CBER BEST Initiative Seminar Series

Date: December 1, 2021

Time: 11:00 -12:00 PM ET

Topic: Vaccine Safety Evaluation Using the Self-controlled Case Series Method

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 self-controlled case series (SCCS) method will be introduced in the context of vaccine safety evaluation, with examples. We will also consider some of the methodological extensions of the SCCS method that have been used in vaccine safety studies, particularly those relevant to studies of COVID-19 vaccine safety.

Presenter: Dr. Heather Whitaker

Dr. Heather Whitaker's past research has primarily focused on self-controlled designs in epidemiology, and she is recognized as a leading expert on the self-controlled case series method. This design is used to study temporal triggers and is frequently used in vaccine safety research. She has been committed to both innovative development of methods and advocating the appropriate use of methodology. Dr. Whitaker maintains a dedicated website and has advised numerous epidemiologists from all over the globe on study design, computation, and interpretation. Dr. Whitaker is now working at UK Health Security Agency (formerly Public Health England) where her work has focused on studies of vaccine effectiveness and antibody studies and surveys.

Registration: https://northeastern.zoom.us/webinar/register/WN_y_s1OpgbTveCmudOrdFJyw