CBER BEST Initiative Seminar Series

Date:
March 22, 2023

Time:
11:00AM -12:00 PM ET

Topic:
Negative controls and p-value calibration in RWE generation

Background:
The CBER BEST Initiative Seminar Series is designed to share and discuss recent research of relevance to ongoing and future surveillance activities of CBER regulated products, namely biologics. The series focuses on safety and effectivenessof biologics including vaccines, blood components, blood-derived products, tissues and advanced therapies. The seminars will provide information on characteristics of biologics, required infrastructure, study designs, and analytic methods utilizedfor pharmacovigilance and pharmacoepidemiologic studies of biologics. They will also cover information regarding potential data sources, informatics challenges and requirements, utilization of real-world data and evidence, and risk-benefitanalysis for biologic products. The length of each session may vary, and the presenters will be invited from outside FDA. Please see the details below for our upcoming seminar. **Anyone can register and join for free.** Stay tuned for more detailsand additional webinars during the course of the year.

Description:
Despite our best efforts to adjust for confounding, selection bias, and measurement error through clever epidemiological design, we cannot guarantee our effect estimates produced from real-world data are free from bias. Negative controls, exposure-outcome pairs where we believe there is no causal relationship, can help understand how accurate our study design and data are. By comparing the estimates we produce for our negative controls to the truth (of no causal) effect, we can infer a probability distribution for systematic error in our study. By integrating this expression of uncertainty about systematic error into our statistics, such as p-values, confidence intervals, and critical values when performing sequential testing, we can demonstrably achieve operating characteristics closer to nominal; Our p-values will lead to type-1 errors closer to our alpha, and our confidence intervals will show coverage closer to alpha. OHDSI has developed tools that facilitate the selection of negative controls, include those controls in our study designs, and perform empirical calibration, making these best practices available to everyone.

Presenter:
Dr. Martijn Schuemie
Research Fellow @Janssen Research & Development

Dr. Martijn Schuemie received his Master's degree in Economics with a major in Information Management. He completed his PhD in Computer Science on the topic of human-computer interaction in virtual reality systems for phobia treatment. In the past, he was employed as an assistant professor at the Erasmus University Medical Center of Rotterdam, where he started by researching the application of text-mining the scientific literature in support of molecular biology. He later moved to pharmacoepidemiology, and was one of the lead investigators in the EU-ADR project tasked with building a prototype drug safety signal detection system using population-level observational data. In 2012 he received a one-year fellowship of the FDA and became an active OMOP investigator. In 2013 Martijn joined Janssen Research and Development, where he continued his research in OMOP and later in OHDSI (Observational Health Data Science Informatics).

Registration:
https://northeastern.zoom.us/webinar/register/WN_0qtPHkPVT46t8P6qh1cxeg