INVESTIGATION ON PUFFING TOPOGRAPHY PARAMETERS AND PRODUCT EVALUATION RECORDED DURING FIVE DAYS OF USE OF THE TOBACCO HEATING SYSTEM 2.2: A COMPARISON WITH CONTINUED COMBUSTIBLE CIGARETTE USE

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Introduction and Objectives

Philip Morris International is currently developing potentially reduced risk products (RRPs) with the intention to reduce smoking-related morbidity and mortality. It is important to measure the way in which individuals consume the product compared to existing tobacco products. This study is part of a global clinical program to assess Tobacco Heating System 2.2 (THS 2.2), a potentially reduced risk product. The objective was to demonstrate reduction in exposure through altered smoking behavior on THS 2.2 compared to combustible cigarettes (CC). This is reported in another poster.

Methods

- Open-label, randomized, controlled, 3-arm parallel groups, confinement study.
- 160 healthy Caucasian smokers aged between 21 and 65 years.
- Subjects smoked CC during 2 days at baseline prior to being randomized for 5 days in 1 of 3 study groups:
  - THS 2.2 arm
  - CC arm
  - Smoking abstinence (SA) arm
- The study was conducted in Poland in 2013 according to ICH GCP, approved by an Independent Ethics Committee, and registered at ClinicalTrials.gov (NCT01959932).
- An analysis of variance (ANOVA), adjusted for baseline value, sex and daily cigarette consumption was applied to the puffing topography parameters with the study arm as a factor.
- Puffing parameters were recorded at baseline for all subjects, and at Day 1 and Day 4 for both the CC and THS 2.2 arms.
- Product evaluation was assessed daily using the modified cigarette evaluation questionnaire (mCEQ).
- Puffing topography parameters and subjective effects.
- A secondary objective was to assess the adaptation to THS 2.2 through puffing topography parameters and subjective effects.
- Differences observed in puffing topography parameters suggest an ongoing adaptation of product use throughout the study.
- Product evaluation however indicates an adaptation extending beyond the observation period of 5 days.

Results

- Product use duration was 22.4% shorter with THS 2.2 arm on Day 4 (95%CI: 13.6-30.2%).
- Puffs were 32.8% more frequent with THS 2.2 arm on Day 4 (95%CI: 18.3-48.2%).
- Total volume inhaled was similar between CC and THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 105.3% [95%CI: 92.6-119.7%]).
- Work was similar between CC and THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 96.8% [95%CI: 82.2-113.9%]).

Conclusions

- These results suggest an adaptation of product use after switching to a new product as of Day 1 with different characteristics to achieve the levels of nicotine desired by the THS 2.2 user.
- Differences observed in puffing topography parameters suggest an ongoing adaptation of product use throughout the study.
- Product evaluation however indicates an adaptation extending beyond the observation period of 5 days.