

CBER BEST Initiative Seminar Series



Date: September 7, 2022

Time: 11:00 -12:00 PM EST

Topic: Quantitative Bias Analysis Methods to Improve Inferences

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: Observational epidemiologic research around vaccine efficacy and safety can provide important insights into causal relationships, but key sources of bias often impair the inferences we draw from these studies. Uncontrolled confounding, selection bias and information bias are common in epidemiologic research and failure to account for their impacts in a quantitative manner (rather than qualitative assessments in discussion sections of manuscripts after conclusions have been drawn) can lead to poor inferences. This talk will give an overview of quantitative bias analysis methods to demonstrate how they can be implemented on both summary and record level data to account for the impact of systematic error on study results and provide some examples using data from the literature on how to apply these methods to vaccines safety data.

Presenter: Matthew P. Fox, DSc, MPH



Matthew Fox, DSc, MPH, is a Professor in the Departments of Epidemiology and Global Health at Boston University. Dr. Fox joined Boston University in 2001. His research interests include treatment outcomes in HIV-treatment programs, infectious disease epidemiology (with specific interests in HIV and pneumonia), and epidemiologic methods. Dr. Fox works on ways to improve retention in HIV-care programs in South Africa from the time of testing HIV-positive through long-term treatment. As part of this work, he is involved in analyses to assess the impact of changes in South Africa's National Treatment Guidelines for HIV. Dr. Fox also does research on quantitative bias analysis and co-authored a book on these methods, [Applying Quantitative Bias Analysis to Epidemiologic Data](#). He is also the host of a public health journal club podcast called [Free Associations](#) designed to help people stay current in the public health literature and

think critically about the quality of research studies and a podcast on Epidemiologic Methods called [SERious Epi](#). He currently teaches a third-level epidemiologic methods class, Advanced Epidemiology as well as two other doctoral level epidemiologic methods courses. Dr. Fox is a graduate of the Boston University School of Public Health with a master's degree in epidemiology and biostatistics and a doctorate in epidemiology.

Registration: https://northeastern.zoom.us/webinar/register/WN_x8wIWP4fRSC5HqoTF1p7Qg