

Actual Use Study of the Potential Reduced-Risk Product (RRP): Tobacco Heating System (THS)

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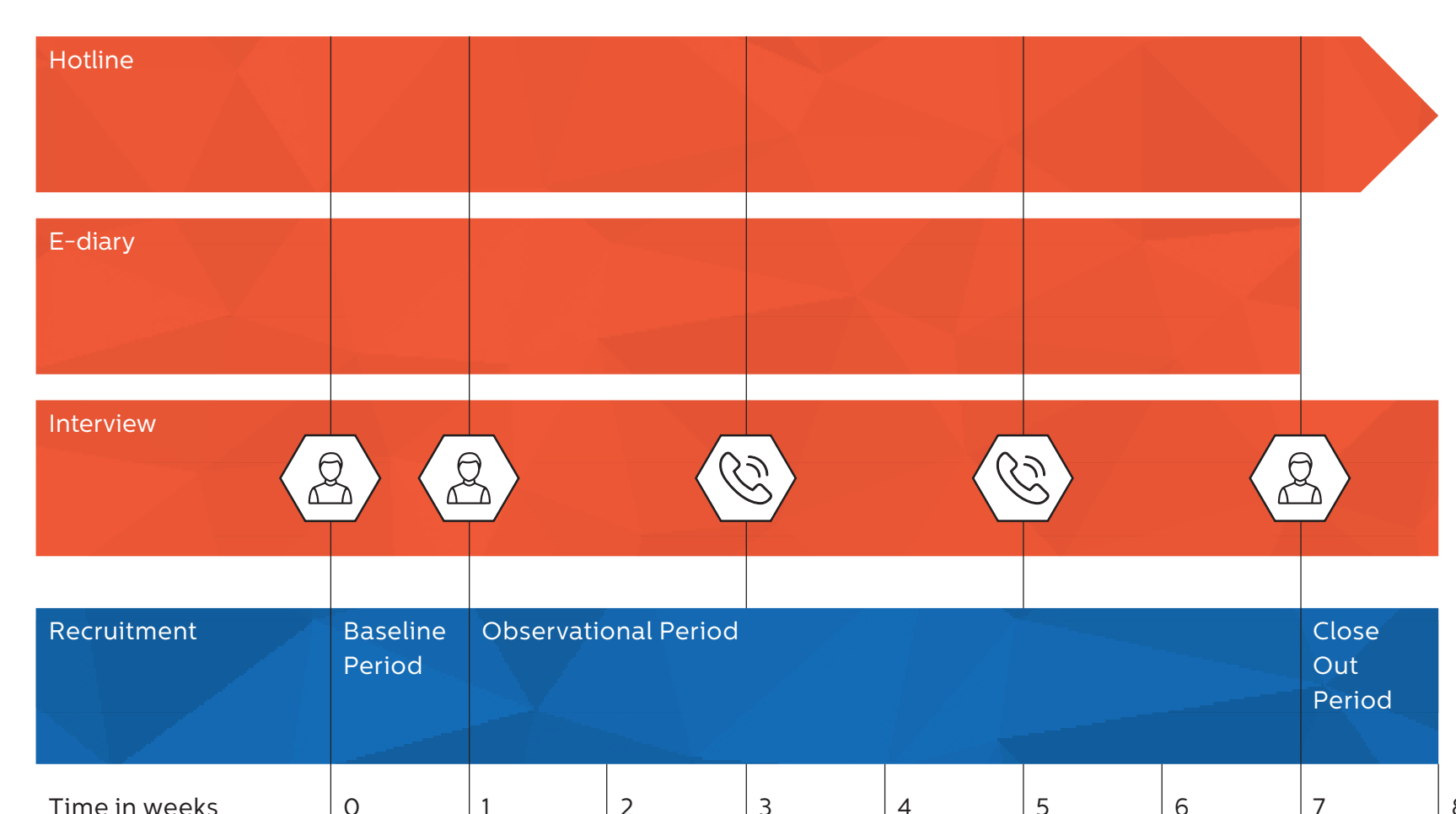
Intro

Philip Morris International (PMI) is developing a number of new products, including potential Reduced-Risk Products (RRPs) with the potential to reduce individual risk and population harm in comparison to smoking cigarettes. These include the “Tobacco Heating System” (THS), comprised of a device and Tobacco Sticks for exclusive use with the device. The Sticks contain tobacco and when used with the THS device produce an aerosol containing nicotine without tobacco combustion. The purpose of this Actual Use Study (AUS) was to investigate how U.S. adult daily smokers of conventional cigarettes (CC) actually used THS.

Study Design

This AUS was designed as a mid-term prospective observational study, implying an assessment of subject-reported stick-by-stick consumption of Tobacco Sticks and CC with participants receiving Tobacco Sticks free of charge. The target population was U.S. adult daily smokers of regular and/or menthol CC aged 18 years and above with no intention of quitting smoking within the next 30 days. The study was conducted in 8 geographical areas of the U.S., and participants were recruited using market research databases. During the entire study, participants were able to consume CC, Tobacco Sticks and any other nicotine-containing product *ad libitum*. They were asked to record CC consumption during the baseline period and Tobacco Sticks and CC consumption during the observational period on an electronic diary.

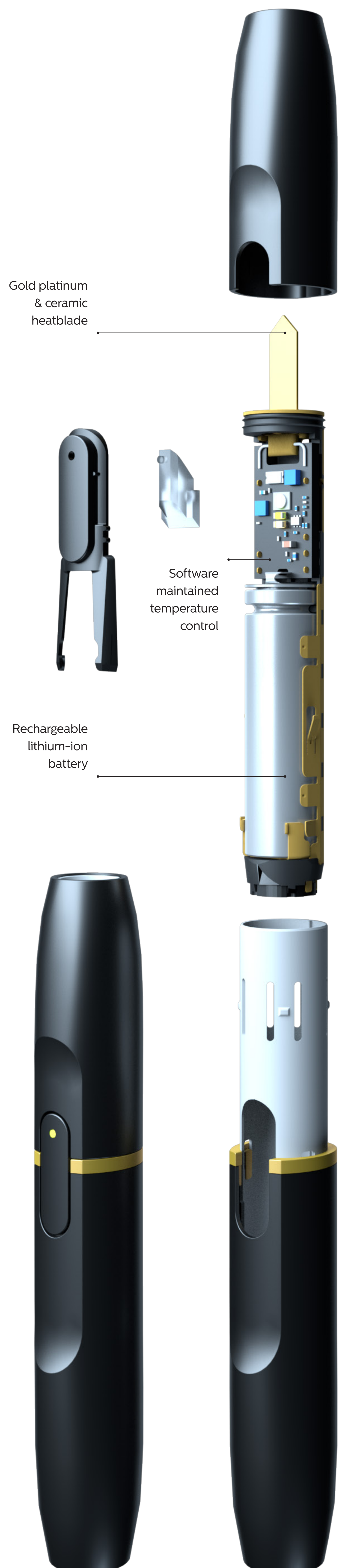
STUDY OVERVIEW



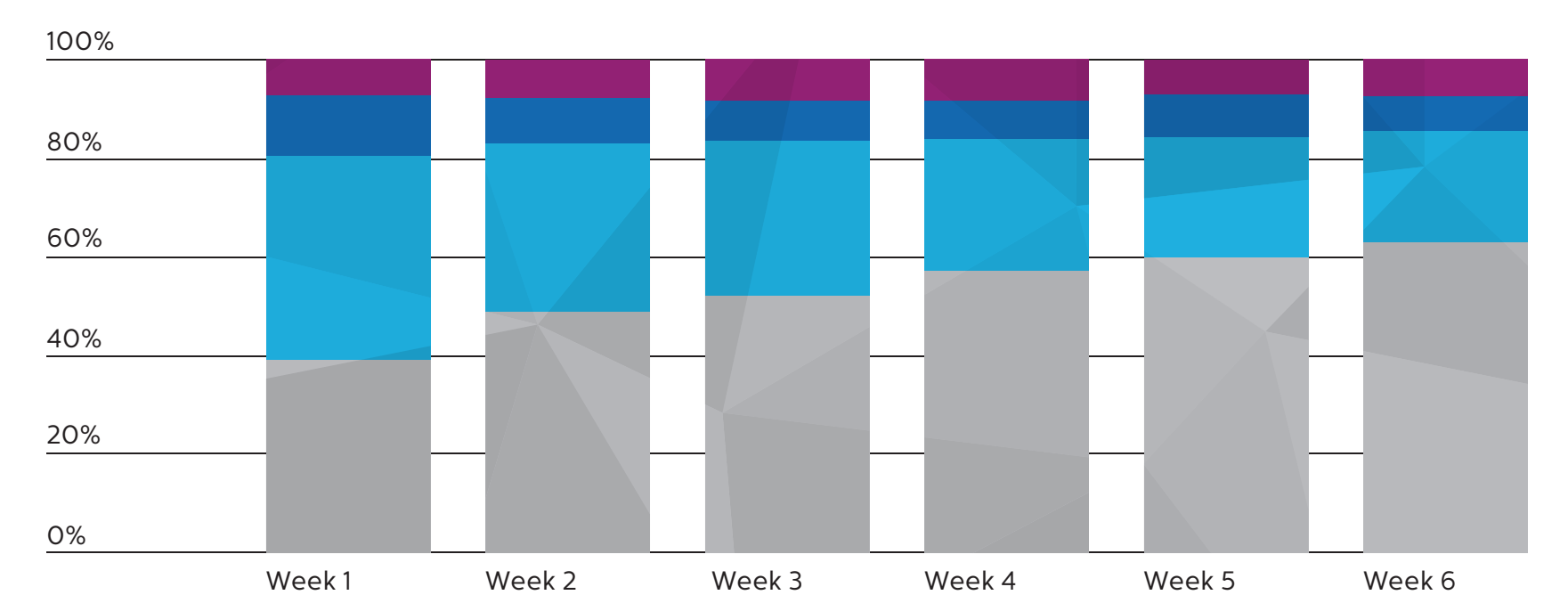
Results

The data indicates that THS has the potential to be fully adopted by a sizeable proportion of adult daily smokers; 7.5% of participants were using Tobacco Sticks exclusively at the end of the observational period.

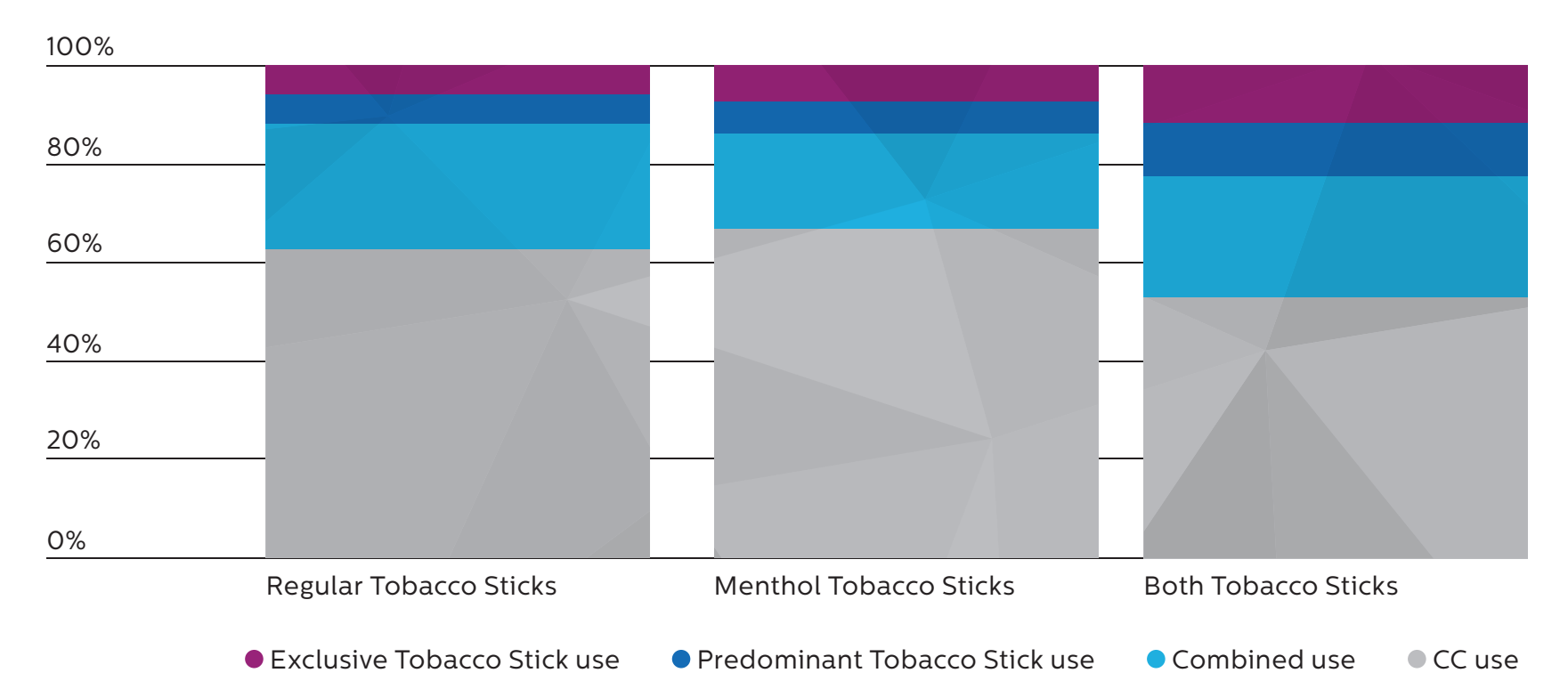
The proportion of participants who completely “switched” to THS was higher in the subgroup who ordered both Tobacco Sticks types compared to those who ordered only menthol or regular Tobacco Sticks.



USAGE CATEGORIES - FAS



USAGE CATEGORIES BY TOBACCO STICKS TYPE AT WEEK 6



AVERAGE NUMBER OF TOBACCO STICKS AND CC REPORTED - PER DAY

Mean (SD)	FAS overall (n=1,106)	Tobacco Sticks use at Week 6 (n=141)	Combined use at Week 6 (n=217)	CC use at Week 6 (n=607)
During baseline period				
Number of CC	10.2 (7.22)	9.0 (5.89)	9.3 (6.34)	10.9 (7.69)
During observational period				
Number of tobacco products (Tobacco Sticks and CC)	9.3 (6.56)	8.1 (5.37)	8.9 (6.21)	9.9 (6.75)
Number of CC	6.3 (5.78)	1.4 (1.57)	4.8 (3.72)	4.8 (3.72)
Number of Tobacco Sticks	3.0 (3.57)	6.7 (4.82)	4.1 (3.06)	1.7 (1.99)

n=number of values reported, CC=conventional cigarettes, FAS=Full Analysis Set.

The average number of tobacco products (Tobacco Sticks and CC) consumed during the observational period per day was lower than the average number of CC per day consumed during the baseline period. A similar pattern was found when looking at results stratified by usage category at Week 6.

Conclusions

Based on the study results several key conclusions can be drawn regarding the likely behaviour of U.S. adult daily smokers.

- 1 A sizeable proportion of adult daily smokers is likely to “switch” from CC to THS and is likely to use Tobacco Sticks exclusively or predominantly as a substitute to CC. The proportion of exclusive use is likely to remain overall stable over time.
- 2 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 a substantial proportion of them is likely to return to CC over time unless they exclusively or predominantly use Tobacco Sticks.
- 3 The availability of several variants of Tobacco Sticks might be a better alternative to increase the transition of adult daily smokers from CC to THS.
- 4 There is no evidence that suggests that the availability of THS would lead to an increase in total tobacco product consumption (Tobacco Sticks and CC).
- 5 No safety concerns about the safety of THS are expected.