CBER BEST Initiative Seminar Series

Date: July 28, 2021

Time: 11:00 -12:00 PM ET

Topic: Statistical Learning with Electronic Health Records Data

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 year.

Description: The adoption of electronic health records (EHRs) has generated massive amounts of routinely collected medical data with potential to improve our understanding of healthcare delivery and disease processes. However, the analysis of EHR data remains both practically and methodologically challenging as it is recorded as a byproduct of billing and clinical care, and not for research purposes. In this talk, I will discuss methods that bridge classical statistical theory and modern machine learning tools in an effort to efficiently and reliably extract insight from EHR data. I will focus primarily on (i) the challenges in obtaining annotated outcome data, such as presence of a disease or clinical condition, from patient records and (ii) how to reduce the annotation burden by leveraging unlabeled data in model estimation and evaluation.

Presenter: Jessica Gronsbell, PhD

Jesse Gronsbell is an Assistant Professor in the Department of Statistical Sciences with a cross-appointment in the Department of Community and Family Medicine at the University of Toronto. Her primary interest is in the development of statistical methods for modern digital health data sources as electronic health records and mobile health data. Prior to joining U of T, Jesse spent a couple of years as a data scientist in the Mental Health Research and Development Group at Alphabet's Verily Life Sciences.

Registration: https://northeastern.zoom.us/webinar/register/WN_dZ18LdXHSgO08jfKDRu3Sw