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Appendix D: Research Analysis Plan - Estimation of Prevalence of IQOS® Use	Version 2.0

Appendix D:

Research Analysis Plan - Estimation of Prevalence of IQOS® Use

Please find on the following pages details about research analysis plan for estimation of prevalence of IQOS® use.

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RESEARCH ANALYSIS PLAN

ESTIMATION OF PREVALENCE OF IQOS® USE

Secondary Analysis of Relevant Data from the ALCS Adult Tobacco Consumer Tracking Study

(Short Title: Secondary Analysis of ATCT)

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V2.0	11/4/2020		In its October 5 th letter, FDA suggested to capture data on flavors of Marlboro HeatSticks® and cigarettes used to understand how menthol and regulator flavors may be associated with behaviors including dual use, quitting, and complete switching.
			To report demographic characteristics of IQOS® users
			To describe ATCT's established criteria for data cleaning, quality control and outlier identification process

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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.

Complete Switching

Complete switching refers to the event of completely transitioning from the established use of one product to now not using the product and the current established use of another tobacco product. Outcomes related to Complete Switching include:

- Complete switching from all tobacco products to IQOS® within the past year
- Complete switching from cigarettes to IQOS® within the past year
- Complete switching from IQOS® to any other tobacco products within the past year
- Complete switching from IQOS® to cigarettes within the past year

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, or every weekend.”

Current Tobacco Product Use

Current tobacco product use refers to using a given tobacco product in the past 30 days, 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.

Initiation

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

- Ever use of a product never used prior to the past year

- Ever established use of a product never used prior to the past year

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) heated tobacco products as ever use of 100 heated tobacco sticks or more,
- 3) cigars as ever use of 50 or more cigars,
- 4) dip/snuff and snus as ever use of 20 or more times per product category,
- 5) e-cigarettes and other e-vapor products as ever used on a consistent basis.

Note: ATCT logically assigns lifetime established use when the reported consumption or frequency satisfies the lifetime established use criterion based on current and past year use consumption or frequency.

Past Year Tobacco Use

Past year tobacco use refers to having used a given tobacco product in the past year or in the past 30 days.

Quitting a Tobacco Product

Quitting a tobacco product refers to having used a given tobacco product to the *lifetime established use criterion*, not using the product in the past 30 days, and having “completely 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*, not using any tobacco product in the past 30 days, and having “completely quit” using all tobacco products.

Tobacco Products

In this study, tobacco products include cigarettes, cigars, pipe tobacco, e-vapor, smokeless tobacco (snus, chewing tobacco, moist smokeless tobacco or dip), oral nicotine products (excluding medicinal nicotine replacement products), hookah, heated tobacco product.

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 Orders.

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. This Estimation of Prevalence of IQOS® Use Research Analysis Plan is one component of the postmarket surveillance program. Specifically, it describes the analyses we intend to conduct using data relevant to IQOS® from ALCS’s ongoing Adult Tobacco Consumer Tracking Study (ATCT).

2 PURPOSE AND OBJECTIVES

2.1 Purpose

The purpose of this secondary analysis is to estimate IQOS® prevalence among adults 21 years of age or older based on relevant data from a population-based consumer survey (i.e. ATCT).

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.

2.2 Objectives

The objectives of this analysis plan are to:

- 1) Estimate prevalence of IQOS® use, in total and by demographic characteristics
- 2) Estimate prevalence of exclusive, dual and poly tobacco use with IQOS®
- 3) Estimate the number of days and amount of tobacco product usage among current IQOS® users
- 4) Describe initiation, quitting and complete switching behaviors relative to IQOS® use

3 OVERVIEW OF THE ADULT TOBACCO CONSUMER TRACKING STUDY

We will analyze data from the ALCS Adult Tobacco Consumer Tracking Study, an on-going cross-sectional computer assisted random-digit dialing telephone interview administered to a nationally representative sample drawn from the U.S. adult civilian non-institutionalized population.

(b) (4)

For any research that will have results projected to the overall population, and prevalence research in particular, probability samples (e.g., RDD telephone) are preferable to non-probability (e.g., internet-based). In probability samples, persons in the population have a known chance of being selected in the sample, margin of error is universally recognized and accepted, and results can be projected to the population at large with a known level of precision. In non-probability samples, some people in the population have no chance (or an unknown chance) of being selected in the sample (coverage bias). The amount of coverage bias and the exact nature of the bias will vary depending on the source (e.g., various online panels).

Quota controls for geography, sex, and other demographic characteristics are used to reduce the reliance on data weighting. It is important to have a demographically/geographically representative sample for the ATCT study, as tobacco usage behavior can vary greatly across different types of adult respondents. Accordingly, the weighting design for ATCT calls for the nesting of certain weighting variables (for example, race/ethnicity within region); however, these data “nests” can potentially include small sample sizes within a subgroup. In order to weight the data successfully, an adequate number of adult respondents are needed in all weighting subgroups, including those that are hardest to reach. This will ensure that the weighting will bring the data into better alignment with reality, rather than distort it from reality.

While data weighting is a common practice, excessive data weighting is not ideal (for example, heavy lifting of underrepresented subgroups and/or extreme reductions to overrepresented subgroups). Additionally, (as mentioned above), adequate numbers of adult respondents are needed within all weighting sub-groups. Therefore, the ATCT study includes quota controls to both reduce the reliance on weighting, as well as to ensure the success of the weighting.

The quota controls are as follows:

- Hard quota controls for region, sex, and mode (landline/cell)
- Soft quota “guardrails” for age, education, and race/ethnicity. These guardrails are not strict quotas for each sub-group, but rather loose guidelines of ± 13 percentage points (pp).

These controls are in place to prevent extreme oversampling of the easiest to reach adult respondents. These quota controls also assure that adequate numbers of adult respondents are available within the nested weighting subgroups, thereby assuring the overall success of the data weighting. In an effort to minimize reliance on these controls, those households reached on landline are asked first for the youngest aged adult male (the hardest population to reach) followed by the youngest aged adult female. However, the need for these controls introduces the possibility of selection bias. While it is impossible to measure selection bias, demographic metrics that are *not* controlled for (such as income) are frequently compared with other statistics reported by federal agencies to ensure consistency and that selection bias is in fact minimal.

3.1 ATCT Tobacco Categories

ATCT is a study designed to measure tobacco prevalence. Eligible adult respondents are asked if they have used any of the following products:

- Cigarettes
- Cigars
- Pipe tobacco
- E-Vapor
- Snus
- Chewing tobacco
- Moist smokeless tobacco or dip
- Oral nicotine products
- Hookah
- Heated tobacco products
- Any Other Tobacco Products not already mentioned.

“Heated tobacco products”, the category to which IQOS® belongs, was added as a new category to ATCT in October 2019. For each of the above products that the adult respondent has used, additional questions are asked to measure amount of usage and consumption. The usual brand within categories used by consumers is also assessed in ATCT. The categories mentioned above will be combined into the following categories for data analysis:

- Cigarettes

- Cigars
- Pipe tobacco
- E-Vapor
- Smokeless tobacco (snus, chewing tobacco, moist smokeless tobacco or dip)
- Oral nicotine products
- Hookah
- Heated tobacco products

Note: Any other tobacco products not already mentioned will not be considered in the analysis.

3.2 ATCT Study Duration

ATCT is fielded on a continuous basis. Data will be analyzed across the most recent 12 month period for the purpose of reporting.

3.3 ATCT Recruitment

A nationally representative sample is drawn from the US adult population through a computer assisted random-digit dialing telephone interview. The sample is based on a probability sampling approach that utilizes landline and cell phone interviewing frames following an equal probability selection method design. (b) (4)

(b) (4) Quota controls for geography, sex, and other demographic characteristics are used to reduce the reliance on data weighting.

3.4 ATCT Inclusion and Exclusion Criteria

(b) (4)

4 SECONDARY ANALYSIS PROCEDURES

We will commence reporting IQOS®-relevant information from ATCT for the purpose of the MRTPA following IQOS® MRTP authorization for a time period specified in the Modified Risk Order (e.g., annual).² The reporting and, ultimately, analysis of the data will follow a step-wise process based on the number of current IQOS® users (used IQOS® brand of heated tobacco product in the past 30 days) identified within the ATCT dataset.

The process will unfold as follows:

- Step 1 Reporting. The number of current IQOS® users in the ATCT dataset will be reported when the MRTPA is granted for IQOS®. The count will be based on data from the most recent 12 moving-month. We will only report counts if the number of current IQOS® users in the ATCT dataset is less than (b)
- Step 2 Reporting. When the number of current IQOS® users in the ATCT dataset reaches (b) we will start to report prevalence at the national level. The reported results include the count and percentage of total current IQOS® users with 95% confidence interval. The results will be based on either the most recent 12 moving-month if we have reported IQOS® use in all 12 months, or the months when ATCT starts to capture current IQOS® users if it is less than 12 months.
- Step 3 Reporting. When the number of current IQOS® users in the ATCT dataset reaches (b), we will start to report all other outcome measures as stated in this analysis plan. Based on sample size calculations, we need at least (b) current IQOS® users in the ATCT data set to start reporting outcome measures for the four objectives.

4.1 Rationale for the Step-wise Reporting Process

We chose a step-wise reporting process because we need enough sample to report prevalence rates that are meaningful and have population representativeness. (b) (4)

(b) (4)

² ALCS currently has a process in place to report IQOS-relevant information from ATCT for the purpose of the IQOS PMTA authorization. When fully executed, this analysis plan will extend beyond the reporting plan devised for the PMTA.

Table 1: Number of current IQOS® user for prevalence estimation based on an annual ATCT sample size of (b) (4)

Number of Current IQOS® Users	Prevalence Estimate (Unweighted)	Approximated 95% Confidence Interval (Unweighted)
(b) (4)		

4.2 Sample Size Calculation

A sufficient sample of current IQOS® users is needed to ensure adequate precision of the estimates (e.g., means, proportions) among IQOS® users. Based on our calculation described below, a sample size of (b) (4) will be needed to achieve a sufficiently narrow confidence interval (NCSS Statistical software, 2017) for the estimates. (b) (4)

(b) (4)

(refer to Table 1).

For additional analysis of the (b) (4) current IQOS® users in ATCT, assuming an expected proportion of 0.5, the confidence interval width is about 0.2 (Figure 1) (Fleiss et al., 2003; Newcombe, 1998), which is practically acceptable. As a result, (b) (4) will be considered the smallest sample size required for additional analysis of current IQOS® users.

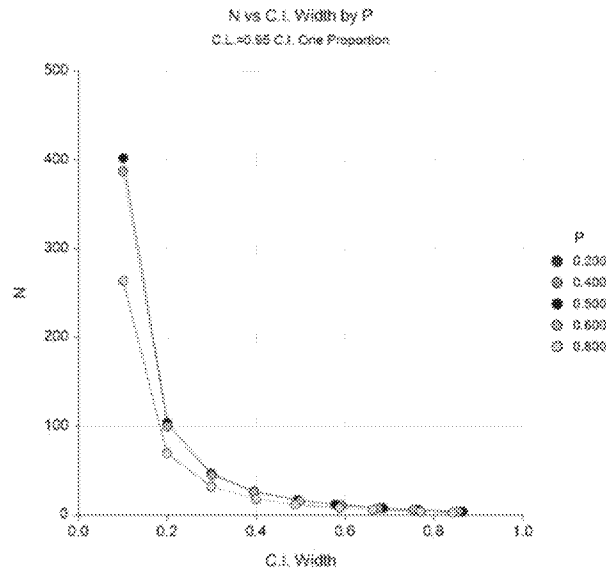


Figure 1: Estimated Sample Sizes for Various Confidence Interval Widths by Expected Proportions

Table 2 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). If the sample size (i.e., the denominator) for an estimate falls below (b) the estimate will not be generated with a note of the 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 sample size of (b) (4) is appropriate for the continuous outcome measures of this study. As shown in Table 3, when we look at continuous measures, with a sample size of (b) we will have a confidence interval width within 5 units given different standard derivations.

Table 2: 95% Confidence Intervals at Various Proportion Points

n	Proportion
	(b) (4)
	(b) (4)

Table 3: Examples of estimated 95% confidence width of continuous variables given

(b) (4)			
Variable	Mean	Standard Deviation	Width Associated with 95% Confidence
			(b) (4)
(b) (4)			

4.3 Secondary Analysis Estimated Timeline

The timing of the secondary analysis of ATCT depends on the distribution and consumer uptake of IQOS® in the marketplace, i.e., the extent of analyses we are able to perform will depend on sufficient numbers of IQOS® users in the marketplace that, in turn, translate into sufficient numbers of current IQOS® users that are included in the ATCT dataset. Currently, IQOS® is in very limited distribution in the United States. IQOS® was first launched into a single market, Atlanta, GA, in September 2019; a second market, Richmond, VA, in November 2019; and a third market, Charlotte, NC, in July 2020. Future expansion is planned to occur, but the pace and breadth of expansion may depend on learning achieved from the early market launches.

We plan to report IQOS®-related data from ATCT in April 30 of each year following the year of issuance of the IQOS®-exposure modification order. To plan timing for the secondary analysis of ATCT, we focused on the minimal sample size thresholds for the step-wise reporting process, i.e., less than (b) (4) reported current IQOS® users. We assume that IQOS® will need to be available in multiple marketplaces beyond the current three and/or in regional distribution in order to reach a level that current IQOS® use can be captured in a nationally representative sample.

Table 4: Estimated Timeline for the Execution of the Secondary Analysis of ATCT

Milestone	Estimated Date
(b) (4)	

We intend to report at the “highest possible step” at each reporting time interval. For example, in reference to Table 4, if there are (b) current IQOS® users in the dataset by the end of Feb 2022, then we intend to execute against Step 2 Reporting, as opposed to Step 1 as currently have forecasted.

5 OUTCOME MEASURES

In this section, we describe the detailed definitions of outcome measures based on self-reported tobacco product usage behavior. In some instances, outcome measures will be stratified by menthol versus non-menthol use. The variety used most often question is asked separately among current IQOS® users and among IQOS® users who used in the past year prior to past 30 days. Therefore, IQOS® users who used IQOS® in the past year, which includes past 30 days and the past 11 months prior to past 30 days answer the variety used most often twice. To stratify IQOS® menthol versus non-menthol use for past year IQOS® use variety, we will report menthol use (reported menthol only for past year and/or past 30-day use variety questions), non-menthol use (reported non-menthol only for past year and/or past 30-day use variety questions) and menthol/non-menthol use (reported both menthol and non-menthol use for past year and past 30-day use variety questions).

Objective 1: Estimate prevalence of IQOS® use, in total and by demographic characteristics. Current and current established IQOS® use, past year and past year established IQOS® use will be stratified by menthol and non-menthol variety.

- Prevalence of *current use* of IQOS®: Percentage of respondents who reported use of IQOS® in the past 30 days among total respondents (21 years of age or older).
- Prevalence of *ever use* of heated tobacco products: Percentage of respondents who reported use of heated tobacco products within the past year or ever used heated tobacco products prior to the past year among respondents 23 years of age or older.³
- Prevalence of *ever established use* of heated tobacco products: Percentage of respondents who reported use of heated tobacco products within the past year or ever used heated tobacco products prior to the past year and having used 100 or more heated tobacco sticks among respondents 23 years of age or older.
- Prevalence of *past year use* of IQOS®: Percentage of respondents who reported use of IQOS® within the past year among respondents 23 years of age or older.⁴
- Prevalence of *past year established use* of IQOS®: Percentage of respondents who reported use of IQOS® within the past year and having used 100 or more Marlboro HeatSticks® among total respondents 23 years of age or older.
- Prevalence of *current established use* of IQOS®: Percentage of respondents who reported use of IQOS® in the past 30 days and having used 100 or more Marlboro HeatSticks® among respondents 23 years of age or older.

Objective 2: Estimate prevalence of exclusive, dual and poly tobacco use with IQOS®. Outcome measures will be stratified by menthol and non-menthol variety among current IQOS® users.

- Prevalence of IQOS® only
- Prevalence of IQOS® plus one other tobacco product
 - IQOS® and cigarettes
 - IQOS® and one other tobacco product, excluding cigarettes
- Prevalence of 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

³ ATCT is a study designed to assess prevalence and tobacco use behaviors of the adult population. Therefore, skip logic is used to avoid gathering information related to tobacco use prior to legal age. Questions that seek information about “prior to the past year” tobacco use are only assessed among respondents 23 years of age or older. *Ever* and *Established Use* for some respondents are derived from “prior to the past year” use behavior and thus are only assessed among those who are 23 years of age or older.

⁴ *Past Year* use can be assessed for respondents age 22 or older; however, since established use for some respondents is derived from “prior to the past year” use behavior, we assess *Past Year* and *Past Year Established Use* among those 23 years of age or older.

- Proportion of the exclusive, dual and poly use groups among current IQOS® users

Objective 3: Estimate the number of days and amount of tobacco product usage among current IQOS® user. Cigarette variety (menthol versus non-menthol) will also be reported among IQOS® users who also smoke cigarettes. Outcome measures will be stratified by IQOS® menthol and non-menthol variety among current IQOS® users.

- Amount of Marlboro HeatSticks® and amount of each other tobacco product used per day on days used in the past 30 days.
- Number of days used IQOS® and each other tobacco product in the past 30 days.

Objective 4: Describe initiation, quitting and complete switching behaviors relative to IQOS® use. These outcomes are assessed among respondents 23 years of age or older.⁵ Outcome measures will be characterized by menthol and non-menthol variety for current IQOS® use or past year prior to past 30-day IQOS® use.

IQOS® Initiation within the past year

- Initiation of IQOS® within the past year among never tobacco users: Percentage of respondents who reported use of IQOS® in the past year among respondents who reported never using any tobacco products prior to the past year.
- Initiation of IQOS® in the past year with established IQOS® use among never tobacco users: Percentage of respondents who reported using of IQOS® in the past year and having used 100 or more Marlboro HeatSticks® among respondents who reported never using any tobacco products prior to the past year.
- Initiation of IQOS® in the past year among IQOS® never users: Percentage of respondents who reported using of IQOS® in the past year among respondents who reported never using IQOS® prior to the past year
- Initiation of IQOS® in the past year with established IQOS® use among IQOS® never users: Percentage of respondents who reported using of IQOS® in the past year and having used 100 or more Marlboro HeatSticks® among respondents who reported never using IQOS® prior to the past year

Complete switching to IQOS® within the past year

- Complete switching from all tobacco products to IQOS® within the past year
 - *among* past year established tobacco users: Percentage of respondents who reported current established use of IQOS® exclusive of all other tobacco

⁵ ATCT is a resource designed initially for business purposes and skip logic is used to avoid gathering information related to tobacco use prior to legal age. Questions that seek information about “prior to the past year” tobacco use are only assessed among respondents 23 years of age or older. *Ever* and *Established Use* for some respondents are derived from “prior to the past year” use behavior and thus are only assessed among those who are 23 years of age or older. *Initiation*, *Switching* and *Quitting* outcomes are defined based on *Established Use* and other criteria. As a result, these outcomes are only assessed among those 23 years of age or older.

products among respondents who reported established use of any tobacco products prior to the past 30 days but within the past year.

- *among* current established IQOS® users: Percentage of respondents who reported current established use of IQOS® exclusive of other tobacco products after past year established use of other tobacco products among current established IQOS® users.
- Complete switching from cigarettes to IQOS® within the past year
 - *among* past year established smokers: Percentage of respondents who reported current established use of IQOS® exclusive of cigarette smoking among respondents who reported established cigarette smoking prior to the past 30 days but within the past year.
 - *among* current established IQOS® users: Percentage of respondents who reported current established use of IQOS® exclusive of cigarette smoking after past year established cigarette smoking among current established IQOS® users.

Complete switching from IQOS® within the past year

- Complete switching from IQOS® to any other tobacco products within the past year
 - *among* past year established IQOS® users: Percentage of respondents who reported established use any tobacco products other than IQOS® in the past 30-day among respondents who reported established use of IQOS® prior to past 30-day but within the past year.
- Complete switching from IQOS® to cigarettes within the past year
 - *among* past year established IQOS® users: Percentage of respondents who reported established smoking cigarettes exclusive of IQOS® use in the past 30 days among respondents who reported established use of IQOS® prior to the past 30 days but within the past year.

Quitting tobacco within the past year

- Quitting IQOS® within the past year: Percentage of respondents who reported having not used IQOS® in the past 30 days and reported having completely quit IQOS® among respondents who reported use of IQOS® prior to the past 30 days but within the past year and having used 100 or more Marlboro HeatSticks®.
- Quitting all tobacco products including IQOS® within the past year: Percentage of respondents who reported having not used any tobacco products in past 30-day and having completely quit all tobacco products among respondents who reported use of IQOS® prior to past 30 day but within the past year and reported having used the tobacco product(s) to lifetime criterion

6 DATA MANAGEMENT AND QUALITY CONTROL PROCESS

All original source information (i.e., the ATCT dataset) obtained or received to conduct the secondary analyses will be maintained by the study lead analyst. ATCT data will not include any personally identification information (PII). All data collected during the conduct of ATCT are declared property of ALCS.

The monthly quality control process for the ATCT data includes different phases. Telephone interviewing supervisory staff reviews the survey before interviewers are briefed. This provides the opportunity for the interviewing supervisors to ask questions and/or provide feedback to the project director. After the first day of interviewing, and continuously throughout the duration of interviewing, project director checks for feedback from interviewers (as noted above). The trained managerial staff monitors approximately 5% of all completed interviews on all studies. Interviewers are monitored on a daily basis, with feedback provided immediately.

Once the monthly data is collected, additional processes are implemented, which includes data recoding, data cleaning, creation of specific metric variables, weighting and exception reporting. These steps occur before the data are transmitted to ALCS. The analyses described in this secondary analysis of ATCT will be conducted on the data file received.

- **Data Recoding:** Verbatim responses are examined and recoded if the response matches existing response options. For example, if “Marlboro” is entered under “other” to a brand question, this response would be removed from “other” and back-coded to the pre-list of brands.
- **Data Cleaning:** Logic checks are implemented to verify questionnaire flow and responses, using automated programs and manual checking. For example, corresponding modules questions should have responses if used a product in past 30 days or past year. If module questions were not answered for a particular product, the past 30-day response for that product would be changed to “don’t know”. Note that such occurrence is extremely rare but it is included in the automated quality control program to ensure there is no programming error. Outliers of tobacco consumption will be identified based on pre-set thresholds (e.g., a maximum of 80 for cigarettes and 80 for heated tobacco product sticks per day on days used). The identified outliers of consumption questions for that particular product are set as missing; all other questions for that product (or form) are left unchanged.
- **Creation of Specific Metric Variables:** Pre-specified variables (e.g., current use, current established use, ever use) will be derived from the raw data.
- **Weighting:** Demographic and geographic profiles of the weighted respondents are compared back to the targets in the weight matrix to assure that weights were properly assigned, and the final sample composition is representative. After the population-weights are applied, the total pop-weighted sample size is checked to confirm that it matches the adult population estimates as provided by the U.S. Census Bureau’s Current Population Survey.
- **Exception Report:** The ATCT exception report is developed including key survey metrics, such as prevalence rates, # of products used, switching rates, and annualized volume estimates.

7 DATA ANALYSIS

Descriptive statistics will be calculated, including medians and quartiles for continuous or count variables (e.g., amount of tobacco use), as well as percentages and counts for categorical variables (e.g., yes/no ever used a tobacco product). Ninety-five percent (95%) confidence intervals will also be calculated when applicable. Estimates with denominator sample sizes less than (b) 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) will not be reported with a note of small sample size.

Prevalence Measures. Prevalence estimates will be reported with 95% confidence intervals for the total sample and by major demographic categories (sex, age, race/ethnicity, income and education).

Demographic Characteristics. Descriptive statistics of the demographic characteristics (sex, age, race/ethnicity, income and education) will be reported for current and current established IQOS® users, past year and past year established IQOS® ever users, ever established users, current and current established IQOS® users, including sample sizes, central tendency measures (e.g. means, medians), variability measures (e.g. standard deviation, range) and 95% confidence intervals.

Tobacco Use Patterns. Descriptive statistics of the self-reported use of tobacco products will be calculated among current IQOS® users. Number of days will be reported in categories using percentages, in addition to mean, median and standard deviation; the amount will be reported with median and IQR for amount of each listed tobacco product used on days used in the past 30 days.

Initiation, Quitting and Complete switching Behaviors. Descriptive statistics of tobacco use behaviors will be calculated, including sample sizes, percentages, counts and 95% confidence intervals.

8 ADMINISTRATIVE

The analysis shall be conducted as described in this analysis plan. Any deviations from the planned analyses and reporting will be documented as amendments.

9 REFERENCES

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Newcombe, R. G. (1998). Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods. *Statistics in Medicine*, 17, 857-872.

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10 APPENDIX – EXAMPLE TABLE SHELLS

10.1 Outcome Measures in Objective 1, Estimate prevalence of IQOS® use, in total and by demographics characteristics

10.1.1 Raw Count of Current IQOS® Users in ATCT by Survey Month

Table 5: Raw Count of Current IQOS® Users by Survey Month (21 years of age or older)

Survey Month	Raw Count of Current IQOS® Users

Note: We intend to complete the table in 10.1.1 throughout the execution of the analysis plan.

10.1.2 Prevalence Estimation of Current IQOS® Use (Given More Than (b) Reported Current IQOS® Use in Most Recent 12 Moving-Month)

Table 6: Prevalence of Current IQOS® Use During Reporting Period (21 years of age or older)

Reporting Period	Current IQOS® Use	
	Raw Count	Prevalence with 95% CI

Note: We intend to complete the table in 10.1.2 when the number of current IQOS® users in the ATCT dataset is more than (b) but less than (b)

10.1.3 Prevalence Estimation of Current IQOS® Use and Current Established IQOS® Use

**Table 7: Prevalence Estimation of Current IQOS® Use (21 years of age or older) (Reporting Period: MMMYYYY-
MMMMYYYY, n=)**

Measure	Raw Count	Prevalence with 95% CI
Current IQOS® Use		
- Current IQOS® Use with Menthol Variety		
- Current IQOS® Use with Non-Menthol Variety		

Note: We intend to complete the table in 10.1.3 and all other analyses included in this research plan when the number of current IQOS® users in the ATCT dataset is (b) or more.

**Table 8: Prevalence Estimation of Current Established IQOS® Use (23 years of age or older) (Reporting Period:
MMMMYYYY-MMMMMYYYY, n=)**

Measure	Raw Count	Prevalence with 95% CI
Current Established IQOS® Use		
- Current Established IQOS® Use with Menthol Variety		
- Current Established IQOS® Use with Non-Menthol Variety		

10.1.4 Prevalence Estimation of Past Year IQOS® Use and Past Year Established IQOS® Use

Table 9: Prevalence of Past Year IQOS® Use and Past Year Established IQOS® Use (23 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY, n=)

Measure	Raw Count	Prevalence with 95% CI
Past Year IQOS® Use		
- IQOS® Menthol ^a		
- IQOS® Non-Menthol ^b		
- IQOS® Menthol/Non-Menthol ^c		
Past Year Established IQOS® Use		
- IQOS® Menthol ^a		
- IQOS® Non-Menthol ^b		
- IQOS® Menthol/Non-Menthol ^c		

Notes: ^a Past year menthol use: reported menthol only for past year and/or past 30-day use variety questions

^b Past year non-menthol use: reported non-menthol only for past year and/or past 30-day use variety questions

^c Past year menthol/non-menthol use: reported both menthol and non-menthol use for past year and past 30-day use variety questions

10.1.5 Prevalence Estimation of IQOS® Use by Major Demographics (Sex, Age, Race/Ethnicity, Income and Education): Raw Count and Weighted Prevalence with 95% CI

Table 10: Prevalence of Current Use by Major Demographics (21 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY)

Major Demos	n	Count	Percentage	95% Confidence Interval
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)				

Table 11: Prevalence of Current Established Use by Major Demographics (23 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY)

Major Demos	n	Count	Percentage	95% Confidence Interval
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)				

Table 12: Prevalence of Past Year Use by Major Demographics (23 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY)

Major Demos	n	Count	Percentage	95% Confidence Interval
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)				

Table 13: Prevalence of Past Year Established Use by Major Demographics (23 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY)

Major Demos	n	Count	Percentage	95% Confidence Interval
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)				

Table 14: Demographic Characteristics and IQOS® Variety of Current, Current Established, Past Year and Past Year Established Use (Reporting Period: MMMYYYY-MMMYYYY)

Major Demos/Variety	Current IQOS® Use	Current Established IQOS® Use	Past Year IQOS® Use	Past Year Established IQOS® Use
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)				
Variety (Menthol ^a , Non-Menthol ^b , Menthol/Non-Menthol ^c)				

Notes: ^a Past year menthol use: reported menthol only for past year and/or past 30-day use variety questions

^b Past year non-menthol use: reported non-menthol only for past year and/or past 30-day use variety questions

^c Past year menthol/non-menthol use: reported both menthol and non-menthol use for past year and past 30-day use variety

**Table 15: Demographic Characteristics of IQOS® Menthol and Non-Menthol Users (Reporting Period: MMMYYYY-
MMMYYYY)**

Major Demos/Variety	Current IQOS® Use		Current Established IQOS® Use		Past Year IQOS® Use			Past Year Established IQOS® Use		
	Menthol	Non-Menthol	Menthol	Non-Menthol	Menthol ^a	Non-Menthol ^b	Menthol/ Non-Menthol ^c	Menthol ^a	Non-Menthol ^b	Menthol/ Non-Menthol ^c
Major Demos (Sex, Age, Race/Ethnicity, Income and Education)										

Notes: ^a Past year menthol use: reported menthol only for past year and/or past 30-day use variety questions

^b Past year non-menthol use: reported non-menthol only for past year and/or past 30-day use variety questions

^c Past year menthol/non-menthol use: reported both menthol and non-menthol use for past year and past 30-day use variety

10.1.6 Prevalence Estimation of Ever Heated Tobacco Product Use and Ever Established Heated Tobacco Product Use

Table 16: Prevalence of Ever Heated Tobacco Product Use and Ever Established Heated Tobacco Product Use (23 years of age or older) (Reporting Period: MMMYYYY-MMMYYYY, n=)

Measure	Raw Count	Prevalence with 95% CI
Ever Heated Tobacco Product Use		
Ever Established Heated Tobacco Product Use		

10.2 Outcome Measures in Objective 2, Estimate Prevalence of Exclusive, Dual and Poly Tobacco Use with IQOS®

Subgroup Analysis may be conducted by demographics characteristics (sex, age, race/ethnicity, income and education) given sufficient sample size (i.e., greater than or equal to (b)).

10.2.1 IQOS® Exclusive and Dual/Poly Use Prevalence

Table 17: Prevalence Estimation of Exclusive, Dual and Poly Tobacco Use with IQOS®

Measure	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Prevalence with 95% CI	Unweighted Count	Prevalence with 95% CI	Unweighted Count	Prevalence with 95% CI
Prevalence of IQOS® only						
Prevalence of IQOS® plus one other tobacco product <ul style="list-style-type: none"> ○ IQOS® and cigarettes ○ IQOS® and one other tobacco product, excluding cigarettes 						
Prevalence of IQOS® plus two or more other tobacco products <ul style="list-style-type: none"> ○ IQOS® and two or more other tobacco products, including cigarettes ○ IQOS® and two or more other tobacco products, excluding cigarettes 						

10.2.2 IQOS® Use by Exclusive and Dual/Poly Use Among Current IQOS® Users

Table 18: Exclusive, Dual and Poly Tobacco Use with IQOS® Among Current IQOS® Users

Measure	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
Proportion of IQOS® only						
Proportion of IQOS® plus one other tobacco product <ul style="list-style-type: none"> ○ IQOS® and cigarettes ○ IQOS® and one other tobacco product, excluding cigarettes 						
Proportion of IQOS® plus two or more other tobacco products <ul style="list-style-type: none"> ○ IQOS® and two or more other tobacco products, including cigarettes ○ IQOS® and two or more other tobacco products, excluding cigarettes 						

10.3 Outcome Measures in Objective 3, Estimate the number of days and amount of tobacco product usage among current IQOS® user

Subgroup Analysis may be conducted by demographics characteristics (sex, age, race/ethnicity, income and education) given sufficient sample size (i.e., greater than or equal to (b)).

10.3.1 Amount of Marlboro HeatSticks® used per day on days used in the past 30 days (n=)

Table 19: Amount of Marlboro HeatSticks® Used per Day on Days Used in the Past 30 Days

Amount of Marlboro HeatSticks® Used per Day – in the Past 30 Days	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
1 Marlboro HeatStick						
2-7 Marlboro HeatSticks®						
8-14 Marlboro HeatSticks®						
15-20 Marlboro HeatSticks®						
20+ Marlboro HeatSticks®						
Mean Number of Marlboro HeatSticks®						
Standard deviation						
Median Number of Marlboro HeatSticks®						
Interquartile Range						

10.3.2 Number of days used IQOS® in the past 30 days

Table 20: Number of Days Used IQOS® in the Past 30 Days

Number of Days Used IQOS®	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
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						
Median number of days used						
Interquartile Range						

10.3.3 Amount of cigarettes smoked per day on days used in the past 30 days

Table 21: Cigarette Menthol and Non-Menthol Smoking Among Current IQOS® Users Who Also Smoke Cigarettes

	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
Cigarette Smoking with Menthol Variety						
Cigarette Smoking with Non- Menthol Variety						

Table 22: Amount of Cigarettes Smoked per Day on Days Used in the Past 30 Days Among Current IQOS® Users Who Also Smoke Cigarettes

Amount of Cigarette Smoked per Day in the Past 30 Days	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
1 stick						
2-7 sticks						
8-14 sticks						
15-20 sticks						
20+ sticks						
Mean number of sticks smoked						
Standard deviation						
Median number of sticks smoked						
Interquartile Range						

10.3.4 Number of days smoked cigarettes in the past 30 days

Table 23: Number of Days Smoked Cigarettes in the Past 30 Days Among Current IQOS® Users Who Also Smoke Cigarettes

Number of Days Smoked Cigarettes	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
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						
Median number of days used						
Interquartile Range						

10.3.5 Amount of e-vapor used per day on days used in the past 30 days

Same consumption tables will be populated for different e-vapor types (i.e. e-liquid, cartridges and disposable e-cigarettes) as well as for cigars, smokeless tobacco (moist smokeless tobacco, snus) and oral nicotine products (in pouch, chewable and lozenge forms).

Table 24: Amount of E-Vapor Used per Day on Days Used in the Past 30 Days Among Current IQOS® Users Who Also Use E-Vapor

Amount of E-Vapor Used per Day in the Past 30 Days	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
1 Unit						
2-7 Units						
8-14 Units						
15-20 Units						
20+ Units						
Mean number of units used						
Standard deviation						
Median number of units used						
Interquartile Range						

10.3.6 Number of days used e-vapor in the past 30 days

Table 25: Number of Days Used E-Vapor in the Past 30 Days Among Current IQOS® Users Who Also Use E-Vapor

Number of Days Used E-Vapor	Overall IQOS® Use (n=)		Menthol IQOS® Use (n=)		Non-Menthol IQOS® Use (n=)	
	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI	Unweighted Count	Proportion with 95% CI
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						
Median number of days used						
Interquartile Range						

10.4 Outcome Measures in Objective 4, Describe initiation, quitting and complete switching behaviors relative to IQOS® use

Subgroup Analysis may be conducted by demographics characteristics (sex, age, race/ethnicity, income and education) given sufficient sample size (i.e., greater than or equal to (b)).

10.4.1 IQOS® Initiation within the past year

Table 26: IQOS® Initiation within the Past Year (23 years of age or older)

Initiation Measure	Base Sample Size	Unweighted Count	Weighted Freq	Proportion with 95% CI
Initiation Among Never Tobacco Users				
Initiation of IQOS [®] within the past year among never tobacco users				
- IQOS [®] Menthol ^a				
- IQOS [®] Non-Menthol ^b				
- IQOS [®] Menthol/Non-Menthol ^c				
Initiation of IQOS [®] in the past year with established IQOS [®] use among never tobacco users				
- IQOS [®] Menthol ^a				
- IQOS [®] Non-Menthol ^b				
- IQOS [®] Menthol/Non-Menthol ^c				
Initiation Among IQOS [®] Never Users				
Initiation of IQOS [®] in the past year among IQOS [®] never users				
- IQOS [®] Menthol ^a				
- IQOS [®] Non-Menthol ^b				

Initiation Measure	Base Sample Size	Unweighted Count	Weighted Freq	Proportion with 95% CI
- IQOS® Menthol/Non-Menthol ^c				
Initiation of IQOS® in the past year with established IQOS® use among IQOS® never users				
- IQOS® Menthol ^a				
- IQOS® Non-Menthol ^b				
- IQOS® Menthol/Non-Menthol ^c				

Notes: ^a Past year menthol use: reported menthol only for past year and/or past 30-day use variety questions

^b Past year non-menthol use: reported non-menthol only for past year and/or past 30-day use variety questions

^c Past year menthol/non-menthol use: reported both menthol and non-menthol use for past year and past 30-day use variety

10.4.2 Complete switching to IQOS® within the past year

Table 27: Complete Switching to IQOS® within the Past Year (23 years of age or older)

Complete Switching Measure	Base Sample Size	Unweighted Count	Weighted Freq	Proportion with 95% CI
Complete switching from all tobacco products to IQOS® within the past year				
Complete switching from all tobacco products to IQOS® within the past year among past year established tobacco users				
- Switch to IQOS® Menthol				
- Switch to IQOS® Non-Menthol				
Complete switching from all tobacco products to IQOS® within the past year among current established IQOS® users				
- Switch to IQOS® Menthol				
- Switch to IQOS® Non-Menthol				
Complete switching from cigarettes to IQOS® within the past year				
Complete switching from cigarettes to IQOS® within the past year among past year established smokers				
- Switch to IQOS® Menthol				
- Switch to IQOS® Non-Menthol				
- Switch from Menthol Cigarettes to IQOS®				
- Switch from Non-Menthol Cigarettes to IQOS®				
Complete switching from cigarettes to IQOS® within the past year among current established IQOS® users				
- Switch to IQOS® Menthol				

- Switch to IQOS® Non-Menthol				
- Switch from Menthol Cigarettes to IQOS®				
- Switch from Non-Menthol Cigarettes to IQOS®				

10.4.3 Complete switching from IQOS® within the past year

Table 28: Complete Switching from IQOS® within the Past Year (23 years of age or older)

Complete Switching Measure	Base Sample Size	Unweighted Count	Weighted Freq	Proportion with 95% CI
Complete switching from IQOS® to any other tobacco products within the past year among past year established IQOS® users				
- Switch from IQOS® Menthol				
- Switch from IQOS® Non-Menthol				
Complete switching from IQOS® to cigarettes within the past year among past year established IQOS® users				
- Switch from IQOS® Menthol				
- Switch from IQOS® Non-Menthol				

10.4.4 Quitting tobacco within the past year

Table 29: Quitting Tobacco within the Past Year (23 years of age or older)

Quitting Measure	Base Sample Size	Unweighted Count	Weighted Freq	Proportion with 95% CI
Quitting IQOS® within the past year				
- Quitting IQOS® Menthol				
- Quitting IQOS® Non-Menthol				
Quitting all tobacco products including IQOS® within the past year				
- Quitting all including IQOS® Menthol				
- Quitting all including IQOS® Non-Menthol				