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Appendix B3: IQOS® Cross-Sectional PACS SAP	Version 3.0

Appendix B3:

IQOS® Cross-Sectional PACS SAP

Please find on the following pages statistical analysis plan for IQOS® Cross-Sectional PACS.

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STATISTICAL ANALYSIS PLAN

Altria Client Services

Protocol Number: (b) (4)

Protocol Name: IQOS® with Marlboro HeatSticks® Cross-sectional Postmarket
Adult Consumer Study (PACS)
(IQOS® Cross-sectional PACS)

Signatures

CRO Survey Statistician: _____

Principal Investigator: _____

(b) (6)

Regulatory Affairs

Altria Client Services LLC

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DEFINITIONS OF TERMS

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 user is someone who reports current tobacco product use and established use of a tobacco product. Unless otherwise specified, IQOS® refers to IQOS® Tobacco Heating System and Marlboro HeatSticks® in this document.

Complete Switching

Complete switching generally refers to the event of completely transitioning from *established use* of one tobacco product to now not using that product and *current established use* of another tobacco product. Outcomes related to complete switching in this study include:

- Complete switching from all tobacco products to IQOS® after first trying IQOS®,
- Complete switching from cigarettes to IQOS® after first trying IQOS®, and
- Complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS®.

Consistent Basis

Consistent basis refers to “using the 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 Tobacco Product Use

Current tobacco product use refers to using a given tobacco product “every day” or “some days” now, irrespective of whether or not the lifetime established use criterion was met.

Established Tobacco Product Use

Established tobacco product use refers to having met or exceeded the *lifetime established use criterion* for a given tobacco product.

Ever Tobacco Product Use

Ever use refers to having used a given tobacco product in a person’s lifetime, irrespective of whether or not the lifetime established use criterion was met.

Former Tobacco Product Use

Former tobacco product use refers to having *ever used* a given tobacco product and now “not at all” using the product, irrespective of whether or not the lifetime established use criterion was met.

Initiation

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

- First tobacco product ever tried
- First tobacco product ever used on a consistent basis

IQOS® Consumer Database

The IQOS® Consumer Database is a database of registered IQOS® consumers in the U.S. These consumers may be existing members of ALCS's Adult Tobacco Consumer Database (ATCD) and flagged as an IQOS® consumer as a result of their registration of their IQOS® device or newly entered into the ATCD by virtue of their purchase and registration of their IQOS® device. Thus, collectively, ALCS will develop a database of IQOS® consumers.

Lifetime Established Use Criterion

For purposes of this research, the lifetime established use criterion is defined for:

1. cigarettes as ever use of 100 or more cigarettes,
2. IQOS® as ever use of 100 or more Marlboro HeatSticks®,
3. cigars as ever use of 50 or more cigars,
4. dip/snuff, chewing tobacco, and snus pouches as ever use of 20 or more times per product,
5. regular pipe as ever use of 50 bowls or more, and
6. all other tobacco products, including e-cigarettes and other e-vapor products, hookah, oral tobacco-derived nicotine products, as ever used on a "consistent basis."

Long-Term Former Tobacco Product Use

Long-term former tobacco product use refers to having *ever used* a given tobacco product, now "not at all" using the product, and having not used the product for 12 months or longer.

Long-Term Former Use of All Tobacco Products

Long-term former use of all tobacco products refers to having *ever used* a tobacco product(s), now "not at all" using any tobacco products, and having not used all tobacco products for 12 months or longer.

Quitting a Tobacco Product

Quitting a tobacco product refers to having used a given tobacco product to the *lifetime established use criterion*, now “not at all” using the product, and having “completely stopped/quit” using the product.

Quitting All Tobacco Products

Quitting all tobacco products refers to having used any tobacco product to the *lifetime established use criterion*, now “not at all” using any tobacco product, and having “completely stopped/quit” using all tobacco products ever used.

Re-Initiation of Cigarette Smoking after First Trying IQOS®

Re-Initiation of Cigarette Smoking after First Trying IQOS® refers to *current use* of cigarettes and having had smoked at least 100 cigarettes and having had not smoked cigarettes for 12 months or longer prior to first trying IQOS®.

Relapse to Cigarette Smoking after First Trying IQOS®

Relapse to Cigarette Smoking after First Trying IQOS® refers to *current use* of cigarettes and having had smoked at least 100 cigarettes and having had not smoked cigarettes for less than 12 months prior to first trying IQOS®.

Tobacco Products

In this study, tobacco products include cigarettes, cigars (regular cigars, cigarillos, little filtered cigars), regular pipes, water pipes/hookahs, e-vapor products (e-cigarettes, e-hookah, e-cigars, e-pipes, mods, vapes, tanks, pods, cartridges), smokeless tobacco (chewing tobacco, “dip”/snuff, snus pouches), oral tobacco-derived nicotine products (excluding medicinal nicotine replacement products), and IQOS®.

1 INTRODUCTION

1.1 Background

Philip Morris Products S.A. (PMP S.A.) developed the IQOS® Tobacco Heating System and Marlboro HeatSticks® (hereinafter referred to as IQOS®) as novel tobacco and nicotine-containing products with the potential to reduce harm or the risk of tobacco-related disease associated with smoking cigarettes. PMP S.A. submitted Modified Risk Tobacco Product Applications for IQOS® to the U.S. Food and Drug Administration (FDA) seeking authorization to market the products as modified risk tobacco products. On July 7, 2020, FDA issued “Modified Risk Granted Orders – Exposure Modification” authorizing IQOS® to be marketed with a reduced exposure claim. The Orders are conditioned upon agreement to conduct postmarket surveillance and studies (PMSS) in accordance with protocols approved by FDA. This document is prepared as part of the PMSS program for IQOS® pursuant to the Order.

1.2 Rationale

The Federal Food, Drug and Cosmetic Act (FDCA) directs the Food and Drug Administration (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” (Food and Drug Administration, 2012). For this reason, ALCS¹ on behalf of the applicant, PMP S.A., plans to conduct certain components of PMSS to assess the effect of the MRTP among U.S. 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, IQOS® with Marlboro HeatSticks® Cross-sectional Postmarket Adult Consumer Study (IQOS® Cross-sectional PACS), is one such study.

1.3 Study Purpose

The purpose of this study is to provide survey data from qualified adult ever established IQOS® users to assess use and perceptions of the IQOS® products and associations with other tobacco use behaviors.

¹ Altria Client Services (ALCS) and the parent of PMP S.A., Philip Morris International Management S.A., have entered into a distribution agreement by which ALCS and its affiliates have exclusive rights to distribute and sell IQOS® in the U.S. after FDA authorization. ALCS affiliate PM USA markets IQOS® in the U.S. Therefore, PMSS that involves the study of consumers and consumption in the U.S. will be conducted by ALCS to be submitted as part of PMSS reporting by PMP S.A.

1.4 Study Objectives

The study objectives are among adult ever established IQOS® users and are as follows:

- To characterize adult ever established IQOS® users, and their tobacco use patterns.
- To characterize risk perceptions of IQOS®.
- To describe initiation, complete switching from cigarette smoking to IQOS®, transitions to/back to cigarette smoking, and quitting behaviors relevant to IQOS® use.

2 STUDY DESIGN, DEVELOPMENT AND METHODS

2.1 Overview

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

During the first execution of the IQOS® Cross-sectional PACS, invitations to participate will be sent to adult tobacco consumers enrolled in the IQOS® Consumer Database. In subsequent executions of the study, adult tobacco consumers may also be recruited from commercial, online panels. All participants, regardless of recruiting mode, will complete the same computerized surveys online. Once a potential participant expresses interest in participating in the study and meets initial qualifying criteria, he/she will be provided the Informed Consent Statement, which includes a summary of the study, the aim of the study, the voluntary nature of his/her participation, and data privacy/confidentiality guidelines.

After agreeing to participate in the study, the potential participant will complete the Participant Screener Survey to determine his/her eligibility for the study. As part of the process of determining eligibility, the potential participant's age will be verified to ensure that he/she meets the inclusion criteria. Eligible participants will then be presented with the "Main Survey," which will collect the detailed study information to assess the study objectives.

Survey questions were designed to characterize patterns of tobacco use, reasons for IQOS® use, risk perceptions, awareness and comprehension of IQOS® MRTP message, and behaviors associated with IQOS®. Most questions assess outcomes at the brand level (i.e., IQOS® with Marlboro HeatSticks®), not at the individual IQOS® variety level (i.e., Marlboro HeatSticks®, Marlboro Smooth Menthol HeatSticks®, Marlboro Fresh Menthol HeatSticks®). However, to help characterize use of individual IQOS® varieties, the survey also includes certain questions specific to individual Marlboro HeatSticks® varieties, such as individual Marlboro HeatSticks® variety/varieties ever used, currently used, and currently used most often. This information will be provided descriptively, and estimates for certain outcomes will be stratified by menthol vs. non-menthol (regular) HeatSticks® use.

Checklist items will be randomized. Skip logic will be incorporated into surveys to reduce participant burden.

2.2 Survey Development and Testing

The IQOS® Cross-Sectional PACS survey items were designed 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 (Hyland et al., 2017; Parsons et al., 2014; The Substance Abuse and Mental Health Services Administration, 2017). Details of the source of all survey items will be provided in a Survey Development History (provided as an appendix item to the Detailed Study Report). Furthermore, ALCS commissioned cognitive testing of the study instrument in early 2020 and updated items when needed.

The survey instruments were designed to be administered electronically. Rationale for choosing this survey mode included: (1) broad reach, speed, and flexibility (e.g., ability to present visual images of tobacco products along with written descriptions when assessing former and current tobacco use behavior; ability for respondents to complete the survey at a pace, time and location of their choosing); (2) automated data collection (e.g., item sequencing, control of answer order, randomization of response alternatives, avoiding interview bias); and (3) availability of survey meta-data (Evans and Mathur, 2005).

3 STUDY POPULATION AND SAMPLE SIZE

3.1 Participants

Participants will include ever established IQOS® users who are qualified² adults 21 years of age or older. Many outcome measures of interest (e.g., risk perceptions of IQOS®) are applicable to all ever established IQOS® users recruited into the study. However, some outcome measures (e.g., number of days used IQOS® in the past 30 days) are only applicable to current established IQOS® users, while others (e.g., quitting all tobacco products after first trying IQOS®) can only be assessed among former established IQOS® users. As a result, ever established IQOS® users will include participants who have ever used at least 100 Marlboro HeatSticks® and will consist of current and former established IQOS® users.

Ever established IQOS® users will be defined as:

- Adults who have ever used at least 100 Marlboro HeatSticks®. Ever established IQOS® users include the following two groups:
 - **Current established IQOS® users:** Adult ever established IQOS® users who now use IQOS® “every day” or “some days”.
 - **Former established IQOS® users:** Adult ever established IQOS® users who now “not at all” use IQOS®.

² Individuals who meet the study inclusion criteria (Section 3.4) and none of the exclusion criteria (Section 3.5) will qualify for the main study and be administered the main survey.

3.2 Sample Size

A sufficient sample size was calculated to ensure adequate precision of the estimates (e.g., means, proportions³). Because certain outcome measures are designed for former established IQOS® users and others for current established users, we apply the sample size calculation to the former established IQOS® user group (assuming it is the minority of ever established IQOS® users). The current established IQOS® user group will be allowed to fill naturally until the sample size for the former established IQOS® user group achieves (b) (4) with a conservative minimum of (b) (4) participants recruited for the current established IQOS® user group⁴. Based on our calculation described below, a sample size of (b) (4) will be needed for former established IQOS® users to achieve a sufficiently narrow confidence interval (NCSS Statistical software, 2017) for the estimates. As an example, assuming an expected proportion of an outcome measure is 0.5 (for example, if the proportion of IQOS® users who state the reason for use is to quit cigarette smoking is 0.5), a sample size of (b) (4)

(b) (4)
(Fleiss et al., 2003; Newcombe, 1998). If a sample size of (b) (4) cannot be achieved for former established IQOS® users, the confidence interval associated with the actual sample size recruited will be reported. Of note, assuming an expected proportion of 0.5, when the sample size drops to $n =$ (b) (4) (Figure 1) (Fleiss et al., 2003; Newcombe, 1998), which is still practically acceptable. As a result, (b) (4) will be considered the smallest sample size required for the former established IQOS® user group. Based on these calculations, we expect a total of ~1000 participants to be interviewed for each wave to yield (b) (4) in the former established IQOS® user group. (A maximum ratio of current to former users of 9:1 would provide a minimum of (b) (4) former established IQOS® users.) The following table (Table 1) shows 95% confidence intervals for various proportions and sample sizes. We expect the estimates to be less precise for rare events (i.e., low proportions). Estimates with denominator sample sizes less than (b) (4) or having a relative standard error greater than 30% will be reported with a note of low statistical precision. Estimates with denominator sample sizes less than (b) (4) will not be reported with a note of small sample size.

Research (Piovesana et al., 2016) has found that a sample size of (b) (4) is required to produce sample means and standard deviations with reasonable precision. Therefore, the estimated minimum sample size of (b) (4) for the former established IQOS® user group is also appropriate for the continuous outcome measures of this study.

The study will begin when it is estimated that the minimum sample size for established IQOS® users can be met. A 5% response rate will be assumed when making this determination.

³ The term “proportions” used here is interchangeable with the term “percentages” used in “Section 4. Outcome Measures,” as percentages are proportions multiplied by 100.

⁴ Recruitment is expected to yield a higher number of current established IQOS® users than former established IQOS® users. The number of current established IQOS® users enrolled in the study is expected to exceed (b) (4) while filling naturally.

Table 1: 95% Confidence Intervals at Various Proportion Points

<i>n</i>	Proportion									
	(b) (4)									
	(b) (4)									

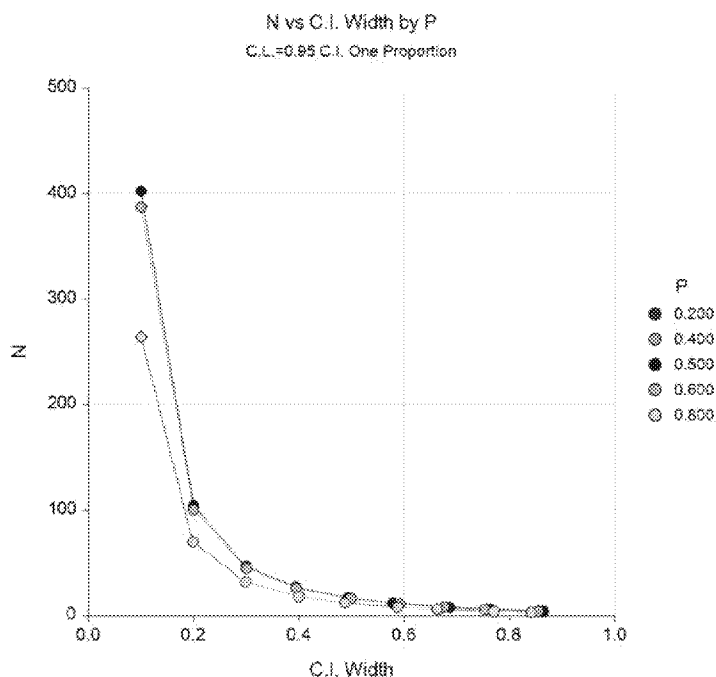


Figure 1: Estimated Sample Sizes for Various Confidence Interval Widths by Expected Proportions

An evaluation of whether the participant population is different than those within the IQOS® Consumer Database will be performed to determine if it is prudent to use model-based methods such as weighting to account for this effect.

3.2.1 Sample Size & Categorical Data

Unless otherwise stated, proportions for categorical variables will be summarized with point estimates and 95% asymptotic confidence intervals. Table 2 presents the confidence interval

sizes for the former established IQOS® user group (b) (4) given different sample proportions. Exact estimation methods will be used instead of asymptotic estimation methods to construct confidence intervals when either pn or qn^5 is less than (b) (4); in these cases, the exact binomial confidence interval (specifically, Clopper-Pearson) will be presented instead (Gravetter and Wallnua, 2014). See Section 8.3.1 for details of statistical analyses of categorical data.

Table 2: 95% Asymptotic confidence intervals for binomial proportions

Binomial Proportions		Asymptotic Confidence Interval	
%		(b) (4)	%
	(b) (4)		

3.2.2 Sample Size & Continuous Data

Table 3 provides an illustration of the estimated width of a 95% confidence interval about the means of two continuous variables assuming a sample size of (b) (4). This Table is for illustration purposes only. See Section 8.3.2 for details of statistical analyses of continuous variables.

Table 3: Estimated 95% confidence width with (b) (4) for two hypothetical continuous variables

Variable	Mean	Standard Deviation	Standard Error
(b) (4)			

3.3 Recruitment Method

Recruitment will occur in the United States when the estimated number of ever established IQOS® users is sufficient to support the study. Participants must have provided informed consent to participate in the study. All qualified participants who complete the survey will

⁵ pn = proportion * sample size, qn = (1-proportion)*sample size

receive a cash or cash equivalent incentive that will be documented in the informed consent at an amount that is commensurate with length and complexity of the survey.

It is anticipated that Philip Morris USA (PM USA), the company that is authorized, under an agreement between PMP S.A.'s parent company, Philip Morris International Management S.A. and ALCS, to distribute, market and sell IQOS® in the U.S., will maintain a database of consumers who purchase the IQOS® device. Based on experience from other countries with similar IQOS® Consumer Databases, it is assumed that IQOS® consumers listed in the IQOS® Consumer Database will comprise [REDACTED] (b) (4) This IQOS® Consumer Database will be utilized to recruit ever established IQOS® users.

The first annual execution of the IQOS® Cross-sectional study will likely entail sending invitations to all members of the IQOS® Consumer Database to achieve the target sample size for the former established IQOS® users. In subsequent executions of the study, adult tobacco consumers may also be recruited from commercial online panels, and probability-based sampling methods (e.g., simple random sampling or stratified sampling) are expected in order to enhance the representativeness of the sample (for example, adult tobacco consumers would be targeted at random by the panel companies if this information is available). Consumers may be invited through e-mail and direct mail communications.

In order to better maximize participation among the IQOS® Consumer Database, participants may be contacted multiple times via multiple channels when possible (e.g., emails, text messages, and mailings). An example of communications for maximizing participant engagement with the survey is depicted in Figure 2:

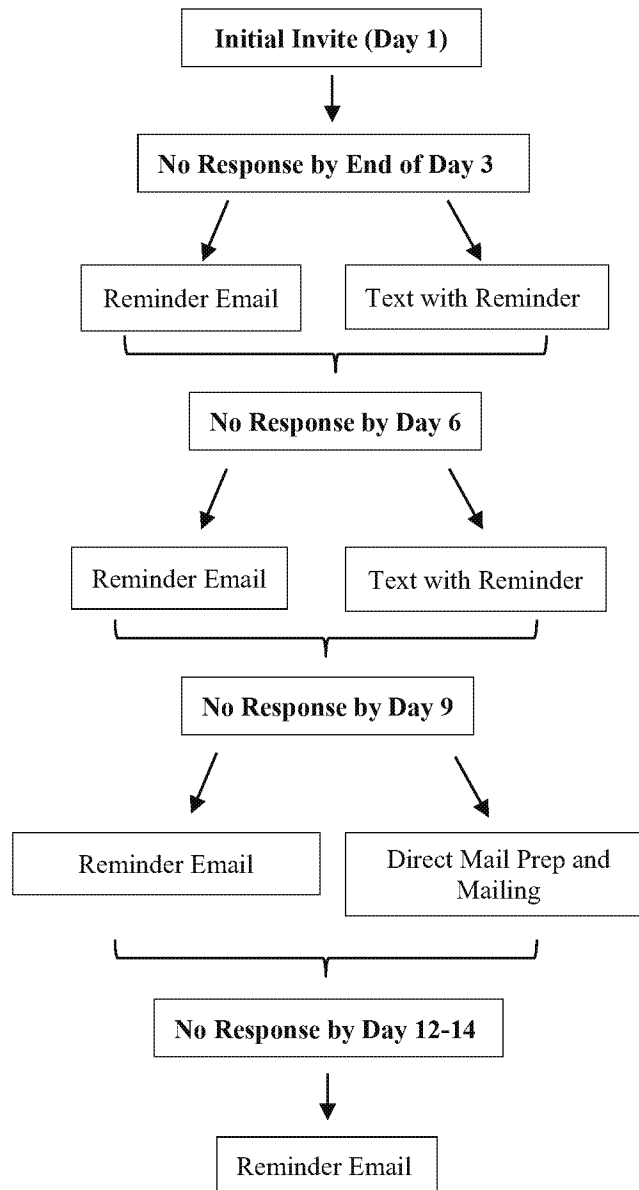


Figure 2: Example of Proposed Timing of Participant Communications

In this example, waves of invitations (with approximately 2000 invitations per wave) will be conducted in a sequential manner with no initiation of a new wave until the sample within the prior wave has been deemed unproductive (i.e. no incremental increase in response rate). All selected participants will be contacted following the same procedure as described above, including all potential participants in the last wave. The procedure will continue until the target sample size has been achieved. The timing/types of communications may be adjusted based on experiences with consumers at the time of recruitment and the response rate in the initial wave(s). Any adjustments will be documented in the final report.

If the study cannot recruit a sufficient number of qualified adult ever established IQOS® users (i.e., at least (b) former established IQOS® users, as outlined in Section 3.2) within the expected 12 weeks of study recruitment, ALCS may decide to close recruiting without achieving the target sample size. If the target sample size cannot be met, certain outcome measures (e.g., those specific to former established IQOS® users) may not be measured with the expected precision.

3.4 Inclusion Criteria

The Participant Screener asks questions regarding demographics and IQOS® use, as well as questions pertaining to other inclusion/exclusion criteria. Participants must satisfy the following criteria at the time of screening to qualify for the study:

(b) (4)

3.5 Exclusion Criteria

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

(b) (4)

3.6 Data Weighting

An evaluation of whether the sample is different than those within the IQOS® Consumer Database will be performed to determine if it is prudent to use model-based methods such as

weighting to account for this effect. Specifically, the demographic distribution of the sample will be compared to the demographic distribution of the members of the IQOS® Consumer Database. In the event there are significant differences, post-stratification sampling weights may be considered.

4 OUTCOME MEASURES

Outcome measures, organized by objectives and research questions, are presented below. The survey item(s) associated with a given outcome measure are indicated next to the measure, and the full list of measured variables will be presented as an appendix item to the Detailed Study Report.

Table shells for reporting findings related to the outcome measures are shown in Appendix B.⁶ For cross-referencing purposes, the table shell number associated with a given outcome measure is indicated next to that measure.

To assist in interpreting this document, please note the following: When proportions or percentages are calculated for an outcome measure, they will be reported along with the 95% confidence interval as discussed in Section 3.2. When means and medians are calculated for an outcome measure, they will be reported along with the 95% confidence interval and quartiles.

4.1 Objective 1 – Use Pattern

4.1.1 *What percentages of ever established IQOS® users report ever tried, use to lifetime criterion and current use of each tobacco product at the time of study assessment and retrospectively prior to first trying IQOS®?*

- i. Outcome Measure: Types of tobacco products ever tried, used to lifetime criterion, and currently using (Table 1)

Ever established IQOS® users, current established IQOS® users, and former established IQOS® users reporting:

- Ever trying tobacco product (Q.19, Q.38, Q.54, Q.65, Q.76, Q.88, Q.103, Q.114)

⁶ The table shells were developed for planning purposes. To aid understanding and reporting, the actual tables presented in the Detailed Study Report may differ in some respects from the table shells shown in Appendix B.

- Meeting the lifetime criteria for use of tobacco product (numeric criterion or consistent basis, as applicable: (Q.20, Q.39, Q.55, Q.66, Q.78, Q.90, Q.104, Q.116)
- Current use of tobacco product (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)

Summary Statistics: Percentages and counts

- ii. Outcome Measure: Types of tobacco products ever tried, used to lifetime criterion, and were currently using prior to first trying IQOS® (Table 2)

Ever established IQOS® users, current established IQOS® users, and former established IQOS® users reporting:

- Ever trying tobacco product prior to first trying IQOS® (Q.45, Q.58, Q.69, Q.80, Q.96, Q.107, Q.118)
- Meeting the lifetime criteria for use of tobacco product (numeric criterion or consistent basis prior to first trying IQOS®, as applicable: (Q.46a, Q.59a, Q.70, Q.82, Q.97b, Q.108a, Q.119b)
- Current use of tobacco product prior to first trying IQOS® (Q.47, Q.60, Q.57, Q.71, Q.83, Q.98, Q.109, Q.120)

Summary Statistics: Percentages and counts

4.1.2 *What percentages of current established IQOS® users use IQOS® exclusively or dual/poly use with cigarettes and /or other tobacco products?*

- i. Outcome Measure: Exclusive or dual/poly tobacco use with IQOS® (Table 3)

Current established IQOS® users reporting current use of (i.e., currently using “every day” or “some days”):

- IQOS® only (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)
- IQOS® plus one other tobacco product (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)
 - IQOS® and cigarettes (Q.22, Q.41)

- IQOS® and one other tobacco product, excluding cigarettes (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)
- IQOS® plus two or more other tobacco products (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)
 - IQOS® and two or more other tobacco products, including cigarettes (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)
 - IQOS® and two or more other tobacco products, excluding cigarettes (Q.22, Q.41, Q.57, Q.68, Q.79, Q.91, Q.106, Q.117)

Summary Statistics: Percentages and counts

ii. Outcome Measure: Menthol and non-Menthol HeatStick and Cigarette Use among Dual Users of IQOS® and Cigarettes (Table 3) -

Among current established IQOS® users who are current established cigarette smokers:

- Preference of menthol cigarettes (Q32)

Outcomes under 4.1.2 will be stratified by menthol vs. non-menthol HeatStick preference. (See definition at the end of Section 4) Among dual users of IQOS and cigarettes, estimates will be further stratified by menthol vs. non-menthol cigarette use.

4.1.3 *How often and how much do current established IQOS® users use IQOS®? How often and how much do ever established IQOS® users smoke cigarettes?*

i. Outcome Measure: Number of days of use of IQOS® and cigarettes in past 30 days

- Number of days used IQOS® in the past 30 days (among current established IQOS® users) (Q.23) (Table 4)
- Number of days used cigarettes in the past 30 days by current and former established IQOS® users (among individuals who are currently smoking cigarettes “every day” or “some days”) (Q.42) (Table 5)

Summary Statistics: For each tobacco product, number of days will be reported in categories using percentages, in addition to means, standard deviations, medians and ranges

Outcomes for IQOS® use will be stratified by menthol vs. non-menthol HeatStick preference. (See definition at the end of Section 4)

ii. Outcome Measure: Amount of Marlboro HeatSticks® and cigarette use in past 30 days

- Number of IQOS® Marlboro HeatSticks® used on days used in past 30 days (among current established IQOS® users) (Q.24) (Table 4)
- Number of cigarettes smoked on days used in past 30 days (among individuals currently smoking “every day” or “some days”) (Q.43) (Table 5)

Summary Statistics: Medians and interquartile range for number/times each listed tobacco product used on days used

Outcomes for IQOS® use will be stratified by menthol vs. non-menthol HeatStick preference. (See definition at the end of section 4)

iii. Outcome Measure: Number of HeatSticks® and cigarettes per day in past 30 days

The number of HeatSticks®/cigarettes per day will be calculate using the following formula:

$$\left(\frac{\text{HeatSticks/Cigarettes used per day on days used in the past 30 days}}{\text{Days used in the past 30 days}} \times \right) \div 30$$

For cigarette per day and HeatSticks per day calculation, a response of “<1” will be coded as 1, and a response of “>50” will be coded as 80⁷.

- Number of HeatSticks® per day in past 30 days (among current established IQOS® users) (Q.23 and Q.24) (Table 4)
- Number of cigarettes per day in past 30 days (among current smokers) (Q.42 and Q.43) (Table 5)

⁷ Based on data from PATH adult wave 4 data, the median number of cigarettes smoked per day is 80 among the 16 individuals who reported smoking more than 50 cigarettes per day.

Summary Statistics: Medians and interquartile range

Outcomes for IQOS® use will be stratified by menthol vs. non-menthol HeatStick® preference. (See definition at the end of Section 4)

4.1.4 How does current tobacco product consumption compare to consumption before trying IQOS®?

- i. Outcome Measure: Amount of tobacco product use before trying IQOS® relative to current tobacco product use (Table 6)

Current established users of each tobacco product reporting:

- Using more, less, or the same amount of each tobacco product per day during the 30 days before they first tried IQOS® compared to the amount currently used per day (Q.48, Q.61, Q.72, Q.84, Q.99, Q.110, Q.121)

Summary Statistics: Percentages and counts

4.1.5 What percentage of ever established IQOS® users report ever use of IQOS® not as intended?

- i. Outcome Measure: Use of IQOS® not as intended (Table 7)

Ever established IQOS® users, current established IQOS® users and former established IQOS® users reporting:

- Ever use of an IQOS® Marlboro HeatStick without using the IQOS® device/how used without using device (Q.34/Q.35a)
- Ever use of an IQOS® Marlboro HeatStick without using the IQOS® device only once, sometimes, most of the time, or all the time (for each way in which the IQOS® Marlboro HeatStick was ever used without using the IQOS® device) (Q.35b)
- Ever use of the IQOS® device with a product other than a Marlboro HeatStick (Q.36a)
- Ever use of an IQOS® device with a product other than a Marlboro HeatStick only once, sometimes, most of the time, or all the time (Q.36b)

- Ever use of IQOS® not as intended (i.e., any of above; Q.34, Q.35a, Q.35b, Q.36a, Q.36b)

Summary Statistics: Percentages and counts

4.2 Objective 2 – Risk Perceptions of IQOS®

4.2.1 What are ever established IQOS® users' risk perceptions of IQOS®?

- Outcome Measure: General Risk to Health – IQOS® and cigarettes (Q.157, Q.159) (Table 8)

Summary Statistics: Perceived Risk Instrument for general risk assessment (PRI-G) composite scores (i.e., sum of 18 items) for IQOS® and for cigarettes among all ever established IQOS® users, current IQOS® established users who are current smokers, current established IQOS® users who are long-term former smokers, and former established IQOS® users, range (minimum/maximum), means, standard deviations, medians and interquartile ranges

Computation of mean risk: $\bar{x} = \frac{\sum x}{n}$

Where:

x = item scores

n = total participants

4.2.2 What are ever established IQOS® users' perceptions of harmful or potentially harmful chemical exposure from IQOS® and related behavioral change?

- Outcome Measure: Perception of harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS® (Table 9)

Ever established IQOS® users, current established IQOS® users and former established IQOS® users:

- Distribution of response options of the question about harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS® (Q.1602).

Summary Statistics: Percentages and counts

ii. Outcome Measure: Understanding of what smokers must do to reduce harmful or potentially harmful chemical exposure (Table 9)

Ever established IQOS® users, current established IQOS® users and former established IQOS® users who identified 'less exposure' when switching completely from cigarettes to IQOS®:

- Distribution of response options of the question that what smokers must do to reduce their exposure to harmful or potentially harmful chemicals (among participants) (Q.161).

Summary Statistics: Percentages and counts

4.3 Objective 3 – Initiation, Complete Switching to IQOS®, Transitions To/Back To Cigarette Smoking, and Quitting Behaviors Relevant to IQOS® Use

4.3.1 *What percentage of ever established IQOS® users initiated tobacco use with IQOS?*

i. Outcome Measure: Initiation (Table 10)

Among ever established IQOS® users, current established IQOS® users, and former established IQOS® users:

- IQOS® as the first tobacco product that they ever tried vs. cigarettes or another one of the listed tobacco products (Q.124)
- IQOS® as the first tobacco product that they ever used on a consistent basis vs. cigarettes or another one of the listed tobacco products (Q.125)

Summary Statistics: Percentages and counts

4.3.2 *What percentage of ever established IQOS® users first tried IQOS® after not using any tobacco products/cigarettes for 12 months or longer?*

i. Outcome Measure: Initiation of IQOS® as long-term former established users of all tobacco products (Table 11)

Among ever established IQOS® users:

- Have used one or more tobacco products to the lifetime criteria and had not used any tobacco products for 12 months or longer

prior to first trying IQOS® (i.e., “First trial of IQOS® after not using any tobacco products for 12 months or longer”). (Q.39, Q.130, Q.55, Q.134, Q.66, Q.136, Q.78, Q.142, Q.90, Q.146, Q.104, Q.150, Q.116, Q.154)

Summary Statistics: Percentages and counts

- ii. Outcome Measure: Initiation of IQOS® as long-term former established smokers (Table 11)

Among ever established IQOS® users:

- Have smoked at least 100 cigarettes and had not smoked cigarettes for 12 months or longer prior to first trying IQOS® (i.e., “First trial of IQOS® after not smoking cigarettes for 12 months or longer”) (Q.39, Q.130)

Summary Statistics: Percentages and counts

4.3.3 *What percentage of current established IQOS® users switched from cigarettes to IQOS®? What percentage of current established IQOS® users switched from all tobacco products to IQOS®?*

- i. Outcome Measure: Complete switching to IQOS® after first trying IQOS® (Table 12)

Among current established IQOS® users:

- Had smoked at least 100 cigarettes, were smoking cigarettes during the 30 days before first trying IQOS®, and became former smokers after first trying IQOS® (i.e., “Complete switching from cigarettes to IQOS® after first trying IQOS®”), regardless of other tobacco product use (Q.39, Q.129)
- Had used at least one tobacco product to lifetime criterion, were using at least one tobacco product during the 30 days before first trying IQOS®, and became former users of all tobacco products after first trying IQOS® (i.e., “Complete switching from all tobacco products to IQOS® after first trying IQOS®”) (Q.39, Q.129, Q.55, Q.133, Q.66, Q.137, Q.78, Q.141, Q.90, Q.145, Q.104, Q.149, Q.116, Q.153)

Summary Statistics: Percentages and counts

Transitions To/Back To Cigarette Smoking

4.3.4 *What percentage of ever established IQOS® users relapse to or re-initiate cigarette smoking after trying IQOS?*

- i. Outcome Measure: Relapse to Cigarette Smoking after First Trying IQOS® (Table 13)

Among ever established IQOS® users:

- Had smoked at least 100 cigarettes and had not smoked for less than 12 months prior to first trying IQOS® and are currently smoking cigarettes “every day” or “some days” (i.e., “*Relapse of cigarette smoking after first trying IQOS®*”) (Q.46a, Q.50)

Summary Statistics: Percentages and counts

- ii. Outcome Measure: Re-Initiation of Cigarette Smoking after First Trying IQOS® (Table 13)

Among ever established IQOS® users:

- Had smoked at least 100 cigarettes and had not smoked for 12 months or longer prior to first trying IQOS® and are currently smoking cigarettes “every day” or “some days” (i.e., “*Re-initiation of cigarette smoking after first trying IQOS®*”) (Q.46a, Q.50)

Summary Statistics: Percentages and counts

4.3.5 *What percentage of ever established IQOS® users never smoked cigarettes before first trying IQOS® and became an established smoker after using IQOS®?*

- i. Outcome Measure: Initiation of established cigarette smoking after trying IQOS® (Table 13)

Among ever established IQOS® users:

- Had never smoked prior to first using IQOS® and have smoked at least 100 cigarettes prior to the assessment (i.e., “initiation of established cigarette smoking after first trying IQOS®”) (Q.39, Q.45)

Summary Statistics: Percentages and counts

4.3.6 *What percentage of former established IQOS® users initiated tobacco use with IQOS® and switched from IQOS® to established smoking?*

- i. Outcome Measure: Complete switching from IQOS® to established smoking after initiating tobacco use with IQOS® (Table 14)

Among former established IQOS® users:

- That IQOS® was the first tobacco product ever tried, have smoked at least 100 cigarettes, and now smoke cigarettes “every day” or “some days” (i.e., “Complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS®”) (Q.124, Q.20, Q.27a, Q.39, Q.41)

Summary Statistics: Percentages and counts

4.4 Objective 3 – Quitting Behaviors

4.4.1 *What percentage of current established cigarette smokers plan to quit or have attempted to quit?*

- i. Outcome Measure: Past 12-month quit attempts (Table 15)

Among current established IQOS® users and former established IQOS® users who are current established cigarette smokers:

- Having stopped smoking cigarettes for more than one day in the past 12 months because they were trying to quit smoking (Q.51)

Summary Statistics: Percentages and counts

ii. Outcome Measure: Motivation to stop (Table 15)

Among current established IQOS® users and former established IQOS® users who are current established cigarette smokers:

- Distribution of motivation to stop responses (Q.52)

Summary Statistics: Percentages and counts

4.4.2 *What percentage of current established IQOS® users quit smoking after first trying IQOS®?*

i. Outcome Measure: Quit smoking after first trying IQOS® (Table 15)

Among current established IQOS® users who are ever established smokers:

- Completely quitting smoking cigarettes after first trying IQOS® (i.e., “*Quitting cigarettes after first trying IQOS®*” (Q.39, Q.127, Q.129)
- Completely quitting smoking cigarettes for 12 months or longer after first trying IQOS® (i.e., “*Quitting cigarettes for 12 months or longer after first trying IQOS®*”) (Q.39, Q.127, Q.128, Q.129)

Summary Statistics: Percentages and counts

4.4.3 *What percentage of former established IQOS® users quit smoking after first trying IQOS®?*

i. Outcome Measure: Quit smoking after first trying IQOS® (Table 15)

Among former established IQOS® users who are ever established smokers:

- Completely quitting smoking cigarettes after first trying IQOS® (i.e., “*Quitting cigarettes after first trying IQOS®*” (Q.39, Q.127, Q.129)

- Completely quitting smoking cigarettes for 12 months or longer after first trying IQOS® (i.e., “*Quitting cigarettes for 12 months or longer after first trying IQOS®*”) (Q.39, Q.127, Q.128, Q.129)

Summary Statistics: Percentages and counts

4.4.4 *What percentage of former established IQOS® users quit all tobacco products after first trying IQOS®?*

i. Outcome Measure: Quitting after first trying IQOS® (Table 15)

Among former established IQOS® users:

- Completely quitting all tobacco products after first trying IQOS® (i.e., “*Quitting all tobacco products after first trying IQOS®*”) (Q.27a, Q.39, Q.127, Q.129, Q.55, Q.131, Q.133, Q.66, Q.135, Q.137, Q.78, Q.139, Q.141, Q.90, Q.143, Q.145, Q.104, Q.147, Q.149, Q.116, Q.151, Q.153)
- Completely quitting all tobacco products for 12 months or longer after first trying IQOS® (i.e., “*Quitting all tobacco products for 12 months or longer after first trying IQOS®*”) (Q.27a, Q.28, Q.39, Q.127, Q.128, Q.129, Q.55, Q.131, Q.132, Q.133, Q.66, Q.135, Q.136, Q.137, Q.78, Q.139, Q.140, Q.141, Q.90, Q.143, Q.144, Q.145, Q.104, Q.147, Q.148, Q.149, Q.116, Q.151, Q.152, Q.153)

Summary Statistics: Percentages and counts

4.4.5 *Tobacco cessation treatment use history among ever established IQOS® users*

i. Outcome Measure: Tobacco cessation treatment use (Table 16)

Among current established IQOS® users and former established IQOS® users:

- Distribution of recency of tobacco cessation treatment use (Q.155)

4.4.6 *Tobacco cessation treatment use among established IQOS® users who switched from cigarettes to IQOS®*

i. Outcome Measure: Tobacco cessation treatment use (Table 16)

Among current IQOS® established users who report that they have smoked at least 100 cigarettes, were smoking cigarettes during the 30 days before first trying IQOS® and became former smokers after first trying IQOS® (i.e., “Complete switching from cigarettes to IQOS® after first trying IQOS®”), regardless of other tobacco product use:

- Distribution of recency of tobacco cessation treatment use (Q.155)

4.4.7 *Tobacco cessation treatment use among current established IQOS® users switched from all tobacco products to IQOS®*

i. Outcome Measure: Tobacco cessation treatment use (Table 16)

Among current IQOS® established users who report that they have used at least one tobacco product to lifetime criterion, were using at least one tobacco product during the 30 days before first trying IQOS® and became former users after first trying IQOS® (i.e., “Complete switching from all tobacco products to IQOS® after first trying IQOS®”):

- Distribution of recency of tobacco cessation treatment use (Q.155)

4.4.8 *What percentage of ever established IQOS® users quit using IQOS®/quit using IQOS® for 12 months or longer?*

i. Outcome Measure: Quitting IQOS® (Table 17)

Among ever established IQOS® users:

- Quitting IQOS® (i.e., “Quitting IQOS®”) (Q.27a)
- Completely quitting IQOS® for 12 months or longer (i.e., “Quitting IQOS® for 12 months or longer”) (Q.28)

Summary Statistics: Percentages and counts

Estimates for outcomes under objective 3 will be provided for menthol (including smooth menthol and fresh menthol) vs. non-menthol (regular) HeatStick users as well as menthol vs. non-menthol cigarette users when applicable and when sample size allows. Menthol and non-menthol users will be classified by responses to questions about menthol or non-menthol HeatSticks or cigarettes used most often. Current users will be asked about their current preference (Q32 for IQOS® use and Q43a for cigarette use), and former users will be asked about their preference when they used IQOS® or smoked cigarettes (Q33 for IQOS® use and Q43b for cigarette use).

5 ADDITIONAL DATA SUMMARIES

5.1 Demographics, Background, and Health-related Information (Tables 18-23)

5.1.1 *Ever established IQOS® users will be characterized by:*

- Sex (percentages and counts) (Q.6)
- Age (percentages, means, medians, ranges, and standard deviations) (Q.2)
- Race (percentages and counts) (Q.8)
- Ethnicity (percentages and counts) (Q.7)
- Education (percentages and counts) (Q.10)
- Income (percentages and counts) (Q.9)
- Marital status (percentages and counts) (Q.166)
- Pregnancy status (percentages and counts) (Q.168)
- Presence of pre-existing medical condition(s) or comorbidities (percentages and counts) (Q.169)
- Presence of mental illness (percentages and counts) (Q.170, Q.171)
- LGBTQ status (percentages and counts) (Q.167)
- Military personnel/veteran status (percentages and counts) (Q.165)
- Length of time using IQOS® and cigarettes, as applicable (means, medians, and standard deviations)
 - Length of time current established IQOS® users report using IQOS® (Q.25)
 - Length of time current established cigarette smokers report smoking cigarettes (Q.44)
- Cigarette and IQOS® dependence

Heaviness of smoking index (HSI) will be calculated based on the following two questions (Heatherton et al., 1989)

1. How soon after you wake up do you use your first IQOS®/smoke your first cigarette? (Q.162, Q.163)
 - A. Within 5 minutes (3 points)
 - B. 6- 30 minutes (2 points)
 - C. 31-60 minutes (1 point)
 - D. After 60 minutes (0 points)
2. During the past 30 days, on the days you used IQOS®, how many Marlboro HeatSticks® did you use per day, on average?/During the past 30 days, on the days you smoked cigarettes, how many cigarettes did you smoke per day, on average? (Q.24, Q.43)
 - A. 10 or fewer (0 points)
 - B. 11-20 (1 point)
 - C. 21-30 (2 points)
 - D. 31 or more (3 points)

HSI score is the sum of points from the above two questions. The HSI score will be further categorized into 0-1, 2-4, and 5-6.

Median and IQR of HSI score and percentages and counts of HSI score categories will be described for the following user groups:

- i. HSI score for IQOS® among current established IQOS® users
 - HSI score for IQOS® among current established IQOS® users who are current established cigarette smokers
 - HSI score for IQOS® among current established IQOS® users who are former established smokers
 - ii. HSI score for cigarette smoking among current established cigarette smokers
 - HSI score for cigarette smoking among current established smokers who are current established IQOS® users
 - HSI score for cigarette smoking among current established smokers who are former established IQOS® users
- Varieties of IQOS® (i.e., Marlboro HeatSticks®, Marlboro Smooth Menthol HeatSticks®, Marlboro Fresh Menthol HeatSticks®) ever used, first used, currently use, currently use most often, and previously used most often (among former established IQOS® users) (percentages and counts)
 - Individual Marlboro HeatStick variety/varieties ever tried (Q.29)
 - First Marlboro HeatStick variety ever tried (Q.30)
 - Individual Marlboro HeatStick variety/varieties currently being used (among current established IQOS® users) (Q.31)

- Individual Marlboro HeatStick variety/varieties currently being used most often (among current established IQOS® users) (Q.32)
- Individual Marlboro HeatStick variety/varieties previously used most often (among former established IQOS® users) (Q. 33)
- Menthol vs. non-Menthol cigarettes use
 - Menthol cigarette use among current smokers (Q.43a)
 - Menthol cigarette use among former smokers (Q.43b)

Statistics reported: Descriptive statistics

5.2 Participation Proportions

5.2.1 Contact proportion

- Number of persons screened for eligibility divided by the total number of persons attempted to be reached for eligibility screening (i.e., the number of invitations sent)

5.2.2 Eligibility proportion

- Number of persons eligible for enrollment (i.e., persons who meet all inclusion criteria and no exclusion criteria) divided by the total number of persons screened for eligibility

5.2.3 Completion proportion

- Number of completed interviews divided by the number of attempted interviews (completed plus partial)

5.2.4 Response proportion

- Number of completed interviews divided by the number of invitations sent

6 SURVEY PERFORMANCE EVALUATION

6.1 Overview

Survey development, testing, and evaluation are viewed as iterative processes that frequently entail examining the performance of the survey instruments (FDA, 2009). The purpose of this section is to provide an analytical plan to evaluate the performance of the survey instruments used in this study. The summary of results will be reported as part of the Detailed Study Report. The full report of the survey performance evaluation will be provided under separate cover and appended to the Detailed Study Report.

6.2 Examination of Survey Administration Meta-Data

The survey administration meta-data file contains the number of seconds a participant takes to complete each question across the entire survey, including both the participant screener and

main survey.⁸ Survey administration meta-data (e.g., the average and fastest survey completion time among participants) will be examined for irregularities to identify issues associated with how participants engaged with the survey.

- a. The total time required to complete the survey will be calculated and depicted graphically using histograms in total and by current and former IQOS® use status. Means, medians, ranges, standard deviations, minimums, and maximums will also be reported in total and by current and former IQOS® use status.
- b. The 5% of participants who complete the survey fastest will be identified and their demographics and tobacco product use patterns will be examined for irregularities relative to the other participants.
- c. Participants that complete the survey over more than one period will be reported by percentage, overall, and by current and former IQOS® use status.

6.3 Data Quality Checks and Treatment of Outliers

A variety of data quality checks will be implemented to identify and flag records that contain forms of potential data falsification or missing data. These records will be examined to understand their influence on study results and for possible exclusion from analysis. Data falsification forms include “speeding,” nondifferentiation, and gibberish/nonsensical verbatim response. The number of respondents that are flagged for each data falsification form will be included in the final survey report.

“Speeding” is completing a questionnaire very quickly, without giving thought to answers. In this study, a participant who completes the main questionnaire in less than 30% of the median completion time of participants with a similar number of tobacco products used will be flagged for review. The amount of time to complete each questionnaire is expected to vary depending on the number of tobacco products used. Median questionnaire duration will be calculated and compared among participants that:

- Use no tobacco products
- Use one tobacco product
- Use two tobacco products
- Use more than two tobacco products

Nondifferentiation of rating, or “straightlining” is when a participant does not differentiate between response options and selects the same response for multiple questions (e.g., selecting

⁸ If a participant completed the survey in multiple sessions, the time between the sessions is added to the first question answered in the next session. In order to compute a more accurate time for these questions where multiple session breaks took place, the times for those questions will be replaced with the average times computed using all other participants.

the first option for a question series). Participants who have answers with 100% similarity for scaled attribute questions with 15 or more dimensions are flagged for review.

Free text fields and verbatim responses that are poor quality (e.g. gibberish, nonsensical responses, single characters, profanity) are flagged for possible removal. The main questionnaire does not contain open-ended questions, so this review will be applied to typed-in “other” responses.

The main analysis will be conducted with the full dataset and sensitivity analyses will be conducted without the flagged responses to determine if the potentially invalid data substantially influence the results. These 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.

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.

7 ADDITIONAL ANALYSES

As needed, additional analyses may be conducted to clarify or further contextualize study outcomes measures. These analyses may be exploratory in nature. These additional supportive analyses will be documented, amended to the SAP, and reported in the final study report.

8 STATISTICAL METHODOLOGIES

8.1 General Considerations

The data will be analyzed and reported both descriptively, primarily using percentages, frequency distributions, means, standard deviations and medians.

8.2 Missing Data

As this is an electronic survey, which requires completion of questions for the survey to be submitted, we do not anticipate any missing data.

8.3 Statistical Analysis of Data

8.3.1 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
Total <i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>
Percent	x.xx%	x.xx%	x.xx%

8.3.2 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 continuous variables

	Ever Established IQOS® Users	Current Established IQOS® Users	Former Established IQOS® Users
Total <i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>
Mean	x.xx	x.xx	x.xx
Standard Deviation	x.xx	x.xx	x.xx
Median	x.xx	x.xx	x.xx

8.4 Coding of Open-Ended Data

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 an “other” response, 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., 2-5%) 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.”

8.5 Reporting Conventions

All summary statistics, including means, medians, and confidence intervals, will be reported to the second decimal place.

9 SUMMARY OF CHANGES TO THE PROTOCOL AND/OR STATISTICAL ANALYSIS PLAN

Any modifications to the Study Protocol or SAP will be documented in amended documents (provided under separate cover, as applicable).

SAP VERSION HISTORY

Version	Version Date	Modification(s)	Reason(s) for Modification(s)
1.0	08/06/2020	(b) (4)	
2.0	11/04/2020		In its October 5 th letter, FDA determined that these changes are necessary to monitor participants' understanding of the risks of using IQOS.
			Reduce respondent burden
			To better understand the role menthol plays in behaviors.
			To provide a granular view of smokers' intention to stop smoking.
			To understand if cessation therapies are being used alongside tobacco products including IQOS and to assess the overall history of cessation treatment use among IQOS users
3.0	12/22/2020		To allow a comparison of cigarette and IQOS® consumption using one-item metrics

10 APPENDIX A: LIST OF VARIABLES (TO BE POPULATED)

11 APPENDIX B: TABLES

Table shells for the outcome measures in Section 4, Section 5 and Section 8 are provided in the following section.

Table 1: Types of Tobacco Products Ever Tried, Used to Lifetime Criterion, and Currently Using (4.1.1.i)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
Ever Tried			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			
Used to Lifetime Criterion (numeric criterion or consistent basis, as applicable)			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			
Current Use			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			

Table 2: Types of Tobacco Products Ever Tried, Used to Lifetime Criterion, and Currently Using Prior to Trying IQOS® (4.1.2.i)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Ever Tried			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			
Used to Lifetime Criterion (numeric criterion or consistent basis, as applicable)			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			
Current Use			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
Any tobacco			

Table 3: Exclusive or Dual/Poly Tobacco Use with IQOS® (4.1.2)

Measure	Current Established IQOS® Users % (CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users Who Prefer non- Menthol HeatSticks % (CI)
Base (Total Participants)	n=xxx	n=xxx	n=xxx
Current use (“every day” or “some days”) of:			
IQOS® only			
IQOS® plus one other tobacco product			
IQOS® and cigarettes			
IQOS® and one other tobacco product, excluding cigarettes			
IQOS® plus two or more other tobacco products			
IQOS® and two or more other tobacco products, including cigarettes			
IQOS® and two or more other tobacco products, excluding cigarettes			
	Among Current Dual Users of IQOS® and cigarettes		
Base (Dual users of IQOS® and cigarettes)	n=xxx	n=xxx	n=xxx
Menthol cigarette preference			
Non-Menthol cigarette preference			

Table 4: Number of Days Used IQOS® in Past 30 Days/Number of IQOS® Marlboro HeatSticks® Used in Past 30 Days (4.1.3.i, 4.1.3.ii)

Measure	Current Established IQOS® Users % (CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users Who Prefer Non-Menthol HeatSticks % (CI)
Base (Total Participants))	n=xxx	n=xxx	n=xxx
During the past 30 days, on how many days did you use IQOS® with Marlboro HeatSticks®?			
1 - 2 days			
3 - 5 days			
6 - 9 days			
10 - 14 days			
15 - 19 days			
20 - 24 days			
25 - 29 days			
30 days			
Mean number of days used			
Standard deviation of days used			
Median number of days used			
Min/Max			
During the past 30 days, on the days you used IQOS® with Marlboro HeatSticks®, how many Marlboro HeatSticks® did you use per day, on average?			
Less than 1			
1			
2			
3			
4			
5-9			
10-14			
15-19			
20+			
Median number of HeatSticks® per day on days used			
IQR			
HeatSticks per day in the past 30 days			
Median number of HeatSticks® per day			
IQR			

Table 5: Number of Days Smoked Cigarettes in Past 30 Days/Numbers of Cigarettes Smoked in Past 30 Days (4.1.3.i, 4.1.3.ii)

Measure	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Current cigarette smokers)	<i>n</i> =XXX	<i>n</i> =XXX
During the past 30 days, on how many days did you smoke cigarettes?		
1 - 2 days		
3 - 5 days		
6 - 9 days		
10 - 14 days		
15 - 19 days		
20 - 24 days		
25 - 29 days		
30 days		
Mean number of days used		
Standard deviation of days used		
Median number of days used		
Min/Max		
During the past 30 days, on the days you smoked cigarettes, how many cigarettes did you smoke per day, on average?		
Less than 1		
1		
2		
3		
4		
5-9		
10-14		
15-19		
20+		
Median number of cigarettes per day on days used		
IQR		
Cigarettes per day in the past 30 days		
Median number of cigarettes per day		
IQR		

Table 6: Amount of Tobacco Product Use Before Trying IQOS® Relative to Current Tobacco Product Use (4.1.4)

Measure	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Current Established Users of Each Tobacco Product)		
Cigarettes	<i>n</i> =XXX	<i>n</i> =XXX
Now smoke fewer cigarettes per day		
Now smoke more cigarettes per day		
Smoke the same number of cigarettes per day now as I did then		
Cigars	<i>n</i> =XXX	<i>n</i> =XXX
Now smoke fewer cigars per day		
Now smoke more cigars per day		
Smoke the same number of cigars per day now as I did then		
Tobacco in a Pipe	<i>n</i> =XXX	<i>n</i> =XXX
Now smoke fewer bowls of tobacco per day		
Now smoke more bowls of tobacco per day		
Smoke the same number of bowls of tobacco per day now as I did then		
Tobacco in a Hookah	<i>n</i> =XXX	<i>n</i> =XXX
Now smoke fewer bowls of tobacco per day		
Now smoke more bowls of tobacco per day		
Smoke the same number of bowls of tobacco per day now as I did then		
E-vapor Products	<i>n</i> =XXX	<i>n</i> =XXX
Now use e-vapor products fewer occasions per day		
Now use e-vapor products more occasions per day		
Use e-vapor products the same number of occasions per day now as I did then		
Smokeless Tobacco	<i>n</i> =XXX	<i>n</i> =XXX
Now use smokeless tobacco fewer times per day		
Now use smokeless tobacco more times per day		
Use smokeless tobacco the same number of times per day now as I did then		
Oral Tobacco-Derived Nicotine Products	<i>n</i> =XXX	<i>n</i> =XXX
Now use oral tobacco-derived nicotine products fewer times per day		
Now use oral tobacco-derived nicotine products more times per day		
Use oral tobacco-derived nicotine products the same number of times per day now as I did then		

Table 7: Use of IQOS® Not as Intended (4.1.5)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Ever use of IQOS® not as intended			
Ever Use of IQOS® Marlboro HeatStick without using IQOS® Device			
<i>Lit up the HeatStick like a cigarette</i>			
Only once			
Sometimes			
Most of the time			
All the time			
<i>Used the HeatStick with another device</i>			
Only once			
Sometimes			
Most of the time			
All the time			
<i>Some other way</i>			
Only once			
Sometimes			
Most of the time			
All the time			
Used IQOS® Device with a product other than an IQOS® Marlboro HeatStick			
Only once			
Sometimes			
Most of the time			
All the time			

Table 8: Risk Perceptions – IQOS® and Cigarettes (4.2.1)

Measure	Ever Established IQOS® Users	Current Established IQOS® Users/Current Cigarette Smokers	Current Established IQOS® Users/Long-Term Former Smokers	Former Established IQOS® Users
Base (Total Participants)	n=XXX	n=XXX	n=XXX	n=XXX
IQOS®				
Mean Composite Score (CI)				
Standard Deviation				
Median				
IQR				
Min/Max				
Cigarettes				
Mean Composite Score (CI)				
Standard Deviation				
Median				
IQR				
Min/Max				

Table 9: Perceptions about IQOS® (4.2.2)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (all respondents)	n=XXX	n=XXX	n=XXX
Perception about Harmful or Potentially Harmful Chemical Exposure When Switching Completely from Cigarettes to IQOS®			
More exposure			
The same exposure			
Less exposure			
No exposure			
Don't know			
Understanding of What Smokers Must Do to Reduce Their Exposure to Harmful or Potentially Harmful Chemicals			
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			

Table 10: Initiation: First Tobacco Product Ever Tried/First Tobacco Product Ever Used on a Consistent Basis (4.3.1.i)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	n=xxx	n=xxx	n=xxx
What was the FIRST product that you EVER tried EVEN ONE TIME?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
What was the FIRST product that you EVER used on a CONSISTENT BASIS?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
IQOS® Users Who Prefer(ed) Menthol HeatSticks % (CI)			
Base (Total Participants)	n=xxx	n=xxx	n=xxx
What was the FIRST product that you EVER tried EVEN ONE TIME?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
What was the FIRST product that you EVER used on a CONSISTENT BASIS?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			

IQOS® Users Who Prefer(ed) non-Menthol HeatSticks % (CI)			
Base (Total Participants)	n=xxx	n=xxx	n=xxx
What was the FIRST product that you EVER tried EVEN ONE TIME?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			
What was the FIRST product that you EVER used on a CONSISTENT BASIS?			
IQOS®			
Cigarettes			
Cigars			
Pipe filled with tobacco			
Hookah			
E-vapor products			
Smokeless tobacco			
Oral tobacco-derived nicotine products			

Table 11: Initiation of IQOS® Among Long-Term Former Established Smokers and Long-Term Former Established Users of All Tobacco Products (4.3.2i-4.3.2.ii)

Measure	Ever Established IQOS® Users % (CI)	Ever Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Ever Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)
Base (Total Participants)	n=XXX	n=XXX	n=XXX
First trial of IQOS® after not using any tobacco products for 12 months or longer			
First trial of IQOS® after not smoking cigarettes for 12 months or longer			
First trial of IQOS® after not smoking cigarettes for 12 months or longer who prefer/preferred menthol cigarettes			
First trial of IQOS® after not smoking cigarettes for 12 months or longer who prefer/preferred non-menthol cigarettes			

NA=Not applicable

Table 12: Complete Switching to IQOS® After First Trying IQOS® (5.3.5.i)

Measure	All Current Established IQOS® Users % (CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)
Base (Total Participants)	n=XXX	n=XXX	n=XXX
Complete switching from all tobacco products to IQOS® after first trying IQOS®			
Complete switching from cigarettes to IQOS® after first trying IQOS®			
Complete switching from menthol cigarettes to IQOS® after first trying IQOS®			
Complete switching from non-menthol cigarettes to IQOS® after first trying IQOS®			

Table 13: Relapse, Re-Initiation and Initiation of Cigarette Smoking After First Trying IQOS® (4.3.4, 4.3.5)

Measure	Ever Established IQOS® Users % (CI)	Ever Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Ever Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)
Base (Total Participants)	n=XXX	n=XXX	n=XXX
Relapse of cigarette smoking after first trying IQOS®			
Relapse to menthol cigarette smoking after first trying IQOS®			
Relapse to non-menthol cigarette smoking after first trying IQOS®			
Re-initiation of cigarette smoking after first trying IQOS®			
Re-initiation of menthol cigarette smoking after first trying IQOS®			
Re-initiation of non-menthol cigarette smoking after first trying IQOS®			
Initiation of established cigarette smoking after first trying IQOS®			
Initiation of established menthol cigarette smoking after first trying IQOS®			
Initiation of established non-menthol cigarette smoking after first trying IQOS®			

Table 14: Complete Switching from IQOS® to Established Cigarette Smoking After Initiating Tobacco Use with IQOS® (4.3.6.i)

Measure	Ever Established IQOS® Users % (CI)	Ever Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Ever Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)
Base (Total Participants)	n=XXX	n=XXX	n=XXX
Complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS®			
Complete switching from IQOS® to menthol cigarettes after initiating tobacco use with IQOS®			
Complete switching from IQOS® to non-menthol cigarettes after initiating tobacco use with IQOS®			

Table 15-1: Past 12 Month Quit Attempts, Motivation to Stop Smoking, and Completely Quit Smoking Cigarettes among Current IQOS® Users (4.4.1 to 4.4.4)

Measure	Current Established IQOS® Users % (CI)	Current Established IQOS® Users who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users who Prefer non-Menthol HeatSticks % (CI)
Base (Current Established Cigarette Smokers)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Past 12-month quit attempts			
Motivation to Stop Smoking			
I don't want to stop smoking.			
I think I should stop smoking but don't really want to			
I want to stop smoking but haven't thought about			
I REALLY want to stop smoking but I don't know when I will			
I want to stop smoking and hope to soon			
I REALLY want to stop smoking and intend to in the next 3 months			
I REALLY want to stop smoking and intend to in the next month			
Base (Ever Established Cigarette Smokers)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Completely Quitting Smoking Cigarettes			
Completely quit smoking cigarettes after first trying IQOS®			
Completely quit smoking cigarettes for 12 months or longer after first trying IQOS®			
Base (Total Participants)	NA	<i>n</i> =XXX	<i>n</i> =XXX
Completely Quitting All Tobacco Products			
Completely quitting all tobacco products after first trying IQOS®	NA		
Completely quitting all tobacco products for 12 months or longer after first trying IQOS®	NA		

NA=Not applicable

Table 15-2: Past 12 Month Quit Attempts, Motivation to Stop Smoking, and Completely Quit Smoking Cigarettes among Former IQOS® Users (4.4.1 to 4.4.4)

Measure	Former Established IQOS® Users % (CI)	Former Established IQOS® Users who Prefer Menthol HeatSticks % (CI)	Former Established IQOS® Users who Prefer non-Menthol HeatSticks % (CI)
Base (Current Established Cigarette Smokers)	n=XXX	n=XXX	n=XXX
Past 12-month quit attempts			
Motivation to Stop Smoking			
I don't want to stop smoking.			
I think I should stop smoking but don't really want to			
I want to stop smoking but haven't thought about			
I REALLY want to stop smoking but I don't know when I will			
I want to stop smoking and hope to soon			
I REALLY want to stop smoking and intend to in the next 3 months			
I REALLY want to stop smoking and intend to in the next month			
Base (Ever Established Cigarette Smokers)	n=XXX	n=XXX	n=XXX
Completely Quitting Smoking Cigarettes			
Completely quit smoking cigarettes after first trying IQOS®			
Completely quit smoking cigarettes for 12 months or longer after first trying IQOS®			
Base (Total Participants)	NA	n=XXX	n=XXX
Completely Quitting All Tobacco Products			
Completely quitting all tobacco products after first trying IQOS®	NA		
Completely quitting all tobacco products for 12 months or longer after first trying IQOS®	NA		

Table 16: Tobacco Cessation Treatment Use (4.4.5 to 4.4.7)

Measure	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (All Participants)	<i>n</i> =xxx	<i>n</i> =xxx
Never used tobacco cessation treatment		
Used tobacco cessation treatment more than 12 months ago		
Used tobacco cessation treatment within 12 months ago		
Used tobacco cessation treatment within the past 30 days		
Base (Current Established IQOS® users who switched from cigarettes to IQOS®)	<i>n</i> =xxx	<i>n</i> =xxx
Never used tobacco cessation treatment		NA
Used tobacco cessation treatment more than 12 months ago		NA
Used tobacco cessation treatment within 12 months ago		NA
Used tobacco cessation treatment within the past 30 days		NA
Base (Current Established IQOS® users who switched from all tobacco to IQOS®)	<i>n</i> =xxx	<i>n</i> =xxx
Never used tobacco cessation treatment		NA
Used tobacco cessation treatment more than 12 months ago		NA
Used tobacco cessation treatment within 12 months ago		NA
Used tobacco cessation treatment within the past 30 days		NA

NA=Not applicable

This table will be repeated for menthol vs. non-menthol Marlboro HeatStick users and menthol vs. non-menthol cigarette smokers when sample size allows.

Table 17: Completely Quitting IQOS® (4.4.5)

Measure	Ever Established IQOS® Users % (CI)	Ever Established IQOS® Users Who Prefer Menthol HeatSticks	Ever Established IQOS® Users Who Prefer non-Menthol HeatSticks
Base (Total Participants)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
Completely Quitting IQOS®			
Completely quitting IQOS®			
Completely quitting IQOS® for 12 months or longer			

Table 18: Demographics and Background Information (5.1.1)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	n=xxx	n=xxx	n=xxx	n=xxx	n=xxx
Gender					
Male					
Female					
Age					
21-24					
25-34					
35-44					
45-54					
55-64					
65+					
Mean Age					
Standard Deviation of Age					
Median Age					
Race/Ethnicity					
White/Caucasian					
Black/African-American					
Hispanic/Latino					
Asian					
Other					
Household Income					
<u>Under \$60,000 (Net)</u>					
Under \$20,000					
\$20,000 - \$29,999					
\$30,000 - \$39,999					
\$40,000 - \$49,999					
\$50,000 - \$59,999					
<u>\$60,000 or More (Net)</u>					
\$60,000 - \$74,999					
\$75,000 - \$99,999					
\$100,000 - \$149,999					
\$150,000 and over					
Prefer not to answer					
Education					
<u>High School or Less (Net)</u>					
Never attended school or only attended kindergarten					
Grades 1 through 8					

(elementary)					
Grades 9 through 12 (no diploma)					
High School Graduate (or equivalent/GED)					
<u>Some College or More (Net)</u>					
Some college (1-4 years, no degree)					
Associates degree (including occupational or academic degrees)					
Bachelor's degree (BA, BS, AB, etc.)					
Master's degree (MA, MS, MENG, MSW, etc.)					
Professional school degree (MD, DDC, JD, etc.)					
Doctorate degree (PhD, EdD, etc.)					
Other					
Employment Status					
<u>Employed (Net)</u>					
Employed for wages					
Self-employed					
<u>Not Employed (Net)</u>					
Out of work for more than 1 year					
Out of work for less than 1 year					
A homemaker					
A student					
Retired					
Unable to work					
Region					
Northeast					
South					
Midwest					
West					
Marital Status					
Married					
Widowed					
Divorced					
Separated					
Never married					
Living with partner					
Do not wish to answer					
Pregnancy Status					

Base (Females age 21-40)	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx	<i>n</i> =xxx
Currently pregnant/nursing					
Not currently pregnant/nursing					
LGBTQ Status					
Heterosexual or straight					
Lesbian or gay					
Bisexual					
Transgender					
Something else					
Don't know/not sure					
Do not wish to answer					
Military Personnel/Veteran Status					
Yes, now on active duty					
Yes, on active duty in the past, but not now					
No, not on active duty, but training for Reserves or National Guard only					
No, never served in the military					

Table 19: Health Related Information (5.1.1)

Measure	Ever Established IQOS® Users % (CI)	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	<i>n=XXX</i>	<i>n=XXX</i>	<i>n=XXX</i>
Have you EVER been told by a doctor, nurse, or other health professional that you had...?			
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)			
Any other heart condition or heart disease			
Chronic obstructive pulmonary disease (COPD)			
Chronic bronchitis			
Emphysema			
Asthma			
Apnea (pauses in breathing during sleep)			
Any other respiratory or lung condition			
Cancer			
Diabetes			
None of the above			
Reported Mental Health Condition			
Yes			
No			
Don't know			
Taking Medication or Receiving Treatment for Mental Health Condition or Emotional Problem			
Yes			
No			
Don't know			

Table 20: Length of Time Using IQOS® and Cigarettes (5.1.1)

Measure	Ever Established IQOS® Users	Current Established IQOS® Users	Former Established IQOS® Users
IQOS®			
Base (Total Participants)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Mean # years (CI)			
Standard deviation			
Median # years			
Cigarettes - Current Established Smokers			
Base (Current Established Smokers)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Mean # years (CI)			
Standard deviation			
Median # years			
Cigarettes - Former Established Smokers			
Base (Former Established Smokers)	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Mean # years (CI)			
Standard deviation			
Median # years			

Table 21: IQOS® Dependence (5.1.1)

Measure	Current Established IQOS® Users % (CI)
Heaviness of Smoking Index (HSI) - IQOS®	
Base (Current Established Cigarette Smokers)	<i>n</i> =XXX
0-1	
2-4	
5-6	
Median HSI Score	
IQR	
Heaviness of Smoking Index (HSI) - IQOS®	
Base (Former Established Cigarette Smokers)	<i>n</i> =XXX
0-1	
2-4	
5-6	
Median HSI Score	
IQR	

Table 22: Cigarette Dependence (5.1.1)

Measure	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Current Established Cigarette Smokers)	<i>n</i> =xxx	<i>n</i> =xxx
Heaviness of Smoking Index (HSI) – Cigarettes		
0-1		
2-4		
5-6		
Median HSI Score		
IQR		

Table 23: HeatSticks® Varieties Trial/Usage (5.1.1)

Measure	Current Established IQOS® Users % (CI)	Former Established IQOS® Users % (CI)
Base (Total Participants)	<i>n</i> =xxx	<i>n</i> =xxx
HeatSticks® Varieties Ever Tried		
Regular HeatSticks®		
Smooth Menthol HeatSticks®		
Fresh Menthol HeatSticks®		
First HeatSticks® Varieties Ever Tried		
Regular HeatSticks®		
Smooth Menthol HeatSticks®		
Fresh Menthol HeatSticks®		
HeatSticks® Varieties Currently Using		
Regular HeatSticks®		NA
Smooth Menthol HeatSticks®		NA
Fresh Menthol HeatSticks®		NA
HeatSticks® Varieties Currently Using Most Often		
Regular HeatSticks®		NA
Smooth Menthol HeatSticks®		NA
Fresh Menthol HeatSticks®		NA
HeatSticks® Varieties Previously Used Most Often		
Regular HeatSticks®	NA	
Smooth Menthol HeatSticks®	NA	
Fresh Menthol HeatSticks®	NA	

NA = Not Applicable

Table 24: Cigarette Smoker Status among Current Established IQOS® Users (5.1.1)

Measure	All Current Established IQOS® Users % (CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (CI)
Base	<i>n</i> =XXX	<i>n</i> =XXX	<i>n</i> =XXX
Never smoker			
Current smoker			
Current Smokers Who Prefer Menthol Cigarettes			
Current Smokers Who Prefer Menthol Cigarettes			
Former smoker			
Former Smokers Who Preferred non-Menthol Cigarettes			
Former Smokers Who Preferred non-Menthol Cigarettes			

NA = Not Applicable

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