Fifteenth Annual Sentinel Initiative Public Workshop
November 08, 2023 | 9:00 a.m. – 5:00 p.m. ET
Hybrid Meeting
National Press Club, Washington D.C. & Zoom Webinar

9:00 a.m. Welcome and Opening Remarks
9:10 a.m. Keynote Address
9:30 a.m. Fireside Chat with Sentinel Initiative Leadership

FDA leadership from the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Center for Device and Radiological Health (CDRH) will provide remarks on major developments and milestones including accomplishments, important regulatory outcomes, and methodology improvements to date. Topics to be addressed include: accomplishments of the 2019-2023 Strategic Plan; how the Biologics Effectiveness and Safety (BEST) System is leveraged to address vaccine safety; and key updates regarding the National Evaluation System for health Technology (NEST).

10:15 a.m. Break
10:25 a.m. International Approaches to the Distributed Networks Data System

This session will provide an international perspective on analyzing big data for regulatory decision-making and monitoring population health. Speakers will spotlight DARWIN EU®, the Data Analysis and Real-World Interrogation Network, followed by a discussion of the key focus areas and parallel approaches used by the Sentinel Initiative and other international efforts in this space.

11:00 a.m. Sentinel System and BEST Operations and Coordinating Center Perspectives

This session will feature perspectives from both the Biologics Effectiveness and Safety (BEST) System operations and Sentinel System operations. Topics will include contributions to the COVID-19 pandemic response, signal identification enhancements using BEST approaches and Sentinel’s Risk Identification and Analysis (ARIA), updates on Prescription Drug User Fee Act (PDUFA) commitments, and the use of the Sentinel and BEST programs as a regulatory resource.

11:50 a.m. Break for Lunch
1:05 p.m. BEST Innovations in Data Infrastructure to Support Safety and Effectiveness Activities

In this session, participants will explore the enhanced capabilities of the BEST infrastructure to monitor the safety of vaccines including COVID-19, influenza, mpox, and RSV vaccines. Speakers will summarize BEST safety and effectiveness activities conducted during FY 23 and methodological advancements to support the robust
development of real-world evidence (RWE) and its potential role in the evaluation of safety and effectiveness.

1:50 p.m.  Break

2:00 p.m.  EHR & Claims Linked Data: Sentinel System’s Efforts at Improving Causal Inference & Broadening Queries

In this session, speakers will highlight Sentinel Initiative efforts from 2019 – 2023 to improve causal inference for the generation of real-world evidence and utilizing data sources beyond electronic health record (EHR) claims data to broaden queries. The session will also detail efforts of the Sentinel Innovations Center to build a linked claims EHR system for pharmacoepidemiology studies.

2:50 p.m.  Leveraging Lessons Learned to Move Beyond COVID-19

This session will reflect on the contributions of BEST and Sentinel in response to the COVID-19 pandemic through a case study presentation. Speakers will discuss how lessons learned can help inform future approaches to outbreaks, epidemics, and pandemics.

3:45 p.m.  Break

4:00 p.m.  Stakeholder Reflections on Sentinel

In this session, external stakeholders will reflect on the Sentinel Initiative successes to date and provide forward looking perspectives on the future direction of data systems such as Sentinel and BEST. Additionally, FDA speakers will provide a future-focused reflection.

4:50 p.m.  Closing Remarks

TBD

5:00 p.m.  Adjourn

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