Study Report
P1-PMX-02-IT | Year 2 (2019-2020)

BEHAVIORAL REGULATORY RESEARCH

Study Title	Cross-Sectional Survey on the Use of Tobacco and Nicotine-Containing Products in the General Adult Population and among Users of IQOS in Italy
Study Number	P1-PMX-02-IT
Product Name	IQOS
Sponsor	Philip Morris Products S.A. Avenue de Rhodanie 50 1007 Lausanne Switzerland
Study Initiation	March 18, 2019
Study Completion	January 31, 2020
Authors	Karina Fischer Steve Roulet Marius Sieverding
Version	Version 1.0
Report Date	February 2021

1 TABLE OF CONTENTS

1.1 TABLES

1.2 FIGURES

2 LIST OF ABBREVIATIONS AND TERMS

Abbreviation	Term
CC	Cigarettes
CI	Confidence Interval
HEETS	Tobacco Sticks (Disposables) to be Used with the IQOS Device
LCL	Lower Confidence Limit
MET	Metabolic Equivalent of Task
NRT	Nicotine Replacement Therapy
PM	Philip Morris
PMI	Philip Morris International Inc. (the general entity)
PMP S.A.	Philip Morris Products S.A. (part of PMI group of companies)
RPC	Rating of Perceived Capacity
SAS	Statistical Analysis System
SRCQ	Self-Reported Changes Questionnaire
TNP	Tobacco or Nicotine-Containing Product
UCL	Upper Confidence Limit
WHO	World Health Organization
Year 1	Reporting year 1 (2018-2019) of the study
Year 2	Reporting year 2 (2019-2020) of the study

Term	Definition
Lifetime criteria	Defined as threshold of lifetime use for each tobacco or nicotine-containing product (TNP) category to qualify as a "user" of the respective TNP. For cigarettes: ≥100 cigarettes; for heated tobacco products: ≥100 sticks/units; for any other innovative product such as e-cigarettes or similar products: ≥100 times. For Other TNPs including (a) Smokeless Tobacco (such as chewing tobacco, snus, snuff, dissolvable), (b) Other Combustible Products (such as cigars, cigarillos, pipes, water-pipes), and (c) Nicotine Replacement Therapy products (NRTs, such as, patch, gum, tablet, inhaler, lozenge, pill) no threshold of lifetime use was defined.
Cigarettes	Include manufactured and roll/make-your own cigarettes
Current use	Defined as having used any TNP more than the respective lifetime criterion and using the TNP either daily or occasionally at the time of the survey.
Former use	Defined as having used any TNP more than the respective lifetime criterion and not using any TNP at the time of the survey.
Never use	Defined as not having used any TNP up to the respective lifetime criterion.
Regular use	Defined as using a TNP either daily or occasionally
Daily use	Defined as those who report currently using at least one TNP daily and have used more than the respective lifetime criterion.
Occasional use	Defined as those who report currently using at least one TNP occasionally (i.e. less than once per day) and have used more than the respective lifetime criterion.
Exclusive use	Defined as currently using only one TNP
Dual use	Defined as currently using two TNPs
Poly use	Defined as currently using more than two TNPs
Initiation of TNP use	Defined as the first time in life a TNP is used regularly. This implies using the product daily or occasional and having used more than the respective lifetime criterion.
Initiation rate of TNP use	Defined as the proportion of the surveyed population that initiated the use of a particular TNP in the last 12 months.
Quitting/Stop using	Defined as having used a particular TNP according to the lifetime criterion (e.g. >100 cigarettes in lifetime) and at the time of the survey not using the TNP anymore, regardless of the consumption of other TNPs.
Quit/Stop using attempt	Defined as having used a particular TNP according to the lifetime criterion (e.g. >100 cigarettes in lifetime) and at the time of the survey having at least once tried to stop using the TNP, regardless of the consumption of other TNPs.
Relapse to a TNP	Defined as using a particular TNP again after stopping/quitting TNPs for ≤12 months during the most recent attempt to quit TNPs.
Re-initiation with a TNP	Defined as using a particular TNP again after stopping/quitting TNPs for >12 months during the most recent attempt to quit TNPs.

3 EXECUTIVE SUMMARY

Study Background and Objectives

This report presents data from the second reporting year (Year 2, 2019-2020) of a repeated cross-sectional survey in Italy. This study investigated current and past tobacco or nicotine-containing product (TNP) use, to understand and characterize how PMI's smoke-free product IQOS was used by the adult Italian population compared to other TNPs. Results from the present reporting Year 2 are also compared with results from the previous reporting Year 1 (2018-2019) when the study was conducted in Italy for the first time.

The study was conducted in a representative sample of the general adult Italian population as well as in a sample of current IQOS users registered in the IQOS user database of PMI's affiliate in Italy. In the sample of the general adult Italian population, the survey interviews were conducted face-to-face, whereas in the IQOS user sample, the surveys were conducted online.

In the present study Year 2, the **General Adult Population Sample** included 6,118 participants with the data being collected between March 18, 2019 and January 31, 2020. The **IQOS User Sample** was comprised of 1,401 participants with the data collection taking place between April 12, 2019 and January 31, 2020.

3.1 GENERAL ADULT POPULATION SAMPLE

Demographic Characteristics

A total of N=6,118 participants of the General Adult Population Sample with a mean age of 51.0 years (SD=16.99, range: 18 to 98) completed the survey in Year 2 (2019-2020). Of those, 51.2% were female and 48.8% were male. The demographic characteristics in Year 2 were similar to those of the General Adult Population Sample in Year 1 (2018-2019).

Prevalence

In Year 2, the current prevalence of overall TNP use in the surveyed General Adult Population Sample (N=6,118) was 26.7% (n=1,636). The current prevalence of cigarette smoking (25.1%, n=1,535) was much higher than that of e-cigarette (1.4%, n=88), HTP [IQOS only] (1.1%, n=67), or any other innovative TNP (0.02%, n=1)[1] use. The current prevalence of other TNP use including smokeless tobacco, other combustible TNPs, and nicotine replacement therapy (NRT) products was 1.1% (n=70). Compared to study Year 1, in year 2 the prevalence of overall current TNP use (25.7% vs. 26.7%) as well as of cigarette (24.3% vs. 25.1%) and HTP (0.7% vs. 1.1%) use was slightly higher, while the prevalence of e-cigarette (1.4% vs. 1.4%) use remained stable and the prevalence of other TNP (1.3% vs. 1.1%) use was slightly lower.

[1] Other innovative TNPs include products such as *Ploom* and *Glo* products.

Frequency and Intensity of TNP Use

Among current cigarette smokers (N=1,535), 95.2% smoked daily with on average 12.9 cigarettes/day, while 3.5% smoked occasionally,[2] i.e. <1 cigarette/day. Among current e-cigarette users (N=88), 81.8% used e-cigarettes daily with on average 19.2 times/day, whereas 15.9% used e-cigarettes occasionally,[3] i.e. <1 time/day. Among current IQOS users (N=67), 76.1% used IQOS daily with on average 8.0 HEETS/day, while 20.9% used IQOS occasionally,[4] i.e. <1 HEETS/day.[5] Compared to Year 1, the prevalence of daily cigarette smoking and daily IQOS use were slightly higher, while the prevalence of daily e-cigarette use was stable. In terms of intensity, the average daily consumption of cigarette smoking and IQOS use was stable, while the average daily consumption of e-cigarettes was slightly higher in Year 2 than Year 1.

Patterns of TNP Use

Among current TNP users (N=1,636), the prevalence of exclusive TNP use (93.8%) was higher than that of dual (4.5%) or poly (1.7%) TNP use. Compared to Year 1, the prevalence of dual TNP use was somewhat lower and that of exclusive and poly TNP use slightly higher in study Year 2.

History of TNP Use (Initiation / Relapse / Re-initiation)

Among participants who were never TNP users more than one year before the survey (N=3,900), 0.41% initiated TNP use with cigarettes, 0.05% with IQOS, and 0.03% with e-cigarettes in the past 12 months. These rates of TNP initiation were similarly low in study Year 1. Among current TNP users (N=1,636), in the past 12 months prior to the survey, 0.92% relapsed to cigarettes, 0.06% to IQOS, and none (0.00%) to e-cigarettes. At the same time, 0.06% re-initiated TNP use with IQOS and none (0.00%) with cigarettes or e-cigarettes. These rates of TNP relapse and re-initiation were on a similarly very low level in study Year 1.

Quitting

Among current cigarette smokers (N=1,535), 10.7% planned to quit smoking within the next 30 days or 6 months and 7.7% had already attempted to quit smoking in the past 12 months with on average 2.5 quit attempts and a duration of 3.0 months. Among participants who smoked more than one year ago (N=1,564), 1.9% successfully quit smoking cigarettes in the past 12 months. Among current IQOS users (N=67), 16.4% planned to stop using IQOS within the next 30 days or 6 months and 11.9% had already attempted to stop using IQOS in the past 12 months with on average 2.9 stop attempts and an average duration of 1.9 months. Among participants who used IQOS more than one year ago (N=94), 28.7% stopped using IQOS in the past 12 months

[2] Some current cigarette smokers did not provide information on daily or occasional cigarette smoking.

[3] Some current e-cigarette users did not provide information on daily or occasional e-cigarette use.

[4] Some current IQOS users did not provide information on daily or occasional IQOS use.

[5] The profile of IQOS users from the general adult population is skewed towards older and female users. Therefore, the estimates of frequency and intensity of IQOS use from the IQOS user sample are more reliable.

and of those 27.3% (n=3) quit all TNPs. The percentage of smokers who planned, attempted, or successfully quit smoking was slightly lower in study Year 2 compared to Year 1. Similarly, the percentage of IQOS users who planned or attempted to stop using IQOS was lower in study Year 2 compared to Year 1.[6]

3.2 IQOS USER SAMPLE

Demographic Characteristics

A total of N=1,401 participants of the IQOS User Sample with a mean age of 36.7 years (SD=12.2, range: 18 to 72) completed the survey in Year 2 (2019-2020). Of those, 57.4% were female and 42.6% were male. Compared to Year 1 (2018-2019), the mean age of IQOS users was slightly lower and the proportion of male IQOS users was higher in Year 2.

Frequency and Intensity of IQOS Use

A total of 96.1% of current IQOS users (N=1,401) were daily IQOS users who consumed on average 13.3 HEETS/day, while 3.2% were occasional IQOS users who consumed <1 HEETS/day).[7] These results are similar to those observed in study Year 1.

Patterns of IQOS Use

Among current IQOS users (N=1,401), 61.7% used IQOS exclusively, 36.0% used IQOS with combustible TNPs, and 2.3% used IQOS together with non-combustible TNPs. These patterns of IQOS use were similar in study Year 1.

History of IQOS Use

Among current IQOS users (N=1,249),[8] 97.0% were adult cigarette smokers when they started using IQOS, while 2.5% were former cigarette smokers, and 0.5% were never smokers indicating that a total of 99.5% of all IQOS users had a smoking history before they started using IQOS. Among those who had a smoking history before they started using IQOS (N=1,243), 97.5% were current smokers at the time they started using IQOS, 0.9% were former smokers who relapsed (≤12 months of smoking abstinence) to TNP use with IQOS, and 1.4% were former smokers who re-initiated (>12 months of smoking abstinence) TNP use with IQOS. The percentage of never smokers who initiated TNP use with IQOS was similar in Year 1. The percentage of IQOS users who relapsed or re-initiated TNP use with IQOS was slightly higher in Year 2, but still at a low level.

[6] For Year 1, information on the number and duration of stop attempts or successful stopping using IQOS is not available.

[7] Some IQOS users did not provide information on daily or occasional IQOS use.

[8] All current IQOS users with available information on the smoking status when they started using IQOS.

Quitting

Among current IQOS users who also smoked (N=459), 33.3% planned to quit smoking cigarettes within the next 30 days or 6 months and 21.1% (n=97) had already attempted to quit smoking cigarettes in the past 12 months with on average 2.1 attempts and a duration of 2.3 months. Among participants who smoked more than one year ago (N=979), 53.1% had successfully quit smoking cigarettes in the past 12 months. Compared to the smokers from the General Adult Population sample in study Year 2, the proportion of IQOS users who also smoked in the IQOS user sample and who planned, attempted, or had successfully quit smoking was markedly higher. These observations related to quitting in study Year 2 were overall similar to those of Year 1.

Risk Perception

Current IQOS users (n=1,401) perceived the health risk [score: 0-100] associated with smoking cigarettes (score: 64.3) as higher than the health risk associated with using IQOS (score: 44.4) resulting in a risk difference score (smoking cigarettes vs. using IQOS) of 19.6. Both the perceived health risk scores for cigarette and IQOS use as well as the corresponding health risk score differences among current IQOS users were similar to those reported in study Year 1.

Respiratory Symptoms

Among current exclusive IQOS users (N=864), 11.5% reported respiratory (i.e. cough and/or phlegm) symptoms, while among current IQOS users who used IQOS together with combustible TNPs (N=505), 19.4% reported respiratory symptoms. Current exclusive IQOS users reported greater improvement in cough (49.1%) and phlegm (45.8%) symptoms in the past 12 months prior to the survey than IQOS users who used IQOS together with combustible TNPs reported improvement in cough (39.4%) and phlegm (40.0%) symptoms. Compared to study Year 1, the proportion of exclusive IQOS users who reported improvement in cough and/or phlegm symptoms was lower in study Year 2, while the proportion of IQOS users who used IQOS together with combustible TNPs and who reported improvement in cough and/or phlegm symptoms was rather similar across the two study years.

Exercise Capacity

In study Year 2, exercise capacity was rated higher among female (10.1 Metabolic Equivalents of Tasks (MET),[9] N=399) and male (11.0 MET, N=465) exclusive IQOS users than among female (9.5 MET, N=187) and male (10.1, N=318) IQOS users who used IQOS together with combustible TNPs. Among exclusive IQOS users (N=864), 50.7% reported an improvement in exercise capacity in the past last 12 months, whereas among IQOS users who used IQOS together with combustible TNPs

[9] Metabolic Equivalents of Tasks (MET) values from 1 to 20 in men and 1 to 18 in women are listed on a progressive scale linked to specific physical activities by choosing the most strenuous activity that they could sustain for at least 30 min. 1 MET equals energy expenditure in terms of oxygen consumption per 1 kg of body mass while sitting at rest. Wisén, A.G., Farazdaghi, R.G. & Wohlfart, B. A novel rating scale to predict maximal exercise capacity. Eur J Appl Physiol 87, 350–357 (2002). https://doi.org/10.1007/s00421-002-0636-y.

(N=505), 40.0% of them reported an improvement in exercise capacity. Compared to study Year 1, the proportion of both exclusive IQOS users and IQOS users who used IQOS together with combustible TNPs and who reported an improvement in exercise capacity was overall slightly lower.

Hygiene, Beauty, and Fitness Benefits

Exclusive IQOS users (N=774)[10] confirmed perceived benefits[11] related to hygiene, beauty, and fitness since they had switched from cigarettes to IQOS according to the following hierarchy: (1) "My breath smells better" (74.8%), (2) "My teeth appears less stained or yellowish" (70.5%), (3) "I feel that it is easier to exercise" (62.5%), (4) "My sense of smell improved' (60.7%), (5) "My sense of taste improved (59.4%), and (6) "The skin on my face appears smoother and firmer" (30.1%). This hierarchy of perceived benefits was identical in study Year 1.

3.3 CONCLUSIONS

The present study report describes Year 2 (2019-2020) data from a repeated cross-sectional study in Italy including both a representative General Adult Population Sample and sample of current IQOS users living in Italy and registered in the IQOS Owner database of PMI's affiliate in Italy. Similar to the previous study Year 1 (2018-2019), cigarettes were by far the most used TNPs in Italy and the majority of current TNP users started TNP use with cigarettes.

Also, as seen in Year 1, smoke-free products such as IQOS and e-cigarettes have established themselves as acceptable alternatives to cigarette smoking with the majority of IQOS users using IQOS exclusively and hence having switched completely away from cigarette.

Moreover, in line with Year 1 data, initiation, relapse, and re-initiation with IQOS were low and nearly all current IQOS users were adult cigarette smokers when they started to use IQOS. Besides, the rate of quitting smoking remained stable across study years.

Furthermore, consistent with Year 1 data of the study, IQOS users perceived that using IQOS is not risk-free, but that the health risk associated with using IQOS is lower compared to the health risk associated with smoking cigarettes. Finally, in line with Year 1 data, exclusive IQOS users perceived health-related improvements in respiratory (cough and phlegm) symptoms and exercise capacity as well as several other benefits related to hygiene, beauty, and fitness much more frequently than IQOS users who did not use IQOS exclusively.

[10] Compared to the total sample size of exclusive IQOS users (N=864), the sub-sample of only N=774 includes only IQOS users with valid data on perceived benefits.

[11] Seven-point rating scale ranging from "strongly disagree" to "strongly agree".

4 OVERALL AIM AND STUDY OBJECTIVES

The overall aim of this study was to investigate the current and past TNP use in the General Adult Population in Italy and among IQOS users registered in the IQOS Owner database of PMI's affiliate in Italy.

More specifically, the study objectives were:

1. Estimate the prevalence of TNP use in the target populations broken down into (a) current, former, and never use, (b) daily and occasional use, and (c) exclusive, dual, and poly use.
2. Describe the past TNP use status to estimate (a) TNP initiation (based on first product regularly used), (b) relapse and re-initiation (based on the most recent attempt to quit TNPs), and (c) intention to quit, quit attempts, and successful quitting of TNPs.
3. Estimate risk perceptions related to cigarettes and IQOS use among current IQOS users.
4. Estimate self-reported perceived changes in health outcomes as well as in hygiene, beauty, and fitness related benefits among current IQOS users.

5 OVERALL STUDY DESIGN AND PLAN

This observational, cross-sectional survey was conducted in two population samples (**Figure 1**):

- A General Adult Population Sample
- An IQOS User Sample

General Adult Population Sample. In each wave, the surveys were conducted by interviewers as part of a multi-purpose survey (Omnibus). The face-to-face interviews of the Omnibus started with a general introduction by the interviewer about the general purpose of the Omnibus. The participant was informed by the interviewer about the survey including the aim, study participation duration, the voluntary nature of participation, confidentiality, use of data, and data privacy. After consenting to participate in the survey, the interviewer proceeded with the demographic questions. Although most of the data collected in the Omnibus were collected using a face-to-face interview approach, including the demographic questions, the main study questionnaire on TNP use was completed by the participant in the form of a computer-assisted self-interviewing (CASI). This approach of collecting TNP use information was preferred in order to avoid bias due to social desirability as participants might feel uncomfortable to answer specific questions in the presence of an interviewer.

***IQOS User Sample*.** In each wave, the surveys were conducted through an online survey. A randomly selected number of IQOS users registered in the IQOS Owner database of PMI's affiliate in Italy were invited to participate in the survey. The potential participants were presented with a consent form, which included information on the aim of the study, study participation duration, the voluntary nature of their participation, confidentiality, use of data, and data privacy. After

consenting to participate, the participants were provided the screener questionnaire. Eligible participants proceeded to the demographic questions and then to the main study questionnaire.

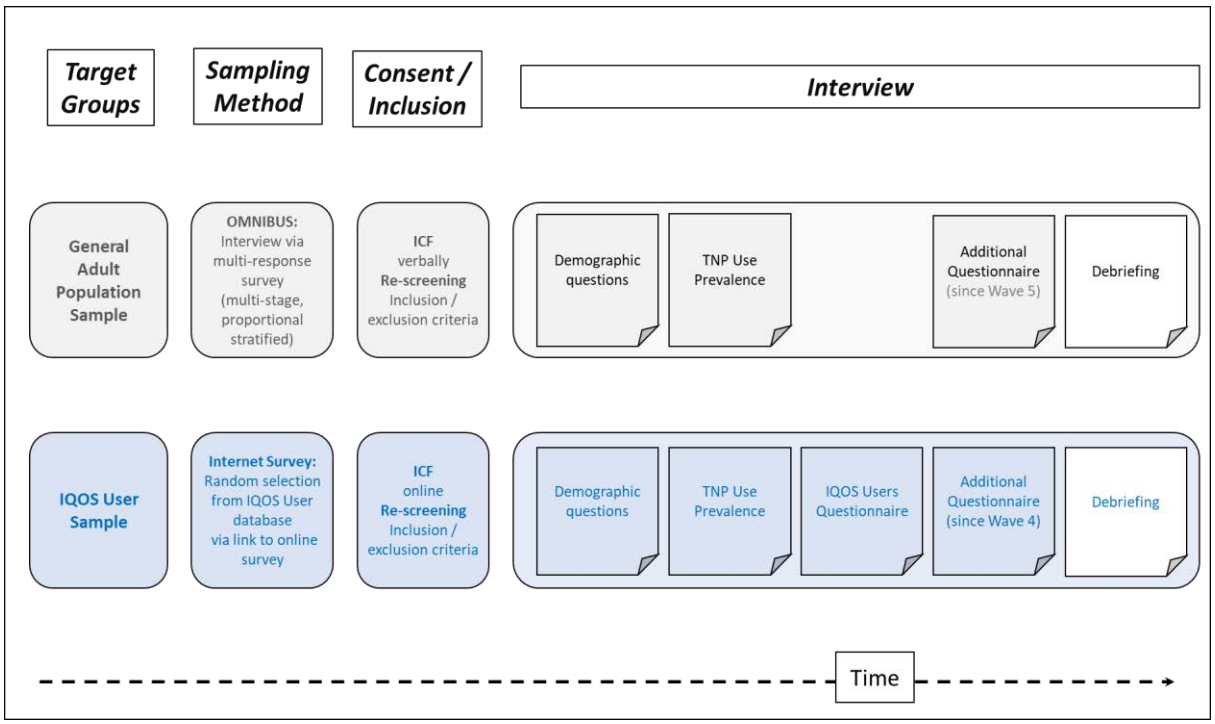

Figure 1 Study Design

5.1 SELECTION OF STUDY POPULATION

5.1.1 GENERAL ADULT POPULATION SAMPLE

5.1.1.1 *STUDY POPULATION*

The target population for the General Adult Population Sample was defined as adults (≥18 years of age) who were living in a registered household in Italy (50,396,628 adults based on the most recent 2011 Italian Census).[12]

5.1.1.2 *SAMPLING FRAME*

Sampling Method

Named adult individuals within households aged 18 years and over were selected on a random basis from the electoral lists of about 140 municipalities located throughout Italy. The sampling

[12] http://demo.istat.it/pop2011/index.html

frame was subdivided into strata through two characteristics: region and size of municipality. The number of interviews carried out in each stratum was set in proportion to the distribution of the population of the strata in the area (proportional stratified sample). Within each stratum, the sampling units (municipalities, electoral wards within municipalities, individuals) were chosen by a multi-stage selection in the following way:

1. In the first stage, selection of municipalities (these are the primary sampling points where the interviews will be conducted – *comune* in Italian). The municipalities were selected within the network of sampling points.
2. In the second stage, in each municipality, an adequate number of electoral wards were extracted at random (each corresponding to a given district of the municipalities) so that the various types of inhabited areas of the municipality were represented in the right proportions (i.e. central and suburban districts, outskirts, and isolated houses).
3. In the third stage, the names and addresses of the people to be interviewed were extracted at random from the electoral lists of the wards selected in the second stage.

Sample Size

The sample size was based on an *expected prevalence* of IQOS use among the surveyed population of 1%. A sample size of 6,085[13] participants per year is sufficient to estimate the prevalence with a 95% confidence and a precision +/- 0.25 percent unit. The achievable accuracy (95% Confidence Interval (CI)) is shown for assumed prevalence in a range of 0.5 to 3% **(Table 1)**.

Table 1 Achievable Accuracy (95% CI) for Assumed Prevalence - General Adult Population Sample

Level	Sample Size	95% Confidence Interval by Prevalence of IQOS use			
	n	0.5%	1%	2%	3%
General Adult Population Sample	6,085	±0.18%	±0.25%	±0.35%	±0.43%

Sampling Frequency

The annual sample comprised the participants from six waves of the survey equally spaced throughout the year **(Figure 2)**.

[13] In total 6,118 participants were included in the General Adult Population Sample

5.1.2 IQOS USER SAMPLE

5.1.2.1 *STUDY POPULATION*

The target group for the IQOS User Sample was defined as adults (≥18 years of age) registered in the IQOS Owner database of PMI's affiliate in Italy and agreed to be contacted for research purposes at the time of registration. More than 760,000 IQOS users from Italy were registered in the IQOS Owner database (as of March 2019).

5.1.2.2 *SAMPLING FRAME*

Sampling Method

IQOS users registered in the IQOS Owner database of PMI's affiliate in Italy were randomly selected from the database and were provided a link to access the online survey.

Sample Size

The sample size calculation was based on an expected percentage of IQOS users fully converted to exclusive IQOS use of 63.4%.[14] A sample size of 1,384[15] participants per year is sufficient to estimate the proportion of fully converted IQOS users with a 95% confidence and a precision of +/- 2.5% units. The achievable accuracy (95% CI) is shown for assumed prevalence in a range of 55% to 70%. **(Table 2)**.

Table 2 Achievable Accuracy (95% CI) for Assumed Prevalence - IQOS User Sample

Level	Sample Size	95% Confidence Interval by Prevalence of IQOS use				
	n	55%	60%	63.4%	65%	70%
IQOS User Sample	1,384	±2.6%	±2.6%	±2.5%	±2.5%	±2.4%

Sampling Frequency

The annual sample comprised the participants from four waves of the survey equally spaced throughout the year **(Figure 2)**.

5.1.3 SAMPLING PERIODS

Each annual sampling (i.e. data collected within a 12-month period) consisted of six (General Adult Population Sample) or four (IQOS User Sample) approximately equally sized waves of

[14] Rate based on cross-sectional study results among IQOS Users in Japan (First PMI cross-sectional study conducted after the commercialization of IQOS).

[15] In total, 1,401 participants were included in the IQOS User Sample.

sampled participants that were equally spaced throughout the year (no more than one wave per month). Each annual sampling comprised both the General Adult Population Sample and the IQOS User Sample. The study year was defined as the 12-month period from start of data collection of the first wave until the end of data collection of the last wave.

The data collection (sampling periods) of PMI's repeated cross-sectional study in Italy in Year 2 (2019-2020) took place from March 13, 2019 to January 31, 2020 for the General Adult Population Sample and from April 12, 2019 to January 31, 2020 for the IQOS User Sample (**Figure 2**).

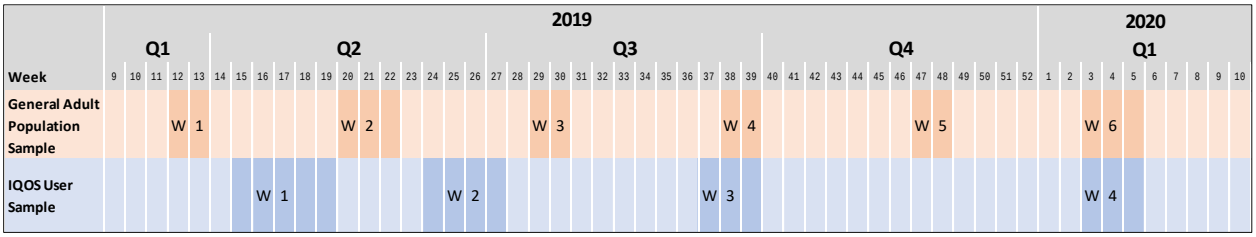

Figure 2 Allocation of Waves over the Survey Period for 2019-2020 (Study Year 2)
Q, Quarter of the year; W, wave.

5.2 INCLUSION AND EXCLUSION CRITERIA

Individuals meeting the following criteria were included in the study:

- Legally permitted to buy TNPs in Italy (≥18 years of age)
- Currently residing in Italy
- Able to read, write, and understand Italian
- Consent to participate in the survey
- For the IQOS User Sample – in addition to the above criteria:
  - Has used more than 100 HEETS tobacco sticks in his or her lifetime
  - Is currently using IQOS
  - Has access to the internet
  - Is currently not employed by Philip Morris International or any of its affiliates

5.3 DATA ANALYSIS

All analyses undertaken were descriptive. Categorical outcome measures were described by presenting the overall number of participants in each participant group as well as the number and proportion of participants in each category. Continuous outcome measures, as applicable, were described by presenting the number of participants in each participant group with non-missing score values as well as the mean, and as applicable, standard deviation, median, and minimum and maximum. In addition, as applicable, unadjusted 95% CI were presented. All analyses were performed with SAS® software (Statistical Analysis System, version 9.4 or higher).

6 RESULTS

6.1 GENERAL ADULT POPULATION SAMPLE

6.1.1 DISPOSITION GROUPS

A total of 15,900 (100%) named candidate persons within households were contacted to participate in the Year 2 study. Of these, 9,374 candidates did not respond for several reasons (6,095 could not be reached, 334 were ineligible, and 2,945 refused to participate). Of the remaining 6,526 (41.0%) individuals who were willing to participate in the study, 408 dropped out before completion, and 6,118 (38.5%) completed the Year 2 survey **(Figure 3)**.

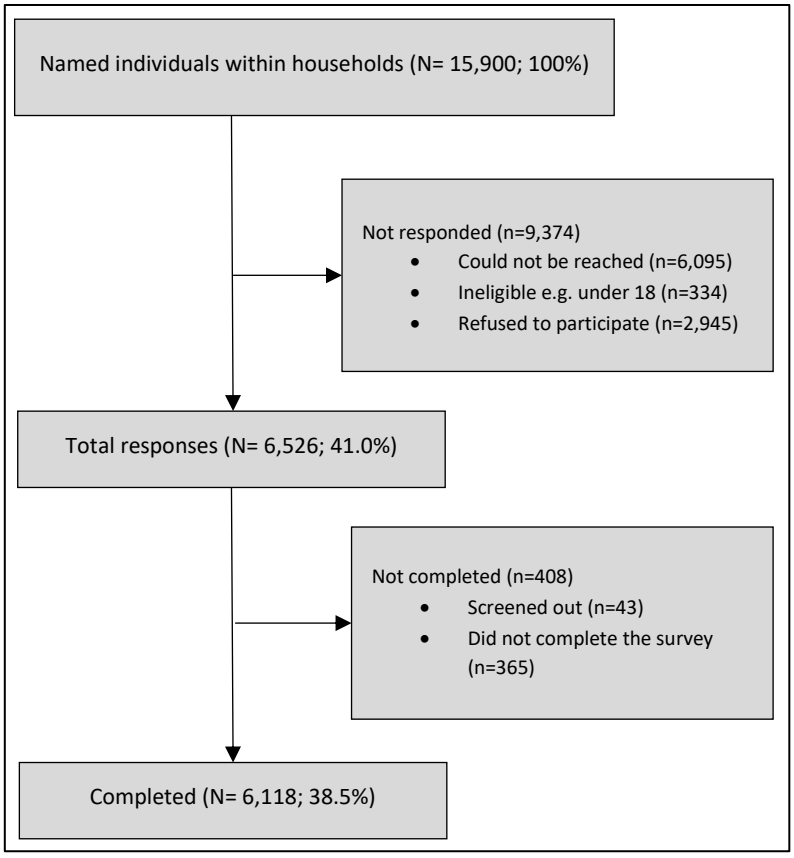

Figure 3 Disposition Groups - General Adult Population Sample

6.1.2 DEMOGRAPHIC CHARACTERISTICS

Over the 12-month survey period of Year 2 (2019-2020), a total of N=6,118 participants from the General Adult Population Sample completed the survey, with a mean age of 51.0 years (SD=16.99; range: 18 to 98) **(Table 3)**. Of those, 51.2% (n=3,133) were female and 48.8%

(n=2,985) were male. The gender and age distribution as well as other demographic characteristics including urban origin (city size), occupation/profession, and level of education of the participants in study Year 2 were similar to those of the General Adult Population Sample in Year 1 (2018-2019).

Table 3 Demographic Characteristics - General Adult Population Sample

Demographic characteristic	**General Adult Population Sample**	**(N=6,118)**
		n (%)
Gender		
	Male	2,985 (48.8%)
	Female	3,133 (51.2%)
Age group		
	18 - 29	781 (12.8%)
	30 - 39	784 (12.8%)
	40 - 49	1,285 (21.0%)
	50+	3,268 (53.4%)
	Min	18
	Median	51
	Mean [95% CI]	51.0 [50.5; 51.5]
	SD	16.99
	Max	98
City Size [inhabitants]		
	Up to 2,000	183 (3.0%)
	2,001-3,000	200 (3.3%)
	3,001-5,000	287 (4.7%)
	5,001-10,000	991 (16.2%)
	10,001-20,000	946 (15.5%)
	20,001-30,000	575 (9.4%)
	30,001-50,000	608 (9.9%)
	50,001-100,000	768 (12.6%)
	100,001-250,000	537(8.8%)
	250,001-499,999	265 (4.3%)
	Over 500,000	758 (12.4%)

Table 3 Demographic Characteristics - General Adult Population Sample – Continued

Demographic characteristic	General Adult Population Sample	(N=6,118)
		n (%)
Highest level of education		
	Degree	746 (12.2%)
	University without degree	275 (4.5%)
	Senior high school with diploma	2,704 (44.2%)
	Senior high school without diploma	383 (6.3%)
	Junior high school with diploma	1340 (21.9%)
	Junior high school without diploma	102 (1.7%)
	Elementary school with leaving certificate	496 (8.1%)
	Elementary school without leaving certificate	69 (1.1%)
	No school	3 (0.0%)
Occupation or profession		
	Retired	1,439 (23.5%)
	White-Collar (employed)	1,257 (20.5%)
	Housewife (working only in the home)	763 (12.5%)
	Owner of shop, Artisan (self-employed)	466 (7.6%)
	Blue-Collar unskilled	462 (7.6%)
	Blue-Collar skilled	400 (6.5%)
	Entrepreneur, Professional (self-employed)	377 (6.2%)
	Student	337 (5.5%)
	Unemployed (or looking for first job)	303 (5.0%)
	Teacher (employed)	151 (2.5%)
	Middle Manager (supervisor, high level technician)	87 (1.4%)
	Executive, Director, Top Management (employed)	31 (0.5%)
	Farmer (self-employed)	21 (0.4%)
	Rural worker (employed)	24 (0.2%)
	Other	1 (0.0%)

6.1.3 PREVALENCE OF CURRENT, PAST, AND NEVER TNP USE

In study Year 2 (2019-2020), 26.7% [95% CI: 25.6%, 27.9%] (n=1,636) of all participants from the General Adult Population Sample (N=6,118) were current TNP users, 10.6% [95% CI: 9.8%, 11.5%] (n=650) were former TNP users, and 62.6% [95% CI: 61.4%, 63.9%] (n=3,832) had never used any TNP (**Figure 4**). The prevalence of current TNP use in Year 2 was similar to that in Year 1 (2018-2019), i.e. 25.7% [95% CI: 24.6%, 26.9%].

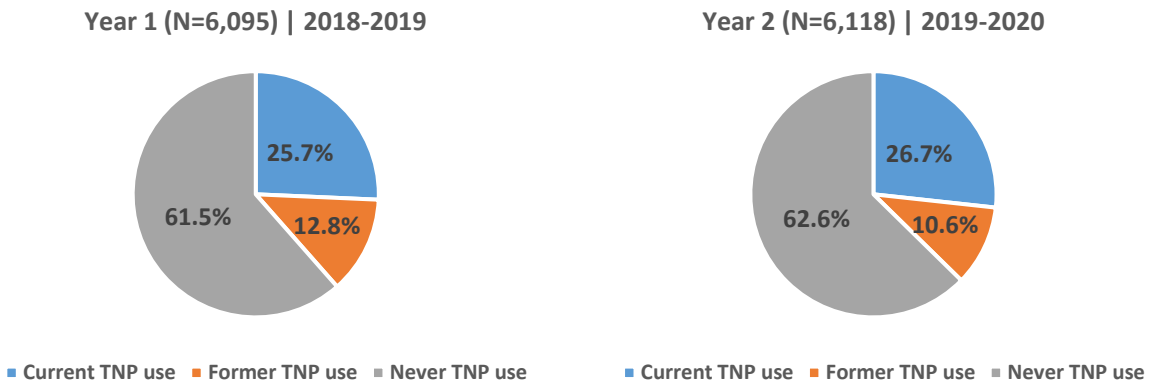

Figure 4 Prevalence of Current, Former and Never TNP Use - General Adult Population Sample
Note: TNP, tobacco or nicotine-containing product.

With regard to current TNP use stratified by gender, in Year 2 the prevalence among men (31.1%; N=2,985) was 1.4 times higher than among women (22.6%; N=3,133). Across age groups, the prevalence of current TNP use was higher among 40-49 (32.4%, N=1,285) and 18-29 (31.5%, N=781) year-olds than among 30-39 (22.3%, N=784) and 50+ (22.1%, N=3,268) year-olds. This pattern across age groups was similar among women, but different among men where current TNP use was higher among 30-39 (40.7%, N=369) and 40-49 (36.4%, N=591) year-olds than among 18-29 (34.7%, N=418) and 50+ (25.9%, N=1,607) year-olds. The largest difference in current TNP use was observed between 30-39 year-old men (40.7%; N=369) and 50+ year-old women (18.3%, N=1,661). Information on current, past, and never TNP use prevalence among participants of the General Adult Population Sample (N=6,118) in Year 2 (2019-2020) is also presented by strata of gender or age (see **below** and **Table 4)**.

Table 4 Prevalence of Current, Past and Never TNP Use by Age and Gender - General Adult Population Sample

	Age Group	N (%)	Statistics	Current TNP Use	Former TNP Use	Never TNP Use
Total population	**18 –29**	**781**	n (%)	246 (31.5%)	36 (4.6%)	499 (63.9%)
		(12.8%)	[LCL (%); UCL (%)]	[28.2%; 34.9%]	[3.2%; 6.4%]	[60.4%; 67.3%]
	30 - 39	**784**	n (%)	253 (22.3%)	54 (6.9%)	477 (60.8%)
		(12.8%)	[LCL (%); UCL (%)]	[29.0%; 35.7%]	[5.2%; 8.9%]	[57.3%; 64.3%]
	40 - 49	**1,285**	n (%)	416 (32.4%)	90 (7.0%)	779 (60.6%)
		(21.0%)	[LCL (%); UCL (%)]	[29.8%; 35.1%]	[5.6%; 8.6%]	[57.8%; 63.4%]
	50+	**3,268**	n (%)	721 (22.1%)	470 (14.4%)	2,077 (63.6%)
		(53.4%)	[LCL (%); UCL (%)]	[20.6%; 23.6%]	[13.1%; 15.7%]	[61.8%; 65.3%]
	Total	**6,118**	n (%)	1,636 (26.7%)	650 (10.6%)	3,832 (62.6%)
		(100%)	[LCL (%); UCL (%)]	[25.6%; 27.9%]	[9.8%; 11.5%]	[61.4%; 63.9%]

Note: LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

Table 4 Prevalence of Current, Past and Never TNP Use by Age and Gender - General Adult Population Sample - Continued

	Age Group	N (%)	Statistics	Current TNP Use	Former TNP Use	Never TNP Use
Female	**18 – 29**	**363**	n (%)	101 (27.8%)	16 (4.4%)	246 (67.8%)
		(11.6%)	[LCL (%); UCL (%)]	[23.2%; 32.8%]	[2.5%; 7.1%]	[62.6%; 72.6%]
	30 - 39	**415**	n (%)	103 (24.8%)	30 (7.2%)	282 (68.0%)
		(13.2%)	[LCL (%); UCL (%)]	[20.7%; 29.3%]	[4.9%; 10.2%]	[63.2%; 72.5%]
	40 - 49	**694**	n (%)	201 (29.0%)	45 (6.5%)	448 (64.6%)
		(22.2%)	[LCL (%); UCL (%)]	[25.6%; 32.5%]	[4.7%; 8.6%]	[60.8%; 68.2%]
	50+	**1,661**	n (%)	304 (18.3%)	143 (8.6%)	1,214 (73.1%)
		(53.0%)	[LCL (%); UCL (%)]	[16.4%; 20.3%]	[7.3%; 10.1%]	[70.8%; 75.3%]
	Total	**3,133**	n (%)	709 (22.6%)	234 (7.5%)	2,190 (69.9%)
		(100%)	[LCL (%); UCL (%)]	[21.1%; 24.2%]	[6.5%; 8.5%]	[68.2%; 71.6%]
Male	**18 - 29**	**418**	n (%)	145 (34.7%)	20 (4.8%)	253 (60.5%)
		(14.0%)	[LCL (%); UCL (%)]	[30.1%; 39.5%]	[2.9%; 7.3%]	[55.6%; 65.3%]
	30 - 39	**369**	n (%)	150 (40.7%)	24 (6.5%)	195 (52.8%)
		(12.4%)	[LCL (%); UCL (%)]	[35.5%; 45.9%]	[4.2%; 9.6%]	[47.6%; 58.1%]
	40 - 49	**591**	n (%)	215 (36.4%)	45 (7.6%)	331 (56.0%)
		(19.8%)	[LCL (%); UCL (%)]	[32.4%; 40.5%]	[5.6%; 10.1%]	[51.8%; 60.1%]
	50+	**1,607**	n (%)	417 (25.9%)	327 (20.3%)	863 (53.7%)
		(53.8%)	[LCL (%); UCL (%)]	[23.8%; 28.2%]	[18.4%; 22.5%]	[51.2%; 56.2%]
	Total	**2,985**	n (%)	927 (31.1%)	416 (13.9%)	1,642 (55.0%)
		(100%)	[LCL (%); UCL (%)]	[29.3%; 32.8%]	[12.7%; 15.3%]	[53.2%; 56.9%]

Note: LCL, Lower Confidence Limit of 95% CI; TNP, tobacco or nicotine-containing product; UCL, Upper Confidence Limit of 95% CI.

The current use prevalence of individual TNP use categories among participants from the General Adult Population Sample (N=6,118) in Year 2 (2019-2020) was 25.1% (n=1,535) for cigarettes, 1.4% (n=88) for e-cigarettes, 1.1% (n=67) for HTPs [IQOS only], and 0.02% (n=1) for any other innovative TNPs.[16] The current use prevalence of other TNPs including smokeless tobacco, other combustible TNPs, and nicotine replacement therapy (NRT) products was 1.1% (n=70) (**Figure 5**).

[16] Other innovative TNPs include products such as *Ploom* and *Glo* products.

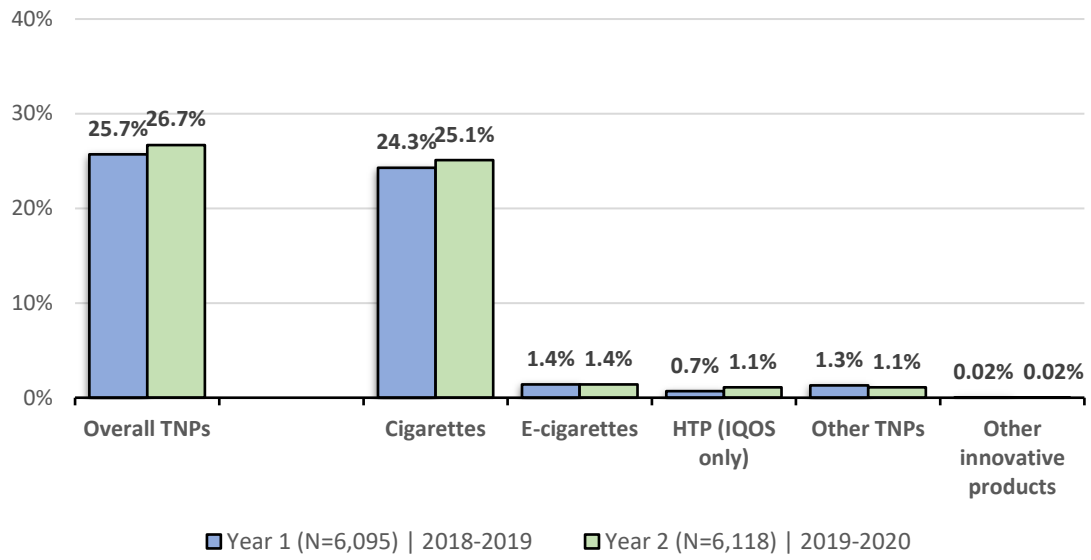

Figure 5 Prevalence of Current TNP Use - General Adult Population Sample - Trend (Year 1 and Year 2)
Note: Cigarettes include manufactured and fine cut/roll-your-own cigarettes. Other TNPs include (a) Smokeless Tobacco (such as chewing tobacco, snus, snuff, dissolvable), (b) Other Combustible Products (such as cigars, cigarillos, pipes, water-pipes), and (c) Nicotine Replacement Therapy products (NRTs, such as, patch, gum, tablet, inhaler, lozenge, pill). Other innovative products include products such as *Ploom* and *Glo* products. HTP, heated tobacco product. TNP, tobacco or nicotine-containing product.

Compared to Year 1 (2018-2019), the current use prevalence of individual TNP categories among participants from the General Adult Population Sample in Year 2 was slightly higher for cigarettes and HTPs, while it remained stable for e-cigarettes and was slightly lower for other TNPs (**Figure 5**).

Information on current use prevalence of individual TNPs (cigarettes, e-cigarettes, and IQOS) among participants of the General Adult Population Sample (N=6,118) in Year 2 (2019-2020) is also presented by strata of gender or age and (if available) compared with data from Year 1 (2018-2019) (see **below** and **Table 5**).

Current Cigarette Smoking. In Year 2, the prevalence of current cigarette smoking among men (29.0%; N=2,985) was 1.4 times higher than among women (21.4%; N=3,133). The prevalence of cigarette smoking among men and women in Year 2 was similar to Year 1. Across age groups, the prevalence of cigarette smoking in Year 2 was highest among 40-49 (31.4%; N=1,285) year-olds and lowest among 50+ (20.4%; N=3,268) while it was intermediate and similar among 18-29 (29.6%, N=781) and 30-39 (29.8%, N=784) year-olds. This pattern of current cigarette smoking prevalence across age groups was also observed within the two gender groups in Year 2. In Year 1, however, the prevalence of current cigarette smoking across age groups rather decreased with age. In Year 2, the largest difference in current cigarette smoking was observed between 30-39 year-old men (38.8%; N=369) and 50+ year-old women (17.5%, N=1,661). These two age groups were also those with the largest difference in current cigarette smoking in Year 1 (**Table 5**).

***Current E-cigarette Use*.** In Year 2 the prevalence of current e-cigarette use among men (2.0%; N=2,985) was 2.2 times higher than among women (0.9; N=3,133). This is similar to the prevalence of current e-cigarette use among men and women observed in Year 1. Across age groups, the prevalence of e-cigarette use in Year 2 was highest among 18-29 (2.8%; N=781) and lowest among 40-49 (1.0%; N=1,285) year-olds, while it was intermediate and equal among 30-39 (1.3%, N=784) and 50+ (1.3%, N=3,268) year-olds. A particular large difference in current e-cigarette use was observed between 18-29 year-old men (5.3% 4.1, N=418) and women (2.7% 1.4, N=363). The largest difference in current e-cigarette use, however, was observed between 18-29 year-old men (4.1%, N=418) and 30-39 year-old women (0.5%, N=415). These observations for prevalence of e-cigarette use across age groups in year 2 are similar to those in Year 1 (**Table 5**).

Current IQOS Use. In Year 2 the prevalence of current IQOS use was 1.4 times higher among men (1.3%, N=2,985) compared to women (0.9, N=3,133). This is similar to the prevalence of IQOS use among men and women in Year 1. Across age groups, the prevalence of IQOS use in Year 2 decreased consistently with age being higher among 18-29 (2.2%, N=781) and 30-39 (2.0%, N=784) year-olds and lower among the 40-49 (0.9%, N=3,268) and 50+ (0.7%, 3,268) year-olds. This decrease of IQOS use prevalence with age was also observed within the two gender groups. This, however, differs from the observations in Year 1 when the prevalence of IQOS use was highest among 30-39 year-olds. In study year 2, the largest difference in current IQOS use was observed between 18-29 year-old women (2.2% N=363), 18-29 year-old men (2.2%, N=418), and 30-39 year-old men (2.2% N=369) compared to 50+ year-old women (0.5%, N=1,661). This is different to Year 1, when the largest difference in current IQOS use prevalence was observed between 18-29 year-old women (0.0%) and 30-39 year-old men (2.5%) (**Table 5**).

Table 5 Prevalence of Current TNP Use by Age and Gender - General Adult Population Sample

	Age Group	N (%)	Statistics	Current overall TNP use	Current Cigarettes User	Current E-Cigarettes User	Current IQOS User
Total population	**18 – 29**	**781**	n (%)	246 (31.5%)	231 (29.6%)	22 (2.8%)	17 (2.2%)
		(12.8%)	[LCL (%); UCL (%)]	[28.2%; 34.9%]	[26.3%; 33.0%]	[1.7%; 4.3%]	[1.2%; 3.5%]
	30 - 39	**784**	n (%)	253 (22.3%)	234 (29.8%)	10 (1.3%)	16 (2.0%)
		(12.8%)	[LCL (%); UCL (%)]	[29.0%; 35.7%]	[26.6%; 33.2%]	[0.6%; 2.4%]	[1.6%; 3.3%]
	40 - 49	**1,285**	n (%)	416 (32.4%)	403 (31.4%)	13 (1.0%)	12 (0.9%)
		(21.0%)	[LCL (%); UCL (%)]	[29.8%; 35.1%]	[28.8%; 34.0%]	[0.5%; 1.8%]	[0.4%; 1.7%]
	50+	**3,268**	n (%)	721 (22.1%)	667 (20.4%)	43 (1.3%)	22 (0.7%)
		(53.4%)	[LCL (%); UCL (%)]	[20.6%; 23.6%]	[19.0%; 22.9%]	[0.9%; 1.8%]	[0.4%; 1.1%]
	Total	**6,118**	n (%)	1,636 (26.7%)	1,535 (25.1%)	88 (1.4%)	76 (1.1%)
		(100%)	[LCL (%); UCL (%)]	[25.6%; 27.9%]	[24.0%; 26.2%]	[1.1%; 1.8%]	[0.8%; 1.4%]

Table 5 Prevalence of Current TNP Use by Age and Gender - General Adult Population Sample – Continued

	Age Group	N (%)	Statistics	Current overall TNP use	Current Cigarettes User	Current E-Cigarettes User	Current IQOS User
Female	**18 – 29**	**363**	n (%)	101 (27.8%)	92 (25.3%)	5 (1.4%)	8 (2.2%)
		(11.6%)	[LCL (%); UCL (%)]	[23.2%; 32.8%]	[20.9%; 30.2%]	[0.4%; 3.2%]	[0.9%; 4.3%]
	30 - 39	**415**	n (%)	103 (24.8%)	91 (21.9%)	2 (0.5%)	8 (1.9%)
		(13.2%)	[LCL (%); UCL (%)]	[20.7%; 29.3%]	[18.0; % 26.3%]	[0.0%; 1.8%]	[0.8%; 3.8%]
	40 - 49	**694**	n (%)	201 (29.0%)	196 (28.2%)	5 (0.7%)	4 (0.6%)
		(22.2%)	[LCL (%); UCL (%)]	[25.6%; 32.5%]	[24.9%; 31.8%]	[0.2%; 1.7%]	[0.1%; 1.5%]
	50+	**1,661**	n (%)	304 (18.3%)	290 (17.5%)	15 (0.9%)	9 (0.5%)
		(53.0%)	[LCL (%); UCL (%)]	[16.4%; 20.3%]	[15.6%; 19.4%]	[0.5%; 1.5%]	[0.2%; 1.1%]
	Total	**3,133**	n (%)	709 (22.6%)	669 (21.4%)	29 (0.9%)	29 (0.9%)
		(100%)	[LCL (%); UCL (%)]	[21.1%; 24.2%]	[19.9%; 22.9%]	[0.5%; 1.3%]	[0.6%; 1.4%]
Male	**18 - 29**	**418**	n (%)	145 (34.7%)	139 (33.3%)	17 (4.1%)	9 (2.2%)
		(14.0%)	[LCL (%); UCL (%)]	[30.1%; 39.5%]	[28.7%; 38.0%]	[2.3%; 6.5%]	[0.9%; 4.1%]
	30 - 39	**369**	n (%)	150 (40.7%)	143 (38.8%)	8 (2.2%)	8 (2.2%)
		(12.4%)	[LCL (%); UCL (%)]	[35.5%; 45.9%]	[33.7%; 44.0%]	[0.9%; 4.3%]	[0.9%; 4.3%]
	40 - 49	**591**	n (%)	215 (36.4%)	207 (35.0%)	8 (1.4%)	8 (1.4%)
		(19.8%)	[LCL (%); UCL (%)]	[32.4%; 40.5%]	[31.1%; 39.1%]	[0.5%; 2.7%]	[0.5%; 2.7%]
	50+	**1,607**	n (%)	417 (25.9%)	377 (23.5%)	28 (1.7%)	13 (0.8%)
		(53.8%)	[LCL (%); UCL (%)]	[23.8%; 28.2%]	[21.4%; 25.7%]	[1.1%; 2.6%]	[0.4%; 1.4%]
	Total	**2,985**	n (%)	927 (31.1%)	866 (29.0 %)	61 (2.0%)	38 (1.3%)
		(100%)	[LCL (%); UCL (%)]	[29.3%; 32.8%]	[27.3%; 30.7%]	[1.5%; 2.7%]	[0.9%; 1.8%]

Note: Cigarettes include manufactured and roll/make-your own cigarettes. LCL, Lower Confidence Limit of 95% CI; UCL, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product.

6.1.4 FREQUENCY AND INTENSITY OF TNP USE

In study Year 2 (2019-2020), 95.2% (n=1,462) of current cigarette smokers (N=1,535) smoked daily (i.e. ≥1 cigarette/day), with on average 12.9 [12.5; 13.2] cigarettes/day, while 3.5% (n=54) smoked occasionally (i.e. <1 cigarette/day), and 1.2% (n=19) did not provide information (**Table 6**). Compared to study Year 1 (2018-2019), in Year 2 the prevalence of daily cigarette smoking (92.8% vs. 95.2%) was slightly higher, while occasional use (5.7% vs. 3.5%) was slightly lower, and average daily cigarette consumption (12.7 vs. 12.9 cigarettes/day) remained rather stable.

Among current e-cigarette users (N=88) in Year 2, 81.8% (n=72) used e-cigarettes daily (i.e. ≥1 time/day) with on average 19.2 [14.1; 24.3] times/day, while 15.9% (n=14) used e-cigarettes occasionally (i.e. <1 time/day), and 2.3% (n=2) did not provide information (**Table 6**). Compared to study Year 1, the prevalence of daily e-cigarette use (82.1% vs. 81.8%) remained rather stable in Year 2, whereas the average daily consumption (18.4 vs. 19.2 times/day) and prevalence of occasional use (13.1% vs. 15.9%) were slightly higher.

Among current IQOS users (N=67) in Year 2, 76.1% (n=51) used IQOS daily (i.e. ≥1 HEETS/day) with on average 8.0 [6.3; 9.8] HEETS/day, while 20.9% (n=14) used IQOS only occasionally (i.e. <1 HEETS/day) and 3.0% (n=2) did not provide information (**Table 6**). Compared to study Year 1, the prevalence of daily IQOS use (71.4% vs. 76.1%) was higher and of occasional use (23.8% vs. 20.9%) slightly lower in Year 2, while the average daily consumption (7.9 vs. 8.0 HEETS/day) remained stable.

Table 6 Consumption per Day Current Users in the Last 3 Months – General Adult Population Sample

		Current Cigarette Smokers	Current E-Cigarette Users	Current IQOS Users
Consumption	**Statistics**	**(N=1,535)**	**(N=88)**	**(N=67)**
Daily use (≥1 TNP/day)	n (%)	1,462 (95.2%)	72 (81.8%)	51 (76.1%)
	[LCL (%); UCL (%)]	[94.0%; 96.3%]	[72%.1; 89.3%]	[64.1%; 85.7%]
Intensity (Sticks or time per day)	Mean	12.9	19.2	8.0
	[LCL; UCL]	[12.5; 13.2]	[14.1; 24.3]	[6.3; 9.8]
Occasional use (<1 TNP/day)	n (%)	54 (3.5%)	14 (15.9%)	14 (20.9%)
	[LCL (%); UCL (%)]	[2.6%; 4.6%]	[8.9%; 25.3%]	[11.9%; 32.6%]
No information	n (%)	19 (1.2%)	2 (2.3%)	2 (3.0%)
	[LCL (%); UCL (%)]	[0.7%; 2.0%]	[0.2%; 8.0%]	[0.3%; 10.4%]

Note: Cigarettes include manufactured and roll/make-your own cigarettes. LCL, Lower Confidence Limit of 95% CI; UCL, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product.

6.1.5 PATTERNS OF TNP USE

Among all current TNP users (N=1,636) in study Year 2 (2019-2020), 93.8% (n=1,534) were exclusive users of only one particular TNP, while 4.5% (n=74) were dual users, and 1.7% (n=28) were poly users. The highest proportions of dual and poly TNP use were together with cigarettes (**Table 7**).

Table 7 TNP Use Patterns - General Adult Population Sample

	Current TNP Users (N=1,636)			
	n	%	LCL (%)	UCL (%)
Exclusive product use	**1,534**	**93.8**	**92.5**	**94.9**
- Cigarettes (CC)	1,442	88.1	86.4	89.7
- E-cigarette	39	2.4	1.7	3.3
- IQOS	28	1.7	1.1	2.5
- One Other Product	25	1.5	0.9	2.3
Dual product use	**74**	**4.5**	**3.6**	**5.7**
- CC & E-cigarette	31	1.9	1.2	2.7
- CC & IQOS	19	1.2	0.7	1.9
- CC & Other Product	18	1.1	0.6	1.8
- Two other Products	3	0.2	0.0	0.6
- IQOS & E-cigarette	2	0.1	0.0	0.5
- IQOS & Other Product	1	0.1	0.0	0.4
Poly product use	**28**	**1.7**	**1.1**	**2.5**
- CC & IQOS & E-cigarette & Other Product(s)	9	0.6	0.2	1.1
- CC & Other Products	5	0.3	0.0	0.8
- CC & IQOS & E-cigarette	4	0.2	0.0	0.7
- CC & IQOS & Other Product(s)	4	0.2	0.0	0.7
- Three other Products	3	0.2	0.0	0.6
- CC & E-cigarette & Other Product(s)	2	0.1	0.0	0.5
- CC & E-cigarette & Other Innovative Product	1	0.1	0.0	0.4

Note: Other Product(s) include (a) smokeless tobacco, (b) other combustible products (such as cigars, cigarillos, pipes, water pipes) and c) Nicotine Replacement Therapy products and are only displayed as sum category. CC, cigarettes include manufactured and roll/make-your own cigarettes. LCL, Lower Confidence Limit of 95% CI; UCL, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product.

Compared to study Year 1 (2018-2019), while the prevalence of dual TNP use (6.1% vs. 4.5%) was somewhat lower in study Year 2, the prevalence of exclusive TNP use (92.7% vs. 93.8%) and poly TNP use (1.2% vs. 1.7%) was slightly higher **(Figure 6)**.

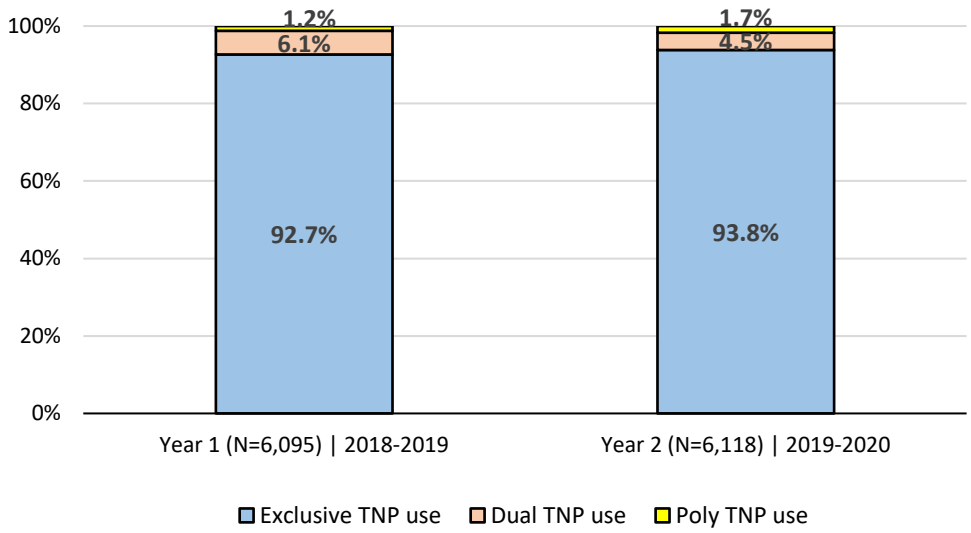

Figure 6 Patterns of TNP Use - General Adult Population Sample, Trend (Year 1 and Year 2)
Note: TNP, tobacco or nicotine-containing product.

6.1.6 HISTORY OF TNP USE

Initiation

Among participants who were never TNP users[17] (N=3,900) more than one year ago before study Year 2 (2019-2020), 0.41% (n=16) initiated TNP use with combustible cigarettes, 0.05% with IQOS (n=2), and 0.03% (n=1) with e-cigarettes in the last 12 months in Year 2 (**Table 8**).

Table 8 TNP Initiation in Never TNP Users – General Adult Population Sample

	Never TNP users [N = 3,900]			
	n	%	LCL (%)	UCL (%)
Cigarettes	16	**0.41%**	**0.23**	**0.67**
IQOS with HEETS	2	**0.05%**	**0.00**	**0.19**
E-cigarettes	1	**0.03%**	**0.00**	**0.15**

Note: Cigarettes include manufactured and roll/make-your own cigarettes. LCL, Lower Confidence Limit of 95% CI; UCL, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product.

These rates of initiation of TNP use in Year 2 were similar to those observed in Year 1 (2018-2019) (**Figure 7**).

[17] Never TNP users: Never used/smoked any TNP until one year prior to the survey

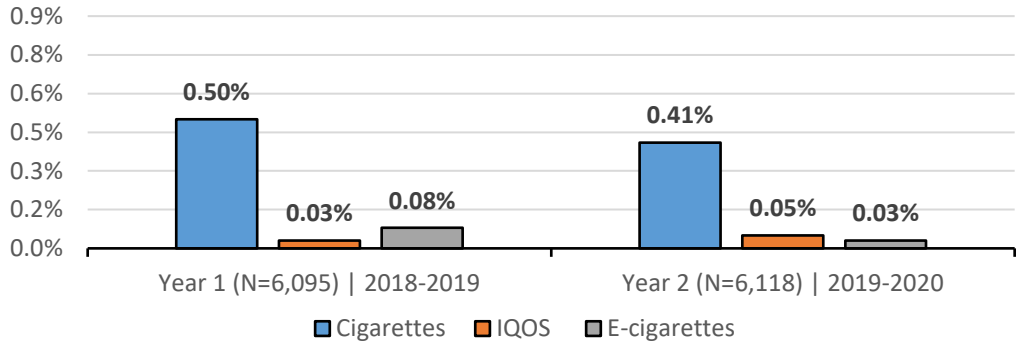

Figure 7 Initiation Rates of TNP Use - General Adult Population Sample, Trend (Year 1 and Year 2)
Note: Cigarettes include manufactured and roll/make-your own cigarettes. TNP, tobacco or nicotine-containing product.

Re-initiation and Relapse

In the last 12 months prior to study Year 2 (2019-2020), 0.92% (n=15) of all current TNP users (N=1,636) relapsed (after ≤12 months of smoking abstinence) to smoking cigarettes, while only 0.06% (n=1) relapsed to TNP use with IQOS, and none (0.00%) to TNP use with e-cigarettes (**Table 9**).

At the same time, only 0.06% (n=1) of all current TNP users (N=1,636) re-initiated (after >12 months of smoking abstinence) TNP use with IQOS, and none re-initiated TNP use with cigarettes (0.00%) or e-cigarettes (0.00%) (**Table 9**).

Table 9 Re-Initiation and Relapse in TNP Users - General Adult Population Sample

	Current TNP Users [N =1,636]		
	n	**%**	**[LCL (%); UCL (%)]**
Relapse to cigarettes	15	**0.92**	[0.51; 1.51]
Re-initiation with cigarettes	0	**0.00**	[0.00; 0.23]
Relapse to IQOS	1	**0.06**	[0.00; 0.35]
Re-initiation with IQOS	1	**0.06**	[0.00; 0.35]
Relapse to e-cigarettes	0	**0.00**	[0.00; 0.23]
Re-initiation with e-cigarettes	0	**0.00**	[0.00; 0.23]

Note: Cigarettes include manufactured and roll/make-your own cigarettes. LCL, Lower Confidence Limit of 95% CI; UCL, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product. Relapse, starting TNP use again after ≤12 months of smoking abstinence; Re-initiation, starting TNP use again after (>12 months of smoking abstinence.

These rates of relapse and re-initiation of TNP use in study Year 2 (2019-2020) are similar to those of Year 1 (2018-2019), and remained low with regards to IQOS and e-cigarettes (**Figure 8**).

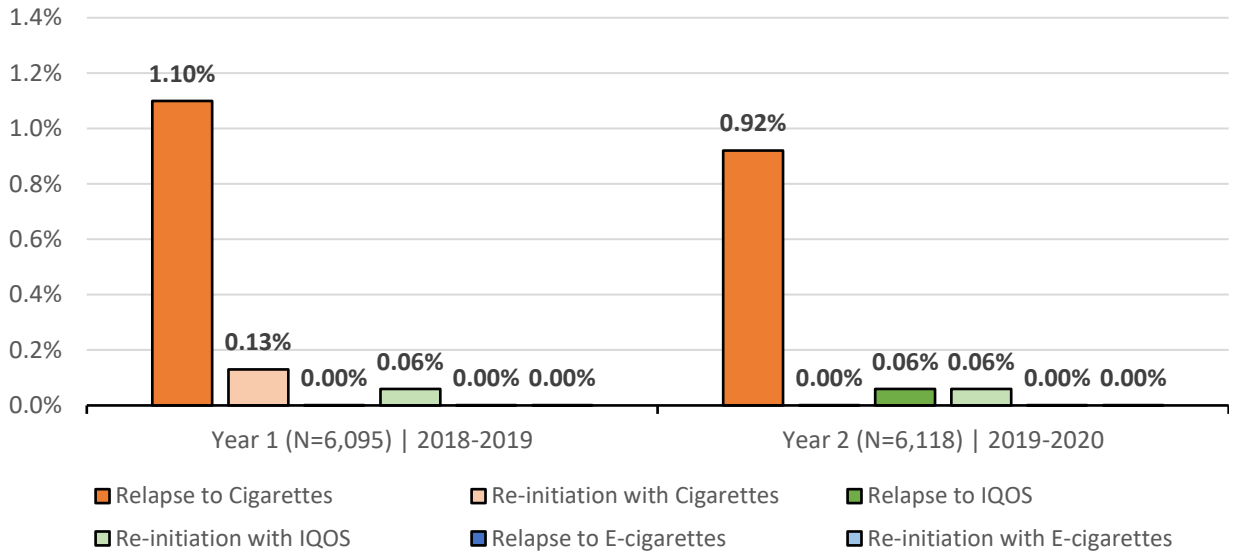

Figure 8 Relapse/Re-Initiation of TNP Use - General Adult Population Sample, Trend (Year 1 and Year 2)
Note: Cigarettes include manufactured and roll/make-your own cigarettes. TNP, tobacco or nicotine-containing product. Relapse, starting TNP use again after ≤12 months of smoking abstinence; Re-initiation, starting TNP use again after >12 months of smoking abstinence.

6.1.7 QUITTING

Interest in and Planning of Quitting/Stop Using

In study Year 2 (2019-2020), 10.7% (n=165) of current cigarette smokers (N=1,535) planned to quit smoking in the next 30 days or 6 months, while 69.1% (n=1,060) were not interested in quitting smoking, and 20.2% (n=310) stated “Don't know/couldn't say” (**Figure 9**).

Among current IQOS users (N=67), 16.4% (n=11) planned to stop using IQOS within the next 30 days or 6 months, whereas 65.7% (n=44) were not interested in stop using IQOS, and 17.9% (n=12) stated “Don't know/couldn't say” (**Figure 9**).

Among current e-cigarette users (N=88), 20.5% (n=18) planned to stop using e-cigarettes in the next 30 days or 6 months, while 54.5% (n=48) were not interested in stop using e-cigarettes, and 25.0% (n=22) stated “Don't know/couldn't say” (**Figure 9**).

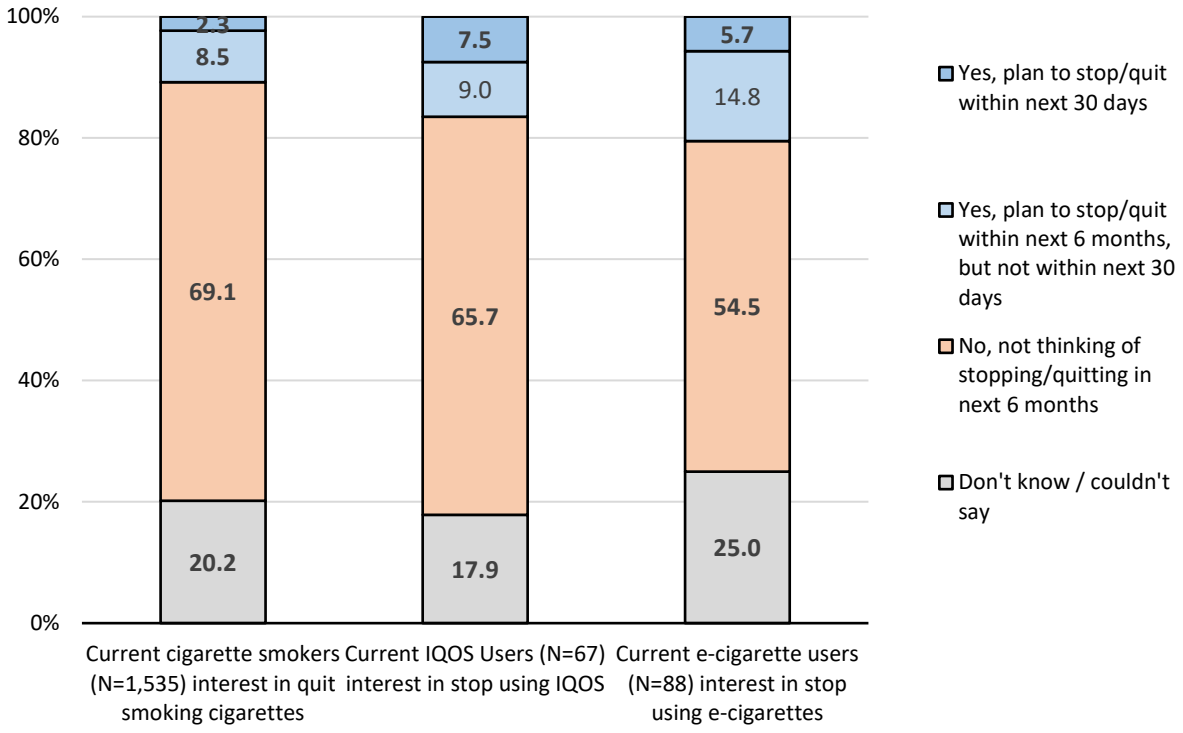

Figure 9 Interest in Quit Smoking/Stop Using IQOS or E-Cigarettes – General Adult Population Sample
Note: Cigarettes include manufactured and roll/make-your own cigarettes.

Quit/Stop Using Attempts

Moreover, in study Year 2 (2019-2020), 7.7% (n=118) of current cigarette smokers (N=1,535) tried to quit smoking in the past 12 months prior to the survey (**Figure 10**) with on average 2.5 [1.8; 3.2] quit attempts and an average duration of 3.0 [2.3; 3.7] months.

Among current IQOS users (N=67), 11.9% (n=8) tried to stop using IQOS in the past 12 months prior to the survey (**Figure 10**) with on average 2.9 [0.4; 5.4] stop attempts and an average duration of 1.9 [0.4; 3.4] months.

Among current e-cigarette users (N=88), 4.5% (n=4) tried to stop using e-cigarettes in the past 12 months prior to the survey (**Figure 10**) with on average 2.0 [0.0; 4.3] stop attempts and an average duration of 1.0 months.

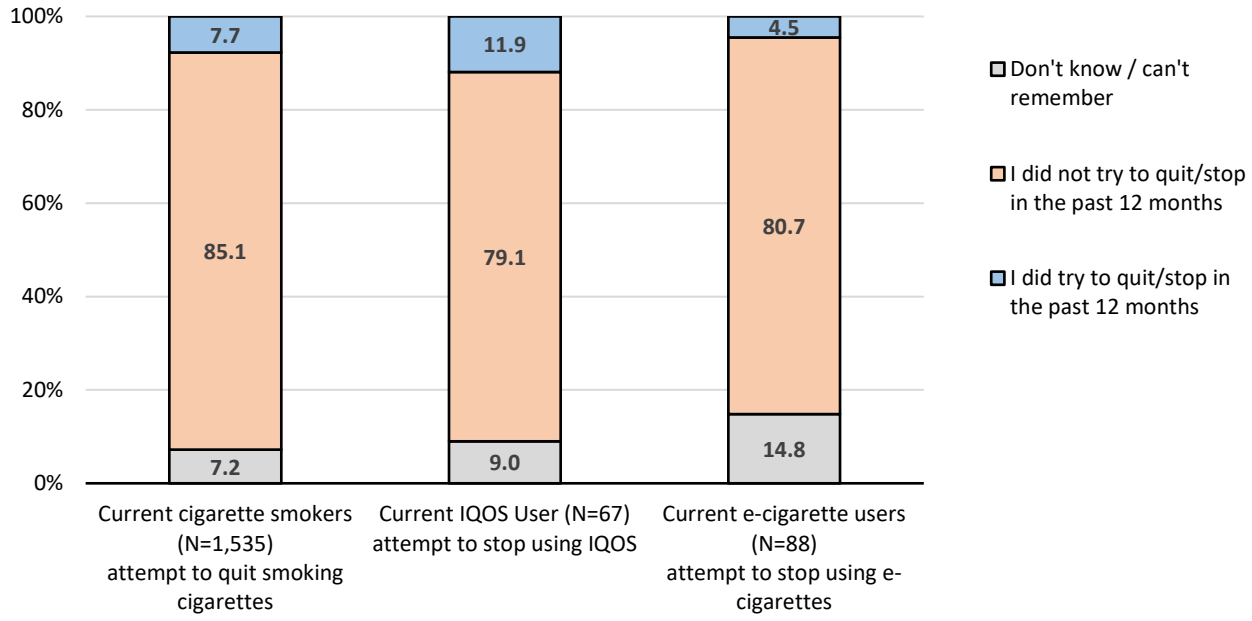

Figure 10 Attempt to Quit Smoking/Stop Using IQOS or E-Cigarettes in Last 12 Months - General Adult Population Sample.
Note: Cigarettes include manufactured and roll/make-your own cigarettes.

Successful Quitting/Stop Using

In study Year 2 (2019-2020), 1.9% (n=29) of participants who had been cigarette smokers more than one year prior to the survey (N=1,564) successfully quit smoking in the past 12 months. Of those, 55.6% (n=15) quit all TNPs, 29.6% (n=8) switched to e-cigarettes, 11.1% (n=3) switched to IQOS, and 3.7% (n=1) used IQOS together with at least one other TNP.

Among IQOS users who had used IQOS more than 12 months prior to the survey (N=94), 28.7% (n=27) stopped using IQOS in the past 12 months. Of those, 54.5% (n=6) switched to cigarettes, 27.3% (n=3) quit all TNPs, 9.1% (n=1) switched to e-cigarettes, and 9.1% (n=1) switched to cigarettes together with at least one other TNP.

Among e-cigarette users who had used e-cigarettes more than 12 months prior to the survey (N=126), 30.2% (n=38) stopped using e-cigarettes in the past 12 months. Of those, 69.2% (n=9) switched to cigarettes, 23.1% (n=3) quit all TNPs, and 7.7% (n=1) used cigarettes together with at least one other TNP.

Compared to study Year 1 (2018-2019), the percentage of smokers who planned to quit smoking (12.5% vs. 10.7%), had already attempted to quit in the past 12 months (9.6% vs. 7.7%), or had successfully quit cigarettes (2.9% vs. 1.9%) or all TNPs (2.0% vs. 1.0%) in the past 12 months was somewhat lower in Year 2 (2019-2020), while the number (2.2 vs. 2.5 attempts) and duration of

quit attempts (2.6 vs. 3.0 months) was slightly higher. Regarding stop using IQOS, compared to study Year 1, the percentage of IQOS users who planned to stop using IQOS (19.1% vs. 16.4%) or had already attempted to stop using IQOS in the past 12 months (16.7% vs. 11.1%) was lower in Year 2.[18]

6.1.8 PERCEIVED HEALTH RELATED SYMPTOMS

6.1.8.1 *RESPIRATORY SYMPTOMS*

In study Year 2 (2019-2020), 5.6% (n=340) of all participants from the General Adult Population Sample (N=6,118) reported respiratory symptoms[19] (part-day or all day), whereas among the subgroup of current exclusive cigarette smokers (N=1,442) a higher percentage of 14.1% (n=204) reported respiratory symptoms.

Regarding the change in respiratory symptoms over the past 12 months prior to the survey, 91.0% (n=5,567) of all participants from the General Adult Population Sample (N=6,118) reported no change in cough symptoms, while 6.4% (n=389) reported an overall improvement, and 2.6% (n=162) reported a deterioration in cough symptoms. Similarly, 93.7% (n=5,731) reported no change in phlegm symptoms, whereas 3.9% (n=237) reported an improvement, and 2.5% (n=150) reported a deterioration.

Among the subgroup of current exclusive cigarette smokers (N=1,442), 89.0% (n=1,284) reported no change in cough symptoms, while 5.5% (n=80) reported an overall improvement, and 5.4% (n=78) reported a deterioration in cough symptoms. Similarly, 92.0% (n=1,327) reported no change in phlegm symptoms, whereas 3.5% (n=50) reported an improvement, and 4.5% (n=65) reported a deterioration.

Compared to Year 1 of the study (2018-2019), the percentage of participants from the General Adult Population Sample (8.1% vs. 5.6%) and of the subgroup of current exclusive cigarette smokers (19.2%[20] vs. 14.1%) who reported respiratory symptoms was overall lower in Year 2.

[18] For study year 1, information on the number and duration of stop attempts or successful stopping using IQOS is not available.

[19] Two subscales of the Medical Research Council Questionnaire (MRCQ) were used to estimate selected respiratory symptoms. Participants were asked to evaluate the presence of cough (3 items) and phlegm symptoms (3 items). Additionally, participants were asked if their respiratory symptoms changed as compared to 12 months ago using a 7-point scales from “very much improved” to “very much worse”.

Medical Research Council on the Aetiology of Chronic Bronchitis. Standardised questionnaire on respiratory symptoms. Br Med J 1960;2:1665.

[20] In Year 1 the percentage 19.2% refers to current adult smokers not to current adult exclusive cigarette smokers.

6.1.8.2 *EXERCISE CAPACITY*

The Rating of Perceived Capacity (RPC)[21] instrument was used to estimate maximal exercise capacity based on metabolic equivalents (MET; the higher the MET value, the better the exercise capacity). Among female participants from the general adult population (N=3,133), average exercise capacity was rated to correspond to 8.7 [8.5; 8.9] MET, while among male participants from the general adult population (N=2,985), average exercise capacity was rated to correspond to 9.9 [9.7; 10.1] MET.

Regarding the change in exercise capacity over the past 12 months prior to the survey (rated on a seven-point scale ranging from "very much improved" to "very much worse"), 79.4% (n=4,858) of all-participants from the General Adult Population Sample (N=6,118) reported no change in exercise capacity, whereas 11.0% (n=676) reported a worsening, and 9.5% (n=584) an improvement.

Among the subgroup of current exclusive cigarette smokers (N=1,442), 82.2% (n=1,186) reported no change in exercise capacity, whereas 9.8% (n=142) reported a worsening, and 7.9% (n=114) an improvement.[22]

Compared to Year 1 of the study (2018-2019), the percentage of participants from the General Adult Population sample who reported an improvement (12.4% vs. 9.5%) in exercise capacity was slightly lower in Year 2, whereas the percentage who reported a worsening (11.8% vs. 11.0%) was rather similar.

Data on Respiratory Symptoms (section **6.2.8.1**), Exercise Capacity (section **6.2.8.2**), and Perceived Benefits of IQOS Use (section **6.2.8.3**) among current IQOS users are reported further below.

[21] Single item questionnaire. MET values from 1 to 20 in men and 1 to 18 in women are listed on a progressive scale linked to specific physical activities by choosing the most strenuous activity that they could sustain for at least 30 min. 1 MET equals energy expenditure in terms of oxygen consumption per 1 kg of body mass while sitting at rest. Wisén, A.G., Farazdaghi, R.G. & Wohlfart, B. A novel rating scale to predict maximal exercise capacity. Eur J Appl Physiol 87, 350–357 (2002). https://doi.org/10.1007/s00421-002-0636-y.

[22] For Year 1, information on the improvement in exercise capacity among exclusive cigarette smokers was not available.

6.2 IQOS USER SAMPLE

6.2.1 DISPOSITION GROUPS

In study Year 2, a total of 55,800 IQOS user candidates from the IQOS Owner database of PMI's affiliate in Italy received an invitation to participate in Year 2 study. Of these, 52,908 candidates did not respond (i.e. did not open the e-mail or did not click on the link). Of the remaining 2,892 (5.2%) who were willing to participate in the study, 391 were not eligible to participate.

Of the remaining 2,501 (4.5%) candidates who were eligible to participate, 1,034 delivered an incomplete questionnaire, and 66 could not be considered since the quota had already been reached. In total, 1,401 (2.5%) participants completed the Year 2 study survey (2019-2020) (**Figure 11**).

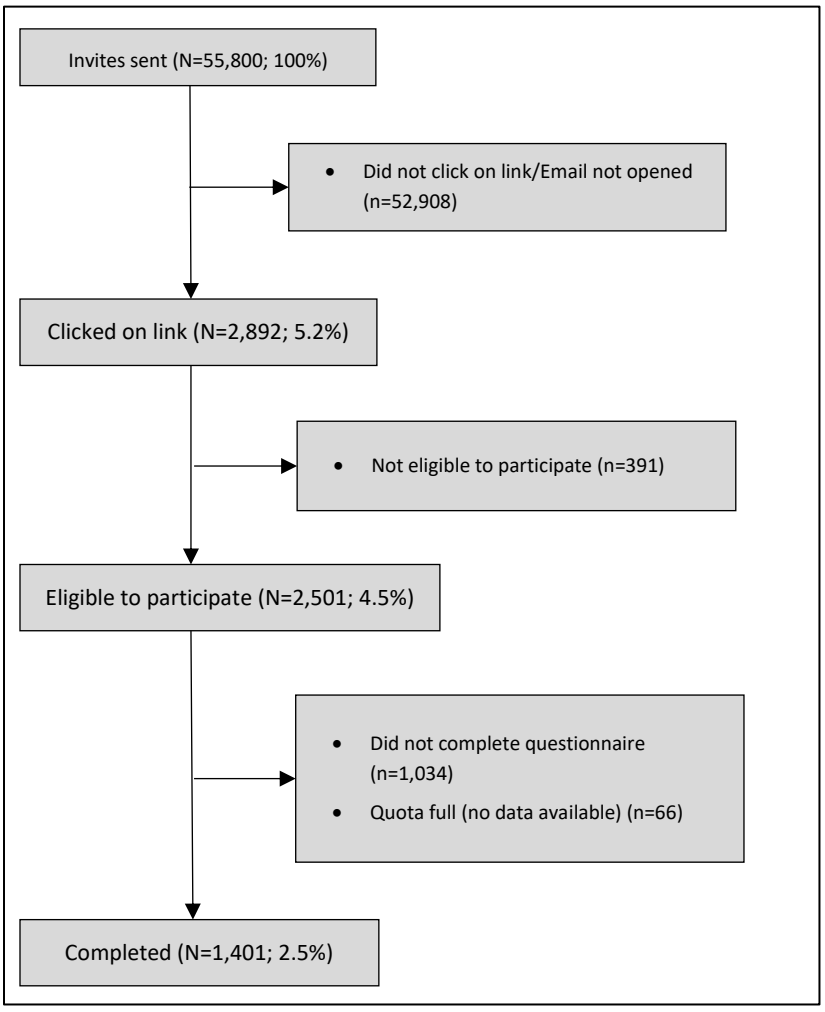

Figure 11 Disposition Groups – IQOS User Sample

6.2.2 DEMOGRAPHIC CHARACTERISTICS

Over the 12-month study period of Year 2 (2019-2020), a total of N=1,401 participants from the IQOS User Sample with a mean age of 36.7 years (SD=12.2; range 18 to 72) completed the study. Of those, 57.4% (n=804) were male and 42.6% (n=597) were female (**Table 10**). Compared to Year 1 (2018-2019), the mean age (39.5 vs. 36.7 years) of IQOS users was slightly lower, while the proportion of male IQOS users (44.3% vs. 57.4%) was higher in Year 2.

Table 10 Demographic Characteristics - IQOS User Sample

Demographic characteristic		**IQOS User Sample (N=1,401)**
		(n %)
Gender		
	Male	804 (57.4%)
	Female	597 (42.6%)
Age group		
	18 - 29	488 (34.8%)
	30 - 39	338 (24.1%)
	40 - 49	337 (24.1%)
	50+	238 (17.0%)
	Min	18
	Median	36
	Mean [95% CI]	36.7 [36.0; 37.4]
	SD	12.27
	Max	72
City Size [inhabitants]		
	Up to 2.000	41 (2.9%)
	2,001-3,000	40 (2.9%)
	3,001-5,000	74 (5.3%)
	5,001-10,000	147 (10.5%)
	10,001-20,000	143 (10.2%)
	20,001-30,000	107 (7.6%)
	30,001-50,000	115 (8.2%)
	50,001-100,000	150 (10.7%)
	100,001-250,000	97 (6.9%)
	Over 250,000	279 (19.9%)
	Don't know	208 (14.8%)

Table 10 Demographic Characteristics - IQOS User Sample – Continued

Demographic characteristic		IQOS User Sample (N=1,401)
		(n %)
Highest level of education		
	Degree	381 (27.2%)
	University without degree	192 (13.7%)
	Senior high school with diploma	638 (45.5%)
	Senior high school without diploma	111 (7.9%)
	Junior high school with diploma	62 (4.4%)
	Junior high school without diploma	14 (1.0%)
	Elementary school with leaving certificate	1 (0.1%)
	Elementary school without leaving certificate	2 (0.1%)
Occupation or profession		
	White-Collar (employed)	410 (29.3%)
	Entrepreneur, Professional (self-employed)	235 (16.8%)
	Student	182 (13.0%)
	Middle Manager (supervisor, high level technician)	81 (5.8%)
	Blue-Collar skilled	76 (5.4%)
	Blue-Collar unskilled	71 (5.1%)
	Unemployed (or looking for first job)	64 (4.6%)
	Executive, Director, Top Management (employed)	50 (3.6%)
	Owner of shop, Artisan (self-employed)	47 (3.4%)
	Teacher (employed)	34 (2.4%)
	Housewife (working only in the home)	29 (2.1%)
	Retired	23 (1.6%)
	Farmer (self-employed)	3 (0.2%)
	Rural worker (employed)	2 (0.1%)
	Other	94 (6.7%)

6.2.3 FREQUENCY AND INTENSITY OF IQOS USE

In study Year 2 (2019-2020), 96.1% (n=1,347) of all current IQOS users (N=1,401) used IQOS daily (i.e. ≥1 HEETS/day) with on average 13.3 HEETS/day, whereas 3.2% (n=45) used IQOS occasionally (i.e. <1 HEETS/day), and 0.6% (n=9) did not provide information (**Table 11**). Compared to study Year 1 (2018-2019), the prevalence of daily (96.8% vs. 96.1%) and occasional (2.9% vs. 3.2%) IQOS use as well as average daily HEETS consumption (13.7 vs. 13.3 HEETS/day) in Year 2 was similar.

The observations for frequency and intensity of IQOS use are also reported for strata by gender (**Table 11**) or age (**Table 12**).

While the percentage of daily use was similar between men (95.6%, N=804) and women (96.8%, N=597), the average daily HEETS consumption was higher among male (14.3 HEETS/day) than female (12.0 HEETS/day) IQOS users (**Table 11**).

Table 11 Current IQOS Consumption in the Last 3 Months – Total and by Gender - IQOS User Sample

		Current IQOS users (N=1,401)			
		Total (N=1,401)		**Male** (N=804)	**Female** (N=597)
HEETS per day - categorical					
Daily use (≥1 HEETS/day)	n (%)	1,347 (96.1%)		769 (95.6%)	578 (96.8%)
Occasional use (<1 HEETS/day)	n (%)	45 (3.2%)		27 (3.4%)	18 (3.0%)
No information	n (%)	9 (0.6%)		8 (1.0%)	1 (0.2%)
HEETS/day - continuous					
	n (%)	1,347 (96.1%)		769 (95.6%)	578 (96.8%)
	n missing	54		35	19
	Min	1		1	1
	Median	13		15	10
	Mean [95% CI]	13.3 [12.9; 13.7]		14.3 [13.7; 14.9]	12.0 [11.4; 12.6]
	SD	7.03		7.22	6.55
	Max	40		40	40

The percentage of daily use was overall similar across age groups, while average daily HEETS consumption was increasing with age from 11.2 HEETS/day among 18-29 year-old IQOS users to 14.9 HEETS/day among 50+ year-old IQOS users (**Table 12**).

Table 12 Current IQOS Consumption in the Last 3 Months - by Age - IQOS User Sample

		Current IQOS users (N=1,401)			
		Age 18 - 29 (N=488)	**Age 30 - 39** (N=388)	**Age 40 - 49** (N=337)	**Age 50+** (N=238)
HEETS/day - categorical					
Daily IQOS use (≥1 HEETS/day)	n (%)	470 (96.3%)	326 (96.4%)	320 (95.0%)	231 (97.1%)
Occasional IQOS use (<1 HEETS/day))	n (%)	14 (2.9%)	10 (3.0%)	15 (4.5%)	6 (2.5%)
No information	n (%)	4 (0.8%)	2 (0.6%)	2 (0.6%)	1 (0.4%)
HEETS/day - continuous					
	n (%)	470 (96.3%)	326 (96.4%)	320 (95.0%)	231 (97.1%)
	n missing	18	12	17	7
	Min	1	1	1	1
	Median	10	15	15	15
	Mean [95% CI]	11.2 [10.6; 11.8]	14.1 [13.4; 14.9]	14.4 [13.6; 15.3]	14.9 [13.8; 16.0]
	SD	6.06	6.59	7.29	8.08
	Max	30	40	40	40

6.2.4 PATTERNS OF IQOS USE

In Year 2 (2019-2020), 61.7% (n=864) of all current IQOS users (N=1,401) used IQOS exclusively, 36.0% (n=505) used IQOS together with combustible TNPs, and 2.3% (n=32) used IQOS in combination with other non-combustible TNPs. The prevalence of exclusive IQOS use was lower among men (57.8%, N=804) than women (66.8%, N=597), but rather similar between age groups, with exclusive use being lowest among 18-29 (58.4%, N=488) and highest among 30-39 (64.8%, N=338) year-old IQOS users **(Table 13)**.

Table 13 IQOS User Patterns - by Age and Gender – IQOS User Sample

	Only IQOS (N=864)	**IQOS with combustible TNPs (N=505)**	**IQOS with non-combustible TNPs (N=32)**
	n (%) [LCL (%); UCL (%)]	n (%) [LCL (%);UCL (%)]	n (%) [LCL (%); UCL (%)]
Full Sample (N=1,401)	864 (61.7%) [59.0%;64.3%]	505 (36.0%) [33.5%; 38.7%]	32 (2.3%) [1.5%; 3.3%]
Male (N=804)	465 (57.8%) [54.3%; 61.3%]	318 (39.6%) [36.1%; 43.1%]	21 (2.6%) [1.6%; 4.0%]
Female (N=597)	399 (66.8%) [62.8%; 70.7%]	187 (31.3%) [27.6%; 35.3%]	11 (1.8%) [0.9%; 3.3%]
Age Group 18-29 (N=488)	285 (58.4%) [53.8%; 62.9%]	190 (38.9%) [34.5%; 43.5%]	13 (2.7%) [1.4%; 4.6%]
Age Group 30-39 (N=338)	219 (64.8%) [59.4%; 69.9%]	113 (33.4%) [20.4%; 38.8%]	6 (1.8%) [0.6%; 3.9%]
Age Group 40-49 (N=337)	209 (62.0%) [56.6%; 67.3%]	122 (36.2%) [31.0%; 41.6%]	6 (1.8%) [0.6%; 3.9%]
Age Group 50+ (N=238)	151 (63.4%) [56.9%; 69.6%]	80 (33.6%) [27.6%; 40.1%]	7 (2.9%) [1.1%; 6.0%]

Note: LCL%, Lower Confidence Limit of 95% CI; UCL%, Upper Confidence Limit of 95% CI. TNP, tobacco or nicotine-containing product.

The prevalence of exclusive IQOS use (59.2% vs. 61.7%), IQOS use together with combustible TNPs (38.6 vs. 36.0), and of IQOS use together with non-combustible TNPs (2.2% vs. 2.3%) was overall similar in Year 1 (2018-2019) and in Year 2 (2019-2020) (**Figure 12**).

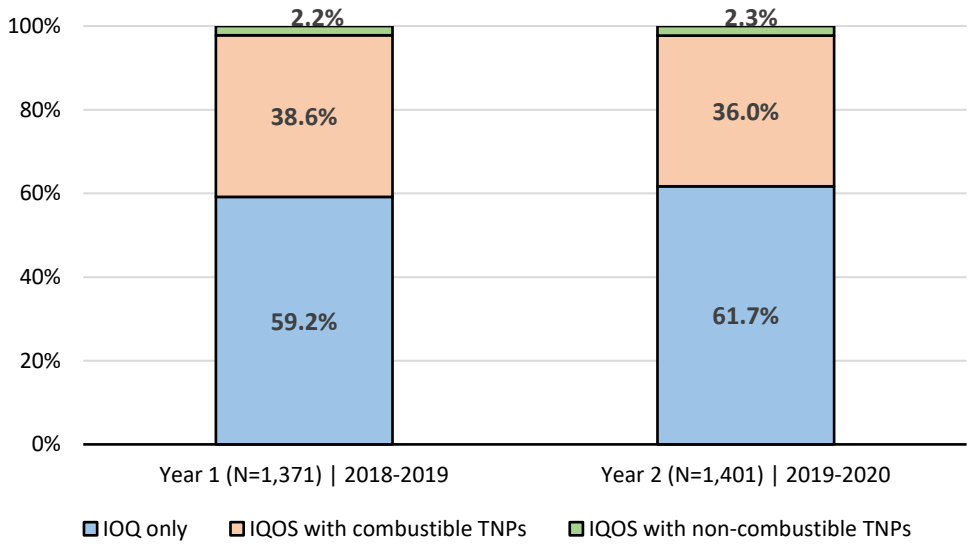

Figure 12 Patterns of TNP Use – IQOS User Sample, Trend (Year 1 and Year 2).
Note: TNP, tobacco or nicotine-containing product.

6.2.5 HISTORY OF IQOS USE

In study Year 2 (2019-2020), 97.0% (n=1,212) of current IQOS users (N=1,249)[23] were adult cigarette smokers when they started using IQOS, while 2.5% (n=31) were former cigarette smokers, and 0.5% (n=6) were never smokers. This indicates that a total of 99.5% of all IQOS users had a smoking history before they started using IQOS, and only 0.5% started TNP use with IQOS (**Figure 13**)

The percentage of IQOS users who had a previous history of TNP use (i.e. who were adult smokers or former smokers) before they started using IQOS (99.3% vs. 99.5%) was similar in Year 1 (2018-2019) and Year 2 (2019-2020) (**Figure 13**).

[23] All current IQOS users with available information on the smoking status when they started using IQOS.

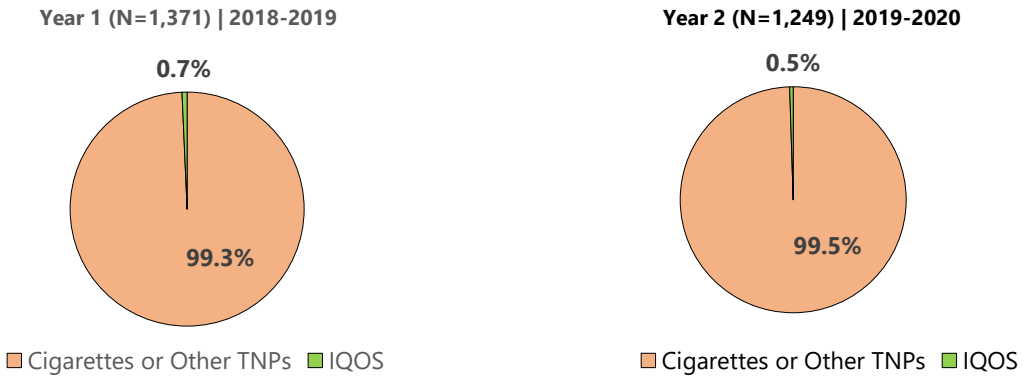

Figure 13 TNP Initiation with IQOS (First TNP used) – IQOS User Sample, Trend (Year 1 and Year 2)
Note: N=1,249 for Year 2 includes all current IQOS users with available information on the smoking status when they started using IQOS. Cigarettes include manufactured and roll/make-your own cigarettes. Other TNPs include (a) Smokeless Tobacco (such as chewing tobacco, snus, snuff, dissolvable), (b) Other Combustible Products (such as cigars, cigarillos, pipes, water-pipes), and (c) Nicotine Replacement Therapy products TNP, tobacco or nicotine-containing product. TNP, tobacco or nicotine-containing product.

In study Year 2, among all IQOS users who had a smoking history before they started using IQOS, i.e. who were ever regular smokers (N=1,243, i.e. 99.5% of 1,249), 97.5% were current smokers when they started using IQOS, 0.9% (n=11) were former smokers who relapsed (after ≤12 months of smoking abstinence) to TNP use with IQOS, 1.4% (n=18) were former smokers who re-initiated (after >12 months of smoking abstinence) TNP use with IQOS, and 0.2% (n=2) could not remember after how many months they started to use IQOS after quitting cigarettes **(Figure 14)**.

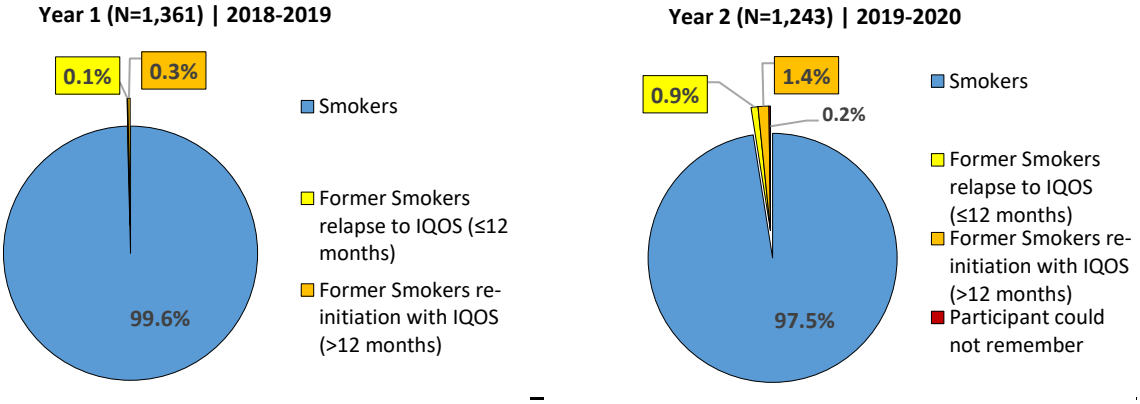

Figure 14 Smoking Status at Time of Start Using IQOS (%) – IQOS User Sample, Trend (Year 1 and Year 2).
Note: Relapse, starting TNP use again after ≤12 months of smoking abstinence; re-initiation, starting TNP use again after >12 months of smoking abstinence.

Compared to study Year 1 (2018-2019), the percentage of IQOS users who relapsed (0.1% vs. 0.9%) to IQOS or re-initiated (0.3% vs. 1.4%) TNP use with IQOS in Year 2 (2019-2020) remained on a very low level but was somewhat higher than in study Year 1 **(Figure 14)**.

6.2.6 QUITTING

Interest in and Planning of Quitting/Stop Using

In study Year 2 (2019-2020), 33.3% (n=153) of current IQOS users who also smoked (N=459), planned to quit smoking cigarettes within the next 30 days or six months **(Figure 15)**. This was a considerably higher percentage than in the General Adult Population Sample, in which only 10.7% of current smokers planned to quit smoking cigarettes (section **6.1.7**).

Among all current IQOS users (N=1,401), 15.2% (n=213) planned to stop using IQOS within the next 30 days or six months.

Among all exclusive IQOS users (N=864), 12.8% (n=111) planned to stop using IQOS within the next 30 days or six months, whereas among IQOS users who used IQOS together with combustible TNPs (N=505), 18.8% (n=95) planned to stop using IQOS within the next 30 days or six months **(Figure 15)**.

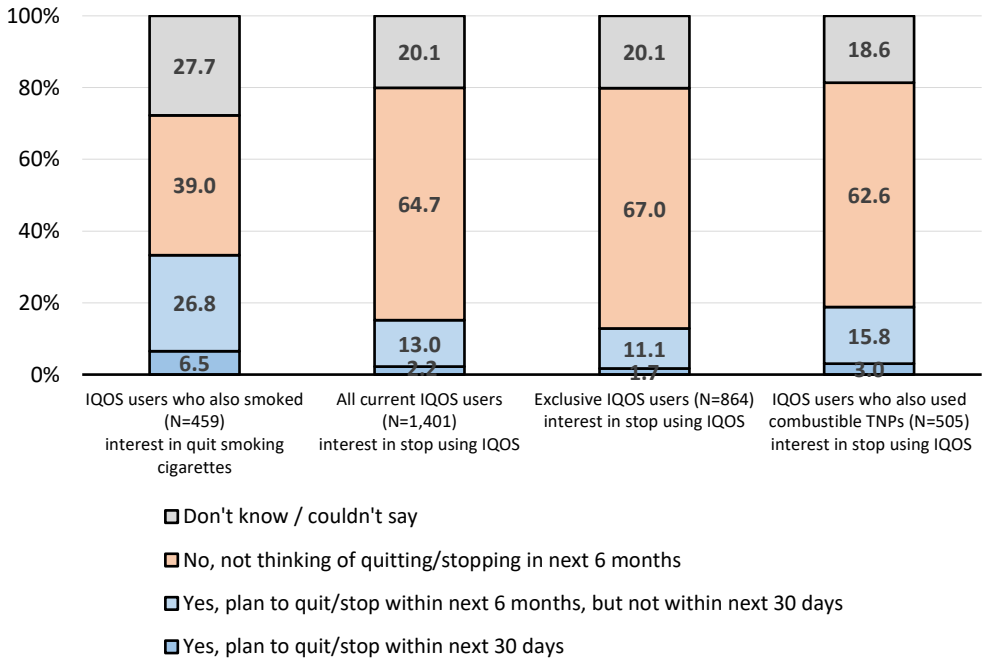

Figure 15 Level of Interest in Stop Using TNPs - IQOS User Sample
Note: Cigarettes include manufactured and roll/make-your own cigarettes

Quit/Stop Using Attempts

Moreover, in study Year 2 (2019-2020), 21.1% (n=97) of all current IQOS users who also smoked (N=459), had attempted to quit smoking cigarettes in the 12 months prior to the survey with on average 2.1 quit attempts and an average duration of 2.3 months.

Among all current IQOS users (N=1,401), 5.8% (n=81) had attempted to stop using IQOS in the past 12 months with on average 6.3 stop attempts and an average duration of 1.5 months. Among exclusive IQOS users (N=864), 5.7% (n=49) had attempted to stop using IQOS in the past 12 months with on average 9.2 [0.0; 24.1] stop attempts and an average duration of 1.5 [0.7; 2.4] months, while among IQOS users who used IQOS together with combustible TNPs (N=505), 5.5% (n=28) had attempted to stop using IQOS in the past 12 months with on average 2.0 [1.1; 2.8] stop attempts and an average duration of 1.7 [0.9; 2.5] months.

Successful Quitting Cigarettes

In terms of successful quitting of cigarettes, in study Year 2 a total of 53.1% (n=520) of all IQOS users who smoked more than one year ago (N=979) had quit smoking cigarettes in the last 12 months. Of those, 92.1% (n=478) switched to IQOS, 4.2% (n=22) to IQOS & other TNPs, 3.1% (n=16) to IQOS & e-cigarettes, 0.4% (n=2) to IQOS & e-cigarettes & other TNPs, and 0.2% (n=1) to IQOS & other innovative products.

Compared to study Year 1 (2018-2019), the percentage of IQOS users in Year 2 who planned to quit cigarettes within the next 30 days or 6 months (34.6% vs. 33.3%), had already attempted to quit in the past 12 months (25.0% vs. 21.1%), or had successfully quit smoking cigarettes in the past 12 months (52.7% vs. 53.1%) as well as the number (2.2 vs. 2.1) and duration (1.8 vs. 2.3 months) of quit attempts were overall similar.

6.2.7 RISK PERCEPTION

In study Year 2 (2019-2020), current IQOS users (N=1,401) perceived the health risk (score from 0 [no-risk] to 100 [very-high risk])[24] associated with smoking cigarettes (score: 64.3 [63.5; 65.0]) as higher compared to the health risk associated with using IQOS (score: 44.4 [43.4; 45.4]) resulting in a health risk score difference of 19.6 [18.6; 20.6] (**Figure 16**). The health risk score (44.4 [43.4; 45.4]) associated with using IQOS also indicates that IQOS was not perceived as risk-free.

[24] Participants were asked to rate the general perceived risk of getting 18 different diseases or adverse health conditions separately for smoking cigarettes or for using IQOS on a 5-point Likert-like scale (ranging from 0 [no risk] to 4 [very high risk]) using PMI's psychometrically validated ABOUT–Perceived Risk, General version, Health Risk Instrument (18-item). Based on the 18 rated items, an overall score ranging from 0 [no risk] to 100 [very high risk] was derived from the total raw score by Rasch model analysis. The ABOUT–Perceived Risk Instrument General version was formerly known as Perceived Risk Instrument General (PRI-G)) and is now part of PMI's ABOUT Toolbox.

Cano S., Chrea C., Salzberger T., Alfieri T., Emilien G., Mainy N., Ramazzotti A., Lüdicke F., Weitkunat R. 2018. Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products. Health and Quality of Life Outcomes. 16 (1), 192-206.

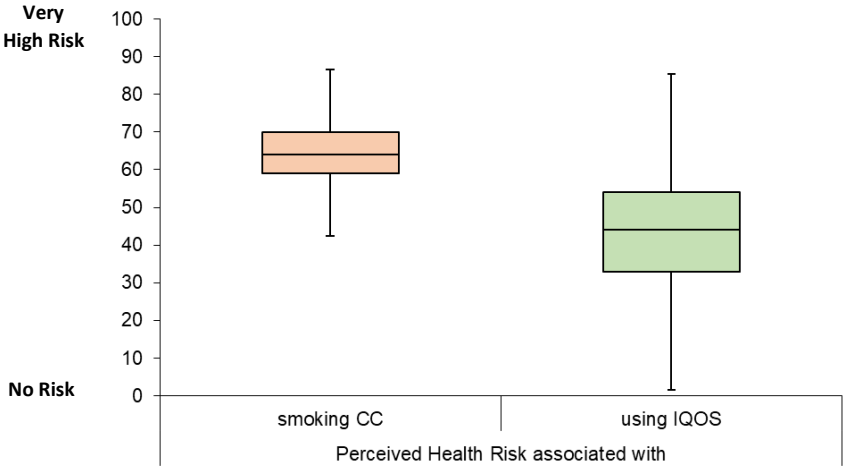

Figure 16 Perception of Health Risk Associated with Smoking Cigarettes/Using IQOS – IQOS User Sample
Note: Risk score (0 [no-risk] to 100 [very-high risk]). CC, cigarettes including manufactured and roll/make-your own cigarettes.

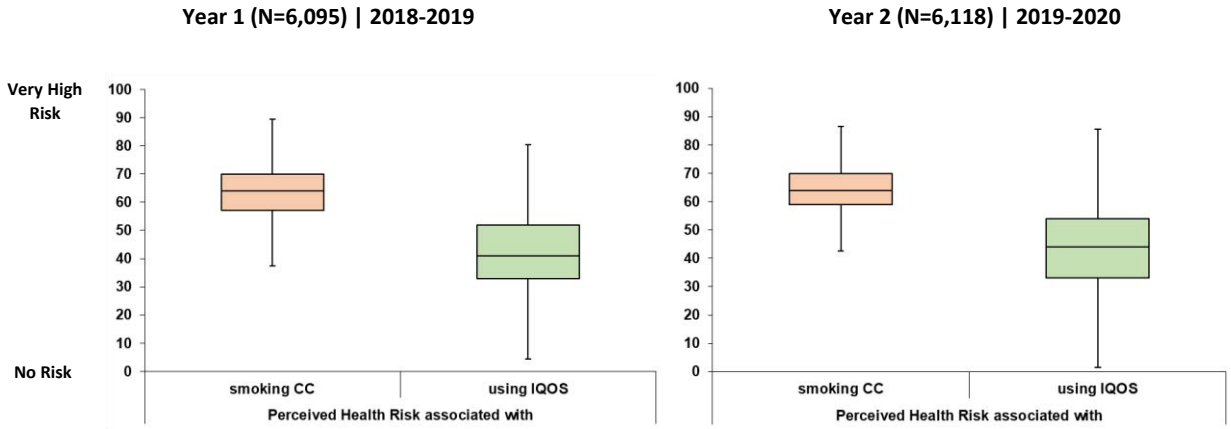

Figure 17 Perception of Health Risk Associated with Smoking Cigarettes /Using IQOS – IQOS User Sample, Trend (Year 1 and Year 2)
Note: CC, cigarettes including manufactured and roll/make-your own cigarettes.

Compared to study Year 1 (2018-2019), the health risk perceived by current IQOS users for smoking cigarettes (scores: 63.7 vs. 64.3) or using IQOS (scores: 42.6 vs. 44.4) as well as the resulting health risk score differences (21.1 vs. 19.9) were similar in Year 2 (2019-2020) (**Figure 17**).

6.2.8 PERCEIVED HEALTH RELATED SYMPTOMS AND ESTHETIC BENEFITS OF IQOS USE

6.2.8.1 *RESPIRATORY SYMPTOMS*

In study Year 2 (2019-2020), 11.5% (n=99) of exclusive IQOS users (N=864), reported respiratory symptoms[25] (part-day or all day), whereas among IQOS users who used IQOS together with combustible TNPs (N=505), 19.4% (n=98) reported respiratory symptoms. In comparison, among current exclusive cigarette smokers (N=1,442) from the General Adult Population Sample, 14.1% reported respiratory symptoms (section **6.1.8.1**).

In study Year 2, 49.8% (n=430) of exclusive IQOS users (N=864) reported no change in cough symptoms in the last 12 months prior to the survey, while 49.1% (n=424) reported an overall improvement, and only 1.2% (n=10) a deterioration. Similar results were observed for phlegm symptoms among exclusive IQOS users (N=864) of which 52.9% (n=457) reported no change in phlegm symptoms, 45.8% (n=396) reported an improvement, and only 1.3% (n=11) reported a deterioration (**Table 14**).

IQOS users who used IQOS together with combustible TNPs (N=505) also reported an improvement in cough (39.4%, n=199) and phlegm (40.0%, n=202) symptoms in the last 12 months prior to the survey, but to a lower extent than exclusive IQOS users (**Table 14**).

Table 14 Change in Cough/Phlegm Symptoms Last 12 Months by IQOS Use Patterns – IQOS User Sample

Change in Cough and Phlegm Symptoms		**Exclusive IQOS**		**IQOS with combustible TNPs**	
[n (%)]		**Year 1 (N=207)**[26] **|** 2018-2019	**Year 2 (N=864) |** 2019-2020	**Year 1 (N=122)**[27] **|** 2018-2019	**Year 2 (N=505) |** 2019-2020
Cough	Has improved	120 (58.0%)	424 (49.1%)	50 (41.0%)	199 (39.4%)
	No change	83 (40.1%)	430 (49.8%)	68 (55.7%)	248 (56.2%)
	Has worsened	4 (1.9%)	10 (1.2%)	4 (3.3%)	22 (4.4%)
Phlegm	Has improved	117 (56.5%)	396 (45.8%)	43 (35.2%)	202 (40.0%)
	No change	89 (43.0%)	457 (52.9%)	76 (62.3%)	248 (56.2%)
	Has worsened	1 (0.5%)	11 (1.3%)	3 (2.5%)	19 (3.8%)

Note: TNP, tobacco or nicotine-containing products.

[25] Two subscales of the Medical Research Council Questionnaire (MRCQ) were used to estimate selected respiratory symptoms. Participants were asked to evaluate the presence of cough (3 items) and phlegm symptoms (3 items). Additionally, participants were asked if their respiratory symptoms changed as compared to 12 months ago using a 7-point scales from “very much improved” to “very much worse”. Medical Research Council on the Aetiology of Chronic Bronchitis. Standardised questionnaire on respiratory symptoms. Br Med J 1960;2:1665.

[26] Sample size N=207 is based on one survey wave (wave 4) only.

[27] Sample size N=122 is based on one survey wave (wave 4) only

Compared to study Year 1 (2018-2019), the proportion of exclusive IQOS users who reported an improvement in cough (58.0% vs. 49.1%) and phlegm (56.6% vs. 45.8%) symptoms was lower in Year 2 (2019-2020). These lower improvements results among exclusive IQOS users in Year 2 might be explained because IQOS users had already felt a large improvement when switching from cigarettes to IQOS in the past so that further improvement was attenuated (**Table 14**). In contrast, the proportion of IQOS users who used IQOS together with combustible TNPs and reported an improvement in cough (41.0% vs. 39.4%) and phlegm (35.2% vs. 40.0%) symptoms was rather similar in Year 1 and Year 2.

6.2.8.2 *EXERCISE CAPACITY*

The Rating of Perceived Capacity (RPC)[28] instrument was used to estimate maximal exercise capacity based on metabolic equivalents (MET; the higher the MET value, the better the exercise capacity).

Among female IQOS users (N=597), maximal exercise capacity was rated slightly higher among exclusive female IQOS users (10.1 [9.6; 10.7] MET; N=399) than among female IQOS users who used IQOS together with combustible TNPs (9.5 [8.8; 10.3] MET; N=187). Similarly, among male IQOS users (N=804), maximal exercise capacity was rated slightly higher among exclusive male IQOS users (11.0 [10.5; 11.5] MET; N=465) than among male IQOS users who used IQOS together with combustible TNPs (10.7 [10.1; 11.3] MET; N=318).

When asked about the change in exercise capacity compared to 12 months prior to the survey, 50.7% (n=438) of all exclusive IQOS users (N=864) reported an improvement in exercise capacity,[29] whereas 40.0% (n=202) of IQOS users who used IQOS together with combustible TNPs (N=505) reported an improvement (**Table 15**). At the same time, only 7.2% (n=62) of exclusive IQOS users reported a worsening in exercise capacity, while 12.1% (n=61) of IQOS users who used IQOS together with combustible TNPs reported a worsening. In comparison, among current exclusive cigarette smokers from the General Adult Population Sample (N=1,442), only 7.9% (n=114) reported an improvement of exercise capacity, while 9.8% (n=142) reported a worsening in exercise capacity (**Table 15**).

Compared to study Year 1 (2018-2019), the proportion of both exclusive IQOS users (56.5% vs. 50.7%) and IQOS users who used IQOS together with combustible TNPs (42.6% vs. 40.0%) and

[28] Single item questionnaire. MET values from 1 to 20 in men and 1 to 18 in women are listed on a progressive scale linked to specific physical activities by choosing the most strenuous activity that they could sustain for at least 30 min. 1 MET equals energy expenditure in terms of oxygen consumption per 1 kg of body mass while sitting at rest. Wisén, A.G., Farazdaghi, R.G. & Wohlfart, B. A novel rating scale to predict maximal exercise capacity. Eur J Appl Physiol 87, 350–357 (2002). https://doi.org/10.1007/s00421-002-0636-y.

[29] A dichotomous variable of “improvement” is derived by combining the 3 positive categories of minimally improved”, “much improved” and “very much improved”.

who reported an improvement in exercise capacity was overall slightly lower in Year 2 (2019-2020).

The lower improvement result particularly among exclusive IQOS users in Year 2 might be explained because IQOS users had already felt a large improvement when switching from cigarettes to IQOS in the past so that further improvement was attenuated **(Table 15)**.

Table 15 Change in Exercise Capacity by IQOS Use Patterns - IQOS User/General Adult Population Sample

Change in exercise capacity	Exclusive IQOS		IQOS with combustible TNPs		General Adult Population Sample Exclusive cigarette smokers	
[n (%)]	Year 1 (N=207) | 2018-2019	Year 2 (N=864) | 2019-2020	Year 1 (N=122) | 2018-2019	Year 2 (N=505) | 2019-2020	Year 1 (N=450)[30] | 2018-2019	Year 2 (N=1,442) | 2019-2020
Has improved	117 (56.5%)	438 (50.7%)	52 (42.6%)	202 (40.0%)	45 (10.0%)	114 (7.9%)
No change	82 (39.6%)	364 (42.1%)	58 (47.5%)	242 (47.9%)	354 (78.7%)	1186 (82.2%)
Has worsened	8 (3.9%)	62 (7.2%)	12 (9.8%)	61 (12.1%)	51 (11.3%)	142 (9.8%)

Note: Cigarettes include manufactured and roll/make-your own cigarettes. TNP, tobacco or nicotine-containing products.

6.2.8.3 *HYGIENE, BEAUTY, AND FITNESS RELATED BENEFITS*

In study Year 2 (2019-2020), current exclusive IQOS users (N=774)[31] were asked to rate their agreement with the improvement of six hygiene, beauty, and fitness related perceived benefits of IQOS use since they switched from cigarettes to IQOS, using the Self-Reported Change Questionnaire (SRCQ).[32] The SRCQ is based on a seven-point rating scale ranging from "strongly disagree" to "strongly agree".

The top three changes in perceived benefits that were confirmed[33] most, were "my breath smells better" (74.8%), "teeth appear less stained or yellowish" (70.5%), and "it is easier to exercise" (62.5%). However, also "sense of smell has improved" (60.7%) and "sense of taste has improved" (59.4%) were confirmed by the majority of exclusive IQOS users **(Table 16)**.

[30] Sample size N=450 is based on two survey waves (wave 5 and 6) only.

[31] Compared to the total sample size of exclusive IQOS users (N=864), the sub-sample of only N=774 includes only IQOS users with valid data on perceived benefits.

[32] The Self-Reported Change Questionnaire (SRCQ) has been developed by PMI and translation into Italian language has been linguistically validated by Transperfect (https://www.transperfect.com).

[33] Selecting "somewhat agree", "agree", or "strongly agree" was considered to confirm the statement.

Table 16 Perceived Benefits – IQOS User Sample

Type of Perceived Benefit	**Exclusive IQOS Users who perceived benefits of IQOS use* [n (%)]**	
	Year 1 (N=732)[34] | 2019-2020	Year 2 (N=774)[35] | 2019-2020
My Breath Smells Better	540 (73.8%)	579 (74.8%)
Teeth Appear Less Stained or Yellowish	523 (71.4%)	546 (70.5%)
It is Easier to Exercise	514 (70.2%)	484 (62.5%)
Sense of Smell Has Improved	458 (62.6%)	470 (60.7%)
Sense of Taste Has Improved	448 (61.2%)	460 (59.4%)
Face Skin Appears Smoother and Firmer	222 (30.4%)	233 (30.1%)

*Current exclusive IQOS users who confirmed that they have perceived benefits of IQOS use since they switched from cigarettes to IQOS by selecting either "somewhat agree", "agree", or "strongly agree" on a 7-point rating scale ranging from "strongly disagree" to "strongly agree". Cigarettes include manufactured and roll/make-your own cigarettes.

The proportions of exclusive IQOS users who confirmed that they perceived a particular benefit were similar in Year 1 (2018-2019) and Year 2 (2019-2020), and the hierarchy of the perceived benefits in Year 2 was identical with that observed in Year 1 (**Table 16**).

[34] Compared to the total sample size of exclusive IQOS users (N=864), the sub-sample of only N=774 includes only IQOS users with valid data on perceived benefits

[35] Compared to the total sample size of exclusive IQOS users (N=812), the sub-sample of only N=732 includes only IQOS users with valid data on perceived benefits.

7 CONCLUSIONS

The present study report describes study Year 2 (2019-2020) data from a repeated cross-sectional study in Italy including both a representative General Adult Population Sample as well as a sample of current IQOS users living in Italy and registered in the IQOS Owner database of PMI's affiliate in Italy. Similar to the previous study Year 1 (2018-2019), study Year 2 data show that cigarettes were by far the most used TNPs in Italy. The study data also show that, in line with the Year 1, the majority of current TNP users started TNP use with cigarettes. Moreover, as seen in Year 1, smoke-free products such as IQOS and e-cigarettes have established themselves as acceptable alternatives with the majority of IQOS users using IQOS exclusively and hence having switched completely away from cigarette. While Year 2 data show that dual use (i.e. IQOS use together with combustible TNPs) existed, the data also show that, similar to Year 1, the majority of IQOS users had completely switched away from cigarettes and were using IQOS exclusively.

In line with study Year 1 data, data from the General Adult Population Sample of Year 2 show that there was very low initiation, re-initiation, and relapse with IQOS as the majority of current TNP users started TNP use with cigarettes. This finding is further supported by data from the IQOS user sample that show that nearly all current IQOS users were adult cigarette smokers when they started using IQOS. Furthermore, the rate of quitting smoking remained stable across study years which suggests that the commercialization of IQOS did not prevent TNP users from quitting smoking cigarettes.

As in Year 1, IQOS users in Year 2 perceived that IQOS is not a risk-free product, but that the health risk associated with using IQOS is lower compared to the health risk associated with smoking cigarettes.

Moreover, similar to study Year 1, the majority of exclusive IQOS users in study Year 2 agreed that their respiratory symptoms (cough and phlegm) and their exercise capacity had improved over the past 12 months. Also, most of the current IQOS users reported positive effects related to hygiene, beauty, and fitness since they switched from cigarettes to IQOS including better smell of breath, less stained or yellowish teeth, greater easier to exercise, and improvement of sense of smell and taste. All those observations on respiratory symptoms, exercise capacity, and hygiene, beauty, and fitness related benefits were overall much more frequently perceived among exclusive IQOS users compared to IQOS users who used IQOS together with combustible TNPs.

8 STRENGTHS AND LIMITATIONS

This cross-sectional study has several strengths. It is an annual repeated collection of data using the same sampling framework and methods over the years, namely face-to-face interviews of a national representative sample of randomly selected participants coupled with an online survey in a large IQOS user sample, providing insights in a sizeable number of IQOS users. The multi-stage random selection of the General Adult Population Sample was based on the electoral lists of about 140 municipalities located throughout Italy. The study applied widely accepted definitions of TNP use in accordance with the guidelines for controlling and monitoring the tobacco epidemic of the World Health Organization.[36]

The respective sample sizes in the General Adult Population and IQOS User Samples were large and provided a sufficiently high level of precision of the main outcomes (i.e. prevalence, initiation, relapse, re-initiation), and the numerous surveys throughout the year ensure a good representation of a full year versus of a single study.

This study also has some limitations. The study relied on self-reported measures and, therefore, may have been impact by different types of reporting bias. Previous studies have shown that the reliability of self-reported smoking in adults has generally been high, suggesting that self-reported data provide reasonably valid estimates of cigarette smoking in the population.[37,38] However, the reliability of self-report assessments for smoke-free products such as IQOS and e-cigarettes has not yet been investigated and confirmed to the same extent.

Some survey questions were about the participant's history of TNP use (e.g. age of start using a TNP regularly), which may have been difficult to remember accurately for those with a long history of TNP use and, therefore, may have been subject to recall bias.

The survey among the IQOS owner population was based on IQOS users who registered their IQOS devices in the IQOS Owner database of PMI's affiliate in Italy and who have agreed to be contacted for research purposes, which means that the study results among this particular audience might not be fully representative of all Italian IQOS users.

[36] World Health Organization. Measuring tobacco use behaviours. IARC Handbook of Cancer Prevention, vol 12. 2008:75-106. Available from: http://publications.iarc.fr/Book-And-Report-Series/Iarc-Handbooks-Of-Cancer-Prevention/Methods-For-Evaluating-Tobacco-Control-Policies-2008.

[37] Rebagliato M. Validation of self-reported smoking. Journal of epidemiology and community health. 2002;56(3):163-164.

[38] Wong SL, Shields M, Leatherdale S, Malaison E, Hammond D. Assessment of validity of self-reported smoking status. Health reports. 2012;23(1):47-53.