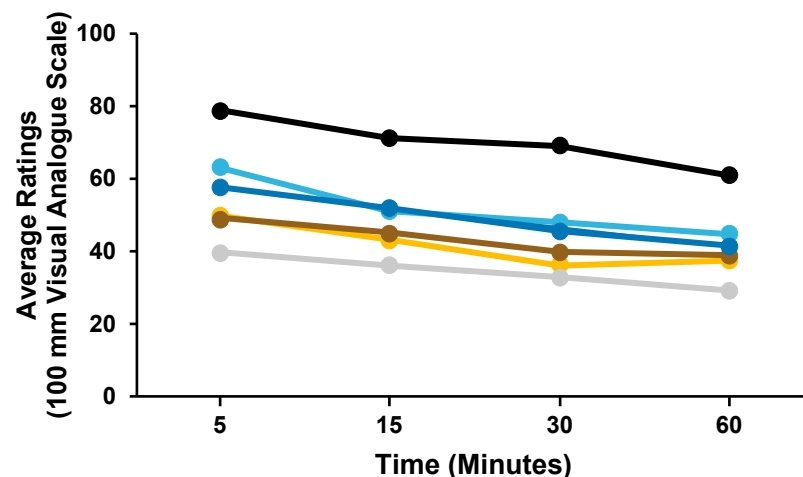


INDIVIDUAL RISK REDUCTION

## Is the product "Pleasant" right now?



## Is the product "Satisfying" right now?



● Menthol 1    ● Menthol 2    ● Nicotine Gum  
● Tobacco 1    ● Tobacco 2    ● Usual Brand Combustible Cigarette

Source: ALCS Clinical Study Report ALCS-REG-23-08-HT.



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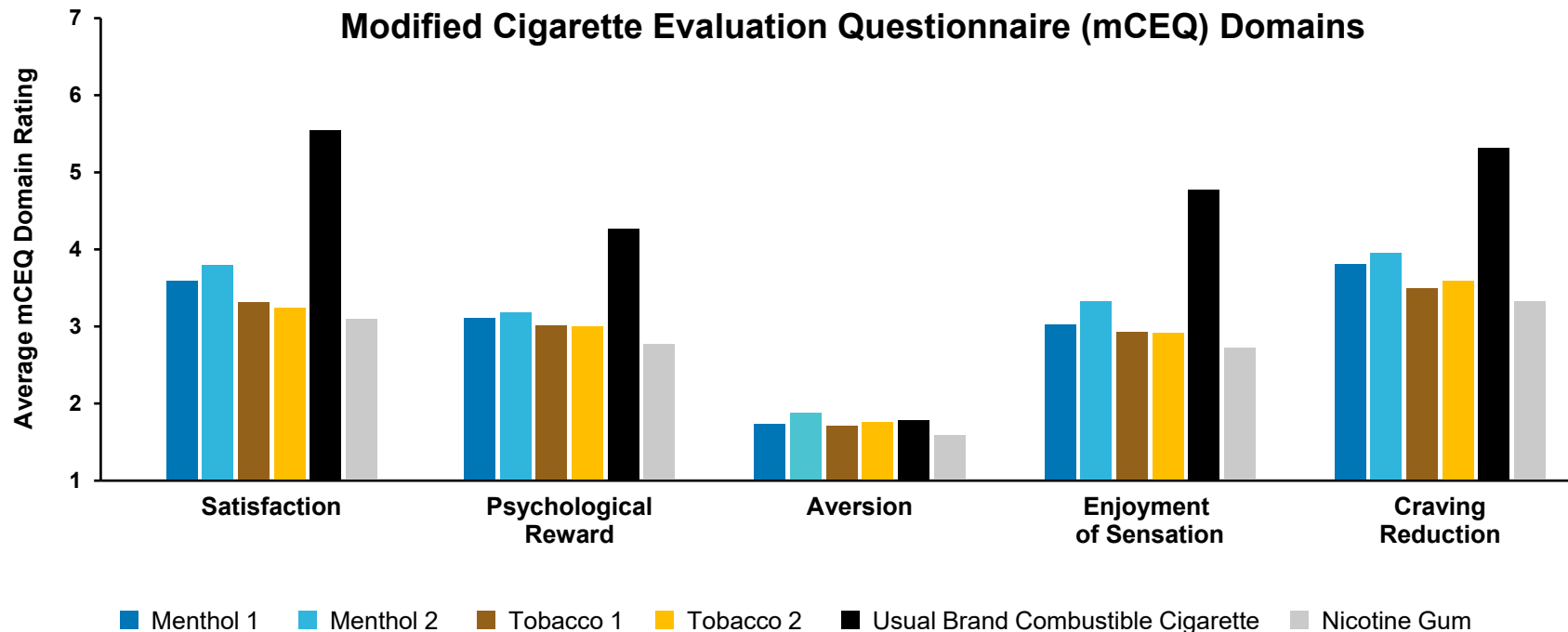
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# Ploom® System is Likely to Have Lower Reinforcing Effects than Cigarettes



INDIVIDUAL RISK REDUCTION



Source: ALCS Clinical Study Report ALCS-REG-23-08-HT.



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# Summary and Conclusion

**Ploom® System**

## **NICOTINE EXPOSURE**

Pharmacokinetics (PK)

**Deliver lower nicotine  
than cigarettes**

## **SUBJECTIVE EFFECTS**

Pharmacodynamics (PD)

Product Liking, Satisfaction, Craving,  
and Withdrawal

**Reduced craving  
and urge to smoke**

**Overall, data suggest Ploom® System is a satisfying and pleasant alternative to smoking for adults who smoke with likely lower abuse liability than a cigarette**



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# Acknowledgments

## Study Team Members

Study Manager: Scott Rensch

Statistical Lead: Gang Sun

Medical Lead: Jianmin Liu

Bioanalytical Lead: Yevgeniya Prepelitskaya

Sr. Director: Jeffery Edmiston





Any

**Questions?**



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