

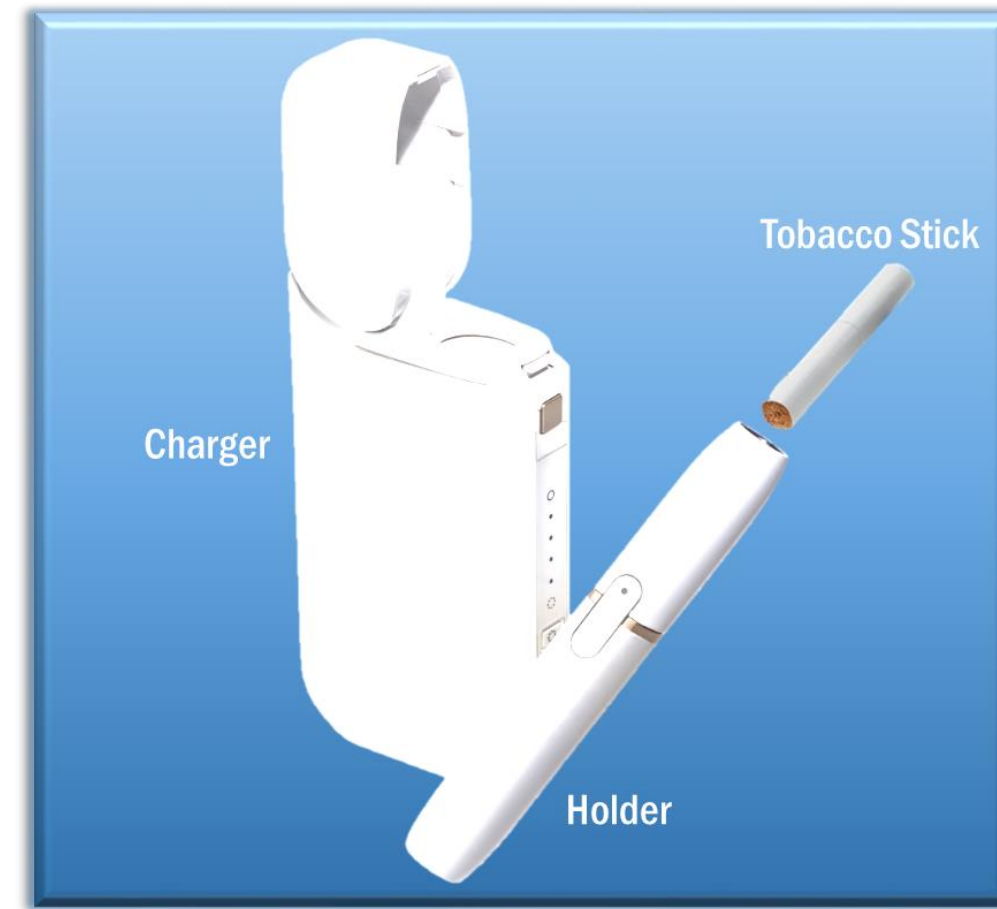
How Do Consumers Use The Candidate Modified Risk Tobacco Product (M RTP): Tobacco Heating System (THS): Analysis of Data From Six Countries

Steve Roulet*¹, Pierpaolo Magnani¹, Gerd Kallischnigg², Stefano Badoglio¹, Kurt Ackermann³, Marcus Veit³, Ariella Dugan⁴, Chris Gage⁴, Claudia Kanitscheider⁵, Mercedes Apecechea⁵, Antonio Ramazzotti¹.

¹ Philip Morris International Management S.A. (PMI), Lausanne, Switzerland, ² ARGUS – Statistics and Information Systems in Environment and Public Health, Berlin, Germany, ³ FehrAdvice & Partners, Zurich, Switzerland, ⁴ Kantar Health LLC, New York, United States of America, ⁵ Kantar Health GmbH, Munich, Germany.

Abstract

Philip Morris International (PMI) conducted consumer studies in several countries for one of its Candidate Modified Risk Tobacco Products (MRTPs), the THS. THS is composed of a Tobacco Heating Device (Holder and Charger) and Tobacco Sticks.



Tobacco Heating System

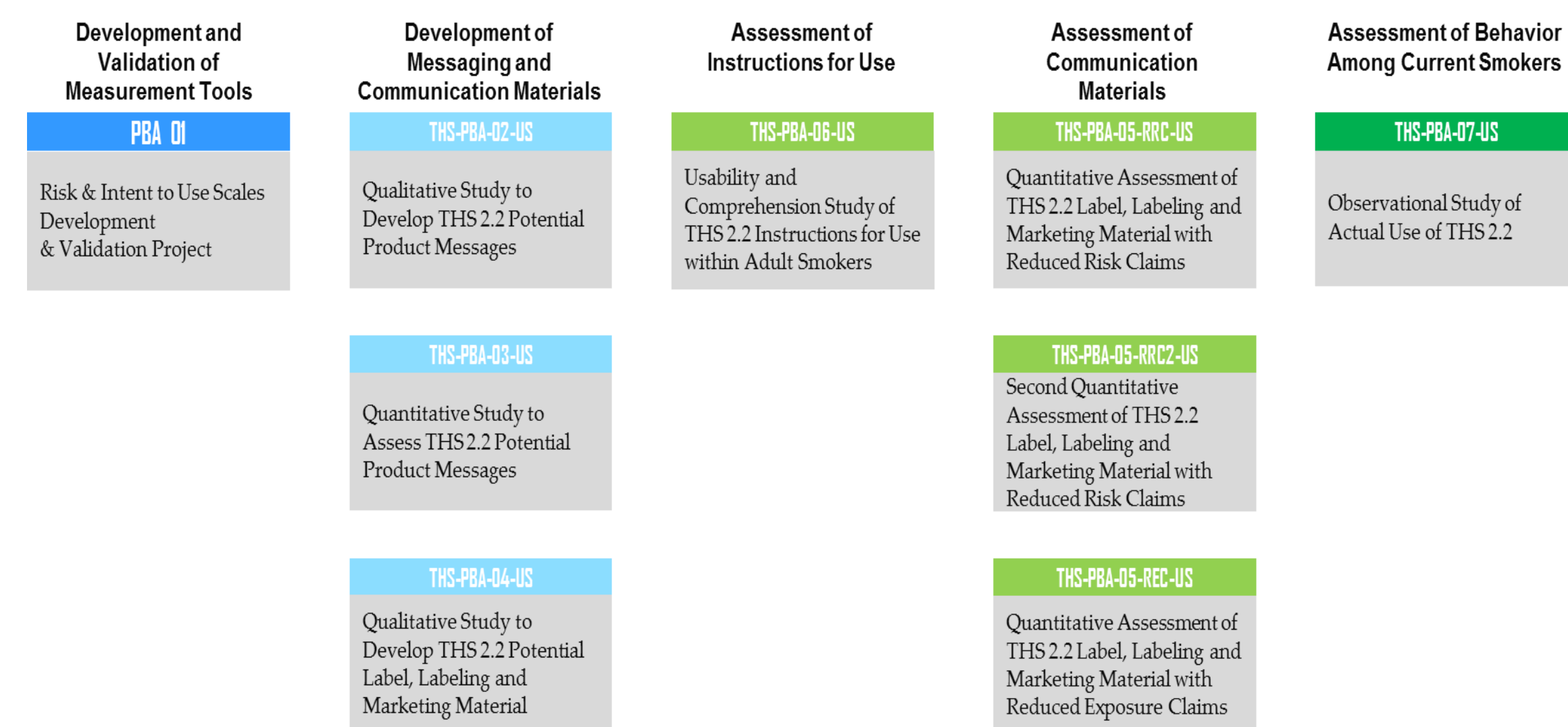
The purpose of these studies were to investigate how adult daily smokers actually used THS in near to real-world conditions. The studies were conducted in Japan, Italy, Germany, Switzerland, South Korea and the U.S. Each study was a single group, prospective observational study, implying an assessment of subject-reported stick-by-stick consumption of Tobacco Sticks and cigarettes (CC). Participants received Tobacco Sticks free of charge on a needed basis and were able to consume Tobacco Sticks, cigarettes and other nicotine containing products *ad libitum*. The length of the observational period was at minimum 4 weeks.

To ensure a good representation of the country adult smoker population, each sample was approximating the distribution of such population according to several key characteristics such as age, sex, race, income, social status and main brand of cigarettes (when appropriate). Participants were recruited using databases maintained by local market research agencies and enrollment was done through interviews in between 2 and 8 central study locations, depending on the country. The number of enrolled participants ranged from 581 in Switzerland to 1,336 in the U.S. A "passive" surveillance mechanism was also put in place to collect spontaneously reported events (e.g. adverse events).

Across those 6 countries, the data show that a sizeable proportion of participants adopted a usage behavior involving either predominant or exclusive use of Tobacco Sticks as between 9.9% in Switzerland and 37.1% in South Korea had switched (i.e. ≥ 70% of tobacco products (Tobacco Sticks and CC) used were Tobacco Sticks) from CC to Tobacco Sticks at the end of the observational period.

Introduction and Objectives

One of these studies, the THS-PBA-07-US Actual Use Study (AUS) was conducted in the U.S. This study is the final element of the THS premarket Perception and Behavior Assessment (PBA) program which aims to provide evidence to one of the key areas of investigation highlighted in the MRTPA Draft Guidance related to the "effect the tobacco product and its marketing may have on tobacco use behavior among current tobacco users". In December 2016, PMI submitted MRTP applications for THS to the Food and Drug Administration (FDA). In May 2017, the FDA accepted to file the applications which are now undergoing substantive scientific review.



THS PBA Program

The purpose of this Actual Use Study was to investigate how U.S. adult daily smokers of cigarettes (CC) actually used THS over time in near to real-world conditions.

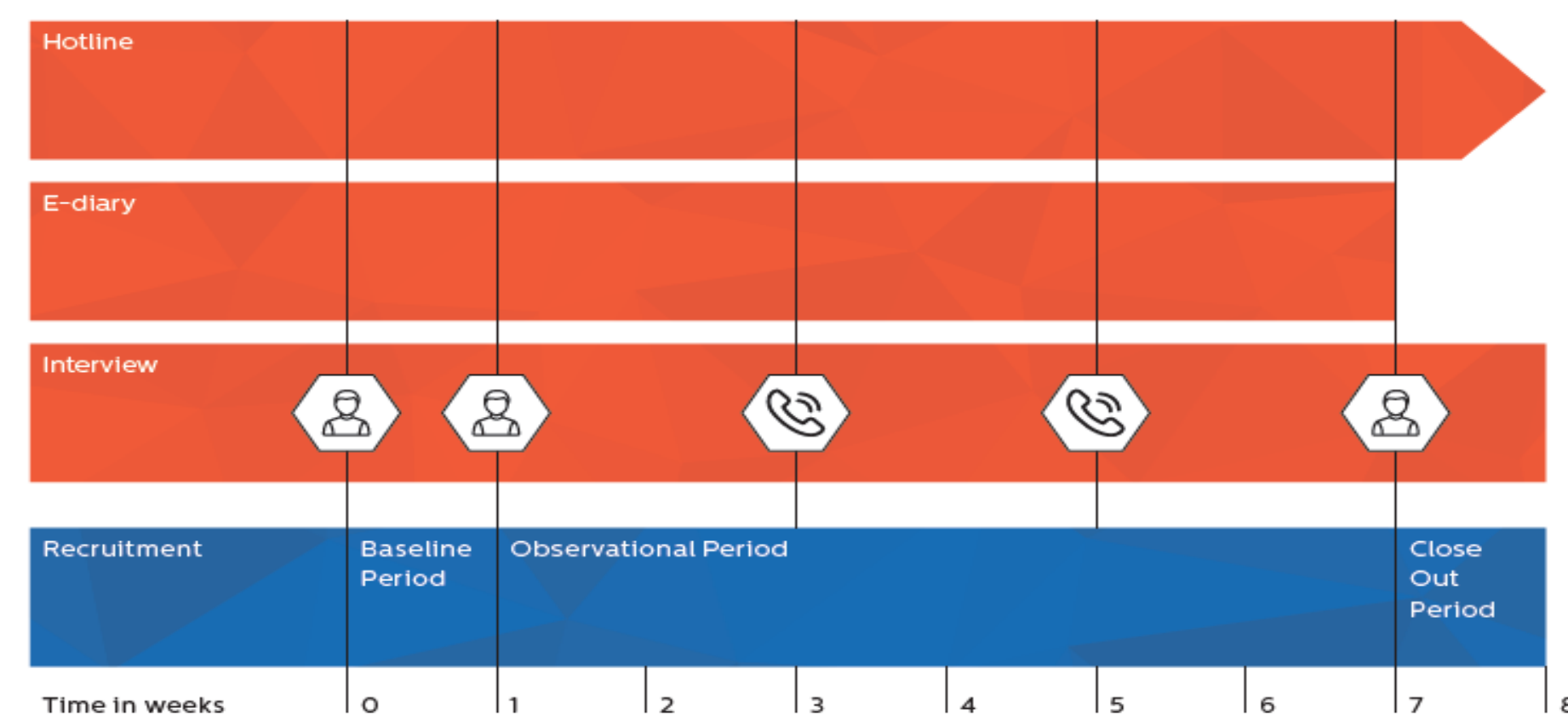
Methods

This Actual Use Study (AUS) was designed as a mid-term prospective observational study, implying an assessment of subject-reported stick-by-stick consumption of THS and of CC with participants receiving THS free of charge.

The target population was U.S. adult daily smokers of regular and/or menthol CC aged 18 years and above (according to minimum local or State legal smoking age). The study sample was composed of daily smokers with no intention to quit smoking within the next 30 days. The study was approved by an Institutional Review Board and conducted in accordance with the Guidelines for Good Epidemiological Practice in 8 geographic areas of the U.S.

The recruitment of candidate participants was done using market research databases. The study did not restrict enrollment using quotas, however, the sampling approximated the adult smoker distribution on sex, age, race and income contained in the CDC 2012 report. 1,336 participants were enrolled and 1,106 participants composed the Full Analysis Set (FAS).

The study design included a baseline, an observational and a close out period. The study began with a 1-week baseline period, during which participants recorded their stick-by-stick-consumption of CC and other nicotine containing products.



Study Design

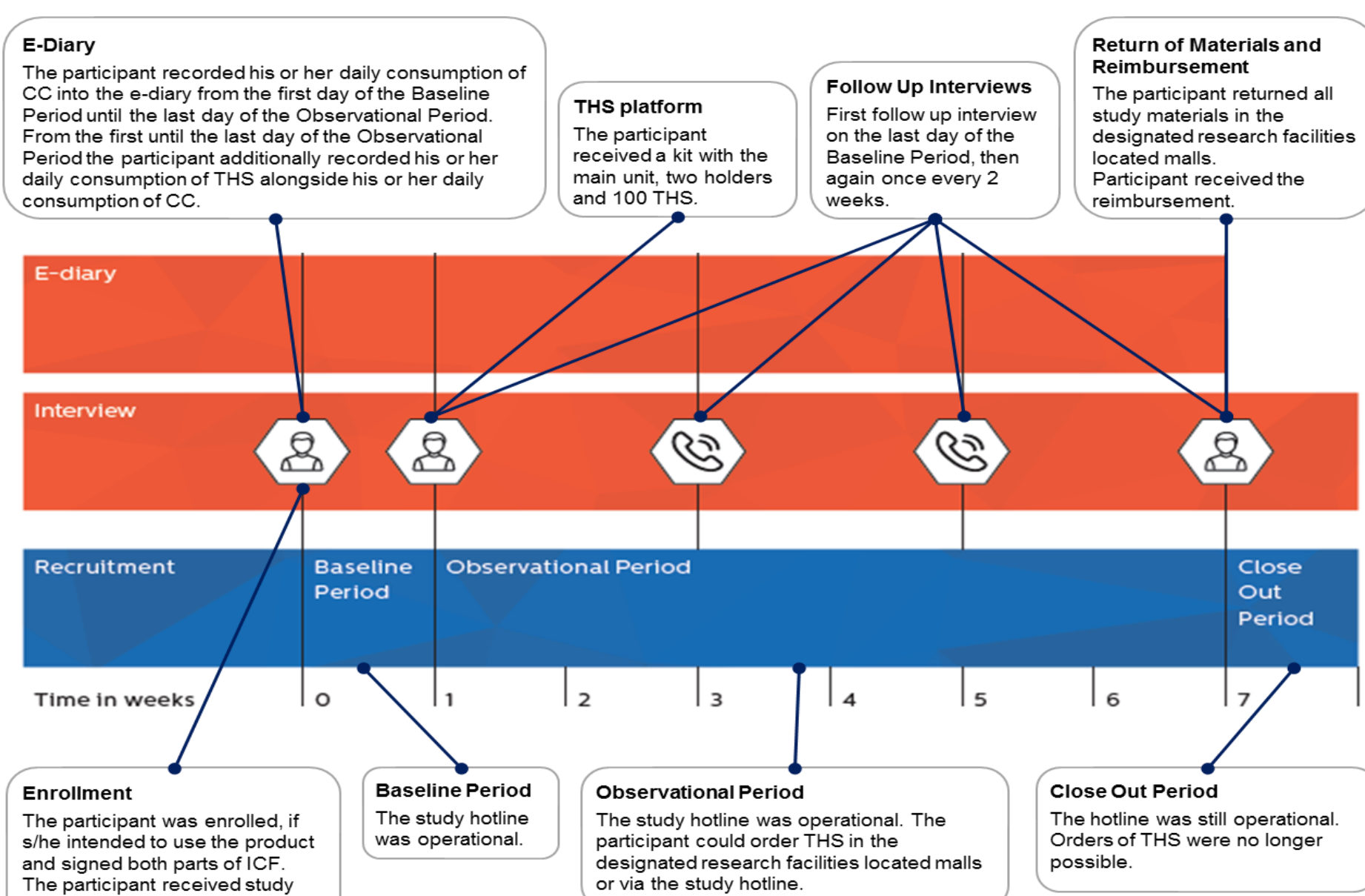
The baseline period served to estimate the participants' regular smoking patterns of CC. During a subsequent 6-week observational period, participants recorded their stick-by-stick consumption of both THS and CC.

The observational period served to assess the development of consumption patterns of THS. At the beginning of the observational period, participants received the Tobacco Heating Device and 5 packs of Tobacco Sticks (pack of 20) in accordance with their stated preference (i.e. regular and/or menthol variants). Participants were able to obtain additional Tobacco Sticks packs by calling the study toll-free telephone hotline or by going to the study site where they had been enrolled.

The study concluded with a 1-week close out period, during which participants were not required to record any data, however, they were able to call the toll-free telephone hotline. This allowed for the continued surveillance of adverse events (AEs).

During the entire study, participants were able to consume CC, THS Tobacco Sticks and any other nicotine containing products *ad libitum*. They were requested to make an entry into an electronic diary every time they consumed a CC during the baseline period and a THS or a CC during the observational period. A sufficiently easy and intuitive electronic diary was used due to the high frequency of daily consumption over an extended period of time.

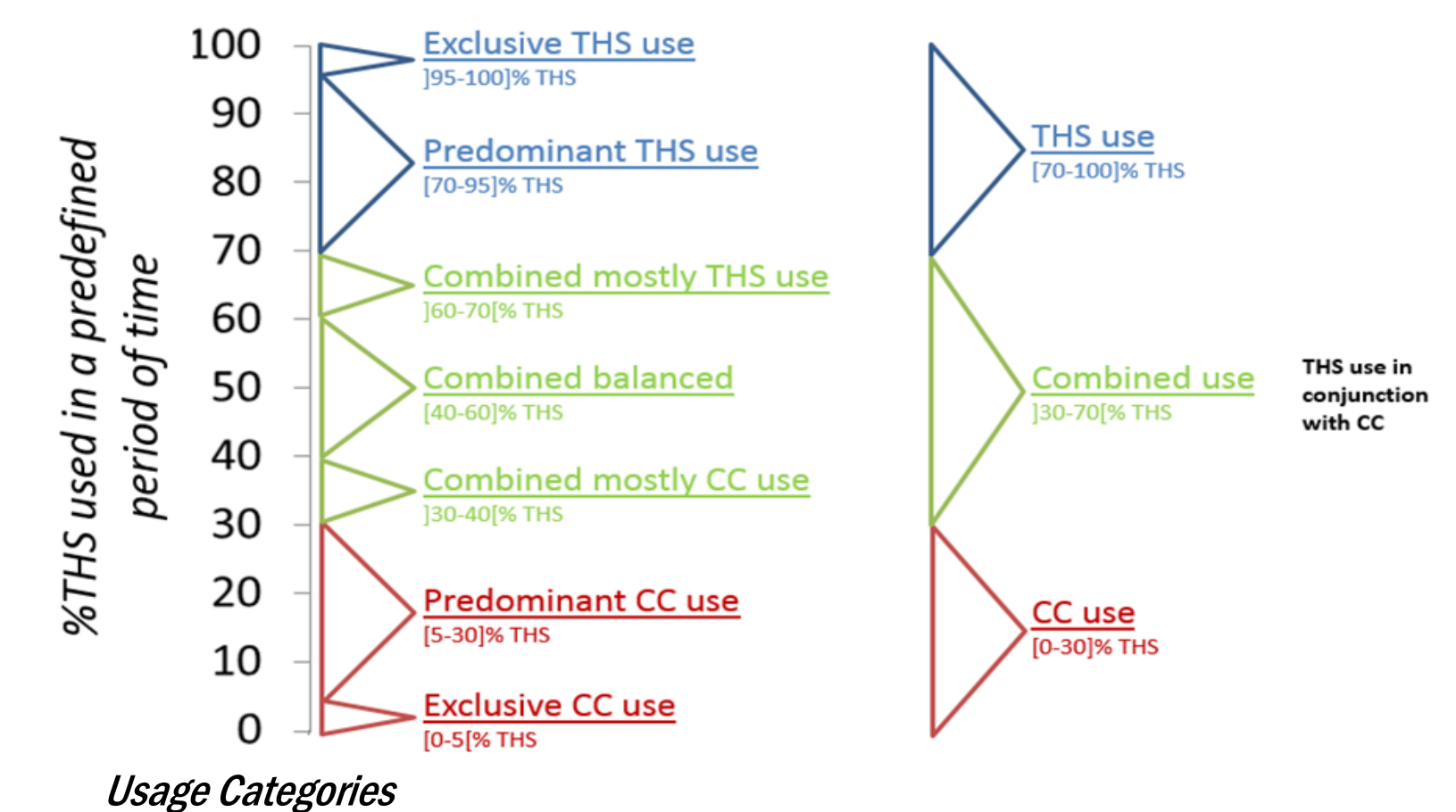
The below figure traces all steps that a participant went through in this AUS from enrollment until end of close out period.



Study Life Cycle of a Participant

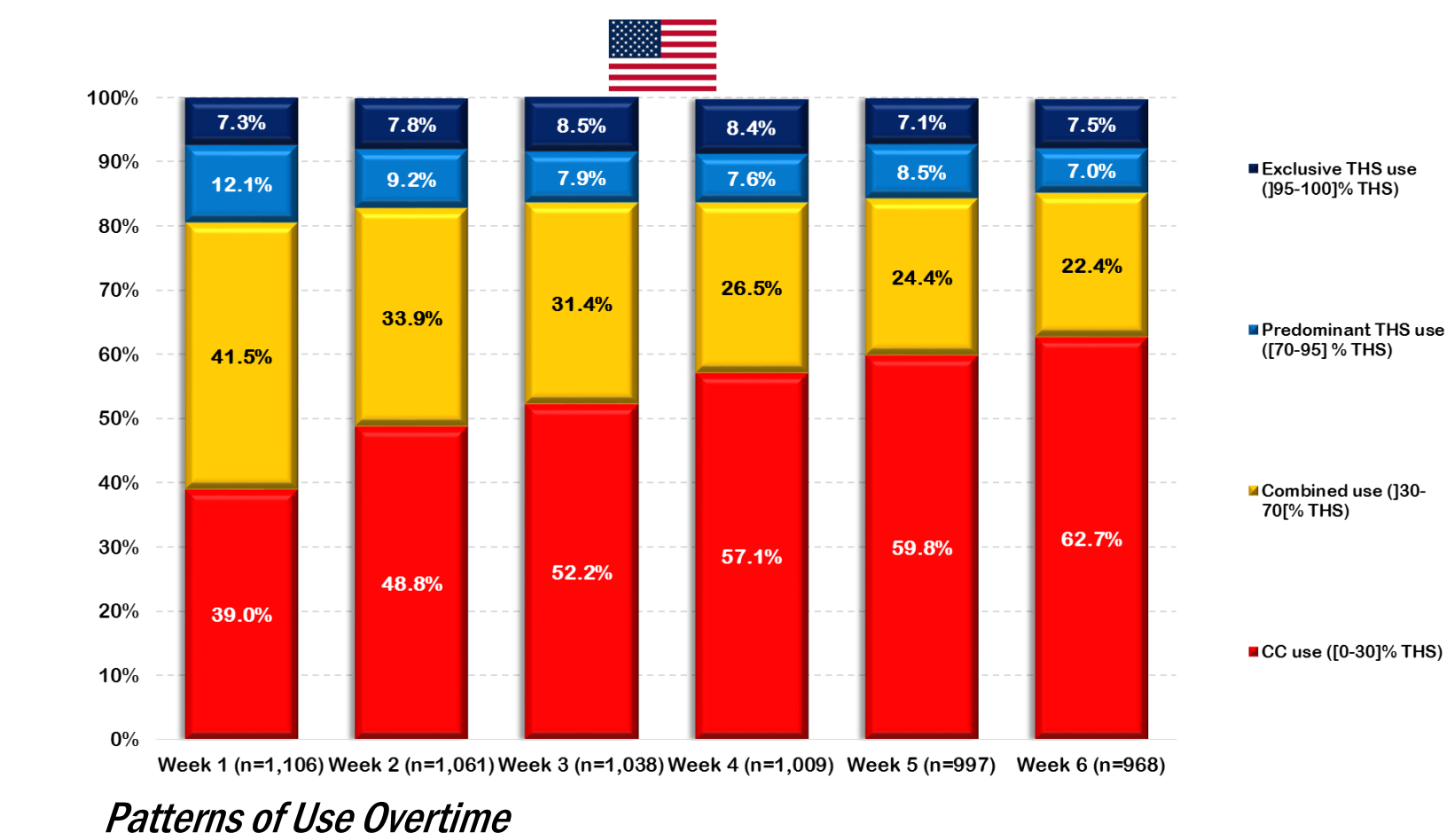
The methods of this AUS were similar to the ones used for the Whole Offer Test (WOT) studies, except that the duration of the observational period of the WOT was shorter (4 weeks) and the data collection method used was pen and paper instead of electronic diary.

The patterns of use were defined using the below usage categories.



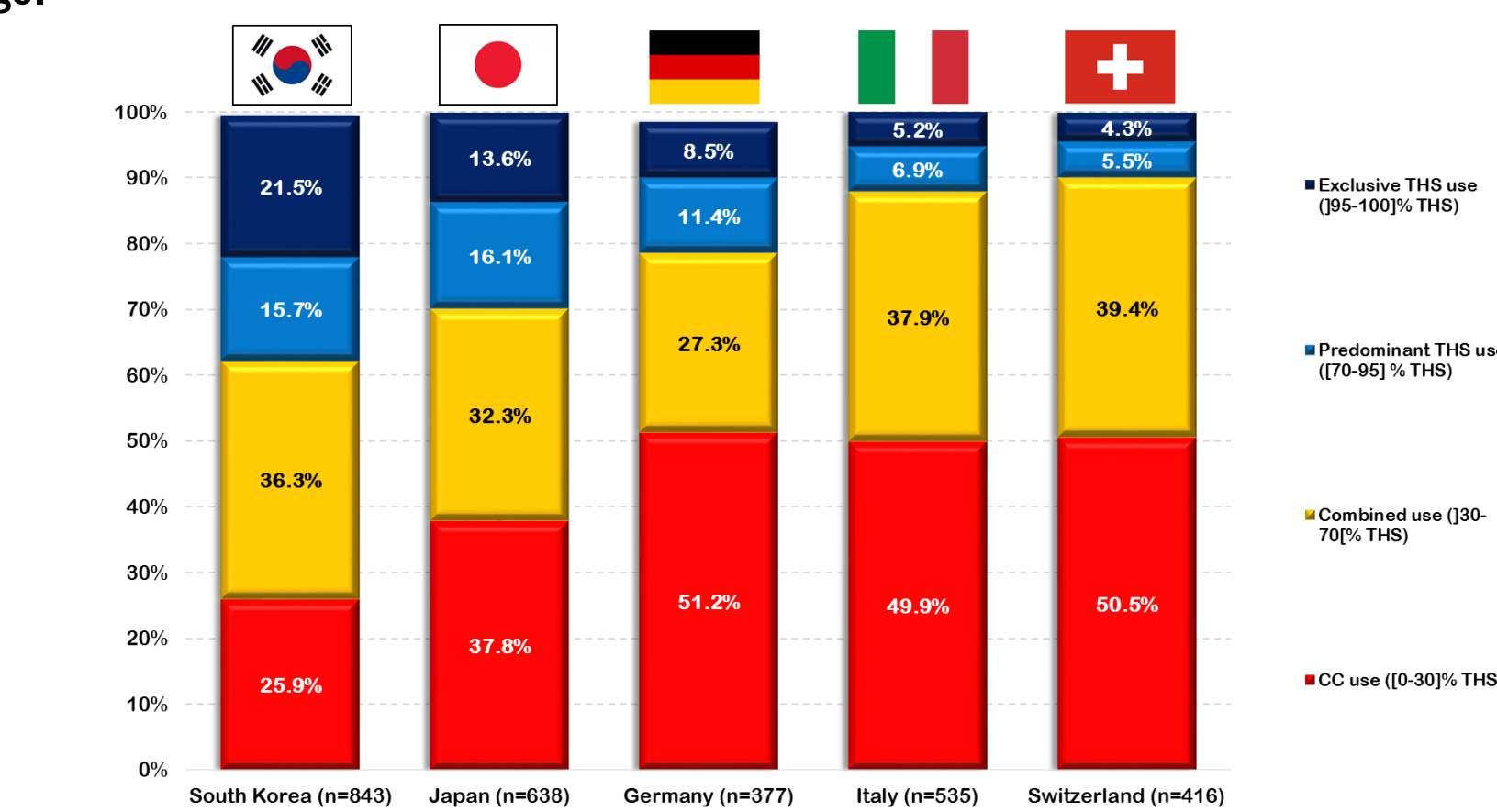
Results

The data indicate that THS has the potential to completely "switch" a sizeable proportion of participants, as 7.5% of the participants were using THS exclusively at the end of the observational period.



Patterns of Use Over Time

Outside the U.S., the data also indicate that THS has the potential to completely "switch" a sizeable proportion of participants, as between 4.3% of the participants in Switzerland and 21.5% of the participants in South Korea were using THS exclusively after 4 weeks of usage.



Patterns of Use at Week 4

Conclusions

Based on those studies, several key conclusions can be drawn regarding the likely behavior of adult daily smokers. A sizeable proportion of adult daily smokers is likely to "switch" from CC to THS and is likely to use THS exclusively or predominantly as a substitute to CC, with the proportion of exclusive use likely to remain overall stable over time. There is a higher likelihood of adoption of THS among adult smokers living in Asia compared to Europe or the U.S. It is likely that a certain proportion of adult daily smokers will use THS and CC in a combined way. The data also indicate that the proportion of combined use is decreasing over time with adult daily smokers either returning to CC or, to a lesser extent, adopting an exclusive or predominant use of THS.

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Competing Financial Interest

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