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# Adult IQOS User Postmarket Cross-Sectional Study in the United States (PMSS-PMX-01-US)

## Appendix 2 – Statistical Analysis Plan (SAP)

<b>Study Title:</b>	Adult IQOS User Postmarket Cross-Sectional Study in the United States
<b>Sponsor</b>	Philip Morris Products S.A. Avenue de Rhodanie 50 1007 Lausanne Switzerland
<b>CRO</b>	(b) (4)
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## SIGNATURES

This Statistical Analysis Plan (SAP) was subject to critical review and has been approved by the Sponsor. The following signatories approved this SAP:

### Authors:

(b) (6) <i>Biostatistician</i>	See electronic signature
(b) (4)	

<b>Emery Ngamasana</b> <i>Manager Regulatory Consumer Research</i>	See electronic signature
Philip Morris Products S.A., Washington, D.C., USA	

### Approvers:

<b>Jessica Seifert, PhD, MPH</b> <i>Head of Regulatory Postmarket Research</i>	See electronic signature
Philip Morris Products S.A., Washington, D.C., USA	

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## List of Abbreviations

Abbreviation	Definition
CI	Confidence Interval
CLP	Customer Loyalty Program
CRO	Contract Research Organization
DMP	Data Management Plan
ENR	All Subjects Enrolled
FDCA	Federal Food, Drug and Cosmetic Act
FTND	Fagerström Test of Nicotine Dependence
HPHC	Harmful or Potentially Harmful Constituent
ICS	Informed Consent Statement
IQOS	IQOS Tobacco Heating System and IQOS Heated Tobacco Sticks
IQR	Interquartile Range
IRB	Institutional Review Board
M	Mean / Average
Max	Maximum
Min	Minimum
MRTPA	Modified Risk Tobacco Application
MTSS	Motivation To Stop Smoking
NHIS	National Health Interview Survey
NSDUH	National Survey of Drug Use and Health
PATH	Population Assessment of Tobacco and Health
PMP	Philip Morris Products
PMSS	Post-Market Surveillance and Studies
Q1	First Quartile
Q3	Third Quartile
SAP	Statistical Analysis Plan
SD	Standard Deviation
TFLs	Tables, Figures, Listings
TNP	Tobacco or Nicotine Product
US	United States

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## 1 Introduction

Philip Morris Products S.A. (PMP) submitted a Modified Risk Tobacco Application (MRTPA) to the US Food and Drug Administration (FDA) seeking authorization to market the IQOS Tobacco Heating System and IQOS heated tobacco sticks (formerly “Marlboro HeatSticks”) as modified risk tobacco products. The IQOS Tobacco Heating System is an electronic device that heats IQOS heated tobacco sticks, generating a nicotine-containing aerosol with significantly fewer harmful and potentially harmful constituents than the smoke generated by combusted tobacco products. Based on the evidence provided in the MRTPA, the FDA issued “Modified Risk Granted Orders – Exposure Modification” authorizing PMP to market IQOS with a reduced exposure claim ([Food and Drug Administration \[FDA\], 2020](#)).

The Orders are conditioned upon the execution of post-market surveillance and studies (PMSS) in accordance with protocols approved by FDA. This document was prepared as part of the PMSS program for IQOS pursuant to the Orders.

The Federal Food, Drug and Cosmetic Act (FDCA) directs the FDA to condition an exposure modification order received under FDCA § 911(g)(2) on the MRTP applicants’ agreement to conduct PMSS (FDCA §§ 911(g)(2)(C)(ii)). “The outcomes evaluated in postmarket surveillance and studies should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use” ([FDA, 2012](#)). For this reason, PMP, plans to conduct certain components of PMSS to assess the effect of the MRTP among US consumers. The program will consist of a collection of data over time that supports an assessment of IQOS in the postmarket setting. The current study, United States (US) Adult IQOS User Postmarket Cross-Sectional Study is one such study.

The purpose of the United States (US) Adult IQOS Users Postmarket Cross-Sectional Study is to provide repeated real-world survey data from cross-sections of adult ever established IQOS users and to assess IQOS use and related risk perceptions and associations with other tobacco use behaviors.

## 2 Objectives

The objectives of this study are to:

1. Describe sociodemographic and health-related characteristics of adult ever established IQOS users.
2. Characterize historical and current tobacco use patterns of adult ever established IQOS users.

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3. Assess adult ever established IQOS users' health risk perceptions related to IQOS use, cigarette smoking, and complete smoking cessation.
4. Characterize IQOS use and other tobacco use patterns, including product initiation, complete switching from cigarette smoking to IQOS, transitions to (never smokers) and back (former smokers) to cigarette smoking, and quitting behaviors relevant to IQOS use.

### 3 Study Design

This study is an online, repeated cross-sectional survey administered annually over the course of four years. Two computerized data collection instruments will be used – a Participant Screener and the Main Survey.

This study intends to recruit adults ( $\geq 21$  years) ever established (i.e., have used 100 or more IQOS heated tobacco sticks in their lifetime) IQOS users in the US. Study invitations with unique links to the Participant Screener will be delivered via email, direct mail, and/or text to adult IQOS purchasers who have registered their device in the US IQOS Customer Loyalty Program (CLP) and opted in to receive communications from PMP. Interested individuals who follow the study invitation link will be directed to begin the Participant Screener. Those not terminated at the initial screen will then be directed to review the study Informed Consent Statement (ICS) detailing the study purpose, the voluntary nature of their participation, data privacy and confidentiality guidelines, and contact information for the Institutional Review Board (IRB) and Contract Research Organization (CRO).

After reviewing the ICS and providing consent to participate in the study, potential participants will complete the Participant Screener Survey to determine their eligibility. Eligible participants will then be administered the Main Survey, that will collect the participant data needed to assess the study objectives.

#### 3.1 Main Survey Instrument

Main Survey items were curated specifically to address the objectives of this study. Wherever feasible, survey items were sourced and/or adapted from national surveys and items used in previous studies, including the Population Assessment of Tobacco and Health (PATH) (Hyland et al., 2017), the National Health Interview Survey (NHIS) (Parsons, 2014), and the National Survey of Drug Use and Health (NSDUH) (Center for Behavioral Health Statistics and Quality, 2023). Furthermore, cognitive testing of the study instrument was executed by Altria Client Services in early 2020 and survey items were updated when needed.

Survey questions will capture participants' historical (e.g., ever use) and current (e.g., past 30-

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day use) IQOS and other TNP use. Generally, most questions pertaining to IQOS will be asked at the brand level (i.e., IQOS with heated tobacco sticks) not at the IQOS heated tobacco sticks variety level (e.g., Bronze heated tobacco sticks). The survey will also capture participants' sociodemographic characteristics (e.g., age, gender, income), pregnancy status, and tobacco use-related health outcome history (e.g., heart attack, COPD).

For enhancement of data validity and data consistency, checklist items will be randomized and skip logic will be incorporated into the questionnaires to reduce participant burden.

### ***Health risk perceptions***

Participants' lifetime health risk perceptions will be measured using the ABOUT™—Perceived Risk instrument (Cano et al., 2018). ABOUT™ is based on an underlying conceptual framework developed from a range of extensive qualitative studies with different populations (adult current smokers, adult former smokers, and adult never smokers), literature review, and input from expert panels (Cano et al., 2018). The short 9-item scale version will be used in this study. This version contains psychometrically valid measures capable of measuring health risk perceptions for different types of tobacco products and various levels of smoking status. The study survey will also capture participants' exposure harm perceptions related to smokers completely switching to IQOS.

### ***Tobacco dependence***

Tobacco dependence for IQOS and cigarettes will be measured using the Fagerström Test of Nicotine Dependence (FTND) (Heatherton et al., 1989). FTND has been validated for use across TNP categories other than cigarettes and has demonstrated good psychometric properties for measuring the intensity of physical dependence on nicotine (Mushtaq & Beebe, 2017; Piper et al., 2020; Sharma et al., 2021).

### ***Motivation to Stop Smoking***

Current established smokers' motivation to quit will be measured based on the Motivation To Stop Smoking (MTSS) scale (Kotz et al., 2013) response selected:

- “I don’t want to stop smoking” (1)
- “I think I should stop smoking but don’t really want to” (2)
- “I want to stop smoking but haven’t thought about when” (3)
- “I REALLY want to stop smoking, but I don’t know when I will” (4)
- “I want to stop smoking and hope to soon” (5)
- “I REALLY want to stop smoking and intend to in the next 3 months” (6)
- “I REALLY want to stop smoking and intend to in the next month” (7)

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Higher MTSS scale scores indicate higher motivation to stop smoking cigarettes.

#### 4 General Definitions

Terms are arranged in alphabetic order. Italicized parts of definitions have their own definition in this section. Users are defined by use behaviors. For example, a current established tobacco or nicotine product (TNP) user is someone who reports both using the TNP in the past 30 days at least once (i.e., current use) and meets the lifetime established criterion for that TNP (i.e., established use). Unless otherwise specified, IQOS refers to IQOS Tobacco Heating System and IQOS heated tobacco sticks in this document.

##### **Complete Switching**

Complete switching generally refers to transitioning from *established use* of a given TNP to reporting no past 30-day use of that TNP (i.e., former established use) and *current established use* of a different TNP.

Outcomes related to complete switching in this study include:

1. Complete switching from cigarettes to IQOS after first trying IQOS will be defined as reporting:

##### Prior to first trying IQOS:

- Met the *lifetime established use criterion* for cigarettes (i.e., 100 or more), AND
- Smoked cigarettes in the 30 days prior to first trying IQOS.

##### At time of assessment:

- Has not smoked cigarettes in the past 30 days, AND
- Is a current established IQOS user.

2. Complete switching from all tobacco products to IQOS after first trying IQOS will be defined as reporting:

##### Prior to first trying IQOS:

- Met the *lifetime established use criterion* for given TNP, AND
- Used given TNP in the 30 days prior to first trying IQOS.

##### At time of assessment:

- Has not used any TNP in the past 30 days, AND
- Is a current established IQOS user.

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3. Completely switching from IQOS to cigarettes after initiating tobacco use with IQOS will be defined as reporting:

At time of assessment:

- IQOS as first TNP ever used, AND
- Is a former established IQOS user, AND
- Is a current established smoker.

### **Consistent Basis**

Consistent basis will be defined as reporting “Yes” to “Have you ever used [tobacco product] routinely or with some type of regularity? Examples might include using the product “every day, a few times every week, only on the weekend.”

### **Current Established Smoker**

Current established smoker will be defined as reporting:

1. Having met the *lifetime established use criterion* for cigarettes (i.e., 100 or more lifetime cigarettes),  
AND
2. Having smoked cigarettes in the past 30 days at time of assessment.

### **Current Established Tobacco or Nicotine Product Use**

Current established use of a given TNP will be defined as reporting:

1. Having met the *lifetime established use criterion* for the given TNP (i.e., 100 or more,  
AND
2. Having used the given TNP in the past 30 days at time of assessment.

### **Current Tobacco or Nicotine Product Use**

Current TNP use will be defined as reporting having used a given TNP in the past 30 days at time of assessment.

### **Ever Established Tobacco or Nicotine Product Use**

Ever established TNP use refers to meeting the *lifetime established use criterion* (see definition below) for a given TNP.

### **Ever Tobacco or Nicotine Product Use**

Ever TNP use will be defined as reporting “Yes” to “Have you ever [used / smoked] [TNP] even one time?”.

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### **Former Established Tobacco or Nicotine Product Use**

Former established TNP use will be defined as reporting:

1. Having met the *lifetime established use criterion* of the given TNP,  
AND
2. No past 30-day use of given TNP at time of assessment.

### **Former Tobacco or Nicotine Product Use**

Former TNP use will be defined as reporting:

1. Having ever used a given TNP, even one time,  
AND
2. Not having used the given TNP in the past 30 days at time of assessment.

### **Initiation**

Initiation of a TNP generally refers to the first use of a given TNP. Outcomes related to initiation in this study include:

1. “First tobacco product ever tried” defined as the given product endorsed in item, “What was the first product you ever tried even one time?”.
2. “First tobacco product ever used on a consistent basis” defined as the given product endorsed in item, “What was the first product you used on a consistent basis?”.
3. Initiation of established cigarette smoking after first trying IQOS:  
Prior to first trying IQOS:
  - Never smoked cigarettes, OR
  - Having not met the lifetime established use criterion for cigarettes (i.e., 100 or more).At time of assessment:
  - Is an established cigarette smoker.

### **Lifetime Established Use Criterion**

The lifetime established use criterion for each TNP will be defined for:

1. Cigarettes as reporting ever having smoked 100 or more cigarettes.
2. IQOS as reporting ever having used 100 or more IQOS heated tobacco sticks.
3. Cigars (including regular cigars, cigarillos, or little filtered cigars) as reporting ever having smoked 50 or more cigars (including regular cigars, cigarillos, or little filtered cigars).
4. Smokeless tobacco (including chewing tobacco, dip, snuff, or snus pouch) as reporting having ever used smokeless tobacco 20 or more times.
5. Regular pipe as reporting ever having smoked 50 bowls or more.
6. Traditional hookah as reporting ever having smoked tobacco in a hookah on a “consistent basis.”

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7. Electronic cigarettes (e-cigarettes) and other e-vapor products as reporting ever having used e-cigarettes on a “*consistent basis*.”
8. Oral nicotine pouches as reporting ever having used oral nicotine pouches on a “*consistent basis*.”

### **Quit Duration**

Quit duration is the length of time since a former established TNP user last used the given established TNP and will be dichotomized into:

- **Short-term TNP quitter** will be defined as reporting not having used a given established TNP for less than 12 months.
- **Long-term TNP quitter** will be defined as reporting not having used a given established TNP for 12 months or longer.

### **Quitting Established Tobacco or Nicotine Product Use**

Quitting established TNP use will be defined as reporting:

1. Having used a given TNP to the *lifetime established use criterion*, AND
2. Having “completely stopped/quit” using the given TNP.

### **Quitting All Established Tobacco or Nicotine Product Use**

Quitting all established TNP use will be defined as reporting:

1. Having used any TNP to the *lifetime established use criterion*, AND
2. Having “completely stopped/quit” using all TNP ever used.

### **Re-Initiation of Cigarette Smoking after First Trying IQOS**

Re-initiation of cigarette smoking after first trying IQOS will be defined as reporting:

#### Prior to first trying IQOS:

- Having met the *lifetime established use criterion* for cigarettes (i.e., 100 or more), AND
- Not having smoked cigarettes for 12 months or longer, AND

#### At time of assessment:

- Past 30-day cigarette smoking.

### **Relapse to Cigarette Smoking after First Trying IQOS**

Relapse to cigarette smoking after first trying IQOS will be defined as reporting:

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Prior to first trying IQOS:

- Having met the *lifetime established use criterion* for cigarettes (i.e., 100 or more), AND
- Not having smoked cigarettes for less than 12 months, AND

At time of assessment:

- Past 30-day cigarette smoking.

### **Tobacco or Nicotine Products**

Tobacco or nicotine products (TNP) include products containing tobacco and/or nicotine. These products may be combustible or non-combustible, depending on intended use.

1. **Combustible Tobacco or Nicotine Products** burn tobacco and produce smoke when consumed / used as intended and include cigarettes, cigars (regular cigars, cigarillos, and little filtered cigars), regular pipes, and traditional hookah (or water pipe).
2. **Non-Combustible Tobacco or Nicotine Products** do not burn tobacco or produce smoke when consumed / used as intended and include heat-not-burn products (e.g., IQOS), smokeless tobacco (dip, snuff, chewing tobacco, and snus pouches), electronic cigarettes (e-cigarettes), and oral nicotine products (excluding nicotine replacement therapy products).

Novel TNP categories may be added to these lists, as well as assessed in this study as they emerge in future US markets.

## **5 Study Endpoints**

All endpoints will be assessed using summary statistics for categorical and/or numerical variables, as described in [Section 9.1](#).

### **5.1 Objective 1 – Describe sociodemographic and health-related characteristics of adult ever established IQOS users.**

Participants' sociodemographic characteristics and select health-related information (see below) will be summarized for the overall sample and by study group. Sociodemographic characteristics and pregnancy status will be further summarized for current established IQOS users by menthol IQOS heated tobacco stick use.

Participants' sociodemographic characteristics will include age, sex, gender identity, sexual orientation, race, ethnicity, education, income, employment status, geographic region, marital status, and military/veteran status.

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Participant health-related information will include:

- Pregnancy status,
- Ever told they had a chronic health condition(s) or comorbidity by a health care provider,
- Ever told they had a mental health condition by a health care provider, and
- Currently receiving treatment for a mental health condition.

## **5.2 Objective 2 – Characterize historical and current tobacco use patterns of adult ever established IQOS users.**

Participants' historical and current tobacco use patterns will be characterized using the following outcome measures and endpoints:

- a. Historical TNP use will be summarized as counts and percentages (n, %) for the overall sample and by study group:

### TNP use history prior to first trying IQOS:

- Ever use of given TNP.
- Met lifetime use criterion of given TNP.
- Used TNP in the 30 days prior to first trying IQOS.

### Historical TNP use at time of assessment:

- Ever use of given TNP.
- Met lifetime use criterion of given TNP.

- b. Current TNP use at time of assessment will be described using summary statistics for the overall sample, by study group, and by menthol IQOS heated tobacco use (where applicable):

- Past 30-day use of given TNP will be described using count (n), and percentage (%).
- Number of days used given TNP in the past 30 days will be described using mean (M), standard deviation (SD), Median, first and third quartiles (Q1, Q3), Minimum (Min), and Maximum (Max).
- Amount of product (IQOS heated tobacco sticks and cigarettes) used on days used in the past 30 days: will be described using M, SD, Median, Q1, Q3, Min and Max.
- Monthly average amount of product (IQOS heated tobacco sticks, cigarettes, and combined sticks and cigarettes) used per day described using M, SD, Median, Q1, Q3, Min and Max.

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- Current use (i.e., amount) of given TNP relative to use in the 30 days prior to first trying IQOS categorized as, and described using n (%):
  - Fewer TNP per day
  - More TNP per day
  - Same TNP amount per day
- Use duration for IQOS described using M, SD, Median, Q1, Q3, Min and Max.
- Smoking duration described using M, SD, Median, Q1, Q3, Min and Max
- Quit IQOS duration (among former established IQOS users) described using n (%), and categorized as:
  - Long-term
  - Short-term

c. IQOS heated tobacco sticks flavor(s) ever and currently used will be summarized using counts and percentages (n, %) for the overall sample and by study group (where applicable):

- Flavor(s) ever tried.
- First flavor ever tried.
- Flavor currently used (among current established IQOS users).
- Flavor currently most often used (among current established IQOS users).
- Flavor most often used when used IQOS (among former established IQOS users).

d. Past 30-day exclusive, dual, or poly use will be measured using counts and percentages for current established IQOS users overall and by current IQOS heated tobacco stick menthol use:

- Exclusive: IQOS only.
- Dual: IQOS plus one other tobacco product:
  - IQOS and one combustible tobacco product.
    - IQOS and cigarettes and stratified by menthol and non-menthol cigarette use.
  - IQOS and one other non-combustible tobacco product
- Poly: IQOS plus two or more other tobacco products:
  - IQOS, at least one combustible tobacco product.
    - IQOS, cigarettes, and one or more other tobacco products (overall and stratified by menthol and non-menthol cigarette use).

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- IQOS and two or more other non-combustible products (i.e., participant’s reporting poly-tobacco use does not include any combustible tobacco products).

e. IQOS Dependence among current established IQOS users will be summarized using Fagerström Tobacco Nicotine Dependence (FTND) scale score (M, SD, Median, Q1, Q3, Min and Max) for current established IQOS users overall and by established smoking status (current or former).

f. Use of IQOS not as intended will be summarized using counts and percentages (n, %) for the overall sample and by study group:

- Ever lit an IQOS heated tobacco stick like a cigarette.
- Ever used an IQOS heated tobacco stick not with an IQOS device.
- Ever used an IQOS device with a product other than IQOS heated tobacco stick.
- Overall, ever use of IQOS not as intended (i.e., endorsing any of the above three behaviors).

Frequency (“Only once”, “Sometimes”, “Most of the time”, or “All the time”) for each endorsed use of IQOS not as intended will also be summarized using counts and percentages.

g. Cigarette smoking status will be summarized as counts and percentages (n, %) for the overall sample, by study group, and current established IQOS user by menthol IQOS heated tobacco stick use:

- Never smoker
- Current smoker (overall and stratified by current menthol cigarette use)
  - Current established smoker
- Former smoker (overall and stratified by former menthol cigarette use)

h. Cigarette Dependence among current established smokers will be summarized using FTND scale score M, SD, Median, Q1, Q3, Min and Max for each study group.

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### **5.3 Objective 3 – Assess adult ever established IQOS users’ health risk perceptions related to IQOS use, cigarette smoking, and complete smoking cessation.**

- a. Participant health risk perceptions related to IQOS use, cigarette smoking, and complete smoking cessation will be summarized using the ABOUT scale score for the overall sample, current established IQOS users, current established IQOS users who are current cigarette smokers, current established IQOS users who are long-term former smokers, and former established IQOS users. Distribution of risk perception will be describe using counts and percentages (n, %).
- b. In addition to health risk perceptions, participants’ perceptions of harmful or potentially harmful constituents (HPHCs) exposure (More, Same, Less, No, or “Don’t know”) following switching from cigarettes to IQOS will be summarized using counts and percentages (n, %) for the overall sample and by study group.
- c. Understanding of what smokers must do to reduce exposure to HPHCs based on closed option categories will be captured for participants who perceive that those switching from cigarettes to IQOS would have less exposure to HPHCs and will be summarized using counts and percentages (n, %).

### **5.4 Objective 4 – Characterize IQOS use and other tobacco use patterns, including: product initiation, complete switching to IQOS, transitions to (never smokers) and back (former smokers) to cigarette smoking, and quitting behaviors relevant to IQOS use.**

- a. Product initiation will be summarized using counts and percentages (n, %) for the overall sample, by study group, and study group by menthol IQOS heated tobacco stick use:
  - IQOS as first TNP ever tried.
  - IQOS as first TNP ever used on a consistent basis.
  - First tried IQOS after not smoking for  $\geq 12$  months (overall and stratified by former menthol cigarette use).
  - First tried IQOS after not using any TNP for  $\geq 12$  months.
- b. Complete Switching to IQOS will be summarized using counts and percentages (n, %) for current established IQOS users overall and by current menthol IQOS heated tobacco stick use:

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- Complete switching from cigarettes to IQOS (overall and stratified by former menthol cigarette use).
  - Complete switching from all tobacco products to IQOS.
- c. Complete switching from IQOS to cigarette smoking will be summarized using counts and percentages (n, %) for the sample overall and stratified by current menthol cigarette use.
- d. Transitions to cigarette smoking after first trying IQOS will be summarized using counts and percentages (n, %) for the overall sample, by study group, and study group by menthol IQOS heated tobacco stick use:
- Relapse to cigarette smoking (overall and stratified by current menthol cigarette use).
  - Re-initiation of cigarette smoking (overall and stratified by current menthol cigarette use).
  - Initiation of established cigarette smoking (overall and stratified by current menthol cigarette use).
- e. Quitting behaviors will be summarized using count and percentage (n, %) for the overall sample, by study group, and study group by menthol IQOS heated tobacco stick use.
- Current established smokers:
    - Past 12-month quit attempt.
    - Motivation to Stop Smoking (MTSS) scale response (1-7; with higher scores indicating higher motivation), based on predefined answer categories.
  - Ever established smokers who completely quit smoking cigarettes after first trying IQOS (overall and stratified by quit duration).
  - Ever established TNP users who completely quit all tobacco products after first trying IQOS (overall and stratified by quit duration; former established IQOS users only).
- f. Last tobacco cessation treatment used will be summarized using counts and percentages (n, %) by study group, as well as summarized independently for current established IQOS users who completely switched from cigarettes to IQOS and for those who switched from all tobacco to IQOS.

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## 6 Relevant Documents

- Study Protocol (Adult IQOS User Postmarket Cross-Sectional Study in the United States – PMSS-PMX-01-US, v1.0, April 22, 2024)
- Study Questionnaire v1.0, April 18, 2024

## 7 Type of Analysis

The SAP covers the final analysis of the Adult IQOS User Postmarket Cross-Sectional Study in the United States – PMSS-PMX-01-US for each Wave. No interim analyses are planned to be conducted.

## 8 General Statistical Considerations

### 8.1 General Principles

The data will be analyzed and reported descriptively, primarily using percentages, frequency distributions, means, standard deviations and medians. The study is not intended to confirm or reject pre-defined hypotheses. Data will be analyzed using SAS Version 9.4 (SAS Institute, Cary, NC, USA).

Participants will include adult ( $\geq 21$  years) ever established IQOS users (i.e., have used 100 or more IQOS heated tobacco sticks at time of enrolment).

Participants will be assigned to one of two ever established IQOS user study groups:

- **Current established IQOS users:** Adult ever established IQOS users who report using IQOS in the past 30 days at time of assessment.
- **Former established IQOS users:** Adult ever established IQOS users who report not having used IQOS in the past 30 days at time of assessment.

In a previous version of this study conducted by Altria Client Services, the prevalence of former established IQOS users was approximately 6.0%. To facilitate sample size estimation, an expected prevalence of 10.0% was used. With an expected ever established user ratio of 9:1 current to former users, a total N size of 1,000 is needed to yield 100 former established users.

Estimates are expected to be less precise for rare events (i.e., low study group prevalence). However, the prevalence of former established users is expected to naturally increase over time (i.e., become less rare) with subsequent increases in estimate precision for this study group.

The following standards will be implemented in reporting small study ns:

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1. All non-zero counts less than 10 will be suppressed.
2. All rates or proportions derived from suppressed counts will also be suppressed.
3. When possible and appropriate, data will be aggregated to minimize the need for suppression.
4. Estimates with denominators less than 50 or having a relative standard error greater than 30.0% will be reported with a note of low statistical precision.

Unless otherwise stated, proportions for categorical variables will be summarized with point estimates and 95% asymptotic (Wald) confidence intervals. [Table 1](#) presents the confidence interval sizes for the former established IQOS user group ( $n = 100$ ) given different sample proportions. Exact estimation methods (specifically, Clopper-Pearson) ([Clopper & Pearson, 1934](#)) will be used instead of asymptotic estimation methods to construct confidence intervals when either  $pn$  or  $qn^1$  is less than 10 ([Gravetter et al., 2021](#)). See [Section 9.1](#) for details of statistical analyses of categorical data.

**Table 1: 95% Asymptotic confidence intervals for binomial proportions**

Binomial Proportions	Asymptotic Confidence Interval ( $n = 100$ )
%	%
20	12.16, 27.84
30	21.02, 38.98
40	30.40, 49.60
50	40.20, 59.80

[Table 2](#) provides an illustration of the estimated width of a 95% confidence interval about the means of two continuous variables assuming a sample size of 100. This table is for illustrative purposes only. See [Section 9.1](#) for details on statistical analyses for continuous variables.

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<sup>1</sup>  $pn$  = proportion \* sample size,  $qn$  = (1-proportion)\*sample size

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**Table 2: Estimated 95% confidence width with n = 100 for two hypothetical continuous variables**

Variable	Mean	Standard Deviation	95% confidence interval width
Number days used <i>Product X</i> in past 30 days among current users	13.8	10.48	4.11
Number of days smoked cigarettes in past 30 days among current <i>Product X</i> users who also smoke cigarettes	25.8	7.53	2.95

The derived datasets and statistical outputs validation level of SAS programs will be specified in a separate Program Validation Plan.

Additional details on the sources of data, the data collection and cleaning activities, data quality control, and data transfers will be defined in a study-specific Data Management Plan (DMP).

## 8.2 Handling of and Premature Discontinuation

Participants will be informed that their participation is completely voluntary, and that they may choose not to participate or to discontinue their participation at any time for any reason. Further, participants will be informed that they may refuse or discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Only subjects with completed questionnaires will be analysed.

## 8.3 Data Rules

### 8.3.1 Definition of Derived Variables

All variables covered in the questionnaires which will be used for analysis are displayed in SAP [Appendix](#) including their respective outcome categories.

The definition or calculation of derived variables from observed items to be displayed in the analysis is described in [Table 3](#).

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**Table 3: Definition of Derived Variables**

Variable Label	Definition	Values
Source (Questionnaire)		
Current Established IQOS User	If Q20 = 5 AND Q22 = 1 then 1; else 0;	0: No 1: Yes
Current Established IQOS User –Menthol used most often	If Q20 = 5 AND Q22=1 AND (Q31= 3 (single select) OR (Q32=multi select AND Q32=3)) then 1; else 0;	0: No 1: Yes
Current Established IQOS User – Menthol not used most often	If Q20 = 5 AND Q22 = 1 AND (Q31 = [1,2] (single select) OR (Q32 = multi select AND Q32 = [1,2])) then 1; else 0;	0: No 1: Yes
Former Established IQOS User	If Q20 = 5 AND Q22 = 2 then 1; else 0;	0: No 1: Yes
Never Cigarette Smoker	If Q38 = 2 then 1; else 0;	0: No 1: Yes
Current Cigarette Smoker	If Q41 = 1 then 1; else 0;	0: No 1: Yes
Current Cigarette Smoker – Menthol smoked in the past 30 days	If Q41 = 1 AND Q43a = 1 then 1; else 0;	0: No 1: Yes
Current Cigarette Smoker – Menthol not smoked in the past 30 days	If Q41 = 1 AND Q43a = 2 then 1; else 0;	0: No 1: Yes
Former Cigarette Smoker	If Q41 = 2 then 1; else 0;	0: No 1: Yes
Former Cigarette Smoker – Menthol last cigarettes smoked	If Q41 = 2 AND Q43b = 1 then 1; else 0;	0: No 1: Yes
Former Cigarette Smoker – Menthol not last cigarettes smoked	If Q41 = 2 AND Q43b = 2 then 1; else 0;	0: No 1: Yes
Current Established Cigarette Smoker	If Q39 = 5 AND Q41 = 1 then 1; else 0;	0: No 1: Yes
Current Established Cigarette Smoker – Menthol smoked in the past 30 days	If Q39 = 5 AND Q41 = 1 AND Q43a = 1 then 1; else 0;	0: No 1: Yes
Current Established Cigarette Smoker – Menthol not smoked in the past 30 days	If Q39 = 5 AND Q41 = 1 AND Q43a = 2 then 1; else 0;	0: No 1: Yes
Former Established Cigarette Smoker	If Q39 = 5 AND Q41 = 2 then 1; else 0;	0: No 1: Yes
Former Established Cigarette Smoker –	If Q39 = 5 AND Q41 = 2 AND Q43b = 1 then 1; else 0;	0: No 1: Yes

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Menthol last cigarettes smoked		
Former Established Cigarette Smoker – Menthol not last cigarettes smoked	If Q39 = 5 AND Q41 = 2 AND Q43b = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
<b>Sociodemographic Characteristics</b>		
Age groups	If Q2(calculated age) = [21-24] then <b>1</b> If Q2(calculated age) = [25-34] then <b>2</b> If Q2(calculated age) = [35-44] then <b>3</b> If Q2(calculated age) = [45-54] then <b>4</b> If Q2(calculated age) = [55-64] then <b>5</b> If Q2(calculated age) = [>64] then <b>6</b>	1: 21-24 2: 25-34 3: 35-44 4: 45-54 5: 55-64 6: 65+
Race-Ethnicity	Race/Ethnicity categories are derived from Q165 (Ethnicity) and Q166 (Race):  - NH, White: If Q165 = 2 AND Q166 = (Exclusively 1) then <b>1</b> ; - NH, Black/African American: If Q165 = 2 AND Q166 = (Exclusively 2) then <b>2</b> ; - NH, Native American or Alaska Native: Q165 = 2 AND Q166 = (Exclusively 5) then <b>3</b> ; - NH, Native Hawaiian or other PI: Q165 = 2 AND Q166 = (Exclusively 4) then <b>4</b> ; - NH, Asian: If Q165 = 2 AND Q166 = (Exclusively 3) then <b>5</b> ; - NH, Other race not listed: If 165 = 2 AND Q166 = (Exclusively 6) then <b>6</b> ; - NH, Multiracial: If Q165 = 2 AND Q166 = any two or more choices then <b>7</b> ; - NH, Prefer not to answer: If Q165 = 2 AND Q166 = 7 then <b>8</b> ; - Hispanic/Latinx: If Q165 = 1 then <b>9</b> ; - Prefer not to answer: If Q165 = 3 then <b>10</b> .	1: NH, White 2: NH, Black/African American 3: NH, Native American or Alaska Native 4: NH, Native Hawaiian or other PI 5: NH, Asian 6: NH, Other race not listed 7: NH, Multiracial 8: NH, Prefer not to answer 9: Hispanic/Latinx 10: Prefer not to answer
Household Income	- If Q167 = [1] then <b>1</b> - If Q167 = [2-6] then <b>2</b> - If Q167 = [7-9] then <b>3</b> - If Q167 = [10] then <b>4</b>	1: Under \$20,000 2: \$20,000 - \$74,999 3: \$75,000 or more 4: Prefer not to answer.
Education	- If Q168 = [1-3] then <b>1</b> - If Q168 = [4] then <b>2</b> - If Q168 = [5 or 6] then <b>3</b> - If Q168 = [7-10] then <b>4</b>	1: Less than High School 2: High School Graduate/GED

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		3: Some College/Associates Degree 4: Bachelor's Degree or More
Employment Status	<ul style="list-style-type: none"> <li>- If Q169 = [1-2] then <b>1</b></li> <li>- If Q169 = [3, 4, 5, or 8] then <b>2</b></li> <li>- If Q169 = [6] then <b>3</b></li> <li>- If Q169 = [7] then <b>4</b></li> </ul>	1: Employed 2: Unemployed 3: Student 4: Retired
Region	If Q3 = [7,20,22,30,31,33,39,40,46] then <b>1</b> If Q3 = [1,4,8,9,10,11,18,19,21,25,34,37,41,43,44,47,49] then <b>2</b> If Q3 = [14,15,16,17,23,24,26,28,35,36,42,50] then <b>3</b> If Q3 = [2,3,5,6,12,13,27,29,32,38,45,48,51] then <b>4</b>	1: Northeast 2: South 3: Midwest 4: West
Marital Status	<ul style="list-style-type: none"> <li>- If Q171 = [1 or 6] then <b>1</b></li> <li>- If Q171 = [2-4] then <b>2</b></li> <li>- If Q171 = [5] then <b>3</b></li> <li>- If Q171 = [7] then <b>4</b></li> </ul>	1: Married / Living with a partner 2: Separated / Divorced / Widowed 3: Never married 4: Prefer not to answer
Military Personnel/Veteran Status	<ul style="list-style-type: none"> <li>- If Q170 = [1-2] then <b>1</b></li> <li>- If Q170 = [3-4] then <b>2</b></li> </ul>	1: Yes - now / were on active duty 2: No - Reserves or National Guard only / never served
<b>TNP Use History</b>		
<b>Before first tried IQOS:</b> Ever tried any tobacco product.	If [Q45 (Cigarettes) = 1 OR Q58 (Cigars) = 1 OR Q69 (Pipe) = 1 OR Q80 (Hookah) = 1 OR Q96 (E-cigarettes) = 1 OR Q108 (Smokeless) = 1 OR Q118 (Oral nicotine) = 1] then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
<b>Monthly average amount of IQOS heated tobacco sticks used /Cigarettes smoked</b>		
Monthly average amount of heated tobacco sticks used per day.	$\frac{([\# \text{ of days used in the past 30 days}] * [\# \text{ of IQOS heated tobacco sticks used per day on days used in the past 30 days}])}{30 \text{ days}}$ $(Q23*Q24)/30$	Continuous/integer
Monthly average amount of cigarettes smoked per day	$\frac{([\# \text{ of days used in the past 30 days}] * [\# \text{ of cigarettes smoked per day on days used in the past 30 days}])}{30 \text{ days}}$ $(Q42*Q43)/30$	Continuous/integer
Combined monthly average amount of heated	(Monthly avg. amount sticks) + (Monthly avg. amount cigarettes)	Continuous/integer

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tobacco sticks and cigarettes used per day	$([Q23*Q24]/30) + ([Q42*Q43]/30)$	
<b>Use duration of IQOS and Cigarettes and IQOS quit duration</b>		
Current established IQOS user – IQOS use duration (in years)	Q25 [Years] + (Q25 [Months]/12)	Years
Former established IQOS user – IQOS use duration (in years)	Q27 [Years] + (Q27 [Months]/12)	Years
Current established cigarette smoker – Smoking duration (in years)	If Q39 = 5 AND Q41=1 then: Q44[Years] + (Q44[Months]/12)	Years
Former established cigarette smoker – Smoking duration (in years)	If Q39 = 5 AND Q41 = 2 then: Q126[Years] + (Q126[Months]/12)	Years
IQOS Short-term quitters	Q22 = 2 AND Q28 = [1-11] then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
IQOS Long-term quitters	Q22 = 2 AND Q28 = [12,13] then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
<b>Current Use Patterns</b>		
IQOS only	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in none of the following past 30-day use questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Dual use: IQOS plus one other tobacco product	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in <u>only one</u> of the following past 30-day use questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Dual use: IQOS and one combustible tobacco product.	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in <u>only one</u> of the following past 30-day use questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah),	0: No 1: Yes

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	AND no response OR answer choice 2 (“No”) is selected in all the following past 30-day questions: Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	
Dual use: IQOS and cigarettes	If Q22 = 1 AND Q41 = 1 AND no response OR answer choice 2 (“No”) is selected in all the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Dual use: IQOS and Menthol cigarette use	If Q22 = 1 AND Q41 = 1 AND Q43a=1 AND no response OR answer choice 2 (“No”) is selected in all the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Dual use: IQOS and Non-Menthol cigarette use	If Q22 = 1 AND Q41 = 1 AND Q43a=2 AND no response OR answer choice 2 (“No”) is selected in all the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Dual use: IQOS and one other non-combustible tobacco product	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in <u>only one</u> of the following past 30-day use questions: Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine), AND no response or answer choice 2 (“No”) is selected in all the following past 30-day questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Poly use: IQOS plus two or more other tobacco products	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in two or more of the following past 30-day questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe),	0: No 1: Yes

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	Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	
Poly use: IQOS, and at least two other tobacco products with at least one of them being a combustible tobacco product	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in at least two of the following past 30-day questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) AND <u>at least one</u> of the past 30-day use questions selected = Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), or Q79 (Hookah) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Poly use: IQOS, cigarettes, and one or more other tobacco products	If Q22 = 1 AND Q41 = 1 AND answer choice 1 (“Yes”) is selected in <u>at least one</u> of the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Poly use: IQOS, Menthol cigarette use, and one or more other tobacco products	If Q22 = 1 AND Q41 = 1 AND Q43a=1 AND answer choice 1 (“Yes”) is selected in <u>at least one</u> of the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Poly use: IQOS, Non-Menthol cigarette use, and one or more other tobacco products	If Q22 = 1 AND Q41 = 1 AND Q43a=2 AND answer choice 1 (“Yes”) is selected in <u>at least one</u> of the following past 30-day questions: Q57 (Cigars), Q68 (Pipe), Q79 (Hookah), Q91 (E-cigarettes), Q106 (Smokeless), Q117 (Oral nicotine) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Poly use: IQOS and two or more other non-combustible products (i.e., participant’s reporting poly-tobacco use does not	If Q22 = 1 AND answer choice 1 (“Yes”) is selected in two or more of the following past 30-day questions: Q91 (E-cigarettes), Q106 (Smokeless),	0: No 1: Yes

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include any combustible tobacco products)	Q117 (Oral nicotine), AND no response or answer choice 2 (“No”) is selected in all the following past 30-day questions: Q41 (Cigarettes), Q57 (Cigars), Q68 (Pipe), Q79 (Hookah) then <b>1</b> ; else <b>0</b> ;	
<b>IQOS Dependence</b>		
FTND Summary Score for IQOS	Recoding: If Q163a = 1 then Q163a_rc = 3 If Q163a = 2 then Q163a_rc = 2 If Q163a = 3 then Q163a_rc = 1 If Q163a = 4 then Q163a_rc = 0  If Q163b = 1 then Q163b_rc = 1 If Q163b = 2 then Q163b_rc = 0  If Q163c = 1 then Q163c_rc = 1 If Q163c = 2 then Q163c_rc = 0  If Q163d = 1 then Q163d_rc = 0 If Q163d = 2 then Q163d_rc = 1 If Q163d = 3 then Q163d_rc = 2 If Q163d = 4 then Q163d_rc = 3  If Q163e = 1 then Q163e_rc = 1 If Q163e = 2 then Q163e_rc = 0  If Q163f = 1 then Q163f_rc = 1 If Q163f = 2 then Q163f_rc = 0  Sum of all recoded variables: Q163a_rc + Q163b_rc + Q163c_rc + Q163d_rc + Q163e_rc + Q163f_rc	Sum of scores from 0-10
<b>Non-intended use of IQOS</b>		
Ever use of IQOS not as intended	If Q34 = 1 in at least one of listed use cases OR Q36a = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
<b>Cigarette Dependence</b>		
FTND Summary Score for Cigarettes	Recoding: If Q162a = 1 then Q162a_rc = 3 If Q162a = 2 then Q162a_rc = 2 If Q162a = 3 then Q162a_rc = 1 If Q162a = 4 then Q162a_rc = 0  If Q162b = 1 then Q162b_rc = 1 If Q162b = 2 then Q162b_rc = 0	Sum of scores from 0-10

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	<p>If Q162c = 1 then Q162c_rc = 1 If Q162c = 2 then Q162c_rc = 0</p> <p>If Q162d = 1 then Q162d_rc = 0 If Q162d = 2 then Q162d_rc = 1 If Q162d = 3 then Q162d_rc = 2 If Q162d = 4 then Q162d_rc = 3</p> <p>If Q162e = 1 then Q162e_rc = 1 If Q162e = 2 then Q162e_rc = 0</p> <p>If Q162f = 1 then Q162f_rc = 1 If Q162f = 2 then Q162f_rc = 0</p> <p>Sum of all recoded variables: Q162a_rc + Q162b_rc + Q162c_rc + Q162d_rc + Q162e_rc + Q162f_rc</p>	
<b>Risk Perception</b>		
Score of Risk Perceptions – Cigarettes	<p>Sum of scores of Q157 converted to scale <b>0 -100</b>, as described in <a href="#">Table 5</a> of ABOUT™. Category “Don’t know” will be treated as described in Section 4 of ABOUT™.</p> <p>Transformed scores will be categorized according to Table 5.</p>	<ul style="list-style-type: none"> <li>• 0-22: No to low perceived risk</li> <li>• 23-34: Low perceived risk</li> <li>• 35-43: Low to moderate perceived risk</li> <li>• 44-60: Moderate perceived risk</li> <li>• 61-71: High perceived risk</li> <li>• 72-78: High to very high perceived risk</li> <li>• 79-100: Very high perceived risk</li> </ul>
Score of Risk Perceptions – IQOS	<p>Sum of scores of Q159 converted to scale <b>0 -100</b>, as described in <a href="#">Table 5</a> of About TM. Category “Don’t know” will be treated as described in Section 4 of ABOUT™.</p> <p>Transformed scores will be categorized according to <a href="#">Table 5</a>.</p>	<ul style="list-style-type: none"> <li>• 0-22: No to low perceived risk</li> <li>• 23-34: Low perceived risk</li> <li>• 35-43: Low to moderate perceived risk</li> </ul>

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		<ul style="list-style-type: none"> <li>• 44-60: Moderate perceived risk</li> <li>• 61-71: High perceived risk</li> <li>• 72-78: High to very high perceived risk</li> <li>• 79-100: Very high perceived risk</li> </ul>
Score of Risk Perceptions – Smoking cessation	Sum of scores of Q159b converted to scale <b>0 -100</b> , as described in <a href="#">Table 6</a> of About TM. Category “Don’t know” will be treated as described in Section 4 of ABOUT™. Transformed scores will be categorized according to <a href="#">Table 5</a> .	<ul style="list-style-type: none"> <li>• 0-22: No to low perceived risk</li> <li>• 23-34: Low perceived risk</li> <li>• 35-43: Low to moderate perceived risk</li> <li>• 44-60: Moderate perceived risk</li> <li>• 61-71: High perceived risk</li> <li>• 72-78: High to very high perceived risk</li> <li>• 79-100: Very high perceived risk</li> </ul>
<b>IQOS Use and Product Use Transitions</b>		
IQOS as first TNP ever tried	If Q124 = 4 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
IQOS as first TNP ever used on a consistent basis	If Q125 = 4 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Ever established smokers before first trying IQOS – First trial of IQOS after not smoking cigarettes for 12 months or longer	If Q46a= 5 AND (Q50 = [12,13] OR Q130 = [12,13]) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Ever established smokers before first trying IQOS – First trial of IQOS after not smoking cigarettes for	If Q46a= 5 AND coalesce (Q43a, Q43b) = 1 AND (Q50 = [12,13] OR Q130 = [12,13]) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes

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12 months or longer, Menthol cigarette use		
Ever established smokers before first trying IQOS – First trial of IQOS after not smoking cigarettes for 12 months or longer, Non-Menthol cigarette use	If Q46a= 5 AND coalesce (Q43a, Q43b) = 2 AND (Q50 = [12,13] OR Q130 = [12,13]) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Ever established TNP user before first trying IQOS– First trial of IQOS after not using any tobacco products for 12 months or longer	Meet the lifetime criteria for use of any TNP prior AND report not having used any TNP for 12 months or longer prior to first trying IQOS.  If: <b>Cigarettes:</b> Q46a = 5 AND (Q50 = [12,13] OR Q130 = [12,13]) AND <b>Cigars:</b> Q59a = [4,5] AND (Q63 = [12,13] OR Q134 = [12,13]) AND <b>Pipe:</b> (Q70a = [4,5] AND (Q74 = [12,13] OR Q138 = [12,13]) AND <b>Hookah:</b> Q82 = 1 AND (Q86 = [12,13] OR Q142 = [12,13]) AND <b>E-cigarettes:</b> Q97b = 1 AND (Q101 = [12,13] OR Q146 = [12,13]) AND <b>Smokeless:</b> Q108a = [3,4,5] AND (Q112 = [12,13] OR Q150 = [12,13]) AND <b>Oral nicotine:</b> Q119b = 1 AND (Q123 = [12,13] OR Q154 = [12,13]) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from cigarettes to IQOS after first trying IQOS	If (Current established IQOS user, Q20 = 5 AND Q22 = 1) AND Q46a = 5 AND Q47 = [1,2] AND Q41 = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from Menthol cigarette use to IQOS after first trying IQOS	If (Current established IQOS user, Q20 = 5 AND Q22 = 1) AND Q46a = 5 AND Q47 = [1,2] AND Q41 = 2 AND Q43b = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from Non-Menthol cigarette use to IQOS after first trying IQOS	If (Current established IQOS user, Q20 = 5 AND Q22 = 1) AND Q46a = 5 AND Q47 = [1,2] AND Q41 = 2 AND Q43b = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from all tobacco products to IQOS after first trying IQOS	If (Current established IQOS use, Q20 = 5 AND Q22 = 1) AND: <b>Cigarettes:</b> (Q41 = 2 AND Q46a = 5 AND Q47 = [1,2]) AND <b>Cigars:</b> (Q57 = 2 AND Q59a = [4,5] AND Q60 = [1,2]) AND <b>Pipe:</b> (Q68 = 2 AND Q70a = [4,5] AND Q71 = [1,2]) AND	0: No 1: Yes

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	<b>Hookah:</b> (Q79 = 2 AND Q82 = 1 AND Q83 = [1,2]) AND <b>E-cigarettes:</b> (Q91 = 2 AND Q97b = 1 AND Q98 = [1,2]) AND <b>Smokeless:</b> (Q106 = 2 AND Q108a = [3,4,5] AND Q109 = [1,2]) AND <b>Oral nicotine:</b> (Q117 = 2 AND Q119b = 1 AND Q120 = [1,2]) then <b>1</b> ; else <b>0</b> ;	
Complete switching from IQOS to cigarettes after initiating tobacco use with IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2) AND Q124 = 4 AND Q39 = 5 AND Q41 = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from IQOS to Menthol cigarettes after initiating tobacco use with IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2) AND Q124 = 4 AND Q39 = 5 AND Q41 = 1 AND Q43a = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Complete switching from IQOS to Non-Menthol cigarettes after initiating tobacco use with IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2) AND Q124 = 4 AND Q39 = 5 AND Q41 = 1 AND Q43a = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Current established IQOS user – Completely quitting smoking cigarettes after first trying IQOS	If (Current established IQOS user, Q20 = 5 AND Q22 = 1) AND Q41 = 2 AND Q46a = 5 AND Q47 = [1,2] AND Q127 = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Relapse to cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [1-11] AND Q41 = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Relapse to Menthol cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [1-11] AND Q41 = 1 AND Q43a = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Relapse to Non-Menthol cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [1-11] AND Q41 = 1 AND Q43a = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Re-initiation of cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [12,13] AND Q41 = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Re-initiation of Menthol cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [12,13] AND Q41 = 1 AND Q43a = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Re-initiation of Non-Menthol cigarette smoking after first trying IQOS	If Q46a = 5 AND Q50 = [12,13] AND Q41 = 1 AND Q43a = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Initiation of established cigarette smoking after first trying IQOS	If Q45 = 2 OR (Q45=1 AND Q46a = [1-4]) AND Q39 = 5 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes

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Initiation of established cigarette smoking after first trying IQOS	If Q45 = 2 OR (Q45=1 AND Q46a = [1-4]) AND Q39 = 5 AND coalesce (Q43a, Q43b) = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Initiation of established cigarette smoking after first trying IQOS	If Q45 = 2 OR (Q45=1 AND Q46a = [1-4]) AND Q39 = 5 AND coalesce (Q43a, Q43b) = 2 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Completely quitting smoking cigarettes after first trying IQOS	If Q41 =2 AND Q46a =5 AND Q47 = [1,2] AND Q127 = 1 then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Completely quitting smoking cigarettes (< 12 months) after first trying IQOS	If Q41 =2 AND Q46a =5 AND Q47 = [1,2] AND Q127 = 1 AND Q128 = [1-11] then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Completely quitting smoking cigarettes (≥ 12 months) after first trying IQOS among	If Q41 =2 AND Q46a =5 AND Q47 = [1,2] AND Q127 = 1 AND Q128 = [12,13] then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Former established IQOS users – Completely quitting all tobacco products after first trying IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2), AND:  <b>Cigarettes:</b> (Q41 = 2 AND Q46a = 5 AND Q47 = [1,2] AND Q127 = 1) AND <b>Cigars:</b> (Q57 = 2 AND Q59a = [4,5] AND Q60 = [1,2] AND Q131 = 1) AND <b>Pipe:</b> (Q68 = 2 AND Q70a = [4,5] AND Q71 = [1,2] AND Q135 = 1) AND <b>Hookah:</b> (Q79 = 2 AND Q82 = 1 AND Q83 = [1,2] AND Q139 = 1) AND <b>E-cigarettes:</b> (Q91 = 2 AND Q97b = 1 AND Q98 = [1,2] AND Q143 = 1) AND <b>Smokeless:</b> (Q106 = 2 AND Q108a = [3,4,5] AND Q109 = [1,2] AND Q147 = 1) AND <b>Oral nicotine:</b> (Q117 = 2 AND Q119b = 1 AND Q120 = [1,2] AND Q151 = 1) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes
Former established IQOS users – Completely quitting all tobacco products (< 12 months) after first trying IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2) AND Q28 = [1-11]:  <b>Cigarettes:</b> (Q41 = 2 AND Q46a = 5 AND Q47 = [1,2] AND Q127 = 1 AND Q128 = [1-11]) AND <b>Cigars:</b> (Q57 = 2 AND Q59a = [4,5] AND Q60 = [1,2] AND Q131 = 1 AND Q132 = [1-11]) AND <b>Pipe:</b> (Q68 = 2 AND Q70a = [4,5] AND Q71 = [1,2] AND Q135 = 1 AND Q136 = [1-11]) AND	0: No 1: Yes

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	<b>Hookah:</b> (Q79 = 2 AND Q82 = 1 AND Q83 = [1,2] AND Q139 = 1 AND Q140 = [1-11]) AND <b>E-cigarettes:</b> (Q91 = 2 AND Q97b = 1 AND Q98 = [1,2] AND Q143 = 1 AND Q144 = [1-11]) AND <b>Smokeless:</b> (Q106 = 2 AND Q108a = [3,4,5] AND Q109 = [1,2] AND Q147 = 1 AND Q148 = [1-11]) AND <b>Oral nicotine:</b> (Q117 = 2 AND Q119b = 1 AND Q120 = [1,2] AND Q151 = 1 AND Q152 = [1-11]) then <b>1</b> ; else <b>0</b> ;	
Former established IQOS users – Completely quitting all tobacco products (≥ 12 months) after first trying IQOS	If (Former established IQOS user, Q20 = 5 AND Q22 = 2) AND Q28 = [12-13]:  <b>Cigarettes:</b> (Q41 = 2 AND Q46a = 5 AND Q47 = [1,2] AND Q127 = 1 AND Q128 = [12,13]) AND <b>Cigars:</b> (Q57 = 2 AND Q59a = [4,5] AND Q60 = [1,2] AND Q131 = 1 AND Q132 = [12,13]) AND <b>Pipe:</b> (Q68 = 2 AND Q70a = [4,5] AND Q71 = [1,2] AND Q135 = 1 AND Q136 = [12,13]) AND <b>Hookah:</b> (Q79 = 2 AND Q82 = 1 AND Q83 = [1,2] AND Q139 = 1 AND Q140 = [12,13]) AND <b>E-cigarettes:</b> (Q91 = 2 AND Q97b = 1 AND Q98 = [1,2] AND Q143 = 1 AND Q144 = [12,13]) AND <b>Smokeless:</b> (Q106 = 2 AND Q108a = [3,4,5] AND Q109 = [1,2] AND Q147 = 1 AND Q148 = [12,13]) AND <b>Oral nicotine:</b> (Q117 = 2 AND Q119b = 1 AND Q120 = [1,2] AND Q151 = 1 AND Q152 = [12,13]) then <b>1</b> ; else <b>0</b> ;	0: No 1: Yes

### 8.3.2 Handling of Data Inconsistencies

Survey logic will be incorporated into the survey instrument to preclude inconsistent responses to separate measures. Quality checks will be performed to ensure the accuracy, integrity, and validity of the data. These include checking the survey instrument programming logic before and after study launch to ensure that the data are collected as specified in the study protocol.

Data quality checks will be implemented to identify and flag records that contain forms of potential data falsification or missing data.

Speeding: Completing the questionnaire very quickly without giving thought to answers provided is considered as “speeding”. Participants who complete the questionnaire in less than 30% of the median completion time of participants reporting similar tobacco product use will

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be flagged as “speeders”. The amount of time to complete each questionnaire is expected to vary depending on the number of other tobacco products used than IQOS. Median questionnaire duration will be calculated and compared among participants that:

- Never used any other tobacco product than IQOS or ever used one other tobacco product.
- Ever used two other tobacco products.
- Ever used three other tobacco products.
- Ever used four other tobacco products.
- Ever used five or more other tobacco products.

The questionnaire is designed to minimize outliers by defining ranges for numeric responses. For example, cigarettes smoked per day has a minimum of ‘<1’ and a maximum of ‘more than 50,’ and the number of days used in the past 30 days can only range from 0 to 30. Therefore, we do not expect any outliers relevant to this analysis plan.

Any corrections made to the raw data set will be thoroughly documented and an explanation/rationale will be provided for each correction. Analytic datasets will be created from the corrected raw dataset reflecting documented changes made. The number of respondents that are flagged for data quality check will be included in the final survey report.

### 8.3.3 Handling of Missing Data

As this is an online survey where participants must provide a response to each question prior to moving to the next item, we do not anticipate any missing data.

## 8.4 Coding

Certain survey questions may allow participants to provide an answer other than what is pre-listed in the response set. These verbatim responses will be reviewed, evaluated, and coded as follows: 1) verbatim responses that were provided as “other” response choice but fit into one of the pre-listed responses will be “up-coded”; 2) responses provided that cannot be “up-coded” will be categorized and frequency of these responses will be evaluated. Responses with a frequency beyond a certain threshold (e.g., 5%) will then be assigned a code, and the coded response will be analyzed and reported as part of the response set for that question. Responses with frequencies below the threshold will be reported as “other.” Nonsensical verbatim responses, meaning verbatim responses that are of poor quality (e.g., gibberish, nonsensical responses, single characters, profanity) will be reported as “not codable”.

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## 8.5 Subject Enrollment and Analysis Sets

Participants must satisfy the following criteria at the time of enrolment to be eligible for the study:

1. US resident
2. 21 years of age or older.
3. Voluntarily consent to serve as a participant in the study by electronically acknowledging an Informed Consent Statement (ICS), with approval or exemption determined by a qualified Institutional Review Board (IRB).
4. Acknowledge willingness and ability to comply with all study requirements as listed in the ICS.  
Meet criteria for inclusion as a current or former established IQOS user (i.e., an individual who has used at least 100 IQOS heated tobacco sticks in lifetime by the time of enrolment.

Participants who meet any of the following exclusion criteria will not be eligible for the study:

1. Unable to read, speak or understand English.
2. Is a current or former employee or has a first-degree relative (e.g., parent, spouse, sibling, child) or household member who is a current or former employee of the tobacco or e-cigarette industry.
3. Is a current or former employee or has a first-degree relative (e.g., parent, spouse, sibling, child) or household member who is a current or former employee of CRO.
4. Is or has a first-degree relative (e.g., parent, spouse, sibling, child) or household member involved in litigation (e.g., as a named party or class representative) with any company involved in the tobacco or e-cigarette industry.

*Note.* The size and composition of the study sample is contingent on product sales and growth in CLP registration each year. To account for this uncertainty and ensure sufficient representation of IQOS use behavior across waves, no initial restrictions will be placed on repeat participants. However, if the incidence of repeat observations across successive waves is high (e.g., > 5.0%) ([Agius et al., 2018](#)), an exclusion criterion or cap may be implemented to ensure sample renewal and independence between waves.

The main analysis will be conducted with the full dataset including all eligible participants who have completed the questionnaire.

In addition, sensitivity analyses will be conducted without participants who have a quality check flag to determine if the potentially invalid data substantially influence the results. These

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sensitivity analyses will be performed to assess the robustness of the results with the exclusion of flagged data. If there are no substantial changes observed, results are considered robust to invalid data. If the number of participants with flags for speeding is <5% (i.e., very few responses are flagged), this sensitivity analysis will not be conducted. The choice for 5% is based on the argument by [Schafer and Olsen \(1998\)](#) that missing data of less than 5% is inconsequential to the overall results.

## 9 Statistical Analysis

### 9.1 Presentation of Analysis Results

#### Summaries of Categorical Data

All summaries of categorical data will present sample sizes and percentages for the total study sample (as applicable) and for current and former IQOS users, as shown in [Table 4](#).

**Table 4: Example summary of percentages for categorical variables**

	Ever Established IQOS Users	Current Established IQOS Users	Former Established IQOS Users
Base (Total Participants)	N = XXX	N = XXX	N = XXX
<b>Ever Tried, n (%) [95% CI]</b>			
Cigarettes	xx (x.x%) [x.x%, x.x%]	xx (x.x%) [x.x%, x.x%]	xx (x.x%) [x.x%, x.x%]
Cigars	xx (x.x%) [x.x%, x.x%]	xx (x.x%) [x.x%, x.x%]	xx (x.x%) [x.x%, x.x%]

CI = Confidence Interval; N = number of subjects; M = Mean; SD = Standard deviation; CPD = Cigarettes per day

Percentages and confidence intervals will be reported to the first decimal place, except percentages of 100%, which has no decimal places presented. Percentages for 0 counts and confidence intervals for categorical data with percentage of 0% and 100% will not be calculated.

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### Summaries of Continuous Data

All summaries of continuous data will present sample sizes, means, standard deviations and medians for the Total Study Sample (as applicable) and for current and former IQOS users, as shown in [Table 5](#).

**Table 5: Example summary for numeric variables**

	Ever Established IQOS Users	Current Established IQOS Users	Former Established IQOS Users
Base (Total Participants)	N = XXX	N = XXX	N = XXX
<b>Number of IQOS heated tobacco sticks per day on days used</b>			
M (SD) [95% CI]	x.x (x.xx) [x.x; x.x]	x.x (x.xx) [x.x; x.x]	x.x (x.xx) [x.x; x.x]
Median [Q1; Q3]	x.x [x.x; x.x]	x.x [x.x; x.x]	x.x [x.x; x.x]
Min / Max	x.x / x.x	x.x / x.x	x.x / x.x

CI = Confidence Interval; N = number of subjects; M = Mean; SD = Standard deviation; Q1 = First Quartile; Q3 = Third Quartile;

Min = Minimum; Max = Maximum

Means, confidence intervals, and quartiles will be reported to the first decimal place. While standard deviation and interquartile range will be reported to the second decimal place.

Confidence intervals for continuous data with standard deviation of 0 will not be displayed.

### Participant Flow Diagram

A participant flow diagram will be created based on the numbers provided by the fieldwork supplier, and not from the dataset. A participant flow diagram will be created for the final report(s) demonstrating the flow of participants from selection/study invitation to the final complete analytic sample (see [Table 6](#)). This information will be provided apart from the dataset by the fieldwork supplier.

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**Table 6: Example summary for response rate**

	Total	
	n	%
Number of individuals invited	xx,xxx	100.0%
Number of individuals without any response	xx,xx	xx%
Number of individuals who clicked the link	xx,xx	xx%
Number of individuals who had an incomplete screener	x,xxx	xx%
Number of individuals who successfully completed the screener	x,xxx	xx%
Number of individuals who were not eligible	x,xxx	xx%
Reasons for non-eligibility		
...	xxx	xx%
Number of individuals who were eligible	x,xxx	xx%
Number of individuals who had an incomplete survey	xx	xx%
Number of overall completed surveys	x,xxx	xx%
Number of excluded surveys due to quality issues	xx	x%
Current established IQOS users	xxx	xx%
Former established IQOS users	xxx	xx%

## 9.2 Safety

Adverse event (AE) reporting will follow the Sponsor's already-established post-market Safety Surveillance Procedures for spontaneously reported events. No analysis of AEs or other safety issues will be performed as a part of this statistical analysis plan.

## 9.3 Subgroup Analysis and Stratifications

Subgroup analyses will be conducted for ever and current IQOS users, with further stratification for menthol vs. non-menthol (regular) use of IQOS heated tobacco sticks used most often, as well as for former IQOS users. These subgroup analyses are described in [Section 5](#) and [Section 11](#).

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## 9.4 Avoiding Bias

This study uses standard measures from national surveillance systems (e.g., Population Assessment of Tobacco and Health Study) that have been validated for use in the study population, reducing the likelihood of reporting bias.

It is possible that participants may not accurately recall their tobacco product use. However, all tobacco use and perception measures used in the study are derived from standard, validated measures, limiting the likelihood of reporting bias.

This study intends to leverage the IQOS Customer Loyalty Program (CLP) Database as the study sampling frame. The IQOS CLP Database is a voluntary consumer registry expected to enrol > 80% of US adult IQOS consumers (based on IQOS CLP Database enrolment in similar markets), increasing the generalizability of study findings to all US adult ever established IQOS users in US markets where the product is available. However, the results of this study may not be generalizable to the broader population of adult IQOS users (i.e., non-established users) or to ever established IQOS users who decide not to participate in research.

Achieving the target sample size for this study is contingent on IQOS sales and subsequent CLP enrolment. Because commercialization is expected to be limited initially to select US markets (e.g., one or two cities) with gradual market expansion to follow, reaching the target N prove difficult in the time (months or year) following product launch. To maximize sample size in the first year of study, invitations to participate in the study may be sent to all opt-in, adult IQOS purchasers in the CLP. Probability-based sampling from the CLP database will likely be used in subsequent study years, as the numbers of IQOS users expand beyond initial points of launch. Study invitations will then be sent until a sufficient sample size is reached. PMP may decide to close recruitment prior to meeting the target sample size. If the target sample size cannot be met, certain study outcomes may not be estimated with the expected precision.

Due to the cross-sectional design, participants may have variable IQOS use histories, including different durations since first establishing IQOS use. This will need to be considered when interpreting the results.

The cross-sectional nature of the study precludes establishing causality for descriptive transitions characterized in analyses and subsequent reports.

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## 10 References

- Agius, P. A., Aitken, C. K., Breen, C., & Dietze, P. M. (2018). Repeat participation in annual cross-sectional surveys of drug users and its implications for analysis. *BMC Res Notes*, 11(1), 349. <https://doi.org/10.1186/s13104-018-3454-y>
- Cano, S., Chrea, C., Salzberger, T., Alfieri, T., Emilien, G., Mainy, N., Ramazzotti, A., Lüdicke, F., & Weitkunat, R. (2018). Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products. *Health Qual Life Outcomes*, 16(1), 192. <https://doi.org/10.1186/s12955-018-0997-5>
- Center for Behavioral Health Statistics and Quality. (2023). *NSDUH 2022 Questionnaire*. Retrieved 12/02/2023 from <https://www.samhsa.gov/data/report/nsduh-2022-questionnaire>
- Clopper, C. J., & Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*, 26(4), 404-413.
- FDA. (2012). *Guidance for Industry: Modified Risk Tobacco Product Applications* <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>
- Food and Drug Administration [FDA]. (2020). *Modified Risk Granted Orders – Exposure Modification* <https://www.fda.gov/media/139797/download?attachment>
- Gravetter, F. J., Wallnau, L. B., Forzano, L.-A. B., & Witnauer, J. E. (2021). *Essentials of statistics for the behavioral sciences*. Cengage Learning.
- Heatherton, T. F., Kozlowski, L. T., Frecker, R. C., Rickert, W., & Robinson, J. (1989). Measuring the heaviness of smoking: using self-reported time to the first cigarette of the day and number of cigarettes smoked per day. *Br J Addict*, 84(7), 791-799. <https://doi.org/10.1111/j.1360-0443.1989.tb03059.x>
- Hyland, A., Ambrose, B. K., Conway, K. P., Borek, N., Lambert, E., Carusi, C., Taylor, K., Crosse, S., Fong, G. T., Cummings, K. M., Abrams, D., Pierce, J. P., Sargent, J., Messer, K., Bansal-Travers, M., Niaura, R., Vallone, D., Hammond, D., Hilmi, N., . . . Compton, W. M. (2017). Design and methods of the Population Assessment of Tobacco and Health (PATH) Study. *Tob Control*, 26(4), 371-378. <https://doi.org/10.1136/tobaccocontrol-2016-052934>
- Kotz, D., Brown, J., & West, R. (2013). Predictive validity of the Motivation To Stop Scale (MTSS): a single-item measure of motivation to stop smoking. *Drug Alcohol Depend*, 128(1-2), 15-19. <https://doi.org/10.1016/j.drugalcdep.2012.07.012>
- Mushtaq, N., & Beebe, L. A. (2017). Psychometric Properties of Fagerström Test for Nicotine Dependence for Smokeless Tobacco Users (FTND-ST). *Nicotine Tob Res*, 19(9), 1095-1101. <https://doi.org/10.1093/ntr/ntx076>

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- Parsons, V. L. (2014). *Design and estimation for the national health interview survey, 2006-2015*. US Department of Health and Human Services, Centers for Disease Control and ....
- Piper, M. E., Baker, T. B., Benowitz, N. L., Smith, S. S., & Jorenby, D. E. (2020). E-cigarette Dependence Measures in Dual Users: Reliability and Relations With Dependence Criteria and E-cigarette Cessation. *Nicotine Tob Res*, 22(5), 756-763. <https://doi.org/10.1093/ntr/ntz040>
- Schafer, J. L., & Olsen, M. K. (1998). Multiple Imputation for Multivariate Missing-Data Problems: A Data Analyst's Perspective. *Multivariate Behav Res*, 33(4), 545-571. [https://doi.org/10.1207/s15327906mbr3304\\_5](https://doi.org/10.1207/s15327906mbr3304_5)
- Sharma, M. K., Suman, L. N., Srivastava, K., Suma, N., & Vishwakarma, A. (2021). Psychometric properties of Fagerstrom Test of Nicotine Dependence: A systematic review. *Ind Psychiatry J*, 30(2), 207-216. [https://doi.org/10.4103/ipj.ipj\\_51\\_21](https://doi.org/10.4103/ipj.ipj_51_21)

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## 11 Appendix

### 11.1 Overview of Tables, Figures, Listings (TFLs)

Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
Objective 1: Sociodemographic and health-related characteristics of adult ever established IQOS users			
Sociodemographic characteristics of adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Sex</li> <li>- Gender Identity</li> <li>- Age</li> <li>- Ethnicity/Race</li> <li>- Household Income</li> <li>- Education</li> <li>- Employment Status</li> <li>- Geographic Region</li> <li>- Marital Status</li> <li>- Sexual Orientation</li> <li>- Military Personnel/Veteran Status</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> </ul>	<a href="#">Table 1</a>
Health-related information of adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult	<ul style="list-style-type: none"> <li>- Pregnancy Status</li> <li>- Frequency of subjects by health-related condition</li> <li>- Number of subjects who reported mental health</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> </ul>	<a href="#">Table 2</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	condition - Number of subjects receiving mental health treatment or medication	<ul style="list-style-type: none"> <li>Current – Non-menthol Stick User</li> <li>Former</li> </ul>	
Objective 2: Historical and current tobacco use patterns of adult ever established IQOS users			
Prior to first trying IQOS – Historical tobacco use patterns of adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Number of subjects who ever tried the TNP type - Number of subjects who used the TNP type to lifetime criterion  <i>Statistics per tobacco type</i>	<ul style="list-style-type: none"> <li>Ever</li> <li>Current</li> <li>Former</li> </ul>	<a href="#">Table 3</a>
At time of assessment – Historical tobacco use patterns among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Number of subjects who ever tried the TNP - Number of subjects who used the TNP to lifetime criterion  <i>Statistics per tobacco type</i>	<ul style="list-style-type: none"> <li>Ever</li> <li>Current</li> <li>Former</li> </ul>	<a href="#">Table 4</a>
At time of assessment – Past 30-day TNP use among adult ever established IQOS users, overall and by study group and menthol IQOS	- Number of subjects who currently use the TNP - Number of days used given TNP in past 30 days - Number of IQOS heated tobacco sticks used on days used in the past 30 days	<ul style="list-style-type: none"> <li>Ever</li> <li>Current</li> <li>Current - Menthol Stick User</li> <li>Current – Non-menthol Stick User</li> </ul>	<a href="#">Table 5</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Number of cigarettes smoked on days used in the past 30 days</li> <li>- Average number of IQOS heated tobacco sticks used per day</li> <li>- Average number of cigarettes smoked per day</li> <li>- Average number of IQOS heated tobacco sticks and cigarettes used per day</li> </ul> <p><i>Statistics per tobacco type</i></p>	<ul style="list-style-type: none"> <li>• Former</li> </ul>	
Current TNP use relative to use in the 30 days prior to first trying IQOS among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Frequency of use of each TNP relative to use prior to first trying IQOS</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> </ul>	<a href="#">Table 6</a>
Use duration of IQOS and Cigarettes and IQOS quit duration among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- IQOS duration of use</li> <li>- Cigarette duration of use (current established smokers)</li> <li>- Cigarette duration of use (former established smokers)</li> <li>- Quit IQOS duration</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> </ul>	<a href="#">Table 7</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
IQOS heated tobacco sticks flavor(s) ever and currently used among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Number of subjects by Heated Tobacco Sticks Flavors Ever Tried</li> <li>- Number of subjects by First Heated Tobacco Sticks Flavors Ever Tried</li> <li>- Number of subjects by Heated Tobacco Sticks Flavors Currently Using</li> <li>- Number of subjects by Heated Tobacco Sticks Flavors Currently Using Most Often</li> <li>- Number of subjects by Heated Tobacco Sticks Flavors Previously Used Most Often</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Former</li> </ul>	<a href="#">Table 8</a>
Past 30-day exclusive, dual, or poly use among current established IQOS users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Current use patterns exclusive, dual, and poly use of IQOS with other TNPs	<ul style="list-style-type: none"> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> </ul>	<a href="#">Table 9</a>
IQOS Dependence among current established IQOS users – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Fagerström Test for Nicotine Dependence (FTND) Summary Score – IQOS</li> <li>- Fagerström Test for Nicotine Dependence (FTND) Summary Score (Current Established Smokers) – IQOS</li> </ul>	<ul style="list-style-type: none"> <li>• Current</li> </ul>	<a href="#">Table 10</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
	- Fagerström Test for Nicotine Dependence (FTND) Summary Score (Former Established Smokers) – IQOS		
Use of IQOS Not as Intended among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Ways used IQOS not as intended	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Former</li> </ul>	<a href="#">Table 11</a>
Cigarette Smoker Status among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Number of cigarette smokers by use of menthol / non-menthol cigarettes	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> </ul>	<a href="#">Table 12</a>
Cigarette Dependence among adult ever established IQOS users, by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Fagerström Test for Nicotine Dependence (FTND) Summary Score - Cigarettes	<ul style="list-style-type: none"> <li>• Current</li> <li>• Former</li> </ul>	<a href="#">Table 13</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
Objective 3: IQOS-related risk perceptions			
Adult ever established IQOS users' ABOUT™ health risk perception scores for IQOS use, cigarette smoking, and complete smoking cessation among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Summary of health risk perception score for IQOS, cigarettes, and smoking cessation	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current – Current Cigarette Smokers</li> <li>• Current – Long- Term Former Smokers</li> <li>• Former</li> </ul>	<a href="#">Table 14</a>
Perceptions about IQOS among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Frequency of perception about IQOS	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Former</li> </ul>	<a href="#">Table 15</a>
Objective 4: Tobacco use dynamics			
Initiation: IQOS As First Tobacco Product Ever Tried/First Tobacco Product Ever Used on a Consistent Basis among adult ever established	<ul style="list-style-type: none"> <li>- Number of subjects who tried IQOS as first TNP ever used</li> <li>- Number of subjects who used IQOS as first TNP on a consistent basis</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current – Menthol Stick User</li> </ul>	<a href="#">Table 16</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Number of subjects who first tried IQOS after not smoking for 12 months and more</li> <li>- Number of subjects who first tried IQOS after not smoking menthol cigarettes for 12 months and more</li> <li>- Number of subjects who first tried IQOS after not smoking non-menthol cigarettes for 12 months and more</li> <li>- Number of subjects who first tried IQOS after not using any tobacco products for 12 months and more</li> </ul>	<ul style="list-style-type: none"> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> <li>• Former – Menthol Stick User</li> <li>• Former – Non-menthol Stick User</li> </ul>	
Complete Switching to IQOS After First Trying IQOS among adult current established IQOS users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Distribution of subjects based on the complete switch from cigarettes or all tobacco products to IQOS	<ul style="list-style-type: none"> <li>• Current</li> <li>• Current – Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> </ul>	<a href="#">Table 17</a>
Complete Switching from IQOS to Cigarette Smoking After Initiating Tobacco Use with IQOS among adult ever established IQOS users – Adult IQOS User Postmarket	- Distribution of subjects based on the complete switch to cigarette	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Ever – Menthol Stick User</li> <li>• Ever – Non-menthol Stick User</li> </ul>	<a href="#">Table 18</a>

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
Cross-Sectional Study in the United States, YYYY (N = XXXX)			
Relapse, Re-Initiation and Initiation of Cigarette Smoking After First Trying IQOS among All Ever Established IQOS Users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Number of subjects who relapsed into cigarette use</li> <li>- Number of subjects who re-initiated cigarette use</li> <li>- Number of subjects who initiated using cigarette</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Ever - Menthol Stick User</li> <li>• Ever - Non-menthol Stick User</li> </ul>	Table 19
Past 12 Month Quit Attempts and Motivation to Stop Smoking among adult ever established IQOS users who are Current Established Smokers, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	<ul style="list-style-type: none"> <li>- Number of subjects who attempted to quit</li> <li>- Frequency of subjects by motivation to stop smoking</li> </ul>	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> <li>• Former - Menthol Stick User</li> <li>• Former - Non-menthol Stick User</li> </ul>	Table 20
Quit behaviors among adult ever established IQOS users who are Ever Established Smokers, overall and by study group and menthol	-- Number of subjects who completely quit smoking cigarettes or all tobacco products	<ul style="list-style-type: none"> <li>• Ever</li> <li>• Current</li> <li>• Current - Menthol Stick User</li> </ul>	Table 21

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Table Name	Statistics	Subgroups of Established IQOS Users	TFL Section No.
IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)		<ul style="list-style-type: none"> <li>• Current – Non-menthol Stick User</li> <li>• Former</li> <li>• Former - Menthol Stick User</li> <li>• Former - Non-menthol Stick User</li> </ul>	
Tobacco Cessation Treatment Use by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)	- Distribution of subjects based on tobacco cessation treatment use	<ul style="list-style-type: none"> <li>• Current</li> <li>• Former</li> </ul>	<a href="#">Table 22</a>

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## 11.2 Mock Tables – Objective 1

**Table 1: Sociodemographic characteristics of adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	N = XXXX
Base (Total Participants)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
<b>Sex, n (%), [95% CI]</b>					
Male					
Female					
<b>Gender Identity, n (%), [95% CI]</b>					
Woman					
Man					
Non-binary					
Transgender					
Another term					
<b>Age</b>					
21-24, n (%), [95% CI]					
25-34, n (%), [95% CI]					
35-44, n (%), [95% CI]					
45-54, n (%), [95% CI]					
55-64, n (%), [95% CI]					
65+, n (%), [95% CI]					
M (SD) [95% CI]					
Median (Q1, Q3)					
Min, Max					
<b>Ethnicity/Race, n (%), [95% CI] U</b>					
NH, White					
NH, Black/African American					
NH, Native American or Alaska Native					
NH, Native Hawaiian or other PI					
NH, Asian					
NH, Other race not listed					

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NH, Multiracial					
NH, Prefer not to answer					
Hispanic/Latinx					
Prefer not to answer					
<b>Household Income, n (%), [95% CI]</b>					
Under \$20,000					
\$20,000 - \$74,999					
\$75,000 or more					
Prefer not to answer					
<b>Education, n (%), [95% CI]</b>					
Less than High School					
High School Graduate/GED					
Some College/Associates Degree					
Bachelor's Degree or More					
<b>Employment Status, n (%), [95% CI]</b>					
Employed					
Unemployed					
Student					
Retired					
<b>Geographic Region, n (%), [95% CI]</b>					
Northeast					
South					
Midwest					
West					
<b>Marital Status, n (%), [95% CI]</b>					
Married / Living with a partner					
Separated / Divorced / Widowed					
Never married					
Prefer not to answer					
<b>Sexual Orientation, n (%), [95% CI]</b>					
Heterosexual or straight					
Lesbian or gay					
Bisexual					
Something else					
Don't know/not sure					
Prefer not to answer					

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Military Personnel/Veteran Status, n (%), [95% CI]					
Yes - now / were on active duty					
No - Reserves or National Guard only / never served					

CI = Confidence Interval; NH = Non-Hispanic; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.

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**Table 2: Health-related information of adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
			Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	
	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]
<b>Pregnancy Status</b>					
Base (Females, age 21-49)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
Currently pregnant/nursing					
Not currently pregnant/nursing					
Base (Total Participants)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
<b>Have you EVER been told by a doctor, nurse, or other health professional that you had...?</b>					
A heart attack (also called myocardial infarction)					
Angina, also called angina pectoris (chest pain or discomfort)					
Congestive heart failure					
Coronary heart disease					
High blood pressure (hypertension)					
High cholesterol (hyperlipidemia)					
Stroke					
Any other heart condition or heart disease					
COPD					
Chronic bronchitis					
Emphysema					
Asthma					
Apnea (pauses in breathing during sleep)					
Any other respiratory or lung condition					
Cancer					
Diabetes					

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None of the above					
<b>Reported Mental Health Condition</b>					
Yes					
No					
Don't know					
<b>Taking Medication or Receiving Treatment for Mental Health Condition or Emotional Problem</b>					
Yes					
No					
Don't know					

CI = Confidence Interval; COPD = Chronic obstructive pulmonary disease

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.

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### 11.3 Mock Tables – Objective 2

**Table 3: Prior to first trying IQOS – Historical tobacco use patterns of adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX	n=XXX	n=XXX
<b>Ever Tried</b>			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-cigarettes			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			
<b>Used to Lifetime Criterion</b>			
Cigarettes <sup>3</sup>			
Cigars <sup>4</sup>			
Pipe filled with tobacco <sup>5</sup>			
Hookah <sup>6</sup>			
E-cigarettes <sup>7</sup>			
Smokeless tobacco <sup>8</sup>			
Oral tobacco-derived nicotine products <sup>9</sup>			
<b>Past 30-Day Use</b>			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-cigarettes			
Smokeless tobacco			
Oral tobacco-derived nicotine products			

CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100 or more IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.

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2. Former established IQOS User – reported meeting lifetime IQOS use (100 or more IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Cigarette lifetime criterion – reported ever having smoked 100 or more cigarettes.
4. Cigar lifetime criterion – reported ever having smoked 50 or more cigars (including regular cigars, cigarillos, or little filtered cigars).
5. Pipe filled tobacco lifetime criterion – reported ever having smoked 50 bowls or more.
6. Hookah lifetime criterion – reported ever having smoked tobacco in a hookah on a “consistent basis”.
7. E-cigarettes lifetime criterion – reported ever having used e-cigarettes on a “consistent basis”.
8. Smokeless tobacco lifetime criterion – reported having ever used smokeless tobacco 20 or more times, including chewing tobacco, dip, snuff, or snus pouch.
9. Oral tobacco-derived nicotine products lifetime criterion – reported ever having used oral nicotine pouches on a “consistent basis”.

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**Table 4: At time of assessment – Historical tobacco use patterns among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX	n=XXX	n=XXX
<b>Ever Tried</b>			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-cigarettes			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
<b>Used to Lifetime Criterion</b>			
Cigarettes <sup>3</sup>			
Cigars <sup>4</sup>			
Pipe filled with tobacco <sup>5</sup>			
Hookah <sup>6</sup>			
E-cigarettes <sup>7</sup>			
Smokeless tobacco <sup>8</sup>			
Oral tobacco-derived nicotine products <sup>9</sup>			

CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Cigarette lifetime criterion – reported ever having smoked 100 or more cigarettes.
4. Cigar lifetime criterion – reported ever having smoked 50 or more cigars (including regular cigars, cigarillos, or little filtered cigars).
5. Pipe filled tobacco lifetime criterion – reported ever having smoked 50 bowls or more.
6. Hookah lifetime criterion – reported ever having smoked tobacco in a hookah on a “consistent basis”.
7. E-cigarettes lifetime criterion – reported ever having used e-cigarettes on a “consistent basis”.
8. Smokeless tobacco lifetime criterion – reported having ever used smokeless tobacco 20 or more times, including chewing tobacco, dip, snuff, or snus pouch.
9. Oral tobacco-derived nicotine products lifetime criterion – reported ever having used oral nicotine pouches on a “consistent basis”.

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**Table 5: At time of assessment – Past 30-day TNP use among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
			Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	
	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]	N = XXXX n (%) [95% CI]
Base (Total Participants)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
<b>Past 30-day use<sup>5</sup></b>					
Cigarettes					
Cigars					
Pipe filled with tobacco					
Hookah					
E-cigarettes					
Smokeless tobacco					
Oral tobacco-derived nicotine products					
<b>Number of days used given TNP in the past 30 days</b>					
<b>Cigarettes</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					
Median (Q1, Q3)					
Min/Max					
<b>Cigars</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
...					
<b>IQOS</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					NA
Median (Q1, Q3)					NA
Min/Max					NA
<b>Number of IQOS heated tobacco sticks used on days used in the past 30 days</b>					
Base	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					NA
Median (Q1, Q3)					NA
Min/Max					NA
<b>Number of cigarettes smoked on days used on days used in the past 30 days</b>					
Base	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					

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Median (Q1, Q3)					
Min/Max					
<b>Average number of IQOS heated tobacco sticks used per day</b>					
Base	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					NA
Median (Q1, Q3)					NA
Min/Max					NA
<b>Average number of cigarettes smoked per day</b>					
Base	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					
Median (Q1, Q3)					
Min/Max					
<b>Average number of IQOS heated tobacco sticks and cigarettes used per day</b>					
Base	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>	<b>n = XXX</b>
M (SD) [95% CI]					NA
Median (Q1, Q3)					NA
Min/Max					NA

TNP = Tobacco or Nicotine Products; CI = Confidence Interval; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile; NA = Not Applicable

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
5. Among current established IQOS users reporting past 30-day IQOS and cigarette use at time of assessment.

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**Table 6: Current TNP use relative to use in the 30 days prior to first trying IQOS among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Past 30-Day Users of Given TNP Prior to First Trying IQOS)					
<b>Cigarettes</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now smoke...</i>					
Fewer per day <sup>5</sup>					
More per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>Cigars</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now smoke...</i>					
Fewer per day <sup>5</sup>					
More per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>Tobacco in a Pipe</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now smoke...</i>					
Fewer per day <sup>5</sup>					
More per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>Tobacco in a Hookah</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now smoke...</i>					
Fewer times per day <sup>5</sup>					
More times per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>E-vapor Products</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now use...</i>					
Fewer times per day <sup>5</sup>					
More times per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>Smokeless Tobacco</b>	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
<i>Now use...</i>					
Fewer times per day <sup>5</sup>					

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More times per day <sup>6</sup>					
Same number per day <sup>7</sup>					
<b>Oral Tobacco-Derived Nicotine Products</b>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>
<i>Now use...</i>					
Fewer per day <sup>5</sup>					
More per day <sup>6</sup>					
Same number per day <sup>7</sup>					

TNP = Tobacco or Nicotine Products; CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
5. "Compared to the 30 days before I first tried IQOS...I now [smoke fewer (TNP) | use (TNP) fewer times] per day."
6. "Compared to the 30 days before I first tried IQOS...I now [smoke more (TNP) | use (TNP) more times] per day."
7. "Compared to the 30 days before I first tried IQOS...I [smoke the same number of (TNP) | use (TNP) the same number of times] per day now as I did then."

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**Table 7: Use duration of IQOS and Cigarettes and IQOS quit duration among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
			Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	
	N = XXXX	N = XXXX	N = XXXX	N = XXXX	N = XXXX
IQOS					
Base (Total Participants)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
M # years (SD) (95% CI)					
Median # years (Q1, Q3)					
Min, Max					
Cigarettes - Current Established Smokers					
Base (Current Established Smokers)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
M # years (SD) (95% CI)					
Median # years (Q1, Q3)					
Min, Max					
Cigarettes - Former Established Smokers					
Base (Former Established Smokers)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
M # years (SD) (95% CI)					
Median # years (Q1, Q3)					
Min, Max					
Quit IQOS duration					
Short-term quitters <sup>5</sup>	NA	NA	NA	NA	
Long-term quitters <sup>6</sup>	NA	NA	NA	NA	

CI = Confidence Interval; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile; NA = Not Applicable

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
5. Short-term quitters - reported no IQOS use in the past 30 days but used it within the last 11 months.
6. Long-term quitters - reported no IQOS use in the past 11 months.

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**Table 8: IQOS heated tobacco sticks flavor(s) ever and currently used among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=xxx	n=xxx	n=xxx
<b>Heated Tobacco Sticks Flavors Ever Tried</b>			
Type 1			
Type 2			
Type 3			
<b>First Heated Tobacco Stick Flavor Ever Tried</b>			
Type 1			
Type 2			
Type 3			
<b>Heated Tobacco Sticks Flavor Currently Using</b>			
Type 1			NA
Type 2			NA
Type 3			NA
<b>Heated Tobacco Sticks Flavor Currently Using Most Often</b>			
Type 1			NA
Type 2			NA
Type 3			NA
<b>Heated Tobacco Sticks Flavor most often used when used IQOS</b>			
Type 1		NA	
Type 2		NA	
Type 3		NA	

CI = Confidence Interval; NA = Not Applicable

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.

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**Table 9: Past 30-day exclusive, dual, or poly use among current established IQOS users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Current Established IQOS Users <sup>1</sup>		
	Current Established IQOS Users <sup>1</sup>	Menthol Stick User <sup>2</sup>	Non-menthol Stick User <sup>3</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX	n=XXX	n=XXX
<b>Exclusive IQOS use</b>			
<b>Dual use (IQOS + 1 other TNP)</b>			
IQOS + 1 combustible TNP			
IQOS + cigarettes			
Menthol cigarette use <sup>4</sup>			
Non-Menthol cigarette use <sup>5</sup>			
IQOS + 1 non-combustible TNP			
<b>Poly use (IQOS + ≥2 other TNP)</b>			
IQOS + 1 combustible TNP + ≥1 other TNP			
IQOS + cigarettes + ≥1 other TNP			
Menthol cigarette use <sup>4</sup>			
Non-Menthol cigarette use <sup>5</sup>			
IQOS + only ≥2 non-combustible TNP			

CI = Confidence Interval; TNP = Tobacco or Nicotine Products

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
3. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
4. Reported smoking menthol cigarettes most often in the past 30 days at time of assessment.
5. Reported not smoking menthol cigarettes most often in the past 30 days at time of assessment.

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**Table 10: IQOS Dependence<sup>1</sup> among current established IQOS users – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Current Established IQOS Users <sup>2</sup>
	N = XXXX
<b>FTND Summary Score</b>	
Base	n=XXX
M (SD) (95% CI)	
Median (Q1, Q3)	
Min/Max	
<b>Current established cigarette smokers</b>	
Base	n=XXX
M (SD) (95% CI)	
Median (Q1, Q3)	
Min/Max	
<b>Former established cigarette smokers</b>	
Base	n=XXX
M (SD) (95% CI)	
Median (Q1, Q3)	
Min/Max	

FTND = Fagerström Test for Nicotine Dependence; CI = Confidence Interval; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile

1. IQOS dependence assessed via FTND (range 1-10) with higher scores indicating greater dependence.
2. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.

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**Table 11: Use of IQOS Not as Intended among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX	n=XXX	n=XXX
<b>Overall ever use of IQOS not as intended</b>			
<i>Ever lit an IQOS heated tobacco stick like a cigarette</i>			
Only once			
Sometimes			
Most of the time			
All the time			
<i>Ever used an IQOS heated tobacco stick not with an IQOS device</i>			
Only once			
Sometimes			
Most of the time			
All the time			
<i>Ever used an IQOS device with a product other than IQOS heated tobacco stick</i>			
Only once			
Sometimes			
Most of the time			
All the time			

CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.

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**Table 12: Cigarette Smoker Status among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Current Established IQOS Users <sup>1</sup>		Former Established IQOS Users <sup>2</sup>
			Menthol Stick User <sup>3</sup>	Non-menthol Stick User <sup>4</sup>	
	N = XXXX	N = XXXX	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base	n=XXX	n=XXX	n=XXX	n=XXX	n=XXX
<b>Never smoker</b>					
<b>Current smoker</b>					
Menthol use					
Non-menthol use					
<b>Current established smoker<sup>5</sup></b>					
Menthol use					
Non-menthol use					
<b>Former smoker<sup>6</sup></b>					
Used menthol					
Did not use menthol					

CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
5. Reported smoking menthol cigarettes most often in the past 30 days at time of assessment.
6. Reported not smoking menthol cigarettes most often in the past 30 days at time of assessment.

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**Table 13: Cigarette Dependence<sup>1</sup> among adult ever established IQOS users, by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

	<b>Current Established IQOS Users<sup>2</sup></b>	<b>Former Established IQOS Users<sup>3</sup></b>
<b>Measure</b>	<b>N = XXXX</b>	<b>N = XXXX</b>
<b>FTND Summary Score</b>		
Base	<i>n=XXX</i>	<i>n=XXX</i>
M (SD) (95% CI)		
Median (Q1, Q3)		
Min/Max		

FTND = Fagerström Test for Nicotine Dependence; CI = Confidence Interval; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile

1. Cigarette dependence assessed via FTND (range 1-10) with higher scores indicating greater dependence.
2. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
3. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.

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## 11.4 Mock Tables – Objective 3

**Table 14: Adult ever established IQOS users' ABOUT™<sup>1</sup> health risk perception scores for IQOS use, cigarette smoking, and complete smoking cessation among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>2</sup>	Current Established IQOS Users <sup>2</sup>		Former Established IQOS Users <sup>3</sup>
			Current Cigarette Smokers <sup>4</sup>	Long-Term Former Smokers <sup>5</sup>	
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX		n=XXX	n=XXX	n=XXX
<b>Perceived risk...IQOS use</b>					
No to Low					
Low					
Low to Moderate					
Moderate					
Moderate to High					
High					
High to Very High					
Very High					
<b>Perceived risk...Cigarette smoking</b>					
No to Low					
Low					
Low to Moderate					
Moderate					
Moderate to High					
High					
High to Very High					
Very High					
<b>Perceived risk...Complete smoking cessation</b>					
No to Low					
Low					
Low to Moderate					
Moderate					

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Moderate to High					
High					
High to Very High					
Very High					

CI = Confidence Interval

1. Participants health-risk perceptions were assessed via the ABOUT - Risk Perception instrument (range, 1 = "No risk" to 5 = "Very high risk") with higher composite scores indicating higher perceived health risk.
2. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
3. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
4. Current cigarette smokers – reported having smoked cigarettes in the past 30 days at time of assessment.
5. Long-term former smokers – reported having ever used cigarettes, even one time and not having used cigarettes in the past 12-months at time of assessment.

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**Table 15: Perceptions about IQOS among adult ever established IQOS users, overall and by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (all respondents)	n=XXX	n=XXX	n=XXX
<b>Perception about Harmful or Potentially Harmful Chemical Exposure When Switching Completely from Cigarettes to IQOS</b>			
More exposure			
The same exposure			
Less exposure			
No exposure			
Don't know			
<b>Understanding of What Smokers Must Do to Reduce Their Exposure to Harmful or Potentially Harmful Chemicals</b>			
Base (respondents who identified 'less exposure')	n=XXX	n=XXX	n=XXX
Stop smoking completely and only use IQOS			
Smoke fewer cigarettes and also use IQOS			
Keep smoking the same amount of cigarettes and also use IQOS			
Don't know			

CI = Confidence Interval

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.

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## 11.5 Mock Tables – Objective 4

**Table 16: Initiation: IQOS As First Tobacco Product Ever Tried/First Tobacco Product Ever Used on a Consistent Basis among adult ever established IQOS users, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established	Current Established <sup>1</sup>	Current Established <sup>1</sup>		Former Established <sup>2</sup>	Former Established <sup>2</sup>	
			Menthol Stick Use <sup>3</sup>	Non-Menthol Stick Use <sup>4</sup>		Menthol Stick User <sup>5</sup>	Menthol Stick Use <sup>6</sup>
			N = XXXX	N = XXXX		N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base	n=XXX	n=XXX	n=XXX	n=XXX	n=XXX	n=XXX	n=XXX
<b>IQOS as first TNP...</b>							
Ever tried							
Ever used on a consistent basis							
<b>First tried IQOS after not smoking for...</b>							
≥12 months							
Used menthol cigarettes							
Did not use menthol cigarettes							
<b>First tried IQOS after not using any TNP for ≥12 months</b>							

CI = Confidence Interval

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1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
3. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
4. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
5. Reported using menthol IQOS heated tobacco sticks most often when IQOS was used.
6. Reported not using menthol IQOS heated tobacco sticks most often when IQOS was used.

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**Table 17: Complete Switching to IQOS After First Trying IQOS among adult current established IQOS users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Current Established <sup>1</sup>	Current Established <sup>1</sup>	Current Established <sup>1</sup>
		Menthol Stick Use <sup>2</sup>	Non-Menthol Stick Use <sup>3</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base	n=XXX	n=XXX	n=XXX
Established past 30-day smokers prior to first trying IQOS <sup>4</sup>	n = XXX	n = XXX	n = XXX
Switched from cigarettes to IQOS <sup>5</sup>			
Established past 30-day smokers prior to first trying IQOS <sup>4</sup> – Menthol cigarette users	n = XXX	n = XXX	n = XXX
Switched from cigarettes to IQOS <sup>5</sup>			
Established past 30-day smokers prior to first trying IQOS <sup>4</sup> – Non-menthol cigarette users	n = XXX	n = XXX	n = XXX
Switched from cigarettes to IQOS <sup>5</sup>			
Established past 30-day TNP user prior to first trying IQOS <sup>4</sup>	n = XXX	n = XXX	n = XXX
Switched from all TNP to IQOS <sup>5</sup>			

CI = Confidence Interval; NH = Non-Hispanic; M = Mean; SD = Standard Deviation; Q1 = First Quartile; Q3 = Third Quartile

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
3. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
4. Established past 30-day TNP user prior to first trying IQOS is defined as met the lifetime established use criterion for given TNP (e.g. cigarettes), and used given TNP in the 30 days prior to first trying IQOS.
5. Complete switching of a given TNP to IQOS refers to transitioning from established use of a given TNP to reporting no past 30-day use of that TNP (i.e., former established use) and current established use of IQOS.

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**Table 18: Complete Switching from IQOS to Cigarette Smoking After Initiating Tobacco Use with IQOS among adult ever established IQOS users – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established IQOS Users
	N = XXXX
	n (%) [95% CI]
Base (Total Participants)	n=xxx
<b>Complete switching from IQOS<sup>1</sup> to...</b>	
Cigarettes	
Menthol use	
Non-menthol use	

CI = Confidence Interval

- Complete switching from IQOS to another TNP is defined as IQOS as the first TNP ever used, being a former established user of IQOS, and being a current established user of another TNP

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**Table 19: Relapse, Re-Initiation and Initiation of Cigarette Smoking After First Trying IQOS among All Ever Established IQOS Users, overall and by menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure		Menthol Stick Use <sup>1</sup>	Non-Menthol Stick Use <sup>2</sup>
	N = XXXX	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]
Base (Total Participants)	n=XXX	n=XXX	n=XXX
<b>Relapse to cigarette smoking after first trying IQOS<sup>3</sup></b>			
Menthol use			
Non-menthol cigarette use			
<b>Re-initiation of cigarette smoking after first trying IQOS<sup>4</sup></b>			
Menthol use			
Non-menthol cigarette use			
<b>Initiation of established cigarette smoking after first trying IQOS<sup>5</sup></b>			
Menthol use			
Non-menthol cigarette use			

CI = Confidence Interval

1. Reported using menthol IQOS heated tobacco sticks.
2. Reported using non-menthol IQOS heated tobacco sticks.
3. Relapse of cigarette smoking after first trying IQOS defined as having met the lifetime established use criterion for cigarettes (i.e., 100 or more) and not having smoked cigarettes for less than 12 months prior to first trying IQOS, as well as past 30-day cigarette smoking at time of assessment.
4. Re-initiation of cigarette smoking after first trying IQOS defined as having met the lifetime established use criterion for cigarettes (i.e., 100 or more) and not having smoked cigarettes for 12 months or longer prior to first trying IQOS, as well as past 30-day cigarette smoking at time of assessment.
5. Initiation of established cigarette smoking after first trying IQOS defined as never smoking cigarettes or not having met the lifetime established use criterion for cigarettes (i.e., 100 or more) prior to first trying IQOS, as well as is an established cigarette smoker at time of assessment.

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**Table 20: Past 12 Month Quit Attempts and Motivation to Stop Smoking among adult ever established IQOS users who are Current Established Smokers<sup>1</sup>, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established	Current Established <sup>1</sup>	Current Established <sup>2</sup>		Former Established <sup>2</sup>	Former Established <sup>3</sup>	
			Menthol Stick Use <sup>4</sup>	Non-Menthol Stick Use <sup>5</sup>		Menthol Stick Used <sup>6</sup>	Non-Menthol Stick Used <sup>7</sup>
			N = XXXX	N = XXXX		N = XXXX	N = XXXX
			n (%) [95% CI]	n (%) [95% CI]		n (%) [95% CI]	n (%) [95% CI]
<b>Base</b>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>	<i>n=xxx</i>
<b>Past 12-month quit attempts</b>							
<b>Motivation to Stop Smoking<sup>8</sup></b>							
I don't want to stop smoking. - <i>Absence of any belief, desire, or intention to stop smoking</i>							
I think I should stop smoking but don't really want to. - <i>Belief only</i>							
I want to stop smoking but haven't thought about. - <i>Moderate desire to stop smoking but no intention</i>							
I REALLY want to stop smoking but I don't know when I will. - <i>Strong desire to stop smoking</i>							

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<i>but no intention</i>							
I want to stop smoking and hope to soon. - <i>Moderate desire and intention to stop smoking</i>							
I REALLY want to stop smoking and intend to in the next 3 months. - <i>Strong desire and medium-term intention to stop smoking</i>							
I REALLY want to stop smoking and intend to in the next month. - <i>Strong desire and short-term intention to stop smoking</i>							

CI = Confidence Interval; NA = Not Applicable

1. Current established smoker – reported having met the lifetime established use criterion for cigarettes (i.e., 100 or more lifetime cigarettes), and having smoked cigarettes in the past 30 days at time of assessment.
2. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
3. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
4. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
5. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
6. Reported using menthol IQOS heated tobacco sticks most often when IQOS was used.
7. Reported not using menthol IQOS heated tobacco sticks most often when IQOS was used.
8. Scale response from ([Kotz et al, 2013](#))

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**Table 21: Quit behaviors among adult ever established IQOS users who are Ever Established Smokers<sup>1</sup>, overall and by study group and menthol IQOS stick use – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Ever Established	Current Established <sup>2</sup>	Current Established <sup>2</sup>		Former Established <sup>3</sup>	Former Established <sup>3</sup>	
			Menthol Stick Use <sup>4</sup>	Non-Menthol Stick Use <sup>5</sup>		Menthol Stick Used <sup>6</sup>	Non-Menthol Stick Used <sup>7</sup>
			N = XXXX	N = XXXX		N = XXXX	N = XXXX
			n (%) [95% CI]	n (%) [95% CI]		n (%) [95% CI]	n (%) [95% CI]
Base (Ever Established Cigarette Smokers)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
Completely quit smoking cigarettes after first trying IQOS							
Completely quit smoking cigarettes for less than 12 months after first trying IQOS							
Completely quit smoking cigarettes for 12 months or longer after first trying IQOS							
Base (Total Participants)	NA	NA	NA	NA	n=xxx	n=xxx	n=xxx
Completely quitting all tobacco products after first trying IQOS	NA	NA	NA	NA			
Completely quitting all tobacco products for less than 12 months after first	NA	NA	NA	NA			

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trying IQOS							
Completely quitting all tobacco products for 12 months or longer after first trying IQOS	NA	NA	NA	NA			

CI = Confidence Interval; NA = Not Applicable

1. Ever Established Smokers refers to meeting the lifetime established use criterion for cigarettes
2. Ever established IQOS users refers to reporting ever having used 100 or more IQOS heated tobacco sticks; ever established cigarette smokers refers to reporting ever having smoked 100 or more cigarettes.
3. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
4. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.
5. Reported using menthol IQOS heated tobacco sticks most often in the past 30 days at time of assessment.
6. Reported not using menthol IQOS heated tobacco sticks most often in the in the past 30 days at time of assessment.
7. Reported using menthol IQOS heated tobacco sticks most often when IQOS was used.
8. Reported not using menthol IQOS heated tobacco sticks most often when IQOS was used.

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**Table 22: Tobacco Cessation Treatment Use by study group – Adult IQOS User Postmarket Cross-Sectional Study in the United States, YYYY (N = XXXX)**

Measure	Current Established IQOS Users <sup>1</sup>	Former Established IQOS Users <sup>2</sup>
	N = XXXX	N = XXXX
	n (%) [95% CI]	n (%) [95% CI]
Base (All Participants)	n=xxx	n=xxx
<b>Used tobacco cessation treatment...</b>		
Within the past 30 days		
More than 30 days ago but within 12 months		
More than 12 months ago		
Never used		
Base (Current Established IQOS users who switched from cigarettes to IQOS)	n=xxx	n=xxx
<b>Used tobacco cessation treatment...</b>		
Within the past 30 days		NA
More than 30 days ago but within 12 months		NA
More than 12 months ago		NA
Never used		NA
Base (Current Established IQOS users who switched from all tobacco products to IQOS)	n=xxx	n=xxx
<b>Used tobacco cessation treatment...</b>		
Within the past 30 days		NA
More than 30 days ago but within 12 months		NA

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More than 12 months ago		NA
Never used		NA

CI = Confidence Interval; NA = Not Applicable

1. Current established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and past 30-day IQOS use at time of assessment.
2. Former established IQOS User – reported meeting lifetime IQOS use (100+ IQOS heated tobacco sticks) and no past 30-day IQOS use at time of assessment.

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