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## Final Study Report

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### **IQOS® WITH MARLBORO HEATSTICKS® CROSS-SECTIONAL POSTMARKET ADULT CONSUMER STUDY (PACS)**

#### **“IQOS® Cross-sectional PACS” – Wave 1**

<b>Title</b>	IQOS® WITH MARLBORO HEATSTICKS® CROSS-SECTIONAL POSTMARKET ADULT CONSUMER STUDY (PACS)
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<b>Sponsor</b>	Altria Client Services LLC 601 E. Jackson Street Richmond, Virginia 23219

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Marketing Authorization Holder(s):	Philip Morris Products S.A. Quai Jeanrenaud 3 Neuchatel, Switzerland, 2000
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POSTMARKET ADULT CONSUMER STUDY (PACS)

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## 1 Synopsis

Study Title	IQOS® WITH MARLBORO HEATSTICKS® CROSS-SECTIONAL POSTMARKET ADULT CONSUMER STUDY (PACS) Wave 1
Study Number	ALCS-CMI-17-36-HT
Active Substance	Not applicable
Sponsor	Altria Client Services LLC 601 E. Jackson Street Richmond, Virginia 23219
Marketing authorization holder(s)	Philip Morris Products S. A. Quai Jeanrenaud 3 Neuchatel, Switzerland, 2000
Investigators	(b) (6) Principal Investigator Altria Client Services LLC 601 E. Jackson Street Richmond, Virginia 23219
Rationale and Background	Philip Morris Products S.A. (PMP S.A.) developed the IQOS® Tobacco Heating System and Marlboro HeatSticks® (hereinafter referred to as IQOS®) as a novel tobacco and nicotine containing product with the potential to reduce harm or the risk of tobacco-related disease associated with smoking cigarettes. This document is prepared as part of the Postmarket Surveillance and Studies (PMSS) program for IQOS® pursuant to orders from the United States (US) Food and Drug Administration (FDA).
Research Questions and Objectives	The purpose of the IQOS® cross-sectional Postmarket Adult Consumer Study (PACS) was to provide survey data from qualified adult ever established IQOS® users to assess use and perceptions of the products and associations with other tobacco use behaviors.  The study objectives were among adult ever established IQOS® users and were as follows:  1. To characterize adult ever established IQOS® users and their tobacco use patterns;  2. To characterize risk perceptions of IQOS®;

	3. To describe initiation, complete switching from cigarette smoking to IQOS®, transitions to/back to cigarette smoking, and quitting behaviors relevant to IQOS® use.
Study Design	<p>This study was a cross-sectional survey of adult established IQOS® users. Two computerized data collection instruments were used – a Participant Screener and Main Survey.</p> <p>After agreeing to participate in the study, the potential participant completed 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 was verified to ensure that he/she met the inclusion criteria. Eligible participants were then presented with the "Main Survey," which collected the detailed study information to assess the study objectives.</p> <p>Survey questions were designed to characterize patterns of tobacco use, risk perceptions, use of IQOS® not as intended, and behaviors associated with IQOS®.</p>
Setting	The survey was self-administered online. The duration of the study, from first participant in through last participant out, was approximately 9 weeks. There were no study stimuli other than the survey questions. Completion time for the Participant Screener and Main Survey together was approximately 20 minutes.
Study Participants and Sample Size	<p>Participants included ever established IQOS® users 21 years of age or older recruited from the IQOS® consumer database.</p> <p><b>Ever established IQOS® users</b> were defined as adults who have ever used at least 100 Marlboro HeatSticks®. Ever established IQOS® users included the following two groups:</p> <ul style="list-style-type: none"> <li>• <b>Current established IQOS® users:</b> Adult ever established IQOS® users who now use IQOS® "every day" or "some days".</li> <li>• <b>Former established IQOS® users:</b> Adult ever established IQOS® users who now use IQOS® "not at all."</li> </ul> <p>In this study, a total of (b)(4) established IQOS® users completed the survey. On 13<sup>th</sup> October 2021 an information letter was sent to all invited individuals, stating that IQOS® will be unavailable for sale in the US as of 29<sup>th</sup> November 2021. Therefore, the sample was split in pre- and post-information letter groups as it could not be ruled out that the communication had impact on the use behavior of current IQOS® users. This report focuses on the individuals who completed the survey before 13<sup>th</sup> October 2021. Results for individuals who completed the survey after 13<sup>th</sup> October are provided in post-text appendices.</p>
Variables and Data Sources	<p><b>Objective 1 - Use patterns</b></p> <ul style="list-style-type: none"> <li>• Types of tobacco products ever tried, used to lifetime criterion, and currently using</li> </ul>

	<ul style="list-style-type: none"> <li>• Types of tobacco products ever tried, used to lifetime criterion, and were currently using prior to first trying IQOS®</li> <li>• Exclusive and dual/poly tobacco use with IQOS®</li> <li>• Number of days of use of IQOS® and cigarettes in past 30 days</li> <li>• Amount of Marlboro HeatSticks® and cigarettes in past 30 days</li> <li>• Amount of tobacco product use before trying IQOS® relative to current tobacco product use</li> <li>• Description of IQOS® use not as intended</li> </ul> <p><b>Objective 2 –Risk perceptions of IQOS®</b></p> <ul style="list-style-type: none"> <li>• Perception of health risk to the average users of IQOS®/cigarette in general</li> <li>• Perception of harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS®</li> <li>• Understanding of what smokers had to do to reduce harmful or potentially harmful chemical exposure</li> </ul> <p><b>Objective 3 - Initiation, complete switching to IQOS®, transitions to/back to cigarette smoking, and quitting behaviors relevant to IQOS® use</b></p> <p>Initiation of tobacco with IQOS®</p> <ul style="list-style-type: none"> <li>• IQOS® as the first tobacco product ever tried</li> <li>• IQOS® as the first tobacco product ever used on a consistent basis</li> </ul> <p>Initiation of IQOS® as long-term former smokers and long-term former tobacco users</p> <ul style="list-style-type: none"> <li>• First trial of IQOS® after not smoking cigarettes for 12 months or longer</li> <li>• First trial of IQOS® after not using all tobacco products for 12 months or longer</li> </ul> <p>Complete Switching from Cigarettes Smoking/All Tobacco to IQOS®</p> <ul style="list-style-type: none"> <li>• Complete switching from cigarettes to IQOS® after first trying IQOS®</li> <li>• Complete switching from all tobacco products to IQOS® after first trying IQOS®</li> </ul> <p>Transitions To/Back To Cigarette Smoking</p> <ul style="list-style-type: none"> <li>• Relapse to cigarette smoking after first trying IQOS® (among those who had smoked cigarettes, but had not smoked cigarettes for less than 12 months prior to first trying IQOS®)</li> <li>• Re-initiation of cigarette smoking after first trying IQOS® (among those who had smoked cigarettes, but had not smoked cigarettes for at least 12 months prior to first trying IQOS®)</li> </ul>
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	<ul style="list-style-type: none"> <li>• Initiation of established cigarette smoking after first trying IQOS® (among those who never smoked cigarettes prior to first trying IQOS®)</li> <li>• Complete switching from IQOS® to cigarette smoking after initiating tobacco use with IQOS® (among those who never used tobacco prior to first trying IQOS®)</li> </ul> <p>Quitting Behaviors</p> <ul style="list-style-type: none"> <li>• Past 12-month cigarette smoking quit attempt</li> <li>• Motivation to stop smoking cigarettes</li> <li>• Quitting cigarettes after first trying IQOS®</li> <li>• Quitting cigarettes for 12 months or longer after first trying IQOS®</li> <li>• Quitting all tobacco products after first trying IQOS®</li> <li>• Quitting all tobacco products for 12 months or longer after first trying IQOS®</li> <li>• Use of tobacco cessation treatments</li> <li>• Quitting IQOS®</li> <li>• Quitting IQOS® for 12 months or longer</li> </ul> <p><b>Characterization of study participants</b></p> <ul style="list-style-type: none"> <li>• Demographic, background, and health-related information</li> <li>• Length of time (i.e., years/months) using IQOS® and cigarettes</li> <li>• Cigarette and IQOS® dependence</li> <li>• Varieties of IQOS® ever used, first used, currently use, currently use most often, and previously used most often (among former established IQOS® users)</li> <li>• Variety of menthol vs. non-menthol cigarettes use</li> </ul> <p>Recruitment was carried out in the US. Philip Morris USA (PM USA) maintains a database of consumers who purchased the IQOS® device. This IQOS® Consumer Database was utilized to recruit IQOS® established users for this study.</p>
Statistical Methods	<p>All summaries of categorical data present sample sizes and percentages, and for continuous data sample sizes, means, standard deviations and medians were presented. Results were presented for the Total Study Sample and for current and former IQOS® users (as applicable and if sample size allowed for).</p> <p>Certain outcome measures were designed for former established IQOS® users and others for current established users only. Proportions or percentages were calculated along with the 95% confidence interval, means and medians along with the 95% confidence interval and quartiles.</p>

	<p>A variety of data quality checks were implemented to identify and flag records that contained forms of potential data falsification or missing data.</p> <p>The main analysis was conducted with the full dataset.</p>
Results	<p>Prior to October 13<sup>th</sup> when a letter was sent to IQOS<sup>®</sup> consumers informing them about IQOS<sup>®</sup> becoming unavailable in the US by November 29<sup>th</sup>, a total of (b)(4) individuals were invited to participate in the survey and (b)(4) completed the interview. The mean age of all current established IQOS<sup>®</sup> users was 44.93 years. Most current IQOS<sup>®</sup> users were in the age groups between 35 and 54, the proportion in the youngest age group (21-24 years) was only 1.59%. Most participants were White (72.89%), followed by Asian (14.35%), Hispanic/Latino (5.47%), and Black/African-American (4.78%).</p> <p>All current established IQOS<sup>®</sup> users had ever tried at least one tobacco product other than IQOS<sup>®</sup> and almost all (98.18%) had ever used at least one product consistently. Almost all current established IQOS<sup>®</sup> users stated that they had ever tried cigarettes (99.32%). Among current IQOS<sup>®</sup> users, the vast majority (93.39%) stated that cigarettes were the first product they ever tried, only one participant (0.23%) reported that IQOS<sup>®</sup> was the first product they ever tried. The proportion of exclusive IQOS<sup>®</sup> use was 35.08% (38.10% in the group of menthol HeatSticks<sup>®</sup> users and 31.73% for non-menthol HeatSticks<sup>®</sup> users). Concurrent use was most commonly reported for cigarettes (48.75%). Among dual users of cigarettes and IQOS<sup>®</sup>, around 49% of individuals preferred menthol HeatSticks<sup>®</sup> ) and 37.5% preferred menthol cigarettes. Approximately half (48.75%) of all current IQOS<sup>®</sup> users were current cigarette smokers, the other half (50.57%) were former cigarette smokers. Most IQOS<sup>®</sup> users had a medium addiction level (Heaviness of Smoking Index [HSI] score of 2-4). Almost one third (31.21%) of users switched completely from cigarettes after first trying IQOS<sup>®</sup>. Among dual users of IQOS<sup>®</sup> and cigarettes, most users (83.09%) stated that they used fewer cigarettes at the time of the survey than before they tried IQOS<sup>®</sup>.</p> <p>Among current IQOS<sup>®</sup> users who were also current cigarette smokers, the mean (SD [standard deviation]) composite score of the perceived risk of using IQOS<sup>®</sup> was 45.81 (15.73), the risk of smoking cigarettes was assessed with a higher composite score of 64.10 (14.95). Most users (80.87%) assessed the chemical exposure to be less when switching completely from cigarettes to IQOS<sup>®</sup>. Only a small proportion (4.78%) thought there was no exposure. When asked what smokers must do to reduce their chemical exposure, the majority (85.35%) thought they should stop smoking completely and only use IQOS<sup>®</sup>.</p> <p>Only a small proportion (2.16%) of ever established IQOS<sup>®</sup> users reported that they first tried IQOS<sup>®</sup> after not using any tobacco products for 12 months or longer, and 5.83% first tried IQOS<sup>®</sup> after not smoking cigarettes</p>

	<p>for 12 months or longer. Only one individual (0.22% of ever established IQOS® users) re-initiated cigarette smoking. None of the former smokers relapsed to cigarette smoking, and none of the never smokers initiated cigarette smoking after first trying IQOS®.</p> <p>Overall, more than half (55.24%) of current established IQOS® users who were also current cigarette smokers attempted to quit smoking in the past 12 months. Around half (51.71%) of current IQOS® users had never used tobacco cessation treatment, slightly less than a third (30.75%) had used tobacco cessation treatment more than 12 months ago. There was no major difference in tobacco cessation treatment use between all IQOS® users and those who switched completely from cigarettes to IQOS®.</p> <p>Among current users, 7.74% reported ever using IQOS® not as intended. Overall, results were similar between the group of IQOS® users who participated in the survey after receiving the information letter (available in post-text appendices) compared to users who participated before receiving the information letter..</p>
Discussion	<p>This study showed that the vast majority of current established IQOS® users have used other tobacco products on a consistent basis before IQOS® initiation. Approximately one in three current established IQOS® users switched to IQOS® from cigarettes. Initiation of IQOS® use among never users and former cigarette and tobacco users was low. Further, current IQOS® users have an appropriate risk perception of IQOS® compared to cigarettes as well as a correct comprehension of the IQOS® exposure claim. Most current IQOS® users (&gt;80%) were not using any tobacco cessation treatment. Taken together, results from this study suggest a great potential of IQOS® to switch cigarette smokers. However, to assess use trajectories over a longer time period, further research is needed.</p>

## 2 List of abbreviations

AE	Adverse Experience
ALCS	Altria Client Services
ATCD	Adult Tobacco Consumer Database
CASRO	Council of American Survey Research Organization
CRO	Contract Research Organization
ESOMAR	European Society for Opinion and Marketing Research
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
GEP	Good Epidemiological Practice
HSI	Heaviness of Smoking Index
ICF	Informed Consent Form
IQR	Interquartile Range
IRB	Institutional Review Board
MRTTP	Modified Risk Tobacco Product
MTSS	Motivation To Stop Scale
N	Number of observations
P	Low Statistical Preciseness
PACS	Postmarket Adult Consumer Study
PATH	Population Assessment of Tobacco and Health
PMP S.A.	Philip Morris Products S.A.
PMSS	Postmarket Surveillance and Studies
PRI-G	Perceived Risk Instrument for General risk assessment
S	Low Sample Size
SAP	Statistical Analysis Plan
SD	Standard Deviation
TLF	Tables, Listings, Figures
US	United States

### 3 Investigator(s)

Name: (b) (6)  
Function: Principal Investigator  
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Address: 601 E. Jackson Street  
Richmond, Virginia 23219  
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#### 4 Other responsible parties

The conduct of this study was outsourced to (b)(4), a Contract Research Organization (CRO).

Contact:

(b)(4)

## 5 Milestones

Milestone	Planned date	Actual date	Comments
Institutional Review Board (IRB) approval	03 August 2021	03 August 2021	
Start of data collection	01 September 2021	14 September 2021	
End of data collection	01 December 2021	15 November 2021	
Completion of Analyses	01 February 2022	10 January 2021	
Final report of study results (Wave 1)	01 April 2022	08 March 2022	

## 6 Rationale and background

Philip Morris Products S.A. (PMP S.A.) developed the IQOS<sup>®</sup> Tobacco Heating System and Marlboro HeatSticks<sup>®</sup> (hereinafter referred to as IQOS<sup>®</sup>) 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 (MRTP) Applications for IQOS<sup>®</sup> to the United States (US) 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<sup>®</sup> 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<sup>®</sup> pursuant to the orders.

The Federal Food, Drug and Cosmetic Act (FDCA) directs the FDA to condition an exposure modification order received under FDCA § 911(g)(2) on the MRTP applicants’ agreement to conduct PMSS (FDCA §§ 911(g)(2)(C)(ii)). “The outcomes evaluated in PMSS should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use”(1).

For this reason, Altria Client Services (ALCS)<sup>1</sup> on behalf of the applicant, PMP S.A., plans to conduct certain components of PMSS to assess the effect of the MRTP among US consumers. The program will consist of a collection of data over time that supports an assessment of IQOS<sup>®</sup> in the postmarket setting. The current study, IQOS<sup>®</sup> with Marlboro HeatSticks<sup>®</sup> Cross-sectional Postmarket Adult Consumer Study (IQOS<sup>®</sup> Cross-sectional PACS), is one such study.

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<sup>1</sup>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<sup>®</sup> in the US after FDA authorization. ALCS affiliate PM USA markets IQOS<sup>®</sup> in the US. 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.

## **7 Research question and objectives**

The purpose of the IQOS® Cross-sectional PACS was to provide survey data from qualified adult ever established IQOS® users to assess use and perceptions of the products and associations with other tobacco use behaviors.

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

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

## 8 Amendments and updates to the study protocol

Amendments and updates to the study protocol that occurred after the start of data collection are listed below:

Version of Protocol	Version Date	Modification(s) to the Protocol	Reason(s) for Modification(s)
(b)(4)	(b)(4)	(b)(4)	(b)(4)

(b)(4)



## 9 Research methods

### 9.1 Study design

This study was an online, cross-sectional survey planned for annual administration over the course of four years<sup>2</sup>. This report summarizes results from the first year (wave 1) of this study. The purpose of IQOS<sup>®</sup> cross-sectional PACS was to provide survey data from qualified adult ever established IQOS<sup>®</sup> users to assess use and perceptions of IQOS<sup>®</sup> products and associations with other tobacco use behaviors. Two computerized data collection instruments were used – a Participant Screener and Main Survey. All participants, regardless of recruiting mode, completed the same computerized surveys online.

Once a potential participant expressed interest in participating in the study and met initial qualifying criteria, he/she was provided the Informed Consent Statement, which included 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 completed 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 was verified to ensure that he/she met the inclusion criteria. Eligible participants were then presented with the "Main Survey," which collected the detailed study information to assess the study objectives.

Survey questions were designed to characterize patterns of tobacco use, risk perceptions, use of IQOS<sup>®</sup> not as intended, and behaviors associated with IQOS<sup>®</sup>. Most questions assessed outcomes at the brand level (i.e., IQOS<sup>®</sup> with Marlboro HeatSticks<sup>®</sup>), not at the variety level (i.e., Marlboro Amber HeatSticks<sup>®</sup>, Marlboro Green Menthol HeatSticks<sup>®</sup>, Marlboro Blue Menthol HeatSticks<sup>®</sup>). However, to help characterize use of individual IQOS<sup>®</sup> varieties, the survey also included certain questions specific to individual Marlboro HeatSticks<sup>®</sup> varieties, such as individual Marlboro HeatSticks<sup>®</sup> variety/varieties ever used, currently used, and currently used most often. This information was provided descriptively and estimates for certain outcomes were stratified by menthol vs. non-menthol (regular) HeatSticks use.

Checklist items were randomized. Skip logic was incorporated into surveys to reduce participant burden.

The IQOS<sup>®</sup> 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

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<sup>2</sup> The study was originally designed to be administered annually; however, IQOS<sup>®</sup> was no longer marketed in the US by 29<sup>th</sup> November 2021, and it is unclear whether or when IQOS<sup>®</sup> will be marketed again in the US. Therefore, it is uncertain whether future waves will be administered.

national surveys and items used in previous studies (2-4). Furthermore, Altria Client Services LLC commissioned cognitive testing of the study instrument in early 2020 and updated items when needed.

## 9.2 Setting

The survey was self-administered online. The duration of the study, from first participant in through last participant out, was approximately 9 weeks.

There were no study stimuli other than the survey questions. The Participant Screener and Main Survey included written descriptions of tobacco products, as well as tobacco product images and IQOS<sup>®</sup> product packaging to facilitate clarity and understanding.

Completion time for the Participant Screener and Main Survey together was approximately 20 minutes. The completion time varied depending on how many different tobacco products the participant reported having ever used.

During the first execution of the IQOS<sup>®</sup> Cross-sectional PACS, invitations to participate were sent to adult tobacco consumers enrolled in the IQOS<sup>®</sup> Consumer Database.

## 9.3 Study participants

### 9.3.1 Eligibility

Participants included ever established IQOS<sup>®</sup> users who were qualified adults 21 years of age or older (for definitions, see [Section 9.4.1](#)). Many outcome measures of interest (e.g., risk perceptions of IQOS<sup>®</sup>) were applicable to all ever established IQOS<sup>®</sup> users recruited into the study. However, some outcome measures (e.g., number of days used IQOS<sup>®</sup> in the past 30 days) were only applicable to current established IQOS<sup>®</sup> users, while others (e.g., quitting all tobacco products after first trying IQOS<sup>®</sup>) could only be assessed among former established IQOS<sup>®</sup> users. As a result, ever established IQOS<sup>®</sup> users included participants who have ever used at least 100 Marlboro HeatSticks<sup>®</sup> and consisted of current and former established IQOS<sup>®</sup> users.

**Ever established IQOS<sup>®</sup> users** were defined as adults who have ever used at least 100 Marlboro HeatSticks<sup>®</sup>. Ever established IQOS<sup>®</sup> users included the following two groups:

- **Current established IQOS<sup>®</sup> users:** Adult ever established IQOS<sup>®</sup> users who now use IQOS<sup>®</sup> “every day” or “some days”.
- **Former established IQOS<sup>®</sup> users:** Adult ever established IQOS<sup>®</sup> users who now use IQOS<sup>®</sup> “not at all.”



### 9.3.2 Inclusion criteria

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

1. US resident 21 years of age or older;
2. Voluntarily consent to serve as a participant in the study by electronically acknowledging an Informed Consent Statement, with approval or exemption determined by a qualified IRB;
3. Acknowledge willingness and ability to comply with all study requirements as listed in the Informed Consent Form (ICF);
4. Meet criteria for inclusion as a current or former established IQOS<sup>®</sup> user (i.e., an individual who has used at least 100 Marlboro HeatSticks<sup>®</sup> in lifetime by the time of enrollment).

### 9.3.3 Exclusion criteria

Participants who met any of the following exclusion criteria did not qualify for the study:

1. Unable to read, speak or understand English;
2. Potential participant is a current or former employee or has a first-degree relative (e.g., parent, spouse, sibling, child) or household member who is a current or former employee of the tobacco industry;
3. Potential participant is a current or former employee or has a first-degree relative (e.g., parent, spouse, sibling, child) or household member who is a current or former employee of (b)(4);
4. Potential participant, a first-degree relative (e.g., parent, spouse, sibling, child) or anyone in his or her household is involved in litigation (e.g., as a named party or class representative) with any company involved in the tobacco industry;
5. Potential participant, if recruited from the IQOS<sup>®</sup> database, had participated in a prior wave of Cross-sectional IQOS<sup>®</sup> PACS study.

## 9.4 Outcome variables

### 9.4.1 Definitions

Terms are arranged in alphabetic order. Italicized parts of definitions have their own definition in this section.

#### 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 US.

(b)(4)

(b)(4)

(b)(4)

Thus, collectively, ALCS developed 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<sup>3</sup> 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®.

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<sup>3</sup> This includes regular cigars, cigarillos, and little filtered cigars.

## 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®.

### 9.4.2 Outcome Variables for objective 1 - Use patterns

*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®?*

▪ Types of tobacco products ever tried, used to lifetime criterion, and currently using:

Percentages and counts of ever established IQOS® users, current established IQOS® users, and former established IQOS® users who reported:

- Ever trying a tobacco product
- Meeting the lifetime criteria for use of a tobacco product (numeric criterion or consistent basis, as applicable)
- Current use of tobacco product

▪ Types of tobacco products ever tried, used to lifetime criterion, and were currently using prior to first trying IQOS®:

Percentages and counts of ever established IQOS® users, current established IQOS® users, and former established IQOS® users who reported:

- Ever trying a tobacco product prior to first trying IQOS®
- Meeting the lifetime criteria for use of a tobacco product (numeric criterion or consistent basis, as applicable) prior to first trying IQOS®
- Current use of tobacco product prior to first trying IQOS®

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

▪ Exclusive and dual/poly tobacco use with IQOS®:

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

- IQOS<sup>®</sup> only
- IQOS<sup>®</sup> plus one other tobacco product
  - IQOS<sup>®</sup> and cigarettes
  - IQOS<sup>®</sup> and one other tobacco product, excluding cigarettes
- IQOS<sup>®</sup> plus two or more other tobacco products
  - IQOS<sup>®</sup> and two or more other tobacco products, including cigarettes
  - IQOS<sup>®</sup> and two or more other tobacco products, excluding cigarettes

Estimates were generated for menthol and non-menthol HeatStick<sup>®</sup> users. Among dual users of IQOS<sup>®</sup> and cigarettes, estimates were further stratified by menthol and non-menthol cigarette use.

*How often and how much do current established IQOS<sup>®</sup> users use IQOS<sup>®</sup>? How often and how much do ever established IQOS<sup>®</sup> users smoke cigarettes?*

- Number of days of use of IQOS<sup>®</sup> and cigarettes in past 30 days:
  - Number of days of use was reported in categories using percentages, in addition to means (standard deviations) and medians (interquartile range, IQR) for number of days used IQOS<sup>®</sup> in the past 30 days (among current established IQOS<sup>®</sup> users)
  - Number of days of use was reported in categories using percentages, in addition to means (standard deviations) and medians (interquartile range, IQR) for number of days used cigarettes in the past 30 days by current and former established IQOS<sup>®</sup> users (among individuals who are currently using cigarettes “every day” or “some days”)

Outcomes for IQOS<sup>®</sup> use were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference.

- Amount of Marlboro HeatSticks<sup>®</sup> and cigarettes in past 30 days:
  - Medians and IQR for number of Marlboro HeatSticks<sup>®</sup> used on days used in past 30 days (among current established IQOS<sup>®</sup> users)
  - Medians and IQR for number of cigarettes smoked on days used in past 30 days (among individuals currently smoking cigarettes “every day” or “some days”)
  - Medians and IQR for number of Marlboro HeatSticks<sup>®</sup> used per day in past 30 days (among current established IQOS<sup>®</sup> users)
  - Medians and IQR for number of cigarettes smoked per day in past 30 days (among individuals currently smoking cigarettes “every day” or “some days”)

Outcomes for IQOS<sup>®</sup> use were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference.

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

- Amount of tobacco product use before trying IQOS® relative to current tobacco product use:
  - Percentages and counts of current established tobacco product users reporting that they used 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

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

- Description of IQOS® use not as intended among ever established IQOS® users, current established IQOS® users, and former established IQOS® users:
  - Percentage and count citing ever use of a Marlboro HeatStick® without using the IQOS® device
  - Percentage and count of how used Marlboro HeatStick® without using the IQOS® device
  - Percentages and count reporting that they ever used a Marlboro HeatStick® without using the IQOS® device only once, sometimes, most of the time, or all the time (for each way it was used without the device)
  - Percentage and count citing ever use of the IQOS® device with a product other than a Marlboro HeatStick®
  - Percentages and count reporting that they ever used the IQOS® device with a product other than a Marlboro HeatStick® only once, sometimes, most of the time, or all the time
  - Ever use of IQOS® not as intended (i.e., any of above)

#### **9.4.3 Outcome Variables for objective 2 –Risk perceptions of IQOS®**

To assess participants' risk perceptions of IQOS®, the following outcomes were assessed.

*What are ever established IQOS® users' risk perceptions of IQOS® and cigarettes?*

- Risk perceptions were collected through the Perceived Risk Instrument for general risk assessment (PRI-G)<sup>4</sup> (5). Items were constructed based on a literature review, focus

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<sup>4</sup> PRI-G was chosen instead of PRI for personal risk assessment (PRI-P) in order to be able to measure risk perceptions of cigarette smoking and IQOS® use among all participants irrespective of respondent's current use status.

groups and expert opinion, and scales were developed and assessed through two US-based web surveys. The resulting 18-item scale contained psychometrically valid measures capable of measuring health risk perceptions for different types of tobacco products and various levels of smoking status. The risk perceptions module included items assessing the perception of health risk to the average users of IQOS®/cigarettes in general.

- Range (min/max), mean, standard deviation, median, and interquartile range of the PRI-G Health risk composite score of IQOS® and cigarettes among all ever established IQOS® users, current established IQOS® users who were current smokers, current established IQOS® users who are long-term former smokers, and former established IQOS® users.

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

- Perception of harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS®:
  - Percentages and counts of ever established IQOS® users, current established IQOS® users, and former established IQOS® users who perceived the level of change in exposure when switching completely from cigarettes to IQOS® (among all participants).
- Understanding of what smokers must do to reduce harmful or potentially harmful chemical exposure:
  - Percentages and counts of current established IQOS® users who responded to each behavioral response item (among participants who identified 'less exposure' when switching completely from cigarettes to IQOS®).

#### **9.4.4 Outcome Variables for objective 3 – Initiation, complete switching to IQOS®, transitions to/back to cigarette smoking, and quitting behaviors relevant to IQOS® use**

##### **9.4.4.1 Initiation, complete switching**

##### **Initiation of Tobacco Use with IQOS®**

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

Two measures of initiation based on measures described in the related scientific literature were adopted. These measures pertained to 1) any use of a tobacco product (4), as represented by the first tobacco product ever used, and 2) the first regular use of a tobacco product (6), as represented by the first tobacco product ever used on a consistent basis.

- Percentage and count of ever established IQOS® users, current established IQOS® users, and former established IQOS® users who reported IQOS® as the first tobacco



product that they ever tried vs. cigarettes or another one of the listed tobacco products (i.e., first tobacco product ever tried).

- Percentage and count of ever established IQOS<sup>®</sup> users, current established IQOS<sup>®</sup> users, and former established IQOS<sup>®</sup> users who reported IQOS<sup>®</sup> as the first tobacco product that they ever used on a consistent basis vs. cigarettes or another one of the listed tobacco products. (i.e., first tobacco product ever used on a consistent basis).

#### **Initiation of IQOS<sup>®</sup> as long-term former smokers and long-term former tobacco users**

*What percentage of ever established IQOS<sup>®</sup> users first tried IQOS<sup>®</sup> after not smoking cigarettes for 12 months or longer?*

- Percentage and count of ever established IQOS<sup>®</sup> users, current established IQOS<sup>®</sup> users, and former established IQOS<sup>®</sup> users who reported that they had smoked at least 100 cigarettes and had not smoked cigarettes for 12 months or longer prior to first trying IQOS<sup>®</sup> (i.e., “First trial of IQOS<sup>®</sup> after not smoking cigarettes for 12 months or longer”).

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

- Percentage and count of ever established IQOS<sup>®</sup> users, current established IQOS<sup>®</sup> users, and former established IQOS<sup>®</sup> users who reported that they had 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<sup>®</sup> (i.e., “First trial of IQOS<sup>®</sup> after not using any tobacco products for 12 months or longer”).

#### **Complete Switching from Cigarette Smoking/All Tobacco to IQOS<sup>®</sup>**

*What percentage of current established IQOS<sup>®</sup> users switched from cigarettes to IQOS<sup>®</sup>?*

- Percentage and count of current IQOS<sup>®</sup> established users who reported that they had smoked at least 100 cigarettes, were smoking cigarettes during the 30 days before first trying IQOS<sup>®</sup> and became former smokers after first trying IQOS<sup>®</sup> (i.e., “Complete switching from cigarettes to IQOS<sup>®</sup> after first trying IQOS<sup>®</sup>”), regardless of other tobacco product use.

*What percentage of current established IQOS<sup>®</sup> users switched from all tobacco products to IQOS<sup>®</sup>?*

- Percentage and count of current IQOS<sup>®</sup> established users who reported that they 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<sup>®</sup>, and became former users of all other tobacco products after first trying IQOS<sup>®</sup> (i.e., “Complete switching from all tobacco products to IQOS<sup>®</sup> after first trying IQOS<sup>®</sup>”).



#### 9.4.4.2 Transitions to/back to cigarette smoking

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

*What percentage of ever established IQOS® users relapse to cigarette smoking after trying IQOS®?*

- Percentage and count of ever established IQOS® users who had smoked at least 100 cigarettes and had not smoked for less than 12 months prior to first using IQOS® and were currently smoking cigarettes “every day” or “some days” (i.e., “Relapse to cigarette smoking after first trying IQOS®”).

##### Re-initiation of Cigarette Smoking after First Trying IQOS®

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

- Percentage and count of ever established IQOS® users who reported that they had smoked at least 100 cigarettes and had not smoked for 12 months or longer prior to first trying IQOS® and were currently smoking cigarettes “every day” or “some days” (i.e., “Re-initiation of cigarette smoking after first trying IQOS®”).

##### Initiation of Established Cigarette Smoking after First Trying IQOS®

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

- Percentage and count of ever established IQOS® users who reported that they had never smoked prior to first using IQOS® and had smoked at least 100 cigarettes prior to the assessment. (i.e., “Initiation of cigarette smoking after first trying IQOS®”).

##### Complete Switching from IQOS® to Cigarette Smoking

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

- Percentage and count of ever established IQOS® users who reported that IQOS® was the first tobacco product ever tried, “not at all” use IQOS®, and smoked cigarettes “every day” or “some days” at the time of the report, and had smoked at least 100 cigarettes (i.e., “Complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS®”).

#### 9.4.4.3 Quitting behaviors

To further describe the participants regarding quitting, several quitting-related measures were assessed:

## Quit Attempts and Trying to Quit Cigarette Smoking

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

- Past 12-month quit attempts:
  - Percentage and count of current established cigarette smokers who reported that they stopped smoking cigarettes for more than one day in the past 12 months because they were trying to quit smoking among current and former established IQOS® users.
- Motivation to stop smoking cigarettes:
  - Percentage and count of current established cigarette smokers to each response option in the Motivation to Stop Scale among current and former established IQOS® users.

Motivation to stop smoking was assessed through the Motivation to Stop Scale (MTSS) (7).

## Quitting Cigarette Smoking After First Trying IQOS®

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

- Percentage and count of ever established cigarette smokers who quit smoking cigarettes among current established IQOS® users.
- Percentage and count of ever established cigarette smokers who quit smoking cigarettes for 12 months or longer among current established IQOS® users.

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

- Percentage and count of ever established cigarette smokers who quit smoking cigarettes among former established IQOS® users.
- Percentage and count of ever established cigarette smokers who quit smoking cigarettes for 12 months or longer among former established IQOS® users.

## Quitting All Tobacco After First Trying IQOS®

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

- Percentage and count of former established IQOS® users who reported quitting all tobacco products after first trying IQOS® (i.e., Quitting all tobacco products after first trying IQOS®).
- Percentage and count of former established IQOS® users who reported 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®).

## **Tobacco Cessation Treatment Use History among Ever Established IQOS® Users**

*Tobacco cessation treatment use:*

Among current and former IQOS® established users:

- Percentage and count of ever use but not past 12 months of tobacco cessation treatments.
- Percentage and count of past 12 month but not current use of tobacco cessation treatments.
- Percentage and count of current use of tobacco cessation treatments.

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

Among current IQOS® established users who reported that they 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:

- Percentage and count of ever use but not past 12 months of tobacco cessation treatments.
- Percentage and count of past 12 month but not current use of tobacco cessation treatments.
- Percentage and count of current use of tobacco cessation treatments.

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

Among current IQOS® established users who reported that they 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 other tobacco products after first trying IQOS® (i.e., “Complete switching from all tobacco products to IQOS® after first trying IQOS®”):

- Percentage and count of ever use but not past 12 months of tobacco cessation treatments.
- Percentage and count of past 12 month but not current use of tobacco cessation treatments.
- Percentage and count of current use of tobacco cessation treatments.

## **Quitting IQOS®**

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

- Percentage and count of ever established IQOS<sup>®</sup> users who reported that they quit IQOS<sup>®</sup> (i.e., “Quitting IQOS<sup>®</sup>”).
- Percentage and count of ever established IQOS<sup>®</sup> users who reported that they quit IQOS<sup>®</sup> for 12 months or longer (i.e., “Quitting IQOS<sup>®</sup> for 12 months or longer”).

Estimates for outcomes under objective 3 were provided for menthol (including smooth menthol and fresh menthol) vs. non-menthol (regular) HeatStick<sup>®</sup> users as well as menthol vs. non-menthol cigarette users when applicable and when sample size allowed.

**The following information was included to characterize study participants:**

Demographic, background, and health-related information

- Sex
- Age
- Race
- Ethnicity
- Education
- Income
- Employment status
- Region
- Marital status
- Pregnancy status
- Presence of pre-existing medical condition(s) or comorbidities
- Presence of mental illness
- LGBTQ status
- Military personnel/veteran status
- Length of time using IQOS<sup>®</sup> and cigarettes
  - Means (standard deviations) and medians (IQR) for length of time current established IQOS<sup>®</sup> users report using IQOS<sup>®</sup> and current established cigarette smokers report smoking cigarettes, as applicable
- Cigarette and IQOS<sup>®</sup> dependence
  - Medians (IQR) and counts and percentages of Heaviness of Smoking Index (HSI) score categories for HSI among current established smokers and corresponding statistics for IQOS<sup>®</sup> among current established IQOS<sup>®</sup> users

- Varieties of Marlboro HeatStick<sup>®</sup> (i.e., Marlboro HeatSticks<sup>®</sup> or Marlboro Amber HeatSticks<sup>®</sup>; Marlboro Green Menthol HeatSticks<sup>®</sup> or Marlboro Smooth Menthol HeatSticks<sup>®</sup>; Marlboro Blue Menthol HeatSticks<sup>®</sup> or Marlboro Fresh Menthol HeatSticks<sup>®</sup>) ever used, first used, currently used, currently used most often, and previously used most often (among former established IQOS<sup>®</sup> users)
  - Percentages and counts of individual Marlboro HeatStick<sup>®</sup> variety/varieties ever tried
  - Percentages and counts of first Marlboro HeatStick<sup>®</sup> variety ever tried
  - Percentages and counts of individual Marlboro HeatStick<sup>®</sup> variety/varieties currently being used (among current established IQOS<sup>®</sup> users)
  - Percentages and counts of individual Marlboro HeatStick<sup>®</sup> variety/varieties currently being used most often (among current established IQOS<sup>®</sup> users)
  - Percentages and counts of individual Marlboro HeatStick<sup>®</sup> variety/varieties previously used most often (among former established IQOS<sup>®</sup> users)
- Varieties of menthol vs. non-menthol cigarette used
  - Percentages and counts of menthol vs. non-menthol cigarette currently using most often among ever established cigarette smokers
  - Percentages and counts of menthol vs. non-menthol cigarette formerly using most often among former established cigarette smokers

## 9.5 Data sources

Recruitment was carried out in the US. All qualified participants who completed the survey had the opportunity to receive a \$40 e-card incentive, whereby (b)(4) participants obtained incentives. Philip Morris USA (PM USA), the company that has been granted license from Philip Morris Products S.A. (PMP S.A.) to distribute, market and sell IQOS<sup>®</sup> in the US, maintained a database of consumers who purchased the IQOS<sup>®</sup> device. This IQOS<sup>®</sup> Consumer Database, which covered approximately 70% of IQOS<sup>®</sup> users in the US, was utilized to recruit IQOS<sup>®</sup> established users for the first annual execution of the study.

Participants were informed that their participation was completely voluntary, and they could choose not to participate or to discontinue their participation at any time for any reason. They were also informed that refusal to participate involved no penalty or loss of benefits to which the participant was otherwise entitled.

The number of qualified adult ever established IQOS<sup>®</sup> users who consented to participate and then prematurely discontinued the survey before completion was recorded.

Premature discontinuation of participation could happen for any of the following reasons:

1. withdrawal of informed consent (participant's decision to withdraw at any time for any reason);
2. failure to comply with study procedures or other protocol requirements;
3. termination of an individual's participation by (b)(4); or
4. termination of the study by the sponsor.

Details on data sources were provided in Protocol Section 5 ([Annex 1](#)).

### 9.5.1 Adverse experience reporting

As this study was observational and conducted on a consumer population using marketed products, it was conducted in compliance with Good Epidemiological Practice (GEP). Adverse Experience (AE) reporting followed ALCS' established consumer research procedure for spontaneously reported AEs. No AEs were reported.

The survey explicitly asked for use of IQOS® not as intended (see Section [9.4.2](#)).

### 9.5.2 Study timeline

The data collection for this survey was conducted between 14<sup>th</sup> September and 15<sup>th</sup> November 2021. Details on the planned study timeline are provided in Protocol Section 5.2 ([Annex 1](#)).

## 9.6 Bias

To prevent multiple surveys per participant, each individual received a unique user ID. This user ID could be entered into the survey to create a unique survey link. If a participant only partially completed the survey, they were able to return to it, but once either the survey was submitted or the participant was screened out, the link could not be re-used.

## 9.7 Sample size

A total of (b)(4) established IQOS® users completed the survey. On 13<sup>th</sup> October 2021 an information letter was sent to all invited individuals, stating that IQOS® will be unavailable for sale in the US as of 29<sup>th</sup> November 2021. Therefore, the sample was split in pre- and post-information letter groups as it could not be ruled out that the communication had impact on the use behavior of current IQOS® users. This report focuses on the individuals who completed the survey before 13<sup>th</sup> October, including (b)(4) current established IQOS® users and (b)(4) former IQOS® users. Therefore, the desired sample size of (b)(4) was achieved for current IQOS® users, but the minimum sample size of (b)(4) was not achieved for former IQOS® users. Details on sample size calculations for categorical and continuous data are provided in SAP Section 3.2 ([Annex 1](#)).

## **9.8 Data transformation**

Certain survey questions allowed participants to provide an answer other than what was pre-listed in the response set. These verbatim responses were 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 were “up-coded”; 2) responses provided that could not be “up-coded” were categorized and frequency of these responses was evaluated. Responses with a frequency beyond 5% were assigned a code, and the coded responses were analyzed and reported as part of the response set for that question. Responses with frequencies below 5% were reported as “other.”

## **9.9 Statistical methods**

### **9.9.1 Main summary measures**

The data was analyzed and reported descriptively, primarily using percentages, means, standard deviations and medians. The output tables were prepared using the statistical software SAS Version 9.4 (Statistical Analysis System, SAS Institute Inc., Cary, North Carolina, US).

### **9.9.2 Main statistical methods**

#### **9.9.2.1 General statistical considerations**

All summaries of categorical data presented sample sizes and percentages for the Total Study Sample (as applicable) and for current and former IQOS® users. All summaries of continuous data presented sample sizes, means, standard deviations and medians for the Total Study Sample (as applicable) and for current and former IQOS® users.

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

#### **9.9.2.2 Analysis sets**

The main analysis was conducted with the full dataset.

Certain outcome measures were designed for former established IQOS® users and others for current established users only. The outcome measures were organized by objectives and research questions.

When proportions or percentages were calculated for an outcome measure, they were reported along with the 95% confidence interval. When means and medians were calculated for an outcome measure, they were reported along with the 95% confidence interval and quartiles.



### 9.9.2.3 Analysis variables

#### 9.9.2.3.1 Analysis of objective 1 – Use pattern

*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

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

- Ever trying tobacco product
- Meeting the lifetime criteria for use of tobacco product (numeric criterion or consistent basis, as applicable)
- Current use of tobacco product

**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®

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

- Ever trying tobacco product prior to first trying IQOS®
- Meeting the lifetime criteria for use of tobacco product (numeric criterion or consistent basis prior to first trying IQOS®, as applicable)
- Current use of tobacco product 30 days prior to first trying IQOS®

**Summary Statistics:** Percentages and counts

*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®

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

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



- IQOS<sup>®</sup> plus two or more other tobacco products
  - IQOS<sup>®</sup> and two or more other tobacco products, including cigarettes
  - IQOS<sup>®</sup> and two or more other tobacco products, excluding cigarettes

**Summary Statistics:** Percentages and counts

- ii. Outcome Measure: menthol and non-menthol HeatStick<sup>®</sup> and cigarette Use among dual users of IQOS<sup>®</sup> and Cigarettes

Among current established IQOS<sup>®</sup> users who were current established cigarette smokers:

- Preference of menthol cigarettes

These outcomes were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference. Among dual users of IQOS<sup>®</sup> and cigarettes, estimates were further stratified by menthol vs. non-menthol cigarette use.

*3. How often and how much do current established IQOS<sup>®</sup> users use IQOS<sup>®</sup>? How often and how much do ever established IQOS<sup>®</sup> users smoke cigarettes?*

- i. Outcome Measure: Number of days of use of IQOS<sup>®</sup> and cigarettes in past 30 days
  - Number of days used IQOS<sup>®</sup> in the past 30 days (among current established IQOS<sup>®</sup> users)
  - Number of days used cigarettes in the past 30 days by current and former established IQOS<sup>®</sup> users (among individuals who are currently smoking cigarettes “every day” or “some days”)

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

Outcomes for IQOS<sup>®</sup> use were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference.

- ii. Outcome Measure: Amount of Marlboro HeatSticks<sup>®</sup> and cigarette use in past 30 days
  - Number of IQOS<sup>®</sup> Marlboro HeatSticks<sup>®</sup> used on days used in past 30 days (among current established IQOS<sup>®</sup> users)
  - Number of cigarettes smoked on days used in past 30 days (among individuals currently smoking “every day” or “some days”)

**Summary Statistics** (only for IQOS<sup>®</sup> Marlboro HeatSticks<sup>®</sup>): Medians and interquartile range for number/times each listed tobacco product used on days used

Outcomes for IQOS<sup>®</sup> use were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference.

- iii. Outcome Measure: Number of HeatSticks<sup>®</sup> per day in past 30 days

The number of HeatSticks<sup>®</sup> per day was calculated using the following formula:

$$\frac{(\text{HeatSticks}^{\text{®}} \text{ used per day on days used in the past 30 days} \times \text{Days used in the past 30 days})}{\div 30}$$

For HeatSticks<sup>®</sup> per day calculation, a response of “<1” was coded as 1, and a response of “>50” was coded as 80<sup>5</sup>.

- Number of HeatSticks<sup>®</sup> per day in past 30 days (among current established IQOS<sup>®</sup> users) (Table 4)

**Summary Statistics:** Medians and interquartile range

Outcomes for IQOS<sup>®</sup> use were stratified by menthol vs. non-menthol HeatStick<sup>®</sup> preference.

*4. How does current tobacco product consumption compare to consumption before trying IQOS<sup>®</sup>?*

- Outcome Measure: Amount of tobacco product use before trying IQOS<sup>®</sup> relative to current tobacco product use

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<sup>®</sup> compared to the amount currently used per day

**Summary Statistics:** Percentages and counts

*5. What percentage of ever established IQOS<sup>®</sup> users report ever use of IQOS<sup>®</sup> not as intended?*

- Outcome Measure: Use of IQOS<sup>®</sup> not as intended

Ever established IQOS<sup>®</sup> users, current established IQOS<sup>®</sup> users and former established IQOS<sup>®</sup> users reporting:

- Ever use of an IQOS<sup>®</sup> Marlboro HeatStick<sup>®</sup> without using the IQOS<sup>®</sup> device/how used without using device
- Ever use of an IQOS<sup>®</sup> Marlboro HeatStick<sup>®</sup> without using the IQOS<sup>®</sup> device only once, sometimes, most of the time, or all the time (for each way in which the IQOS<sup>®</sup> Marlboro HeatStick<sup>®</sup> was ever used without using the IQOS<sup>®</sup> device)

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<sup>5</sup> Based on data from PATH adult wave 4 data, the median number of cigarettes smoked per day is 80 among the (b)(4) individuals who reported smoking more than 50 cigarettes per day.

- Ever use of the IQOS® device with a product other than a Marlboro HeatStick®
- 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
- Ever use of IQOS® not as intended

**Summary Statistics:** Percentages and counts

9.9.2.3.2 Analysis of objective 2 – Risk perceptions

*1. What are ever established IQOS® users' risk perceptions of IQOS®?*

- Outcome Measure: General Risk to Health – IQOS® and cigarettes

**Summary Statistics:** 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 were current smokers, current established IQOS® users who were long-term former smokers, and former established IQOS® users, range (minimum/maximum), means, standard deviations, medians, and interquartile ranges.

Computation of mean risk:  $\bar{x} = (\sum x)/n$

Where x = item scores and n = total participants.

For the computation of mean risk only participants will be considered with no “Don’t know” response in any of the 18 items.

*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®

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®

**Summary Statistics:** Percentages and counts

- Outcome Measure: Understanding of what smokers had to do to reduce harmful or potentially harmful chemical exposure

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 about what smokers had to do to reduce their exposure to harmful or potentially harmful chemicals (among participants)

**Summary Statistics:** Percentages and counts

9.9.2.3.3 Analysis of objective 3 - Initiation, complete switching to IQOS<sup>®</sup>, transitions to/back to cigarette smoking, and quitting behaviors relevant to IQOS<sup>®</sup> use

9.9.2.3.3.1 *Initiation, complete switching*

1. *What percentage of ever established IQOS<sup>®</sup> users initiated tobacco use with IQOS?*

i. Outcome Measure: Initiation

Among ever established IQOS<sup>®</sup> users, current established IQOS<sup>®</sup> users, and former established IQOS<sup>®</sup> users:

- IQOS<sup>®</sup> as the first tobacco product that they ever tried vs. cigarettes or another one of the listed tobacco products
- IQOS<sup>®</sup> as the first tobacco product that they ever used on a consistent basis vs. cigarettes or another one of the listed tobacco products

**Summary Statistics:** Percentages and counts

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

i. Outcome Measure: Initiation of IQOS<sup>®</sup> as long-term former established users of all tobacco products

Among ever established IQOS<sup>®</sup> users:

- Had 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<sup>®</sup> (i.e., “First trial of IQOS<sup>®</sup> after not using any tobacco products for 12 months or longer”)

**Summary Statistics:** Percentages and counts

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

Among ever established IQOS<sup>®</sup> users:

- Had smoked at least 100 cigarettes and had not smoked cigarettes for 12 months or longer prior to first trying IQOS<sup>®</sup> (i.e., “First trial of IQOS<sup>®</sup> after not smoking cigarettes for 12 months or longer”)

**Summary Statistics:** Percentages and counts

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®

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
- 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®”)

**Summary Statistics:** Percentages and counts

9.9.2.3.3.2 *Transitions to/back to cigarette smoking*

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®

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®”)

**Summary Statistics:** Percentages and counts

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

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 were currently smoking cigarettes “every day” or “some days” (i.e., “Re-initiation of cigarette smoking after first trying IQOS®”)

**Summary Statistics:** Percentages and counts

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®

Among ever established IQOS® users:

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

**Summary Statistics:** Percentages and counts

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

- Outcome Measure: Complete switching from IQOS® to established smoking after initiating tobacco use with IQOS®

Among former established IQOS® users:

- That IQOS® was the first tobacco product ever tried, had smoked at least 100 cigarettes, and smoked cigarettes “every day” or “some days” at the time of the report (i.e., “Complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS®”)

**Summary Statistics:** Percentages and counts

9.9.2.3.3.3 *Quitting behaviors*

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

- Outcome Measure: Past 12-month quit attempts

Among current established IQOS® users and former established IQOS® users who were 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

**Summary Statistics:** Percentages and counts

- Outcome Measure: Motivation to stop

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

- Distribution of motivation to stop responses

**Summary Statistics:** Percentages and counts

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

- Outcome Measure: Quit smoking after first trying IQOS®

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

- Completely quitting smoking cigarettes after first trying IQOS® (i.e., “Quitting cigarettes after first trying IQOS®”)
- 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®”)

**Summary Statistics:** Percentages and counts

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

- i. Outcome Measure: Quit smoking after first trying IQOS®

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

- Completely quitting smoking cigarettes after first trying IQOS® (i.e., “Quitting cigarettes after first trying IQOS®”)
- 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®”)

**Summary Statistics:** Percentages and counts

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

- i. Outcome Measure: Quitting after first trying IQOS®

Among former established IQOS® users:

- Completely quitting all tobacco products after first trying IQOS® (i.e., “Quitting all tobacco products after first trying IQOS®”)
- 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®”)

**Summary Statistics:** Percentages and counts

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

- i. Outcome Measure: Tobacco cessation treatment use

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

- Distribution of recency of tobacco cessation treatment use

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

- i. Outcome Measure: Tobacco cessation treatment use



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

- Distribution of recency of tobacco cessation treatment use

7. *Tobacco cessation treatment use among current established IQOS<sup>®</sup> users switched from all tobacco products to IQOS<sup>®</sup>*

- i. Outcome Measure: Tobacco cessation treatment use

Among current IQOS<sup>®</sup> established users who reported that they 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<sup>®</sup> and became former users after first trying IQOS<sup>®</sup> (i.e., “Complete switching from all tobacco products to IQOS<sup>®</sup> after first trying IQOS<sup>®</sup>”):

- Distribution of recency of tobacco cessation treatment use

8. *What percentage of ever established IQOS<sup>®</sup> users quit using IQOS<sup>®</sup>/quit using IQOS<sup>®</sup> for 12 months or longer?*

- i. Outcome Measure: Quitting IQOS<sup>®</sup>

Among ever established IQOS<sup>®</sup> users:

- Quitting IQOS<sup>®</sup> (i.e., “Quitting IQOS<sup>®</sup>”)
- Completely quitting IQOS<sup>®</sup> for 12 months or longer (i.e., “Quitting IQOS<sup>®</sup> for 12 months or longer”)

**Summary Statistics:** Percentages and counts

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

**9.9.2.4 Additional data summaries**

9.9.2.4.1 Demographics, background, and health-related information

Ever established IQOS<sup>®</sup> users were characterized by:

- Sex (percentages and counts)
- Age (percentages, means, medians, ranges, and standard deviations)



- Race (percentages and counts)
- Ethnicity (percentages and counts)
- Education (percentages and counts)
- Employment Status (percentages and counts)
- Region (percentages and counts)
- Income (percentages and counts)
- Marital status (percentages and counts)
- Pregnancy status (percentages and counts)
- Presence of pre-existing medical condition(s) or comorbidities (percentages and counts)
- Presence of mental illness (percentages and counts)
- LGBTQ status (percentages and counts)
- Military personnel/veteran status (percentages and counts)
- Length of time using IQOS<sup>®</sup> and cigarettes, as applicable (means, medians, and standard deviations)
  - Length of time current established IQOS<sup>®</sup> users reported using IQOS<sup>®</sup>
  - Length of time current established cigarette smokers reported smoking cigarettes
- Cigarette and IQOS<sup>®</sup> dependence

HSI was calculated based on the following two questions (8):

1. How soon after you wake up do you use your first IQOS<sup>®</sup>/smoke your first cigarette?
  - 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<sup>®</sup>, how many Marlboro HeatSticks<sup>®</sup> 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?<sup>6</sup>

- A. 10 or fewer (0 points)
- B. 11-20 (1 point)
- C. 21-30 (2 points)
- D. 31 or more (3 points)

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

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

- i. HSI score for IQOS<sup>®</sup> among current established IQOS<sup>®</sup> users
  - HSI score for IQOS<sup>®</sup> among current established IQOS<sup>®</sup> users who were current established cigarette smokers
  - HSI score for IQOS<sup>®</sup> among current established IQOS<sup>®</sup> users who were former established smokers
- ii. HSI score for cigarette smoking among current established cigarette smokers<sup>7</sup>
  - HSI score for cigarette smoking among current established smokers who were current established IQOS<sup>®</sup> users
  - HSI score for cigarette smoking among current established smokers who were former established IQOS<sup>®</sup> users
- Varieties of IQOS<sup>®</sup> (i.e., Marlboro HeatSticks<sup>®</sup>, Marlboro Smooth Menthol HeatSticks<sup>®</sup>, Marlboro Fresh Menthol HeatSticks<sup>®</sup>) ever used, first used, currently use, currently use most often, and previously used most often (among former established IQOS<sup>®</sup> users) (percentages and counts)
  - Individual Marlboro HeatStick<sup>®</sup> variety/varieties ever tried
  - First Marlboro HeatStick<sup>®</sup> variety ever tried
  - Individual Marlboro HeatStick<sup>®</sup> variety/varieties currently being used (among current established IQOS<sup>®</sup> users)

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<sup>6</sup> For cigarettes, different answer categories were used: Less than 1 or 1; 2 -19; 20 – 49; 50 – 99; 100 or more.

<sup>7</sup> HSI score for cigarette smoking was not calculated as for the second question about the number of smoked cigarettes different answer categories were used.

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

Statistics reported: Descriptive statistics

#### 9.9.2.4.2 Participation proportions

- 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)
- Eligibility proportion:
  - Number of persons eligible for enrollment (i.e., persons who met all inclusion criteria and no exclusion criteria) divided by the total number of persons screened for eligibility
- Completion proportion:
  - Number of completed interviews divided by the number of attempted interviews (completed plus partial)
- Response proportion:
  - Number of completed interviews divided by the number of invitations sent

#### 9.9.3 Missing values

As this was an electronic survey, which required completion of questions for the survey to be submitted, missing data were not expected. However, missing data were encountered for some questions with “Don’t know” answer categories and the respective percentages were included in the tables.

#### 9.9.4 Sensitivity analysis

The main analysis was conducted with the full dataset and sensitivity analyses were conducted without the flagged responses (if applicable) to determine if the potentially invalid data substantially influenced the results. These sensitivity analyses were performed to assess the robustness of the results with the exclusion of flagged data. For the first wave, no data were excluded and thus no sensitivity analysis was performed

### **9.9.5 Amendments to the statistical analysis plan**

The SAP was updated to adapt categories for number of cigarettes smoked per day, calculation of number of cigarettes per day in past 30 days, and cigarette dependence. In addition, for the computation of mean risk only participants were considered with no “Don’t know” response in any of the 18 items. For Table 3 in the Tables, Listings, and Figures (TLF) the outcome measure menthol and non-menthol HeatStick<sup>®</sup> and cigarette use among dual users of IQOS<sup>®</sup> and cigarettes was calculated for all current established users of IQOS<sup>®</sup> and cigarettes, regardless of other tobacco product use, in addition to participants who exclusively use IQOS<sup>®</sup> and cigarettes. Additionally, “Stroke” was included as a category for “Health-Related Information”.

### **9.10 Quality control**

#### **9.10.1 Study performance evaluation**

##### **9.10.1.1 Overview**

Survey development, testing, and evaluation were viewed as iterative processes that frequently entailed examining the performance of the survey instruments (9). The full report of the survey performance evaluation was provided under separate cover.

##### **9.10.1.2 Examination of survey administration meta-data**

The survey administration meta-data file contained the number of seconds a participant took to complete each question across the entire survey, including both the Participant Screener and Main Survey. Survey administration meta-data (e.g., the average and fastest survey completion time among participants) were examined for irregularities to identify issues associated with how participants engaged with the survey.

Further details are provided in SAP Section 6.2 ([Annex 1](#)).

##### **9.10.1.3 Data quality checks and treatment of outliers**

A variety of data quality checks were implemented to identify and flag records that contained forms of potential data falsification or missing data. These records were examined to understand their influence on study results and for possible exclusion from analysis. Data falsification types included “speeding,” nondifferentiation, and gibberish/nonsensical verbatim response. No participants were removed.

Further details are provided in SAP Section 6.3 ([Annex 1](#)).

The questionnaire was designed to minimize outliers by defining ranges for numeric responses. For example, cigarettes smoked per day had a minimum of ‘<1’ and a maximum of ‘more than 50,’ and the number of days used in the past 30 days could only range from 0 to 30. Therefore, outliers were not expected.

### 9.10.2 Data validation

Survey logic was incorporated into the survey instrument to preclude inconsistent responses to separate measures. Clarification probes and redirects could be incorporated, as needed. Various checks were performed to ensure the accuracy, integrity, and validity of the data. These included quality checking the survey instrument program logic before and after study launch to ensure that the data were collected as specified in the study protocol.

After performing data quality checks, no participants were removed from the data set.

Representatives of ALCS periodically assessed data quality and study integrity. This was accomplished through telephone and email exchanges with Cerner Enviza (formerly Kantar Health), which was carried out on an ongoing basis throughout study planning, execution, and reporting.

### 9.10.3 Survey response database lock

On completion of the study, after data collection has been deemed complete, the survey response database was locked on 15<sup>th</sup> November 2021, and data was no longer subject to change.

### 9.10.4 Data transfer of study results

Study data were electronically transferred by (b)(4) to ALCS on 07<sup>th</sup> March 2022. Data transferred to ALCS did not include any participant personal identification information.

### 9.10.5 Data handling

All data collected during the study were declared property of ALCS, irrespective of the location of the data and any vendor contributing to the study.

### 9.10.6 Protection of human subjects

This study did not involve intervention. Therefore, the risks presented to the participant were minimal. Nevertheless, study conduct followed the principles set forth by the Belmont Report and, where applicable, guidelines established under 21 CFR Parts 50 and 56.

(b)(4) submitted a new study application to (b)(4) IRB on 19<sup>th</sup> July 2021. The submission included a request for waiver of documentation of informed consent, the study protocol, recruitment materials, and the study instrument (which includes the ICF). An application for the investigator was submitted to the IRB for (b)(4) on 22<sup>nd</sup> July 2021. The (b)(4) determined that the study met the guidelines for Expedited Review and provided comments to Cerner Enviza (formerly Kantar Health) on 20<sup>th</sup> July 2021. The ICF was updated per the IRB's request to change the compensation language from blue font to black font, and to include the statement, "The study investigator receives compensation from the sponsor for activities unrelated to this

study. This compensation is not related to the outcome of the study. If you have any concerns about this financial relationship, please ask the research staff.” The recruitment materials were updated per the IRB’s request to unbold the compensation amount, so compensation was not emphasized. The study staff also updated the recruitment materials to include images before resubmitting the updated documents to the IRB on 30<sup>th</sup> July 2021. (b)(4) approved the study and (b)(4) as Principal Investigator on 3<sup>rd</sup> August 2021. No amendments were submitted to the IRB for this study. The IRB approval letter is provided in [Annex 1](#).

This study was conducted in compliance with the study protocol and, where applicable, in accordance with the Guidelines for GEP (IEA, 2007), Council of American Survey Research Organization’s (CASRO) Code of Standards and Ethics (CASRO, 2016), and the International Chamber of Commerce/European Society for Opinion and Marketing Research’s (ESOMAR) International Code on Market and Social Research (ESOMAR, 2016). Freely given informed consent was obtained from every participant. Participants electronically consented to participate in the study by clicking a box next to the word “Agree” at the end of the Informed Consent Statement.

The rights, safety and well-being of the participants were the most important considerations. Study personnel involved in conducting this study were qualified by education, training, and experience to perform their respective task(s).

Study staff were to fully inform the participant of all pertinent aspects of the study and of any new information relevant to the participant’s willingness to continue participation in the study. Study staff documented this communication. Participants had the ability to call/email study staff with any study-related questions.

#### **9.10.7 Study records**

Participants were identified in any reports by study participant identification numbers only (not full participant names). All data were captured via a secure data collection system. All data were captured in real time through a web-enabled portal and all responses were time and date stamped. All electronic records were stored in a secure survey response database with access restricted only to those individuals requiring it. (b)(4) (b)(4) maintained all study-related records, including recruitment and screening information and study data, for the term of the contract under which the study was conducted and for at least four years after the issuance of the final study report, or sponsor designated length of time.

## 10 Results

### 10.1 Participants

Surveys were completed between 14<sup>th</sup> September and 15<sup>th</sup> November 2021. Information on the study sample is shown in [Table 1](#).

A total of 18,764 individuals were initially invited to participate in the survey. Along with a reminder sent on 12<sup>th</sup> October 2021, an additional 494 individuals were invited for study participation. On 13<sup>th</sup> October 2021 an information letter was sent to all invited individuals, stating that IQOS® will be unavailable for sale in the US as of 29<sup>th</sup> November 2021. Therefore, the sample was split in pre- and post-information letter groups as it could not be ruled out that the communication had impact on the use behavior of current IQOS® users. Therefore, this report focuses on the pre-information letter group. Results for the full study sample are provided in [Annex 1](#), TLF\_Full, and for the post-information letter group in [Annex 1](#), TLF\_Post.

**Table 1: Response rate**

	Total		14 <sup>th</sup> September through 13 <sup>th</sup> October		14 <sup>th</sup> October through 15 <sup>th</sup> November	
	n	%	n	%	n	%
Number of individuals invited*	(b)(4)					
Number of individuals without any response						
Number of individuals who clicked the link						
Number of individuals who had an incomplete screener						
Number of individuals who were not eligible						
Number of individuals who successfully completed the screener						
Number of individuals who had an incomplete survey						
Number of overall completed surveys						
Current users						
Former users						

\*A reminder was sent to all individuals who were initially invited on 12<sup>th</sup> October 2021. An additional sample of (b)(4) was invited for study participation at this timepoint.  
n: Number of observations

Overall, (b)(4) were invited to participate in the survey. Of those, (b)(4) (10.5%) clicked the link, (b)(4) successfully completed the screener, and (b)(4) completed the survey, which equals to 3.6% of invitations sent out. Of those who clicked the link, about half (b)(4) 51%) were not eligible for the survey, and approximately a third (b)(4), 35%) did not complete the screener.

Until 13<sup>th</sup> October 2021 (pre-information letter), 7.1% of the individuals invited to participate in the survey clicked the link. The screener was completed by (b)(4) and the overall interview was successfully completed by (b)(4), which equals to 2.5% of invitations sent out.

After 13<sup>th</sup> October 2021 (post-information letter), the proportion of individuals who clicked the link was slightly lower, at 3.9% of invitations sent out. Consequently, the proportion of individuals who completed the screener and the overall interview was also lower, at 1.3%, which resulted in (b)(4) completed questionnaires.

Around three quarters (total sample: 74.6%, pre-information letter: 76.4%, post-information letter: 71.7%) of screen failures were due to respondents using less than 100 HeatSticks®.

Please note that, due to low participant numbers, outcomes for the subgroup of former IQOS® users are not shown. The results for this subgroup are available in [Annex 1](#), TLF\_Full, TLF\_Pre, and TLF\_Post.

10.2 Descriptive data

Demographics and background information of current established IQOS® users can be found in [Table 2](#).

Table 2: Demographics and background information of current IQOS® users

Measure	Current Established IQOS® Users	Current Established IQOS® Users Who Prefer Menthol HeatSticks	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks
Base (Total Participants)	(b)(4)	(b)(4)	(b)(4)
Gender [% (95% CI)]	(b)(4)		
Male			
Female			



Measure	Current Established IQOS® Users	Current Established IQOS® Users Who Prefer Menthol HeatSticks	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks
<b>Age [% (95% CI)]</b>	<b>(b)(4)</b>		
21 - 24			
25 - 34			
35 - 44			
45 - 54			
55 - 64			
65+			
<b>Mean Age [years (95% CI)]</b>			
Standard Deviation [years]			
Median Age [years (25% quartile, 75% quartile)]			
<b>Race/Ethnicity [% (95% CI)]</b>			
White/Caucasian, non- Hispanic			
Black/African-American, non-Hispanic			
Hispanic/Latino			
Asian, non-Hispanic			
Native Hawaiian or other Pacific Islander, non- Hispanic			
American Indian or Alaska Native, non-Hispanic			
Other, non-Hispanic			
<b>Household Income [% (95% Under \$60,000 (Net)</b>			
Under \$20,000			
\$20,000 - \$29,999			
\$30,000 - \$39,999			
\$40,000 - \$49,999			
\$50,000 - \$59,999			

Measure	Current Established IQOS® Users	Current Established IQOS® Users Who Prefer Menthol HeatSticks	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks
<b>\$60,000 or More (Net)</b>	<b>(b)(4)</b>		
\$60,000 - \$74,999			
\$75,000 - \$99,999			
\$100,000 - \$149,999			
\$150,000 and over			
Prefer not to answer			
<b>Education [% (95% CI)]</b>			
<b>High School or Less (Net)</b>			
Never attended school or only attended kindergarten			
Grades 1 through 8			
Grades 9 through 12 (no diploma)			
High School Graduate (or equivalent/GED)			
<b>Some College or More (Net)</b>			
Some college (1-4 years, no degree)			
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			

Measure	Current Established IQOS® Users	Current Established IQOS® Users Who Prefer Menthol HeatSticks	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks
<b>Employment Status [% (95% CI)]</b>			
<b>Employed (Net)</b>	<b>(b)(4)</b>		
Employed for wages			
Self-employed			
<b>Not Employed (Net)</b>			
Out of work for more than 1 year			
Out of work for less than 1 year			
A homemaker			
A student			
Retired			
Unable to work			

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 18

Overall, a higher proportion of current IQOS® users were male vs. female (59.91% vs. 40.09%). This proportion was similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®. The mean age of all current users was 44.93 years. Most current IQOS® users were in the age groups between 35 and 54, the proportion in the youngest age group (21-24 years) was only 1.59%. Current established users who preferred menthol HeatSticks® tended to be younger compared to those who preferred non-menthol HeatSticks® (43.16 years vs. 46.89 years.” Most participants were White (72.89%), followed by Asian (14.35%), Hispanic/Latino (5.47%), and Black/African-American (4.78%). Among users of menthol HeatSticks® the proportion of Asian participants was notably higher compared to non-menthol HeatSticks® (21.65% vs. 6.25%, respectively), while the proportion of White participants was lower (64.50% vs. 82.21%, respectively).

The household income was \$60,000 or more for most participants (60.59%). Most participants had some college education or more (78.82%), whereby a quarter of participants had a master’s degree (26.20%), and another quarter went to college for 1-4 years with no degree (25.51%). Most participants were employed for wages (65.15%), 19.36% were not employed, and 15.49% were self-employed. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®.

Almost all current users were from the South of the US (99.77%)<sup>8</sup>. Around half of the participants were married (54.90%), followed by never married (17.31%) and divorced (15.03%). Less than 1% of females (1 participant) aged between 21-49 years reported being pregnant or currently nursing. Most users were heterosexual (87.47%), followed by lesbian or gay (5.24%). Most users never served in the military (87.47%), while 8.43% were on active duty in the past, but not now. These proportions were similar for users of menthol HeatSticks<sup>®</sup> compared to users of non-menthol HeatSticks<sup>®</sup> ([Annex 1](#), TLF\_Pre, Table 18).

When asked about their health-related information, more than half (54.44%) of participants stated they have never had any of the conditions assessed. The most common diagnosis was hypertension (22.55%), followed by hyperlipidemia (20.50%), asthma (10.48%), diabetes (7.29%), and sleep apnea (6.38%). The proportions of other conditions were below 5%. Around a quarter (27.56%) of current IQOS<sup>®</sup> users stated they had a mental health condition, whereby 18.79% of current IQOS<sup>®</sup> users were taking medication or receiving treatment for a mental health condition ([Annex 1](#), TLF\_Pre, Table 19).

### 10.3 Outcome data

The main outcome for characterization of IQOS<sup>®</sup> users and tobacco use patterns is described in [Section 10.4.1](#), for risk perception in [Section 10.4.2](#). Initiation, switching, transitions, and quitting behaviors can be found in [Section 10.4.3](#).

## 10.4 Main results

### 10.4.1 Tobacco use patterns

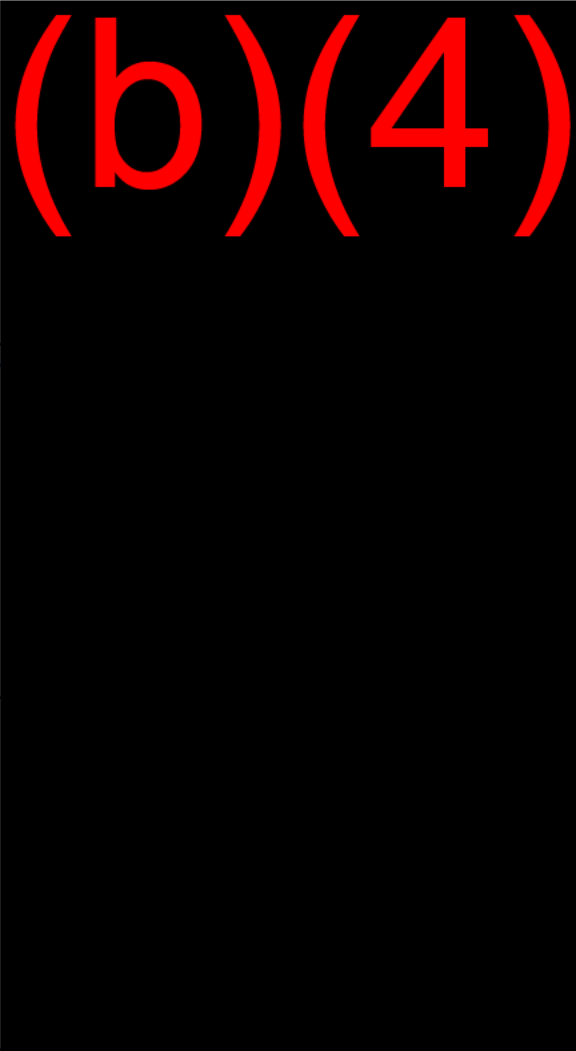
#### 10.4.1.1 Types of tobacco products used

The types of tobacco products that current IQOS<sup>®</sup> users ever tried, used, and were currently using, at the time of the survey and prior to trying IQOS<sup>®</sup>, are presented in [Table 3](#).

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<sup>8</sup> Please note that at the time of this study IQOS<sup>®</sup> was marketed only in selected regions of the US.

**Table 3: Types of tobacco products ever tried, used to lifetime criterion, and currently using, among current IQOS® users**

Measure	Types of tobacco products ever tried, used, and currently using at the time of the survey % (95% CI)	Types of tobacco products tried, used, and currently using 30 days prior to trying IQOS® % (95% CI)
Base (Total Participants)	(b)(4)	(b)(4)
<b>Ever tried</b>		
Cigarettes		
Cigars*		
Pipe filled with tobacco		
Hookah		
E-vapor products		
Smokeless tobacco		
Oral tobacco-derived nicotine products		
Any tobacco**		
<b>Ever used to lifetime criterion (numeric criterion)</b>		
Cigarettes		
Cigars*		
Pipe filled with tobacco		
Hookah		
E-vapor products		
Smokeless tobacco		
Oral tobacco-derived nicotine products		
Any tobacco**		
<b>Current use</b>		
Cigarettes		
Cigars*		
Pipe filled with tobacco		
Hookah		
E-vapor products		
Smokeless tobacco		
Oral tobacco-derived nicotine products		
Any tobacco**		

\* This includes regular cigars, cigarillos, and little filtered cigars

\*\* This refers to any tobacco product other than IQOS®

CI: Confidence Interval, n: Number of observations

Source: [Annex 1](#), TLF\_Pre, Table 1 and Table 2

All current established IQOS® users had ever tried at least one tobacco product and almost all had ever used at least one product to the lifetime criterion at the time of the survey (98.18%) or prior to IQOS® initiation (96.13%). Almost all current IQOS® users stated that

they had ever tried cigarettes (99.32%). Around two thirds of users had tried e-vapor products (72.21%) and cigars<sup>9</sup> (63.78%), less than one third had tried hookah (31.89%), smokeless tobacco (25.74%), pipe filled with tobacco (20.73%), and oral tobacco-derived nicotine products (20.05%). When asked about ever tobacco usage on a consistent basis, the vast majority of current IQOS<sup>®</sup> users stated that they had used cigarettes (96.58%), followed by e-vapor products (44.65%), cigars<sup>9</sup> (20.73%), and smokeless tobacco (15.03%).

The proportions of tobacco products ever tried or used on a consistent basis prior to trying IQOS<sup>®</sup> were similar in all categories, indicating that the vast majority of users tried or used these products before trying IQOS<sup>®</sup>.

Current use at the time of the survey was most commonly reported for cigarettes (48.75%), followed by e-vapor products (20.05%), and cigars<sup>9</sup> (13.90%). Around two thirds (64.92%) of users reported that they were using at least one other tobacco product in addition to IQOS<sup>®</sup> at the time of the survey. During the 30 days prior to trying IQOS<sup>®</sup> most users reported cigarette use (91.57%), followed by e-vapor products (29.61%) and cigars<sup>9</sup> (15.72%). The vast majority (95.22%) reported using any tobacco product prior to trying IQOS<sup>®</sup>.

At the time of the survey, approximately half (48.75%) of all current IQOS<sup>®</sup> users were current cigarette smokers, the other half (50.57%) were former cigarette smokers. Only 0.68% were never cigarette smokers. All current IQOS<sup>®</sup> users (100.00%), however, had tried any tobacco other than IQOS<sup>®</sup>. Preference for menthol vs. non-menthol cigarettes was largely consistent with preference for menthol vs. non-menthol HeatSticks<sup>®</sup> ([Annex 1](#), TLF\_Pre, Table 24).

#### 10.4.1.2 Exclusive and dual/poly tobacco use

Information on exclusive use of IQOS<sup>®</sup> and on dual or poly tobacco product use is presented in [Table 4](#).

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<sup>9</sup> This includes regular cigars, cigarillos, and little filtered cigars.

**Table 4: Exclusive and dual/poly tobacco use**

Measure	Current Established IQOS® Users % (95% CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (95% CI)
<b>Current use at the time of the survey ('every day' or 'some days') of:</b>			
Base (Total Participants)	(b)(4)	(b)(4)	(b)(4)
IQOS® only	(b)(4)		
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			
<b>Among Current Dual Users of IQOS® and cigarettes</b>			
Base (Dual users of IQOS® and cigarettes only)	(b)(4)	(b)(4)	(b)(4)
Menthol cigarette preference	(b)(4)		
Non-Menthol cigarette preference			
Unknown			
Refused to answer			
Base (Dual users of IQOS® and cigarettes regardless of other tobacco products)			
Menthol cigarette preference			
Non-Menthol cigarette preference			
Unknown			
Refused to answer			

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: Annex 1, TLF\_Pre, Table 3

Around a third (35.08%) of current users stated that they were exclusively using IQOS®. In the group of menthol HeatSticks® users this proportion was 38.10% and 31.73% for non-



menthol HeatSticks<sup>®</sup> users. Use of IQOS<sup>®</sup> plus one other tobacco product was reported by 42.60% of current users, mainly for cigarettes (29.16%). Slightly more than 20% of users (22.32%) used IQOS<sup>®</sup> plus two or more other tobacco products, mainly including cigarettes. These proportions were similar for users of menthol HeatSticks<sup>®</sup> compared to users of non-menthol HeatSticks<sup>®</sup>.

Among current dual users of IQOS<sup>®</sup> and cigarettes only, the majority (73.02%) of IQOS<sup>®</sup> users who preferred menthol HeatSticks<sup>®</sup> stated that they preferred menthol cigarettes, and the vast majority (95.38%) of IQOS<sup>®</sup> users who preferred non-menthol HeatSticks<sup>®</sup> stated that they preferred non-menthol cigarettes. Among current dual users IQOS<sup>®</sup> and cigarettes (regardless of other products), around 94% of menthol cigarette smokers preferred menthol HeatSticks<sup>®</sup>, and about 79% of non-menthol cigarette smokers preferred non-menthol HeatSticks<sup>®</sup>. Among dual users of cigarettes and IQOS<sup>®</sup> only, a slightly larger proportion of individuals preferred menthol HeatSticks<sup>®</sup> (b)(4), around 49%) compared to the proportion that preferred menthol cigarettes (37.50%). These proportions were similar for current dual users of IQOS<sup>®</sup> and cigarettes regardless of other tobacco products.

10.4.1.3 Frequency of IQOS<sup>®</sup>/Cigarette use

The number of days participants had used IQOS<sup>®</sup> in the past 30 days, as well as the number of HeatSticks<sup>®</sup> participants had used per day in the past 30 days, are shown in Table 5.

Table 5: Number of days participants used IQOS<sup>®</sup> in past 30 days and number of IQOS<sup>®</sup> Marlboro HeatSticks<sup>®</sup> used in past 30 days

Measure	Current Established IQOS <sup>®</sup> Users % (95% CI)	Current Established IQOS <sup>®</sup> Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS <sup>®</sup> Users Who Prefer non-Menthol HeatSticks % (95% CI)
Base (Total Participants)	(b)(4)	(b)(4)	(b)(4)
During the past 30 days, on how many days did you use IQOS <sup>®</sup> with Marlboro HeatSticks?			
0 days	(b)(4)		
1 - 2 days			
3 - 5 days			
6 - 9 days			
10 - 14 days			
15 - 19 days			
20 - 24 days			
25 - 29 days			
30 days			



Measure	Current Established IQOS® Users % (95% CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (95% CI)
<b>Mean number of days used</b>	<b>(b)(4)</b>		
Standard deviation of days used			
<b>Median number of days used</b> (25% quartile, 75% quartile)			
Min/Max			
<b>During the past 30 days, on many Marlboro HeatSticks®</b>			
Missing			
Less than 1			
1			
2			
3			
4			
5-9			
10-14			
15-19			
20+			
<b>Median number of HeatSticks® per day on days used</b> (25% quartile, 75% quartile)			
IQR			
<b>Median number of HeatSticks® per day in the past 30 days</b> (25% quartile, 75% quartile)			
IQR			

CI: Confidence Interval, IQR: Interquartile Range, Max: Maximum, Min: Minimum, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 4

During the past 30 days, more than two thirds (70.39%) of users stated that they had used IQOS® daily, and an additional 15.72% stated that they had used IQOS® almost daily (20-29 days). The mean (SD [standard deviation]) number of days was 26.23 (7.16) days (median: 30 days). When asked about the number of HeatSticks® used on those days, the most common response was 20 or more (38.72%), followed by 10-14 (23.01%) and 15-19

(15.03%). The median number of HeatSticks® per day on days used was 15. These values were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®.

The nicotine dependence of IQOS® users was assessed via the two questions “How soon after you wake up do you use your first IQOS®?” and “During the past 30 days, on the days you used IQOS®, how many Marlboro HeatSticks® did you use per day, on average?”. The answers to these questions are summarized via the HSI score, shown in Table 6.

Table 6: IQOS® dependence

Measure	Current Established IQOS® Users % (95% CI)	
	Former Established Cigarette Smokers	Current Established Cigarette Smokers
<b>Heaviness of Smoking Index (HSI) - IQOS®</b>		
0 - 1	(b)(4)	(b)(4)
2 - 4	(b)(4)	(b)(4)
5 - 6	(b)(4)	(b)(4)
<b>Median HSI Score</b> (25% quartile, 75% quartile)	(b)(4)	(b)(4)
<b>IQR</b>	(b)(4)	(b)(4)

CI: Confidence Interval, HSI: Heaviness of smoking index, IQR: Interquartile range, n: Number of observations

Source: Annex 1, TLF\_Pre, Table 21

Most IQOS® users had a HSI score of 2-4 (53.81% of current cigarette smokers, 60.28% of former cigarette smokers), which is considered a medium degree of addiction, followed by 0-1 (36.19% of current cigarette smokers, 24.77% of former cigarette smokers), representing low degree of addiction. A high degree of addiction to IQOS® (HSI score 5-6) was reported by lower proportions (10.00% of current cigarette smokers, 14.95% of former cigarettes smokers). Former cigarette smokers had a median HSI score of 3, while current cigarette smokers had a median HSI score of 2.

The number of days current IQOS® users had smoked cigarettes in the past 30 days, as well as the number of cigarettes they had smoked in the past 30 days, are shown in Table 7.

**Table 7: Number of days participants smoked cigarettes in past 30 days and numbers of cigarettes smoked in past 30 days**

Measure	Current Established IQOS® Users % (95% CI)
Base (Current cigarette smokers)	(b)(4)
<b>During the past 30 days, on how many days did you smoke cigarettes?</b>	<b>(b)(4)</b>
0 days	
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 (25% quartile, 75% quartile)	
Min/Max	
<b>During the past 30 days, on the days you smoked cigarettes, how many cigarettes did you smoke per day, on average?</b>	
Less than 1 or 1	
2 - 19	
20 - 49	
50 - 99	
100 or more	
<b>How soon after you wake up do you smoke your first cigarette?</b>	
Within 5 minutes	
6 – 30 minutes	
31 – 60 minutes	
After 60 minutes	

CI: Confidence Interval, Max: Maximum, Min: Minimum, n: Number of observations, P: Low Statistical Preciseness

Source: Annex 1, TLF\_Pre, Table 5 and Table 22

During the past 30 days, less than half of current IQOS® users who were also current cigarette smokers stated that they used cigarettes on 30 days (48.13%), followed by 20-24 days (8.88%), 6-9 days (7.48%), and 3-5 days (7.01%). The mean (SD) number of days they used cigarettes was 20.53 (11.07) days (median: 28 days). On these days, more than two thirds of users smoked on average 2-19 cigarettes (68.22%), and around one fifth

smoked 20 or more cigarettes. Around a third of users stated that they smoked their first cigarettes within 6-30 minutes after waking up (33.81%), followed by within 5 minutes after waking up (26.67%) and after 60 minutes (23.33%).

#### 10.4.1.4 Change in tobacco use behavior

The change in use behavior of other tobacco products among current IQOS® users is shown in Table 8.

**Table 8: Amount of tobacco product use 30 days before trying IQOS® relative to current tobacco product use**

Measure	Current Established IQOS® Users % (95% CI)
Base (Established Users of Each Tobacco Product 30 days Before Trying IQOS®)	
<b>Cigarettes</b>	(b)(4)
Now smoke fewer cigarettes per day	(b)(4)
Now smoke more cigarettes per day	
Smoke the same number of cigarettes per day now as I did then	
<b>Cigars*</b>	
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	
<b>E-vapor Products</b>	
Now use E-vapor products on fewer occasions per day	
Now use E-vapor products on more occasions per day	
Use the E-vapor products on the same number of occasions per day now as I did then	

\*This includes regular cigars, cigarillos, and little filtered cigars

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: Annex 1, TLF\_Pre, Table 6

When asked about their change in tobacco use behavior, most IQOS® users who currently smoked cigarettes at the time of the survey (83.09%) stated that they used fewer cigarettes now than before they tried IQOS®. Slightly more than half (56.76%) stated that they now use fewer cigars<sup>10</sup>, while slightly less than half (43.24%) smoked the same number of cigars<sup>10</sup> per day. Most users (68.25%) also used fewer e-vapor products per day. For users of pipe, hookah, smokeless tobacco and oral tobacco-derived nicotine products, the sample size was too small for meaningful calculations (Annex 1, TLF\_Pre, Table 6).

<sup>10</sup> This includes regular cigars, cigarillos, and little filtered cigars.

10.4.1.5 Use of IQOS® not as intended

Details on use of IQOS® not as intended are shown in Table 9.

Table 9: Use of IQOS® not as intended

Measure	Current Established IQOS® Users % (95% CI)
Base (Total Participants)	(b)(4)
Ever use of IQOS® not as intended	(b)(4)
Ever Use of IQOS® Marlboro HeatStick® without using IQOS® Device	
Lit up the HeatStick® like a cigarette	
Used the HeatStick® with another device	
Some other way	
Used IQOS® Device with a product other than an IQOS® Marlboro HeatStick®	

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness  
Source: Annex 1, TLF\_Pre, Table 7

Among current users, 7.74% reported ever using IQOS® not as intended. The most common mode of unintended use was using the IQOS® device with a product other than an IQOS® Marlboro HeatStick® (4.10%), followed by lighting the HeatStick® like a cigarette (3.42%). Due to the low sample size of unintended use of IQOS®, the frequency of unintended use is not presented (Annex 1, TLF\_Pre, Table 7).

10.4.1.6 Length of time using IQOS® and Cigarettes

Current established IQOS® users had been using IQOS® for a mean (SD) time of 1.13 (0.81) years (median: 0.92 years). Those users who were also current cigarette smokers had been smoking cigarettes for 23.22 (12.04) years (median: 22.04 years). Those who were former cigarette smokers had been smoking cigarettes for 21.35 (11.99) years (median: 20.00 years) (Annex 1, TLF\_Pre, Table 20).

10.4.2 Risk perceptions

Participants were asked to assess the risk to cigarette smokers and the risk to IQOS® users on developing 18 health conditions, such as having a bad cough, poor gum health, and lung cancer, on a 5-point scale (where 1 = no risk, 5 = very high risk). The scores for all these health conditions were summarized as a composite score (maximum score of 90), shown in Table 10.

**Table 10: Risk perceptions - IQOS® and cigarettes**

Measure	Current Established IQOS® Users/Current Cigarette Smokers	Current Established IQOS® Users/Long-Term Former Smokers
Base (Total Participants)	(b)(4)	(b)(4)
<b>IQOS®</b>	<b>(b)(4)</b>	
Mean Composite Score (95% CI)		
Standard Deviation		
Median (25% quartile, 75% quartile)		
IQR		
Min/Max		
Missing		
<b>Cigarettes</b>		
Mean Composite Score (95% CI)		
Standard Deviation		
Median (25% quartile, 75% quartile)		
IQR		
Min/Max		
Missing		

\*Risk perception composite score was only calculated for those users who provided a risk assessment for each item

CI: Confidence Interval, IQR: Interquartile Range, Max: Maximum, Min: Minimum, n: Number of observations

Source: [Annex 1](#), TLF\_Pre, Table 8

Among current IQOS® users who were also current cigarette smokers, the mean (SD) composite score of the risk of using IQOS® was 45.81 (15.73) (median: 41). This was similar for current IQOS® users who were former cigarette smokers. The risk of smoking cigarettes was assessed with a higher composite score of 64.10 (14.95) (median: 64) by current IQOS® users who were also current cigarette smokers. For current IQOS® users who were former cigarette smokers the composite score was 68.64 (16.13) (median: 71).

Details on perceptions about chemical exposure reduction with IQOS® are shown in [Table 11](#).



**Table 11: Perceptions about IQOS® related to MRTP messages**

Measure	Current Established IQOS® Users % (95% CI)
Base (all respondents)	(b)(4)
<b>Perception about harmful or potentially harmful chemical exposure when switching completely from cigarettes to IQOS®</b>	
More exposure	(b)(4)
The same exposure	
Less exposure	
No exposure	
Don't know	
<b>Understanding of what smokers must do to reduce their exposure to harmful chemicals</b>	
Base (respondents who identified 'less exposure')	(b)(4)
Stop smoking completely and only use IQOS®	
Smoke fewer cigarettes and also use IQOS®	
Keep smoking the same amount of cigarettes and also use IQOS®	
Don't know	

CI: Confidence Interval, MRTP: Modified Risk Tobacco Product, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 9

The majority of users (80.87%) assessed the chemical exposure to be less when switching completely from cigarettes to IQOS®. Notably smaller proportions thought IQOS® posed the same exposure (8.88%) or no exposure (4.78%) to harmful or potentially harmful chemicals. When asked what smokers must do to reduce their chemical exposure, the majority (85.35%) thought they should stop smoking completely and only use IQOS®. A smaller proportion (7.89%) thought they should smoke fewer cigarettes and also use IQOS®.

### 10.4.3 Initiation, switching, transitions, and quitting behaviors

#### 10.4.3.1 Initiation of IQOS® and complete switching to IQOS®

Information on the first tobacco product ever tried and the first tobacco product ever used on a consistent basis among current established IQOS® users is shown in [Table 12](#).

**Table 12: Initiation – first tobacco product ever tried and first tobacco product ever used on a consistent basis**

Measure	Current Established IQOS® Users % (95% CI)
Base (Total Participants)	(b)(4)
<b>What was the FIRST product that you EVER tried EVEN ONE TIME?</b>	
Missing	(b)(4)
IQOS®	
Cigarettes	
Cigars*	
Pipe filled with tobacco	
Hookah	
E-vapor products	
Smokeless tobacco	
Oral tobacco-derived nicotine products	
Other tobacco product	
<b>What was the FIRST product that you EVER used on a CONSISTENT BASIS?</b>	
Missing	
IQOS®	
Cigarettes	
Cigars*	
Pipe filled with tobacco	
Hookah	
E-vapor products	
Smokeless tobacco	
Oral tobacco-derived nicotine products	
Other tobacco product	

\* This includes regular cigars, cigarillos, and little filtered cigars

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 10

Among current IQOS® users, the vast majority (93.39%) stated that cigarettes were the first product they ever tried, only a small proportion stated smokeless tobacco (2.96%). Only one participant (0.23%) stated that IQOS® was the first product they ever tried. The vast majority (92.48%) also stated that cigarettes were the first product they used on a consistent basis, and 4.10% stated it to be IQOS®. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks® ([Annex 1](#), TLF\_Pre, Table 10).



Participants were asked whether they first tried IQOS® after not using cigarettes or any tobacco product for 12 months or longer. The proportions of ever established IQOS® users who initiated IQOS® after formerly using other tobacco products are shown in Table 13.

**Table 13: Initiation of IQOS® among long-term former established smokers and long-term former established users of all tobacco products**

Measure	Ever Established IQOS® Users % (95% CI)	Ever Established IQOS® Users Who Prefer(red) Menthol HeatSticks % (95% CI)	Ever Established IQOS® Users Who Prefer(red) non-Menthol HeatSticks % (95% CI)
Base (Total Participants)	(b)(4)	(b)(4)	(b)(4)
First trial of IQOS® after not using any tobacco products for 12 months or longer	(b)(4)		
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			

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: Annex 1, TLF\_Pre, Table 11

Only a small proportion (2.16%) of ever established IQOS® users stated that they first tried IQOS® after not using any tobacco products for 12 months or longer, and 5.83% of them first tried IQOS® after not smoking cigarettes for 12 months or longer. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®.

The proportions of current IQOS® users who completely switched to IQOS® after first trying it are shown in Table 14.

**Table 14: Complete switching to IQOS® after first trying IQOS®**

Measure	Current Established IQOS® Users % (95% CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS® Users Who Prefer non-Menthol HeatSticks % (95% CI)
Base (Total Participants)	<b>(b)(4)</b>		
Complete switching from all tobacco products to IQOS® after first trying IQOS®			
Complete switching from cigarettes to IQOS® after first trying IQOS®			
Base (Established smokers who smoked during the past 30 days prior to trying IQOS® and prefer(red) menthol cigarettes)			
Complete switching from menthol cigarettes to IQOS® after first trying IQOS®			
Complete switching from menthol cigarettes to IQOS® menthol HeatSticks® after first trying IQOS®			
Complete switching from menthol cigarettes to IQOS® non-menthol HeatSticks® after first trying IQOS®			
Base (Established smokers who smoked during the past 30 days prior to trying IQOS® and prefer(red) non-menthol cigarettes)			
Complete switching from non-menthol cigarettes to IQOS® after first trying IQOS®			
Complete switching from non-menthol cigarettes to IQOS® menthol HeatSticks® after first trying IQOS®			
Complete switching from non-menthol cigarettes to IQOS® non-menthol HeatSticks® after first trying IQOS®			

CI: Confidence Interval, n: Number of observations, NA: Not Applicable, P: Low Statistical Preciseness, S: Low Sample Size

Source: [Annex 1](#), TLF\_Pre, Table 12

Overall, a quarter (25.06%) of current users switched completely to IQOS® from all tobacco products after first trying IQOS®. Almost one third (31.21%) of users switched completely

from cigarettes after first trying IQOS®. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®.

Among established smokers who smoked during the past 30 days prior to trying IQOS® and preferred menthol cigarettes, around a third (35.33%) switched completely to IQOS® after first trying IQOS®. Almost all of those (34.67%) switched to menthol HeatSticks®. Among established smokers who smoked during the past 30 days prior to trying IQOS® and preferred non-menthol cigarettes, also around a third (35.43%) switched completely to IQOS® after first trying IQOS®. Around a quarter (26.91%) switched to non-menthol HeatSticks®, while 8.52% switched to menthol HeatSticks®. Notably, the proportion of those who switched completely from non-menthol cigarettes to IQOS® was similar among current established IQOS® users who prefer menthol HeatSticks® compared to non-menthol HeatSticks® (38.78% vs. 34.48%, respectively).

10.4.3.2 Transitions to/back to cigarette smoking

None of the ever established IQOS® users relapsed to cigarette smoking after not smoking for less than 12 months before first trying IQOS®, and none of the never smokers initiated cigarette smoking after first trying IQOS®. Only one individual (0.22% of ever established IQOS® users) re-initiated cigarette smoking after not smoking for 12 months or longer before first trying IQOS® (Annex 1, TLF\_Pre, Table 13).

None of the ever established IQOS® users reported complete switching from IQOS® to cigarettes after initiating tobacco use with IQOS® (Annex 1, TLF\_Pre, Table 14).

10.4.3.3 Quitting behaviors

Quit attempts during the past 12 months and motivation to stop smoking are detailed in Table 15.

Table 15: Past 12 month quit attempts, motivation to stop smoking, and completely quit smoking cigarettes

Measure	Current Established IQOS® Users % (95% CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS® Users Who Prefer non- Menthol HeatSticks % (95% CI)
Base (Current Established Cigarette Smokers)	(b)(4)	(b)(4)	(b)(4)
Past 12-month quit attempts	(b)(4)		

Measure	Current Established IQOS® Users % (95% CI)	Current Established IQOS® Users Who Prefer Menthol HeatSticks % (95% CI)	Current Established IQOS® Users Who Prefer non- Menthol HeatSticks % (95% CI)
<b>Motivation to stop smoking</b>	<b>(b)(4)</b>		
Missing			
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			
<b>Base (Ever Established Cigarette Smokers)</b>			
Completely quit smoking cigarettes after first trying IQOS®			
Completely quit smoking cigarettes for 12 months or longer after first trying IQOS®			

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 15-1

Overall, more than half (55.24%) of current established IQOS® users who were also current cigarette smokers attempted to quit smoking in the past 12 months. On the MTSS scale, users most frequently responded with “I think I should stop smoking but don't really want to” (27.62%), followed by “I REALLY want to stop smoking but I don't know when I will” (22.86%). The proportion stating “I think I should stop smoking but don't really want to” was 34.91% among users of menthol HeatSticks®, while it was 20.19% among users of non-menthol HeatSticks®.

Overall, around a third (32.08%) of current IQOS® users who had ever been established cigarette smokers completely quit smoking cigarettes after first trying IQOS®. For 14.39%,

this had already lasted for 12 months or longer. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks®.

Usage of tobacco cessation treatment is shown in [Table 16](#).

**Table 16: Tobacco cessation treatment use**

Measure	Current Established IQOS® Users % (95% CI)
<b>Base (All Participants)</b>	(b)(4)
Never used tobacco cessation treatment	(b)(4)
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	
Don't know	
Refused to answer	
<b>Base (Current Established IQOS® users who switched from cigarettes to IQOS®)</b>	(b)(4)
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	
Don't know	
Refused to answer	
<b>Base (Current Established IQOS® users who switched from all tobacco to IQOS®)</b>	(b)(4)
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	
Don't know	
Refused to answer	

CI: Confidence Interval, n: Number of observations, P: Low Statistical Preciseness

Source: [Annex 1](#), TLF\_Pre, Table 16-1

Around half (51.71%) of current IQOS® users had never used tobacco cessation treatment, slightly less than a third (30.75%) had used tobacco cessation treatment more than 12 months ago. These proportions were similar for those users who switched from cigarettes to IQOS® and for those users who switched from all tobacco to IQOS®. Also, these proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks® and for users of menthol cigarettes compared to users of non-menthol cigarettes ([Annex 1](#), TLF\_Pre, Table 16-2 to Table 16-5).



Among ever established IQOS® users, 4.10% had completely quit IQOS®, and 0.65% had quit IQOS® for 12 months or longer. These proportions were similar for users of menthol HeatSticks® compared to users of non-menthol HeatSticks® ([Annex 1](#), TLF\_Pre, Table 17).

## 10.5 Other analyses

### 10.5.1 Use of HeatSticks® varieties

Trial and usage of HeatSticks® varieties are shown in [Table 17](#).

**Table 17: HeatSticks® varieties trial/usage**

Measure	Current Established IQOS® Users % (95% CI)
Base (Total Participants)	(b)(4)
<b>HeatSticks® Varieties® Ever Tried</b>	(b)(4)
Amber/Regular HeatSticks	
Green Menthol/Smooth Menthol HeatSticks	
Blue Menthol/Fresh Menthol HeatSticks	
<b>First HeatSticks® Varieties Ever Tried</b>	
Amber/Regular HeatSticks	
Green Menthol/Smooth Menthol HeatSticks	
Blue Menthol/Fresh Menthol HeatSticks	
Not sure of type	
<b>HeatSticks® Varieties Currently Using*</b>	
Amber/Regular HeatSticks	
Green Menthol/Smooth Menthol HeatSticks	
Blue Menthol/Fresh Menthol HeatSticks	
<b>HeatSticks® Varieties Currently Using* Most Often</b>	
Amber/Regular HeatSticks	
Green Menthol/Smooth Menthol HeatSticks	
Blue Menthol/Fresh Menthol HeatSticks	

\*This refers to current use at the time of the survey.

CI: Confidence Interval, n: Number of observations

Source: [Annex 1](#), TLF\_Pre, Table 23

Most current users had tried Amber/Regular HeatSticks® (72.44%), Green Menthol/Smooth Menthol HeatSticks® (69.48%), and Blue Menthol/Fresh Menthol HeatSticks® (57.63%). The first variety ever tried was most commonly Amber/Regular (53.76%), followed by Green Menthol/Smooth Menthol (30.30%), and Blue Menthol/Fresh Menthol (15.95%). When asked about the HeatSticks® variety they were currently using at the time of the survey, most users also responded with Amber/Regular (51.03%), followed

by Green Menthol/Smooth Menthol (35.54%), and Blue Menthol/Fresh Menthol (27.33%). When asked about the HeatSticks® variety they were using most often, responses were similar.

### 10.5.2 Comparison of results pre-information letter vs. post-information letter

Overall, results were similar between the group of IQOS® users who participated in the survey after receiving the information letter compared to users who participated before receiving the information letter.

No meaningful demographic differences were observed. There was a slight numerical difference regarding the percentage of users with mental health issues in the pre- vs. post-information letter group (28.08% vs. 22.67%, respectively) ([Annex 1](#), TLF\_Pre, Table 19 and TLF\_Post, Table 19).

Regarding tobacco product use, the proportion of users who had tried e-vapor products was 72.21% in the pre-group and 79.13% in the post-group, for hookah it was 31.89% in the pre-group and 39.81% in the post-group. This was similar during the 30 days prior to trying IQOS® ([Annex 1](#), TLF\_Pre, Table 1, TLF\_Pre, Table 2, TLF\_Post, Table 1, and TLF\_Post, Table 2). Among dual users of IQOS® and cigarettes, menthol cigarette preference in the pre-group was 37.50%, in the post-group it was 30.51% ([Annex 1](#), TLF\_Pre, Table 3 and TLF\_Post, Table 3). The median number of days on which IQOS® users had smoked cigarettes during the past 30 days was 28 days in the pre-group and 20 days in the post-group ([Annex 1](#), TLF\_Pre, Table 5 and TLF\_Post, Table 5). The time between waking up and smoking the first cigarette was 5 minutes for 26.67% and 6-30 minutes for 33.81% of smokers in the pre-group, while it was 5 minutes for 17.02% and 6-30 minutes for 41.49% of smokers in the post-group ([Annex 1](#), TLF\_Pre, Table 22 and TLF\_Post, Table 22). Among e-vapor product users, the proportion of users stating that they use less e-vapor products than before trying IQOS® was 68.25% in the pre-group and 58.82% in the post-group ([Annex 1](#), TLF\_Pre, Table 6 and TLF\_Post, Table 6).

Risk perceptions of IQOS® and cigarettes were similar between both groups.

Regarding initiation of tobacco use, there was a slight numerical difference in IQOS® users for whom the first product they ever used on a consistent basis were cigarettes (91.34% in the pre-group and 83.02% in the post-group) ([Annex 1](#), TLF\_Pre, Table 10 and TLF\_Post, Table 10). The switching rate from cigarettes to IQOS® was 31.21% in the pre-group and 26.21% in the post-group ([Annex 1](#), TLF\_Pre, Table 12 and TLF\_Post, Table 12). Regarding quitting attempts, the proportion of cigarette smokers who don't want to stop smoking was 12.38% in the pre-group and 6.38% in the post-group ([Annex 1](#), TLF\_Pre, Table 15-1 and TLF\_Post, Table 15 -1). Among those users who switched from cigarettes to IQOS®, the proportion of users who had never used tobacco cessation treatment was 51.82% in the pre-group and 38.89% in the post-group ([Annex 1](#), TLF\_Pre, Table 16-1 and TLF\_Post, Table 16 -1).

## **10.6 Adverse experiences**

This study did not actively ask for AEs. No spontaneously reported AEs were recorded through ALCS' consumer research procedure.

Use of IQOS<sup>®</sup> not as intended is presented in Section [10.4.1.5](#).



## 11 Discussion

### 11.1 Key results

This study was an online cross-sectional survey. Prior to sending an information letter about IQOS® being unavailable in the US (until 13<sup>th</sup> October), a total of (b)(4) were invited to participate in the survey, 2.5% completed the interview. Due to low participant numbers in the subgroup of former IQOS® users, only the results for current IQOS® users are shown. Overall, a slightly higher proportion of current IQOS® users was male (59.91%). The mean age of all current users was 44.93 years, the mean age of non-menthol HeatSticks® users was slightly higher. Most current IQOS® users were in the age groups between 35 and 54, the proportion in the youngest age group (21-24 years) was only 1.59%. Current established users who preferred menthol HeatSticks® tended to be younger compared to those who preferred non-menthol HeatSticks® (43.16 years vs. 46.89 years). Most participants were White (72.89%), followed by Asian (14.35%), Hispanic/Latino (5.47%), and Black/African-American (4.78%). When asked about their health-related information, participants most commonly stated they had been diagnosed with hypertension (22.55%), followed by hyperlipidemia (20.50%), asthma (10.48%), diabetes (7.29%), and sleep apnea (6.38%). Around a quarter (27.56%) of current users stated they had a mental health condition, whereby 18.79% of users were taking medication or receiving treatment for a mental health condition.

The purpose of this study was to characterize tobacco use patterns of IQOS® users. All current established IQOS® users had ever tried at least one tobacco product and almost all (98.18%) had ever used at least one product consistently. Almost all current established IQOS® users stated that they had ever tried cigarettes (99.32%). Around two thirds of users had tried e-vapor products (72.21%) and cigars<sup>11</sup> (63.78%), less than one third had tried hookah (31.89%), smokeless tobacco (25.74%), pipe filled with tobacco (20.73%), and oral tobacco-derived nicotine products (20.05%). The proportions of IQOS® users ever using other tobacco products consistently were similar for cigarettes, but lower for other products. Around two thirds (64.92%) of users reported that at the time of the survey they were currently using any tobacco product other than IQOS®, while around a third (35.08%) of users stated that they were only using IQOS®. Concurrent use was most commonly reported for cigarettes (48.75%), followed by e-vapor products (20.05%), and cigars<sup>11</sup> (13.90%). The proportion of exclusive IQOS® use was 38.10% in the group of menthol HeatSticks® users and 31.73% for non-menthol HeatSticks® users. Among dual users of cigarettes and IQOS®, a slightly larger proportion of individuals preferred menthol HeatSticks® (63 of 128 participants, around 49%) compared to that of menthol cigarettes (37.50%). Use of IQOS® plus one other tobacco product was reported by 42.60% of current users, mainly for

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<sup>11</sup> This includes regular cigars, cigarillos, and little filtered cigars.

cigarettes (29.16%). Slightly over 20% of users (22.32%) used IQOS<sup>®</sup> plus two or more other tobacco products, mainly including cigarettes. Approximately half (48.75%) of all current IQOS<sup>®</sup> users were current cigarette smokers, the other half (50.57%) were former cigarette smokers. Only 0.68% were never cigarette smokers.

During the past 30 days, the majority (70.39%) of users stated that they had used IQOS<sup>®</sup> on 30 days, the mean (SD) number of days was 26.23 (7.16) days. When asked about the number of HeatSticks<sup>®</sup> used on those days, the most common response was 20 or more (38.72%). Most IQOS<sup>®</sup> users had a medium addiction level (HSI score of 2-4) (53.81% of current cigarette smokers, 60.28% of former cigarette smokers), followed by a low addiction level (HSI score of 0-1) (36.19% of current cigarette smokers, 24.77% of former cigarette smokers). During the past 30 days, less than half of current IQOS<sup>®</sup> users who were also current cigarette smokers stated that they used cigarettes on 30 days (48.13%), the mean (SD) number of days they used cigarettes was 20.53 (11.07) days. On these days, more than two thirds of users smoked on average 2-19 cigarettes (68.22%). When asked about their change in tobacco use behavior, most users (83.09%) stated that they used fewer cigarettes at the time of the survey than before they tried IQOS<sup>®</sup>.

Among current users, 7.74% reported ever using IQOS<sup>®</sup> not as intended. The most common mode of unintended use was using the IQOS<sup>®</sup> device with a product other than a HeatStick<sup>®</sup> (4.10%), followed by lighting the HeatStick<sup>®</sup> like a cigarette (3.42%).

Current established IQOS<sup>®</sup> users had been using IQOS<sup>®</sup> for about one year on average. Most current users had tried Amber/Regular HeatSticks<sup>®</sup> (72.44%), Green Menthol/Smooth Menthol HeatSticks<sup>®</sup> (69.48%), and Blue Menthol/Fresh Menthol HeatSticks<sup>®</sup> (57.63%). When asked about the HeatSticks<sup>®</sup> variety they were currently using at the time of the survey, most users also responded with Amber/Regular (51.03%), followed by Green Menthol/Smooth Menthol (35.54%), and Blue Menthol/Fresh Menthol (27.33%).

Another objective of this study was to characterize risk perceptions of IQOS<sup>®</sup>. Among current IQOS<sup>®</sup> users who were also current cigarette smokers, the mean (SD) composite score of the perceived risk of using IQOS<sup>®</sup> was 45.81 (15.73) (median: 41). The risk of smoking cigarettes was assessed with a higher composite score of 64.10 (14.95) (median: 64). For current IQOS<sup>®</sup> users who were former cigarette smokers the composite score was 68.64 (16.13) (median: 71). Most users (80.87%) assessed the chemical exposure to be less when switching completely from cigarettes to IQOS<sup>®</sup>. Only a small proportion (4.78%) thought there was no exposure. When asked what smokers must do to reduce their chemical exposure, the majority (85.35%) thought they should stop smoking completely and only use IQOS<sup>®</sup>.

Further, this study evaluated initiation, complete switching from cigarette smoking, transitions to/back to cigarette smoking, and quitting behaviors. Among current IQOS<sup>®</sup> users, the vast majority (93.39%) stated that cigarettes were the first product they ever tried,

only a small proportion stated smokeless tobacco (2.96%). Only one participant (0.23%) reported that IQOS<sup>®</sup> was the first product they ever tried. The vast majority (92.48%) also stated that cigarettes were the first product they used on a consistent basis, for 4.10% it was IQOS<sup>®</sup>. Only a small proportion (2.16%) of ever established IQOS<sup>®</sup> users reported that they first tried IQOS<sup>®</sup> after not using any tobacco products for 12 months or longer, and 5.83% of them first tried IQOS<sup>®</sup> after not smoking cigarettes for 12 months or longer.

Overall, a quarter (25.06%) of current users switched completely to IQOS<sup>®</sup> from all tobacco products after first trying IQOS<sup>®</sup>. Almost one third (31.21%) of users switched completely from cigarettes after first trying IQOS<sup>®</sup>. Only one individual (0.22% of ever established IQOS<sup>®</sup> users) re-initiated cigarette smoking. None of the former smokers relapsed to cigarette smoking, and none of the never smokers initiated cigarette smoking after first trying IQOS<sup>®</sup>.

Overall, more than half (55.24%) of current established IQOS<sup>®</sup> users who were also current cigarette smokers attempted to quit smoking in the past 12 months. Around a third (32.08%) of current established IQOS<sup>®</sup> users who had ever been established cigarette smokers completely quit smoking cigarettes after first trying IQOS<sup>®</sup>. Around one fifth of IQOS<sup>®</sup> users stated the intention to stop smoking cigarettes in the near future. Around half (51.71%) of current IQOS<sup>®</sup> users had never used tobacco cessation treatment, slightly less than a third (30.75%) had used tobacco cessation treatment more than 12 months ago. There was no major difference in tobacco cessation treatment use between all IQOS<sup>®</sup> users and those who switched completely from cigarettes to IQOS<sup>®</sup>.

Overall, results were similar between the group of IQOS<sup>®</sup> users who participated in the survey after receiving the information letter compared to users who participated before receiving the information letter.

## 11.2 Strengths and limitations

The study design and resulting data present various strengths. Within this study, a comprehensive approach was applied to describe current use patterns of IQOS<sup>®</sup> including unintended use, risk perception of IQOS<sup>®</sup> use and cigarette smoking as well as changes in use behavior in the context of IQOS<sup>®</sup> initiation among established IQOS<sup>®</sup> users. The large sample size of current IQOS<sup>®</sup> users and a diverse sample composition in terms of demographics allowed for detailed analyses of these topics. However, a larger sample size of former IQOS<sup>®</sup> users would be needed to allow for assessments of this group.

Some limitations are associated with the design of this study. Given the cross-sectional design of the study, respondents may not recall their behaviors accurately, which could lead to a reporting bias in this survey. However, this is a limitation inherent to all survey methods. In addition, all information was based on self-reporting. Nonetheless, self-reporting surveys remain the cornerstone of international epidemiological tobacco research,

and the results of previous studies have shown that self-administered questionnaires might adequately capture tobacco use in populations (10).

A further limitation of the study is associated with the fact that participants were recruited from a database of consumers who purchased the IQOS® device. It cannot be ruled out that the overall population of IQOS® users in the US is different to the population in the database regarding demographic characteristics and use patterns. In addition, the response rate was relatively low. Furthermore, there might be a self-selection bias for those with a positive attitude/opinion towards IQOS® compared to those who stopped using IQOS® and therefore had no interest in participation, which resulted in a lower number of responses from former established IQOS® users.

Prospective studies will be needed to adequately assess long-term usage patterns.

### 11.3 Interpretation

IQOS® was authorized by the US FDA as a MRTP (11). This cross-sectional study among established IQOS® users, as part of the postmarket surveillance program, shows how IQOS® is used after initiation and the risk perception associated with IQOS®. However, during screening the most frequent reason for screen failure was the use of less than 100 Marlboro HeatSticks®. This shows that not all participants who purchased IQOS® also adopted the product for continued use.

This study shows that the vast majority of current established IQOS® users have used other tobacco products on a consistent basis before IQOS® initiation, in particular cigarettes (on average more than 20 years). Most current IQOS® users were in the age groups between 35 and 54, the proportion in the youngest age group (21-24 years) was below 2%. The sample of current established users had used IQOS® for an average of one year. During this time around a third of current IQOS® users who had ever been established cigarette smokers completely quit smoking after first trying IQOS®. One quarter even switched completely to IQOS® without concurrent use of any other tobacco product. In addition to the one third of IQOS® users who switched to IQOS®, more than 80% of those who were still smoking reported smoking fewer cigarettes at the time of this survey compared to 30 days before IQOS® initiation. In line with this, less than 50% of current cigarette smokers reported daily cigarette consumption. Furthermore, one fifth expressed the desire and intention to stop smoking cigarettes in the near future, and more than half of current IQOS® users who were also cigarette smokers attempted to quit smoking in the past 12 months.

Although more than a third of the participants reported use of IQOS® only, dual use and multi product use was common among current established IQOS® users, which may be due to the fact that IQOS® is a relatively new product, and some IQOS® users were new users who had not completely switched to IQOS®.

About half of current established IQOS® users never used any tobacco cessation treatment, and slightly less than a third used tobacco cessation treatment more than 12 months ago.

Interestingly, there was no major difference in tobacco cessation treatment use between all IQOS<sup>®</sup> users and those who switched from cigarettes to IQOS<sup>®</sup>. Taken together, IQOS<sup>®</sup> use does not seem to interfere with tobacco cessation treatment.

In addition to switching and quitting, the study also collected information about undesirable outcomes such as initiation and relapse, as per FDA requirement (12). In this study only one out of (b)(4) stated that IQOS<sup>®</sup> was the first tobacco product they ever tried. However, around 4% said that IQOS<sup>®</sup> was their first tobacco product used on a consistent basis. Among long-term former established cigarette smokers around 6% initiated the use of IQOS<sup>®</sup> after not smoking cigarettes for 12 months or longer, this proportion was only around 2% for long-term former users of all tobacco products. Only a very small percentage (0.22%) of ever established IQOS<sup>®</sup> users re-initiated cigarette smoking, none of the never smokers initiated cigarette smoking after first trying IQOS<sup>®</sup>, and none of the former smokers relapsed to cigarette smoking.

The likelihood that consumers will use the product as intended or designed (as recommended by the FDA (1)) was assessed for using HeatSticks<sup>®</sup> without the IQOS<sup>®</sup> device and for using the IQOS<sup>®</sup> device with other consumables. Overall, unintended use of IQOS<sup>®</sup> was low (with around 8%), which suggests correct understanding and use of the IQOS<sup>®</sup> device and IQOS<sup>®</sup> Marlboro HeatSticks<sup>®</sup> in order to reduce exposure to harmful or potentially harmful chemicals.

Another important aspect of postmarket surveillance studies is the assessment of risk perception of MRTPs compared to cigarettes and the comprehension level of modified claims to ensure overall harm reduction. Overall, IQOS<sup>®</sup> users rated the risk of developing several health conditions for IQOS<sup>®</sup> as considerably lower than for cigarette smoking, although they acknowledged that the use of IQOS<sup>®</sup> is not risk-free. Further, the majority had a good comprehension that completely switching from cigarettes to IQOS<sup>®</sup> reduces the exposure to harmful or potentially harmful chemicals. Only a small proportion thought there was no exposure. Participants also correctly understood that in order to have less exposure to harmful or potentially harmful chemicals they have to stop smoking completely and only use IQOS<sup>®</sup>. However, around 8% of the current IQOS users thought that a reduction of cigarette consumption would be sufficient to reduce the exposure level. Thus, these results suggest that current IQOS<sup>®</sup> users have a reasonable risk perception of IQOS<sup>®</sup> compared to cigarettes and a correct comprehension of the exposure claim.

#### 11.4 Generalizability

Male and female participants of different age groups and different ethnicities were recruited from the IQOS<sup>®</sup> database, which however might differ from the overall population of IQOS<sup>®</sup> users in the US. Wherever feasible, survey items were sourced and/or adapted from national surveys and items used in previous studies (2-4) to allow for comparisons with other studies. As the study was conducted in the US only, the generalizability of the results for other geographical regions may be limited.

## 12 Other information

Not applicable.

### 13 Conclusion

In this study a comprehensive approach was applied to describe risk perceptions of IQOS<sup>®</sup> use and cigarette smoking, tobacco use behaviors, as well as changes in use behavior in the context of IQOS<sup>®</sup> use among established IQOS<sup>®</sup> users. Approximately one in three current established IQOS<sup>®</sup> users switched to IQOS<sup>®</sup> from cigarettes. Furthermore, current IQOS<sup>®</sup> users have an appropriate understanding of risk perception of IQOS<sup>®</sup> compared to cigarettes as well as a correct comprehension of the IQOS<sup>®</sup> exposure claim. Initiation of IQOS<sup>®</sup> use among never users and former cigarette and tobacco users was low, and thus no gateway effect could be observed. Taken together, results from this study suggest a great potential of IQOS<sup>®</sup> to switch cigarette smokers, especially those with a fairly long history of smoking and who were not using any smoking cessation treatment.

Among dual users of cigarettes and IQOS<sup>®</sup>, a larger proportion of individuals preferred menthol HeatSticks<sup>®</sup> compared to the proportion that preferred menthol cigarettes. Within the study no major behavioral differences were observed for menthol and non-menthol variants of Marlboro HeatSticks<sup>®</sup>. These results suggest that menthol HeatStick<sup>®</sup> varieties are well received and used, even among non-menthol cigarette smokers.

However, to assess use trajectories over a longer time period, further research is needed. In particular, it should be analyzed how stable complete switching is, whether dual users are able to switch completely over time, and if former IQOS<sup>®</sup> users switch back to cigarettes, transition to other tobacco products or are able to quit the use of all tobacco consumption.



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## 15 Appendices

### Annex 1. List of stand-alone documents

Number	Document reference	Date	Title
1	9102.B1-IQOS-XS-Protocol	01 June 2021	Protocol version 3.1
2	B3-FINAL_iqos-cross-sectional-PACS-sap --v3.2 -- 20220307	07 March 2022	Statistical Analysis Plan version 3.2
3	9102.B2-IQOS-XS-Instrument v.1.1_9.2.2021_clean	01 June 2021	Survey instrument version 1.1
4	ALCS-CMI-17-36-HT_IRB Approval Letter	03 August 2021	IRB Approval Letter
5	IQOS Cross-sectional PACS_TLF_Full Sample_V2.0_20220210	10 February 2022	Tables, listings, figures including all respondents (TLF_Full)
6	IQOS Cross-sectional PACS_TLF_Pre-Group_V2.0_20220210	10 February 2022	Tables, listings, figures including respondents pre-information letter (TLF_Pre)
7	IQOS Cross-sectional PACS_TLF_Post-Group_V2.0_20220210	10 February 2022	Tables, listings, figures including respondents post-information letter (TLF_Post)

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