CROM Workshop

Claim Comprehension and Intention Study for JUUL E-cigarette Products: Findings and CROM-Related Measurement

24 May 2022 | 2:00 to 4:30 pm CET

PROGRAMME

AGENDA

2:00 p.m. - 2:05 p.m.	Introduction to the Workshop	**Christelle Chrea**, PhD Philip Morris Products & CROM Consortium Coordinator
2:05 p.m. - 3:35 p.m.	Claim Comprehension and Intention Study for JUUL E-cigarette Products: Findings and CROM-Related Measurement	**Stacey McCaffrey**, PhD JUUL Labs Inc. & **Saul Shiffman**, PhD Pinney Associates
3:35 p.m. - 3:45 p.m.	**Break**	
3:45 p.m. - 4:25 p.m.	Audience Q&A following speakers presentations	Moderated by **Christelle Chrea**
4:25 p.m. - 4:30 p.m.	Closing remarks	**Christelle Chrea**

WORKSHOP ABSTRACT

Claim Comprehension and Intention Study for JUUL E-cigarette Products: Findings and CROM-Related Measurement

Non-combusted tobacco products are increasingly seen as having potential for harm reduction. Yet, smokers often harbor misperceptions about their risks relative to conventional cigarettes, which impede their transitioning to lower-risk products such as ENDS. This makes communication of accurate relative-risk information important. Accordingly, in some jurisdictions, regulations include provisions for communicating accurate risk information to potential consumers. To ensure effective, accurate, and not misleading communication, regulators may require extensive testing of risk-messaging to ensure appropriate impact on various populations. The US FDA's Modified-Risk Tobacco Product Application (MRTPA) process required for claims is a prominent example.

MRTPA claim testing studies and other related tobacco product perception and intention studies (TPPIS) rely on consumer-reported outcome measures (CROM) as key endpoints, and thus can illustrate the methodological considerations in using such measures in regulatory applications. This workshop brings out some of these considerations, exploring them within the context of a recently executed MRTPA Claims Testing study. Examples to be discussed during the presentation include:

Assessing impact of an MRTP claim on switching behavior among those who have never tried the product: Combining behavioral intentions and actual use data to estimate future behavioral states
Asking smokers about their intention to adopt and subsequently switch completely to a product that they may have never tried poses measurement challenges, particularly related to smokers' ability to accurately estimate such future behavior involving multiple hypothetical steps. Here, we share an approach to estimating switching behavior by combining self-reported data on intention to use a product from a Claims Testing study with self-reported actual use data from a longitudinal study.

Is it possible to assess claim comprehension without capturing participants' opinions? Application of a comprehension practice item with feedback to reduce measurement error of claim comprehension
A particular challenge in measuring claim comprehension is capturing comprehension of what is explicitly stated in the claim, as opposed to consumers' beliefs about the claim; i.e., understanding versus opinion. Leveraging a common strategy from psychoeducational assessment, presenters will discuss the application of a practice item to the assessment of claim comprehension intended to reduce this source of extraneous variation.

Impact of claim message credibility on risk perceptions and behavioral intentions toward the product
Claim credibility, including source credibility and believability of the claim, can play a critical role in either bolstering or hindering the potential impact of health messages, including MRTP claims. Results from a recent Claims Testing study are used to illustrate the impact of credibility on risk perceptions and behavioral intentions. These results also highlight the importance of incorporating Credibility measures into Claims Testing studies and provide direction for future research.

Assessing the public's understanding of the nicotine risk continuum.
As part of communicating about an MRTP's risks, FDA asks sponsors to provide data on perceived risks of the MRTP in the context of risks of other tobacco and nicotine products; that is, the perceived risks of the MRTP in the context of what FDA has referred to as the 'nicotine risk continuum.' The presenters will illustrate a method for helping respondents express their perceptions of where the MRTP falls on the risk continuum, and how this method can be used to assess the impact of a health claim.

BIOSKETCHES

Dr. Stacey McCaffrey is a Psychometrician at JUUL Labs, Inc. where she leads the experimental behavioral research program. Dr. McCaffrey specializes in both qualitative and quantitative psychometric research methodologies, and has developed and validated measures of behavioral intentions, risk perception, claim comprehension for use in research submitted as part of tobacco product applications to the FDA.

Prior to her work at JUUL Labs, Dr. McCaffrey was extensively involved in NIH and industry-funded research efforts targeting the opioid epidemic. These efforts included development of a computer adaptive testing version of opioid addiction severity as well as brief screening tools for adults who may be at risk for opioid misuse. As a consultant at PatientsLikeMe, Inc. she also led Robert Wood Johnson Foundation funded research to better understand patient priorities in healthcare, and developed several patient-reported outcome instruments to measure global and disease-specific health-related quality of life.

Dr. McCaffrey is leading the CORESTA Consumer Reported Outcome Measures (CROM) Working Group 02 (WG02) along with Esther Afolalu (PMI). She received her PhD in Clinical Psychology from Nova Southeastern University (Florida, USA) in 2015. Dr. McCaffrey is also a licensed clinical psychologist.

Saul Shiffman, Ph.D., is Research Professor of Psychology (Clinical and Health Psychology), Psychiatry, Pharmaceutical Sciences, and Clinical Translational Science at the University of Pittsburgh. He also serves as Senior Scientific Advisor at Pinney Associates, which consults to JUUL Laboratories on e-cigarettes and tobacco harm reduction. Dr. Shiffman has published over 450 scientific papers on topics including smoking patterns, nicotine dependence, smoking cessation and relapse, smoking cessation treatment, e-cigarette use, and tobacco harm reduction, as well as on measurement and research methods. His papers have received over 50,000 citations in the scientific literature.

Dr. Shiffman has been involved in a number of regulatory submissions to the US Food and Drug Administration's Center for Tobacco Products, and presented at the Tobacco Products Scientific Advisory Committee, as well as other FDA Advisory Committees.

Dr. Shiffman is the recipient of the Ovid Ferno Award "for breakthroughs in clinical research," awarded by the Society for Research on Nicotine and Tobacco and the Research-to-Practice award "for exemplary work in translating or extending behavioral medicine from research into practical application," awarded by the Society for Behavioral Medicine. Dr. Shiffman has been elected a Fellow of the American Psychological Association, the Association for Psychological Science, the Society of Behavioral Medicine, and the Society for Research on Nicotine and Tobacco. Dr. Shiffman served on the Board of Scientific Advisors of the American Psychological Association, and on advisory panels to the US National Institutes of Health and to a number of NGOs internationally.