Duke | MARGOLIS INSTITUTE for Health Policy

Sixteenth Annual Sentinel Initiative Public Workshop
November 7, 2024 | 9:00 a.m. – 4:15 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 Institute for Health Policy

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

Patrizia Cavazzoni, U.S. Food and Drug Administration

9:25 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 discuss major developments and milestones to date including accomplishments, important regulatory outcomes, and methodology improvements. Leadership will also highlight where the Sentinel Initiative has come from, where the Initiative is now, and the direction of future work.

Moderator: *Mark McClellan*, Duke-Margolis Institute for Health Policy

Panelists:

- *Steve Anderson,* U.S. Food and Drug Administration
- *Gerald J. Dal Pan,* U.S. Food and Drug Administration
- *Danica Marinac-Dabic,* U.S. Food and Drug Administration

Moderated Discussion and Q&A

9:45 a.m. **Regulatory Applications of RWD: Highlights from the Sentinel System**

In this session, presenters will highlight notable activities from the Sentinel System's Innovation Center and Operations Center, plus recent regulatory projects from this past year. They will also highlight accomplishments and updates since the Fifteenth Annual Sentinel Initiative Public Workshop and how Sentinel's evidentiary goals have been operationalized, including through efforts like the Real-World Evidence Data Enterprise.

Moderator: *Victoria Gemme*, Duke-Margolis Institute for Health Policy

Presenters

- *Rishi J. Desai,* Harvard Medical School and Brigham and Women's Hospital
- *Jamal T. Jones,* U.S. Food and Drug Administration
- *Sebastian Schneeweiss,* Harvard Medical School and Brigham and Women's Hospital

- *Darren Toh,* Harvard Medical School and Harvard Pilgrim Health Care Institute

Moderated Discussion and Q&A

11:00 a.m. **Break**

11:15 a.m. **Vaccine Monitoring: Regulatory Impact of the BEST System**

In this session, presenters will explore recent advancements in the Biologics Effectiveness and Safety (BEST) System infrastructure to monitor vaccine safety and effectiveness. Speakers will highlight examples of BEST safety and effectiveness activities conducted during the 2024 fiscal year including recent studies of Respiratory Syncytial Virus (RSV) vaccine safety and vaccine effectiveness. The session will conclude with a discussion of recent methods development work as part of the efforts to continually improve approaches to vaccine safety surveillance. Throughout these presentations, we will hear about the cutting-edge methods and continual development and improvement of approaches used in studies to support the generation of robust real-world evidence (RWE) to evaluate the safety and effectiveness of biologics and support regulatory decision-making.

Moderator: *Christina Silcox*, Duke-Margolis Institute for Health Policy

Presenters

- *Joann F. Gruber,* U.S. Food and Drug Administration
- *Mao Hu,* Acumen LLC
- *Patricia C. Lloyd,* U.S. Food and Drug Administration
- *Yun Lu,* U.S. Food and Drug Administration

Moderated Discussion and Q&A

12:30 p.m. **Break for Lunch**

1:40 p.m. **Insights into the Future: Sentinel System 3.0**

Presenters will provide insight on how the results of Sentinel System's Innovation Center projects have informed current directions of the FDA's implementation of the Real-World Evidence Data Enterprise in the Sentinel System and to ultimately shape the future Sentinel System 3.0. The discussion will provide an overview of goals and milestones for the new contract recompete.

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

Presenters

- *Patricia Bright,* U.S. Food and Drug Administration
- *Amarilys Vega,* U.S. Food and Drug Administration

Moderated Discussion and Q&A

2:15 p.m. **BEST System Innovations to Anticipate**

Panelists will provide insight into CBER's vision and aspirations for the future of the BEST System. Speakers will discuss technological advancements and the incorporation of these technologies into the BEST System. Furthermore, panelists will highlight the program's dedication to continual evaluation and improvement and the future expansion of CBER's work. This includes efforts with other populations of interest and product areas—including cell and gene therapies.

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

Presenters

- *Hussein Ezzeldin,* U.S. Food and Drug Administration
- *Joann F. Gruber,* U.S. Food and Drug Administration
- *Merianne R. Spencer,* U.S. Food and Drug Administration
- *Carla Zelaya,* U.S. Food and Drug Administration

Moderated Discussion and Q&A

3:00 p.m. **Break**

3:15 p.m. **Perspectives on Future Opportunities for the Sentinel Initiative**

In this session, interested parties will share their perspectives on the future of the Sentinel Initiative, including approaches for accessing and analyzing available healthcare data sources to help FDA meet its mission. We will hear about upcoming opportunities to align joint efforts, processes, and tools across the Sentinel ecosystem.

Moderator: *Trevan Locke*, Duke-Margolis Institute for Health Policy

Panelists

- *Andrew Bate*, GSK plc.
- *Frederic S. Resnic,* Lahey Health and UMass Chan School of Medicine
- *Mary Beth Ritchey,* CERobs Consulting LLC and Rutgers University
- *Patrice Verpillat,* European Medicines Agency

FDA Participants

- *Robert Ball,* U.S. Food and Drug Administration
- *Richard Forshee,* U.S. Food and Drug Administration

Moderated Discussion and Q&A

4:00 p.m. **Closing Remarks**

Gerrit Hamre, Duke-Margolis Institute for Health Policy

4:15 p.m. **Adjourn**

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