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**

Mark McClellan, Duke-Margolis Center for Health Policy

9:10 a.m.   **Keynote Address**

Janet Woodcock, US Food and Drug Administration

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).

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Panelists:

- *Steve Anderson,* US Food and Drug Administration
- *Gerald Dal Pan,* US Food and Drug Administration
- *Danica Marinac-Dabic,* US Food and Drug Administration

Moderated Discussion and Q&A

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.

Moderator: Rachele Hendricks-Sturrup, Duke-Margolis Center for Health Policy

Presentation:

- *Daniel Morales,* European Medicines Agency

Additional Panelists:

- *Melissa Kampman,* Health Canada
- *David Moeny,* US Food and Drug Administration

Moderated Discussion and Q&A

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 the Active Risk Identification and Analysis (ARIA) system, updates on Prescription Drug User Fee Act (PDUFA) commitments, and the use of the Sentinel System and BEST programs as a regulatory resource.

Moderator: Gerrit Hamre, Duke-Margolis Center for Health Policy

Presentations:

- *Margaret Anderson,* Deloitte
- *Darren Toh,* Harvard Medical School and Harvard Pilgrim Health Care Institute
- *Yoganand Chillarige,* Acumen, LLC
- *John Seeger,* Optum Epidemiology

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 Biologics Effectiveness and Safety (BEST) System 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 the 2023 fiscal year and methodological advancements to support the robust development of real-world evidence (RWE) and its potential role in the evaluation of safety and effectiveness.

Moderator: Christina Silcox, Duke-Margolis Center for Health Policy

Presentations:

- *Joann Gruber,* US Food and Drug Administration
- *Mao Hu,* Acumen, LLC
- *Patricia Lloyd,* US Food and Drug Administration
- *Lauren Peetluk,* Optum Epidemiology

Moderated Discussion and Q&A

1:50 p.m.   **Linked-Claims EHR Data: Sentinel System's Efforts at Improving Causal Inference & Broadening Queries**

In this session, speakers will highlight Sentinel System efforts from 2019 – 2023 to improve casual inference for the generation of real-world evidence. Speakers will also discuss Sentinel Innovations Center efforts to link and utilize claims and electronic health records (EHRs) data to broaden queries, by building a linked claims-EHR system for pharmacoepidemiology studies.

Moderator: Rachele Hendricks-Sturrup, Duke-Margolis Center for Health Policy

Presentations:

- *Jennifer Nelson,* Kaiser Permanente Washington Health Research Institute
- *Sebastian Schneeweiss,* Harvard Medical School and Brigham and Women's Hospital
- *Richard Wyss,* Harvard Medical School and Brigham and Women's Hospital

Reactant Remarks:

- *Robert Ball,* US Food and Drug Administration

Moderated Discussion and Q&A

2:35 p.m.   **Break**

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

This session will reflect on the contributions of Biologics Effectiveness and Safety (BEST) System and the Sentinel System 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.

Moderator: Christina Silcox, Duke-Margolis Center for Health Policy

Presentations:

- *Richard Forshee,* US Food and Drug Administration
- *Silvia Perez-Vilar,* US Food and Drug Administration
- *Susan Winckler,* Reagan-Udall Foundation for the FDA

Moderated Discussion and Q&A

3:50 p.m.   **Stakeholder Reflections on the Sentinel Initiative**

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 Biologics Effectiveness and Safety (BEST) System. Additionally, FDA speakers will provide a future-focused reflection.

Moderator: Trevan Locke, Duke-Margolis Center for Health Policy

Opening Remarks:

- *Jeffrey Brown,* TriNetX
- *Philip Goodney,* Dartmouth College
- *Anna McCollister,* Patient Advocate, Patient Engagement and Data Use, Access and Governance
- *Heather Rubino,* Pfizer, Inc.

Reactant Remarks:

- *Steve Anderson,* US Food and Drug Administration
- *Patricia Bright,* US Food and Drug Administration

Moderated Discussion and Q&A

4:50 p.m.   **Closing Remarks**

Gerrit Hamre, Duke-Margolis Center for Health Policy

5:00 p.m.   **Adjourn**