CBER BEST Initiative Seminar Series

Date:
October 25, 2023

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

Topic:
KEEPER: Standardized structured data from electronic health records as an alternative to chart review for case adjudication and phenotype evaluation

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:
Chart review as the current gold standard for phenotype evaluation cannot support observational research at scale. It is expensive, time-consuming, and variable. In this talk, we will discuss how structured data can support efficient phenotype evaluation and case adjudication. We will show Knowledge-Enhanced Electronic Patient Profile Review system (KEEPER) that extracts a patient’s structured data elements relevant to a given phenotype and presents them in a standardized fashion that follows clinical reasoning principles.

We will discuss its performance compared to manual chart review for four conditions (diabetes type I, acute appendicitis, end stage renal disease and chronic obstructive lung disease) and will demonstrate that it can achieve similar accuracy and higher inter-rater reliability compared to chart review at a fraction of time.

Presenter:
Dr. Anna Ostropolets

Dr. Ostropolets completed her PhD in Biomedical Informatics at Columbia University. Her work centered on developing methods for improving reliability of observational evidence generated in large distributed networks and applying those methods to real-world clinical problems. Prior to joining Columbia University, she received her MD from Kharkiv National Medical University and worked as a Knowledge Engineer contributing to ontology development for the OHDSI (Observational Health Data Science Informatics) Standardized Vocabularies. She currently works at Odysseus Data Services where she continues to create new methods and tools for reliable and efficient evidence generation with specific focus on phenotyping algorithms, clinical ontologies, and decision support system. Her work has been published in clinical informatics (JBI, JAMIA, JMIR Medical Informatics), and medical journals (Circulation, BMJ, Lancet Rheumatology, Rheumatology, Lancet Digital Health).

Registration:
https://northeastern.zoom.us/webinar/register/WN_edPLSTwcT-KsaydBkiQ6xQ