PMI RESEARCH & DEVELOPMENT

Active Product Surveillance
P1-SUR-02-US

Study Type: Internet Forum Monitoring

Product: *iQOS* with *HeatSticks*

Country: United States

Sponsor: Philip Morris Products S.A.
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Version Status: FINAL
Version: 1.0
Version Date: 10/7/2016

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PROTOCOL CONCEPT

Background

Philip Morris Products S.A. (PMP S.A.) is developing novel nicotine and tobacco containing products with the potential to reduce harm or the risk of tobacco-related disease associated with smoking conventional cigarettes. In accordance with the United States Food and Drug Administration (FDA), PMP S.A. must demonstrate that "the product, as it is actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." (FDA 2012)

iQOS is one of these novel tobacco products. *iQOS* was designed to replicate the ritual of smoking – without combustion. Instead of burning tobacco, the *iQOS* system heats tobacco, producing an aerosol that contains significantly less harmful and potentially harmful constituents compared to cigarette smoke.

Altria Client Services, LLC (ALCS) is exploring the use of Internet forum monitoring to compliment the post-market surveillance. This infrastructure, if developed, would allow us to utilize and monitor online discussions related to the use patterns, consumer perceptions (including risk perception), and health-related information pertaining to *iQOS* with *HeatSticks*, its brand family, and product category. It will also allow us to monitor any discussions, if present, related to abuse, misuse, and product tampering. ALCS has successfully conducted proof of concept study to assess the feasibility of Internet forums as a component of post-market surveillance program for e-Vapor products.

ALCS is planning to conduct similar proof of concept study for *iQOS* with *HeatSticks* after the product is introduced into a commercial market. The outcome of the proof of concept study will drive a decision to develop a systematic data collection infrastructure for *iQOS* with *HeatSticks*.

Objectives of the proof of concept study

- To identify Internet forum sites with the presence of *iQOS* with *HeatSticks* conversation
- To assess feasibility of systematic data collection and storage in support of *iQOS* with *HeatSticks* post-market surveillance activities
- To explore frequency and volume of *iQOS* with *HeatSticks* content as relates to:
    - product use patterns;
    - consumer perceptions (including risk perceptions);
    - health related information;
    - information about product characteristics such as brand and flavor references; and
    - information related to product abuse, misuse, and tampering

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Internet Forums Identification and Selection Process

Selection of the Internet forums will be conducted in step-wise manner to ensure that a systematic and replicable process is followed. The first step will focus on the identification of all eligible Internet forums, then the eligible Internet forums will be evaluated against the inclusion and exclusion criteria to make a final selection, such as:

- Website includes a message board component (i.e., a forum)
- Forum is structured in a typical, hierarchical format
- Forum promotes free/open discussion
- Forum is maintained by moderators
- Forum content is unedited / uneditable
- Forum content is publically available
- Forum is primarily an English language site
- Forum is only intended for US audience
- Forum includes content related to commercial/recreational use of *iQOS* with *HeatSticks*, other products using similar technology as *iQOS* (as applicable), and cigarettes, e-vapor, or other tobacco products that can provide context for the surveillance
- Forum has frequent daily activity within the past 30 days

The number of Internet forums to be included in the final selection will be based on iterative application of inclusion/exclusion criteria and the learnings from the ongoing Internet forum monitoring process for the e-Vapor category.

Systematic Data Collection and Storage Process

Our goal is to develop an automated data collection system that can support close to real time, ongoing extraction and storage of content discussed on selected Internet forums. Following are the steps we plan to explore in the proof of concept study to assess overall feasibility:

- Development of web grabber application,
- Design of the database architecture, and
- Development of secured storage and retrieval procedures.

Coding of Data from the Internet Forums

To assure consistent classification of the content discussed on the selected Internet forums we will be developing a qualitative coding manual. We plan to conduct comprehensive literature review and concept mapping exercise to establish the content validity of the coding manual as it relates to following outcome categories:

- Product use patterns;
- Consumer perceptions (including risk perceptions);
- Health related information;
- Information about product characteristics such as brand and flavor references; and
- Information related to abuse, misuse, and tampering.

The coding manual will be developed in a manner that it is flexible, as the content and topics of discussion may vary over.

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Data Analysis

The data will be summarized quantitatively and qualitatively. A quantitative analysis of posts will provide context and understanding of the overall landscape of discussion across the monitored Internet forums. It will provide counts of the key concepts and outcomes of interest associated with *iQOS* with *HeatSticks* and in relation to selected comparators, as well as indicate whether or not the frequency of these conversations change over time. A qualitative analysis would provide further context to the quantitative analysis of individual concepts/outcomes.

Reporting

The outcome of the proof of concept study will be summarized in the detailed study report. The final study report will also provide a recommendation regarding the next step for the ongoing Internet forum surveillance of iQOS. We plan to include our findings in the *iQOS* Annual Surveillance Summary Report as soon as it becomes available.

Standards

- Good pharmacovigilance practices (GVP) related to Internet forum monitoring will be followed to the extent defined in the PMP S.A. processes, including the identification of adverse events.
- Appropriate measures will be implemented to ensure that the data collection and reporting processes are compliant with data privacy laws.

ABBREVIATIONS	
ALCS	Altria Client Services
CFR	Code of Federal Regulation
FDA	Food and Drug Administration
PMP	Philip Morris Products, SA

REFERENCES	
[1]	FDA (Food and Drug Administration), Guidance for industry - Modified risk tobacco product applications - Draft Guidance. 2012. (FDA 2012)

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