# CBER BEST Initiative Seminar Series

**BEST**

**Date:**
May 5, 2021

**Time:**
11:00 -12:00 PM EDT

**Topic:**
Understanding Informed Presence in 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 course of the year.

**Description:** Electronic Health Records (EHR) data have become a key data source for clinical research. Their relative availability and abundance make them very appealing for analytic tasks ranging from comparative effectiveness research, disease surveillance, population health, and predictive modeling. However, as has been widely documented, as a real-world data source, there are a number of analytic challenges with EHR data. One of the key challenges of EHR data relates to the observability of the underlying data. While fundamentally a missing data problem, we have termed this process *informed presence* to highlight that what we observe is informative. In this talk I will provide some illustrations for how informed presence can bias insights and inference with EHR data as well as discuss some approaches – both analytical and design based – that can mitigate these biases. Ultimately EHR data are an extremely useful data source, though like any complicated data source need to be used thoughtfully.

**Presenter:**
Dr. Ben Goldstein, PhD, MPH



Benjamin Goldstein is Associate Professor of Biostatistics and Bioinformatics at Duke University. He is a member of the Duke Clinical Research Institute and serves as the Science Lead for the Children's Health Discovery Initiative. Dr. Goldstein's research focuses on the meaningful use of electronic health records data. His work sits at the intersection of biostatistics, biomedical informatics, machine learning and epidemiology. He works closely with the Duke University Health System developing, implementing and evaluating risk prediction and clinical decision support tools. He also studies how patients' informative visit process can impact inference in EHR based studies. Dr. Goldstein received his PhD in Biostatistics and MPH in Biostatistics and Epidemiology from UC Berkeley.

**Registration**:
https://northeastern.zoom.us/webinar/register/WN_UkPMnpakQ4qRMJS7O459pA