Date: June 26, 2024

Time: 11:00 -12:00 PM EST

Topic: Applying Machine Learning in Distributed Networks to Support Activities for Post-Market Surveillance of Medical Products: Opportunities, Challenges, and Considerations

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 attend and join for free. Stay tuned for more details and additional webinars during the course of the year.

Description: Access to larger amounts and more complex types of electronic health data in distributed data networks like the US Food and Drug Administration’s Sentinel System and the Observational Health Data Sciences and Informatics (OHDSI) Program has created a growing interest to use more flexible machine learning techniques to enhance their various activities. However, the siloed storage and diverse nature of the databases in these distributed networks create unique challenges. This presentation will discuss various opportunities for using flexible machine learning techniques to enhance the activities of distributed networks that monitor the post-market safety and effectiveness of medical products. It will also describe unique challenges that these networks face when applying such methods, discuss approaches and considerations for addressing these challenges, and provide examples of projects and efforts that the Sentinel System and OHDSI Program have undertaken in these areas. These efforts underscore the important role that machine learning will likely play in advancing the capabilities of distributed networks for post-market surveillance in the years to come.

Presenter: Dr. Jenna Wong, PhD, Assistant Professor, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Dr. Jenna Wong, PhD is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. She received her MSc in Epidemiology from the University of Ottawa and her PhD in Epidemiology from McGill University. She also previously worked at the Institute for Clinical Evaluative Sciences in Ontario, Canada, conducting population-based studies using data from linked provincial administrative healthcare databases. Her research focuses on generating evidence to inform the appropriate and safe use of marketed medications in real-world settings, particularly when they are used beyond their labeled indications in the absence of supporting data. She has extensive experience working with large electronic healthcare databases, including administrative claims and electronic health record data, where another major focus of her research is on leveraging machine learning to improve tasks like risk adjustment, computable phenotyping, imputing missing data, and extracting information from more complex data types, to enhance the utility of real-world data in pharmacoepidemiologic research.

Zoom webinar link: https://columbiacuimc.zoom.us/j/97509828718?pwd=ekhyeFxc2dJdkhGaDVPRHJvaUJLUT09