CBER BEST Initiative Seminar Series

Date:
February 8, 2023

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

Topic:
Bayesian Safety Surveillance with Adaptive Bias Correction

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 effectiveness of 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 utilized for 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-benefit analysis 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 details and additional webinars during the course of the year.

Description:
In this presentation, we will discuss a collaborative project with the FDA CBER BEST Initiative to improve on post-market vaccine safety surveillance procedures through Bayesian sequential analysis. Post-market surveillance on approved vaccine products is essential for addressing safety concerns. The goal is to detect rare or high-risk adverse events that often go undetected in clinical trials due to limited sample sizes. Collaborating with FDA CBER, we have developed a Bayesian alternative surveillance procedure that tackles these challenges in sequential analysis of observational data. The standard statistical approach for surveillance is Maximum Sequential Probability Ratio Test (MaxSPRT). Through comprehensive empirical evaluations on large-scale observational healthcare databases, we show that, compared to MaxSPRT, our Bayesian method offers more flexibility on the surveillance schedule, more transparency and interpretability in decision-making, and better error control through statistical correction of bias in observational data.

Presenter:
Dr. Fan Bu
Postdoctoral Research Fellow, CBER BEST - OHDSI Program @University of California - Los Angeles

Fan Bu obtained her PhD in Statistics from Duke University and is currently a Postdoctoral Researcher at the Department of Biostatistics at UCLA. She is interested in developing novel statistical and computational tools for complex structures in modern data formats, especially in generating reliable and reproducible evidence from real-world data in public health. During the last year, she has been one of the leading investigators for the FDA BEST contract with OHDSI.

Registration:
https://northeastern.zoom.us/webinar/register/WN_fMRo46n8Twqdeo23ktRqbQ