An observational cohort study in Japan to assess the patterns of product use and population-level differences in clinical risk endpoints between iQOS users and combustible cigarette smokers


Philip Morris International R&D, Switzerland

Tobacco harm reduction is a public health strategy to lower the health risks to individual tobacco users and benefit the health of the population as a whole. Philip Morris International is developing a portfolio of products, including iQOS with the potential to reduce the risks of diseases associated with smoking conventional cigarettes.

PMI has conducted a series of clinical studies in Japan to assess the nicotine pharmacokinetic profile and reductions in exposure to harmful and potentially harmful constituents (HPHCs). Now that has been launched in Japan, PMI is starting a Post-Market Program in Japan including an observational cohort study, the “LYFE” Study (April 2016).

The LYFE Study will enroll 2000 iQOS users, 2000 CC smokers and 760 never-smokers over a period of 4 years in equally distributed annual waves and will follow participants for up to 5 years. The study is designed to assess how consumers use of tobacco and nicotine products (including iQOS) change over time, the patterns of product use and behavioral trajectories of smoking. Participants will complete questionnaires at enrollment and then at up to 13 time-points over the follow-up period.

In addition a Clinical Sub-Study will enroll 2280 participants, 760 iQOS consumers, matched 1:1 with CC smokers and never-smokers. Participants in the Clinical Sub-Study will have 2 clinical site visits (at 1 and 3 years) to perform physical exams and collect biological samples to assess population-level differences in biomarkers of exposure and clinical risk endpoints.