

Actual Use Study of The Candidate Modified Risk Tobacco Product (M RTP): Tobacco Heating System (THS)

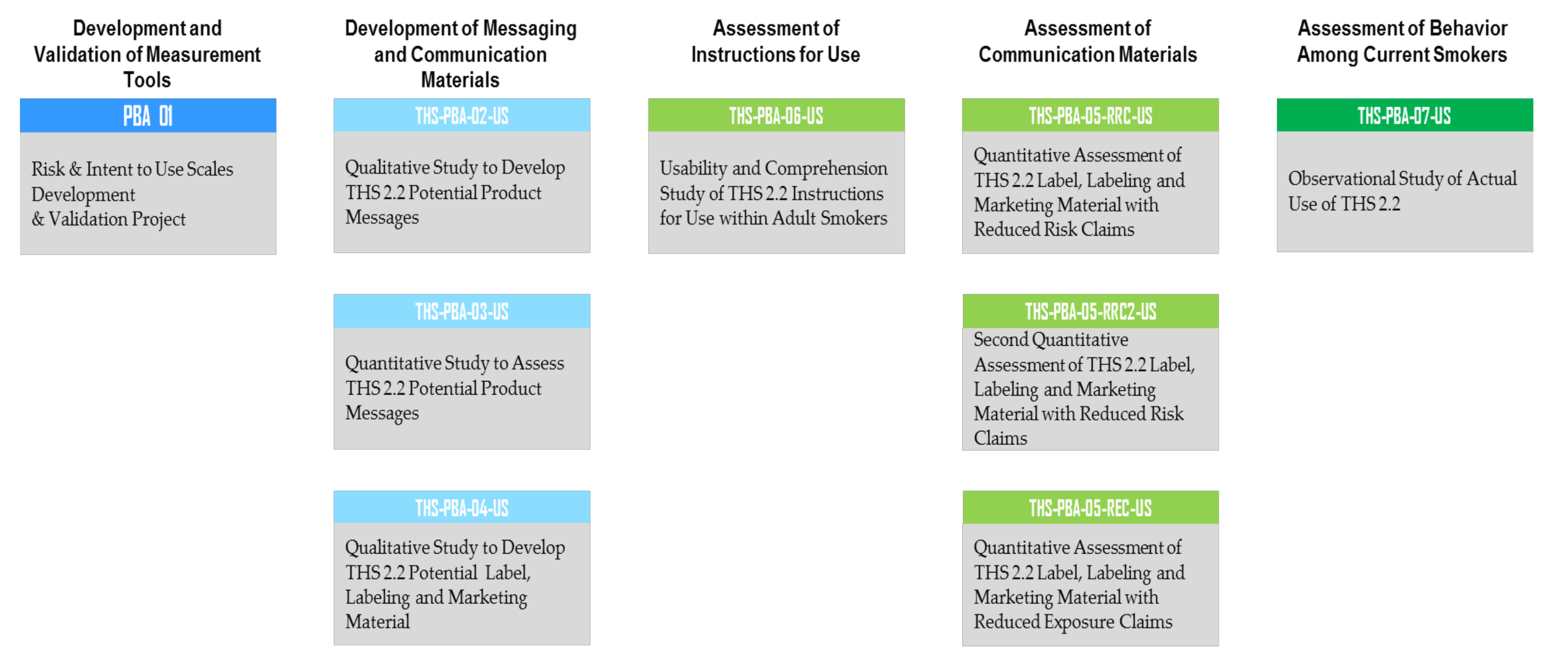
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Introduction and Objectives

Philip Morris International (PMI) is developing a number of new products, including candidate Modified Risk Tobacco Products (M RTPs), which have the potential to reduce individual risk and population harm in comparison to smoking cigarettes.

One of PMI's candidate M RTPs is the “Tobacco Heating System”. The THS is comprised of a device and tobacco sticks branded as “*HeatSticks*” designed to be exclusively used with the device. *HeatSticks* contain tobacco and when used with the THS device produce a nicotine containing aerosol, but without combustion of tobacco.

The THS-PBA-07-US Actual Use Study (AUS) is the final element of THS premarket Perception and Behavior Assessment (PBA) program with the aim to provide evidence to one of the key areas of investigation highlighted in the M RTPA Draft Guidance related to the “effect the tobacco product and its marketing may have on tobacco use behavior among current tobacco users”.



THS PBA Program

The purpose of this AUS study was to investigate how U.S. adult daily smokers of cigarettes (CC) actually used THS

Method

This AUS was designed as a mid-term prospective observational study, implying an assessment of subject-reported stick-by-stick consumption of *HeatSticks* and of CC with participants receiving *HeatSticks* 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 conducted 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.

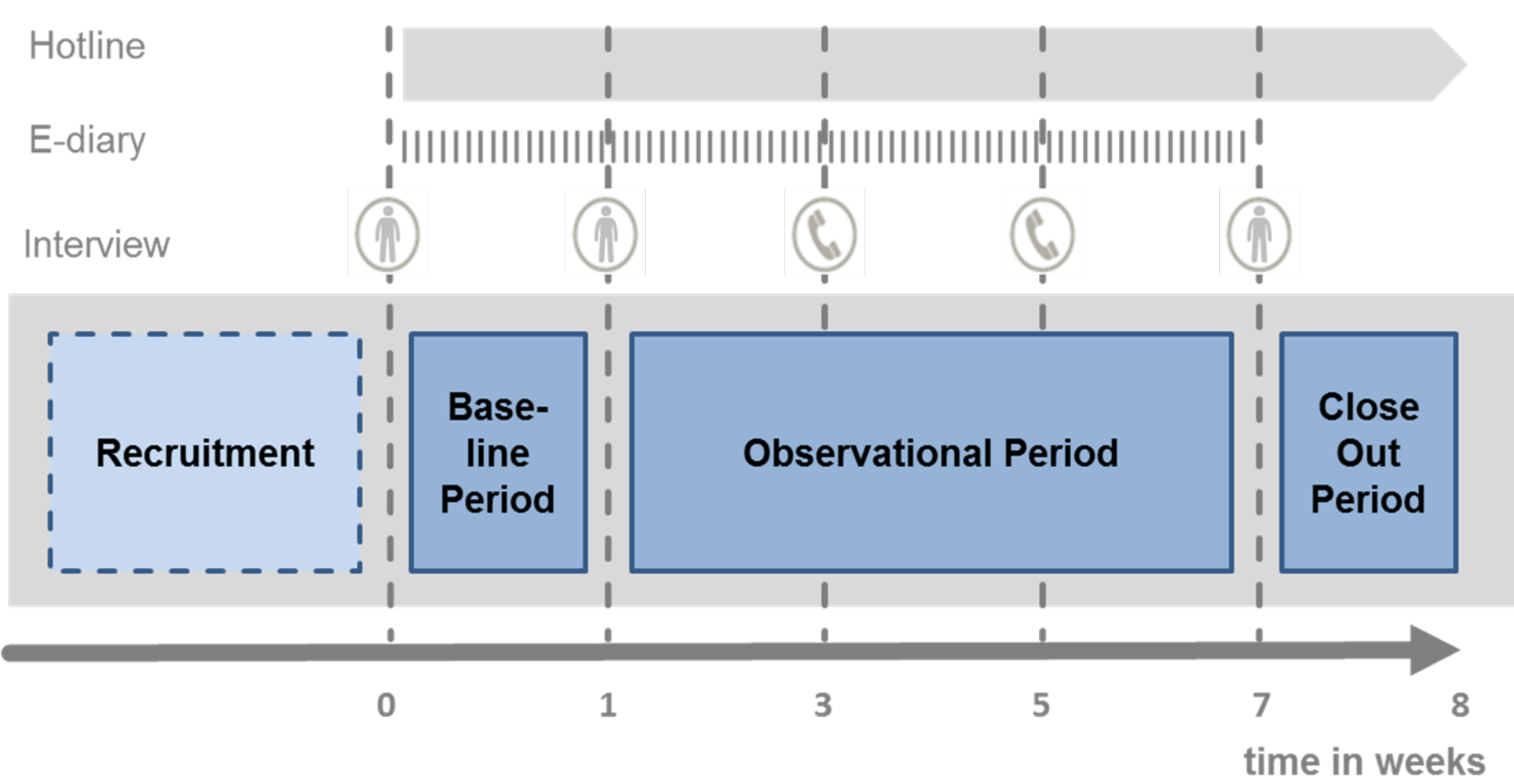
First Subject In was on 21 September 2015 and Last Subject Out was on 07 January 2016. 1,336 participants were enrolled, 1'106 participants composed the Full Analysis Set (FAS).

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 products containing nicotine.

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 *HeatSticks* and CC.

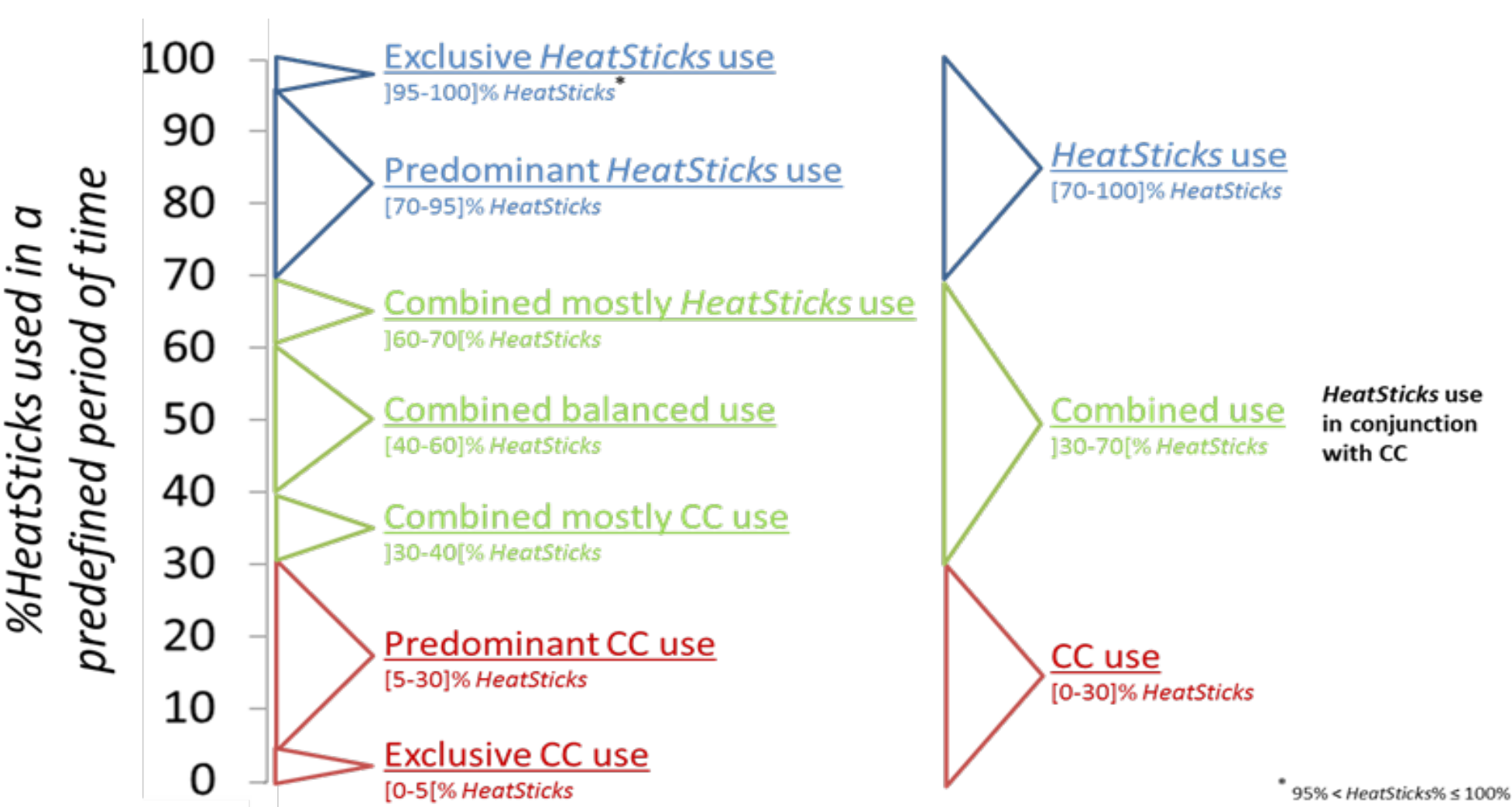
The observational period served to assess the development of consumption patterns of *HeatSticks*.

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, *HeatSticks* and any other product containing nicotine *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 *HeatStick* or a CC during the observational period.

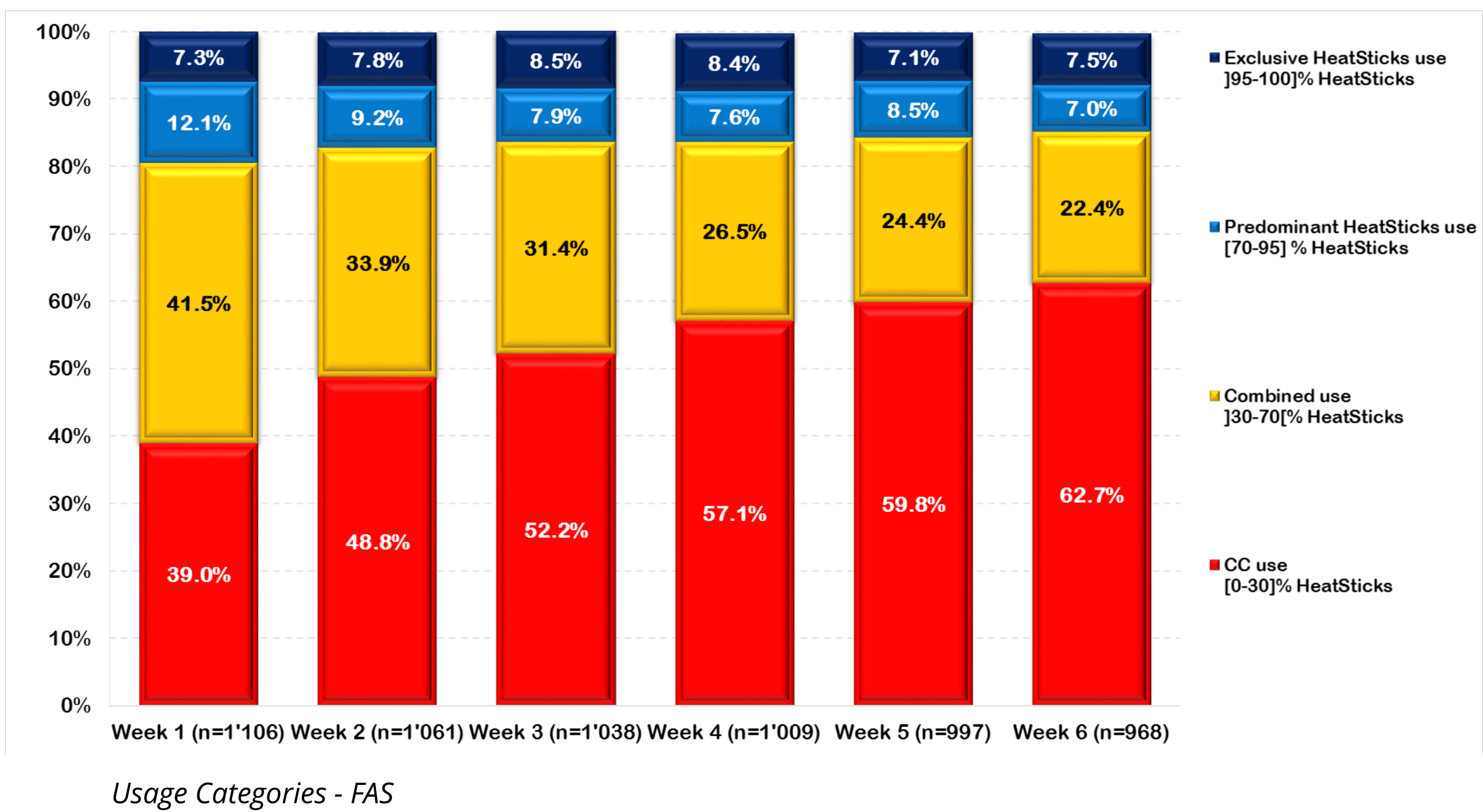
The patterns of use were defined using the below usage categories.



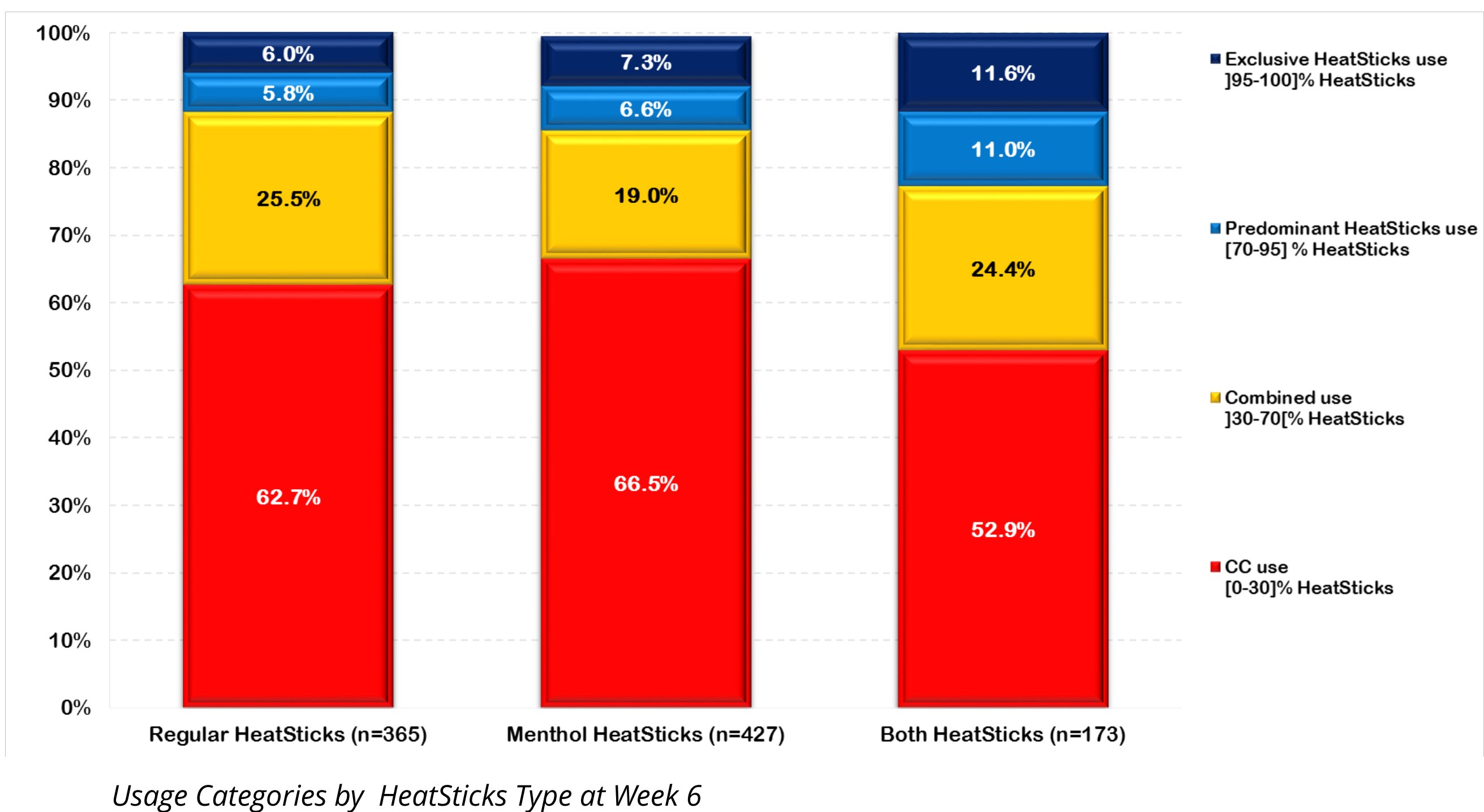
Usage Categories

Results

The data indicates that THS has the potential to completely “switch” a sizeable proportion of participants, as 7.5% of the participants were using *HeatSticks* exclusively at the end of the observational period.



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



The average number of tobacco products (*HeatSticks* 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.

	Average number of <i>HeatSticks</i> and CC reported – Per day			
	FAS overall (n=1,106)	<i>HeatSticks</i> use at Week 6 (n=141)	Combined use at Week 6 (n=217)	CC use at Week 6 (n=607)
Mean (SD)				
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 (<i>HeatSticks</i> 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)	8.3 (6.32)
Number of <i>HeatSticks</i>	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.

A certain number of AEs were spontaneously reported during the study. The majority of the reported AEs were not health-related (e.g. product quality issues). Eight cases were assessed as serious and in 5 out of those 8 cases, a causal relationship between the use of THS and the reported events cannot be excluded. Based on the information on AEs, no safety concerns about THS emerged during this study.

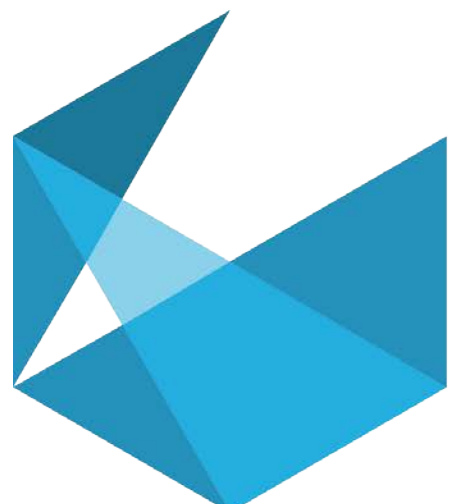
Conclusions

- Based on the study results several key conclusions can be drawn regarding the likely behavior of U.S. adult daily smokers.
- A sizeable proportion of adult daily smokers is likely to “switch” from CC to THS and is likely to use *HeatSticks* exclusively or predominantly as a substitute to CC. The proportion of exclusive use is likely to remain overall stable over time.
 - 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 adopt a usage behavior involving either exclusive or predominant use of *HeatSticks*.
 - The availability of several variants of *HeatSticks* might be a better alternative to increase the transition of adult daily smokers from CC to THS.
 - There is no evidence that suggests that the availability of THS would lead to an increase in total tobacco product consumption (*HeatSticks* and CC).
 - No safety concerns about the safety of THS is expected.

REFERENCES

CDC (Centers for Disease Control and Prevention), Department of Health and Human Services, Office of the Surgeon General. Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Rockville (MD). 2012.

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