Abstract

Large international programs increasingly generate large and complex toxicology-relevant data sets. Moreover, industrial R&D endeavors may generate even larger amounts of data but are not as proactive in the area of data sharing. Therefore, sharing these industry-owned datasets represents a great opportunity to push forward frontiers of knowledge for the scientific community as a whole.

A proof of concept database and website (INTERVALS) has been developed to share results from in vivo inhalation studies as well as in vitro studies conducted by Philip Morris International (PMI) that assess potential Modified Risk Tobacco Products (MRTPs). Data modeling took into account the latest standards in terms of data sharing and reproducible research. Given the successful development of the initial infrastructure, the goal is to grow this initiative to establish a public repository for 21st century pre-clinical systems toxicology MRTP assessment data.

In addition, with a goal to maintain scrutiny in data analysis and interpretation, we have developed and applied the sbv IMPROVER methodology to verify the output of research processes in industry. Whereas computational methods are benchmarked using computational challenges, a verification program engaging panels of independent experts confirms the excellence of the scientific methods used and the integrity of the results shared.

Transparency in Science

Several studies have shown that much peer-reviewed scientific literature is not reproducible for a variety of reasons 1-6.

Contributing factors include inadequate documentation of methods and datasets and incomplete sharing of data and methods with the community, which are essential for an experiment’s replication or analysis.

It is crucial that the science is right, i.e. to ensure that:
• Experiments are repeated
• Reagents are validated
• Analyses and statistical tests are appropriate
• All results, including negative and positive controls are shown
• If appropriate, the study is blinded.

A consistent, science-based framework should be used for identification of innovative alternative products that could significantly reduce disease and death caused by cigarette smoking 7-9. Moreover, processes and platforms such as INTERVALS that encourage transparent sharing of data in a way that allow easy review and understanding should facilitate objective evaluation of the evidence 10.

Novel Tobacco Products and Alternative Products Supporting Harm Reduction

Smoking causes serious diseases, including cardiovascular disease, lung cancer and chronic obstructive pulmonary disease. In addition to existing smoking-related disease, in addition to existing smoking-related disease and chronic obstructive pulmonary disease. In addition to existing smoking-related disease, in addition to existing smoking-related disease, smoking can be hazardous to public health. This tobacco harm reduction approach depends on developing products that meet two conditions. Firstly, they need to present less risk of harm than continued cigarette smoking and second, they should be satisfying so that smokers switch to them. Philip Morris International (PMI) is developing a portfolio of potentially reduced risk products (PRPs)11,12 which addresses a wide range of adult smoker preferences12.

Independent Verification

To complement the peer review of publications reporting individual studies, a deeper review was conducted to obtain an independent assessment of several nonclinical and clinical studies, including in vivo inhalation studies, in vitro assays, and clinical PV studies designed to evaluate the relative effects of PRPs in comparison with a reference cigarette.

We engaged SciPinion LLC (https://scipinion.com/) to identify and recruit key opinion leaders in 5 separate panels on an objective and non-sponsored manner. At no stage was PMI aware of the identity of the individuals who participated in the review. The reviewers had access to all publications and raw data from the studies via a web portal designed for external review. The panelists were asked to answer multiple questions regarding study design, methods, quality of data, and interpretation of results to judge the validity of the conclusions regarding the relative effects of THS 2.2. Overall results were very positive, being supportive or very supportive of the study methods and results.

*Reduced-Risk Products ("PRPs")—the terms we use to refer to products that generate, use, limit, and/or prevent the levels of harmful and potentially harmful compounds found in tobacco smoke.

Competing Financial Interest

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