# CBER BEST Initiative Seminar Series

**Date:**
June 14, 2023

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

**Topic:**
Avoidable and bias-inflicting methodological pitfalls in real-world studies of medication safety and effectiveness

**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 effectivenessof 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 utilizedfor 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-benefitanalysis 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:**
Real-world data offer great potential to estimate treatment effectiveness and safety, when RCTs are not available, but come with limitations. Many RWE studies, however, incur substantial bias not from data limitations or lack of randomization, but from avoidable, bias-inducing study design choices. In her talk, Dr. Bykov will present major sources of avoidable bias in RWE studies of medication safety and effectiveness and discuss potential solutions and current efforts to improve the quality of RWE studies.

**Presenters:**
Dr. Katsiaryna Bykov
Assistant Professor of Medicine, Harvard School of Medicine

Katsiaryna Bykov, PharmD, ScD, is an Assistant Professor of Medicine at Harvard Medical School and an Associated Epidemiologist in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. She received her Doctor of Pharmacy degree from Temple University School of Pharmacy in Philadelphia and her Doctor of Science degree in Epidemiology from Harvard T.H. Chan School of Public Health. Dr. Bykov has conducted multiple observational studies on comparative safety and effectiveness of medications, impact of healthcare interventions, and signal detection in electronic healthcare data. She has also contributed to numerous methodological investigations on conducting research in large, population-based healthcare databases. Her recent work has been focused on developing novel methods and data-screening approaches for detecting and evaluating clinically relevant drug-drug interactions in electronic healthcare databases.

**Registration**:
https://northeastern.zoom.us/webinar/register/WN_jjX35XI9TdCLydXs3tA2WQ#/registration