Fourteenth Annual Sentinel Initiative Public Workshop
Zoom (Virtual)
November 15th-16th 2022

Day 1

1:00 p.m.   **Welcome and Overview**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

1:10 p.m.   **Keynote Address**
Patrizia Cavazzoni, US Food and Drug Administration

1:25 p.m.   **Fireside Chat with Sentinel Initiative Leadership**
FDA Center leadership from the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) will consider major milestones achieved by the Sentinel Initiative and how the Sentinel System, Biologics Effectiveness and Safety (BEST) System, and National Evaluation System for health Technology (NEST) are being leveraged to address emerging policy issues including COVID-19 response efforts and monkeypox surveillance activities. FDA Center leadership will also provide their perspectives on strategic aims for the continued development of the Sentinel Initiative.

Moderator: **Mark McClellan,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **Gerald Dal Pan**, US Food and Drug Administration
- **Steven Anderson**, US Food and Drug Administration

Moderated Discussion and Q&A

2:00 p.m.   **Reflections on PDUFA VI Commitments and Looking Ahead to PDUFA VII**
This session will highlight recent Prescription Drug User Fee Act (PDUFA) commitments for improving the Sentinel Initiative. The presentation will provide an overview of the FDA's progress made towards fulfilling the PDUFA VI commitments and consider the upcoming strategic goals for the Sentinel Initiative under the PDUFA VII commitment letter.

Presentation: **Patricia Bright**, US Food and Drug Administration

2:10 p.m.   **Break**

2:30 p.m.   **BEST Operations and Coordinating Center Perspectives**
This session will discuss the implementation of key studies supporting COVID-19 response efforts by the Biologics Effectiveness and Safety (BEST) System. Discussion will include considerations for conducting near real-time surveillance and evaluation of

safety signals with more comprehensive and robust studies. A brief discussion about how BEST has been utilized in the current monkeypox outbreak will be also presented.

Moderator: **Rachele Hendricks-Sturrup,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **Azadeh Shoaibi,** US Food and Drug Administration
- **Mao Hu,** Acumen LLC
- **Yoganand Chillarige,** Acumen LLC
- **Hui-Lee Wong,** US Food and Drug Administration

Moderated Discussion and Q&A

3:40 p.m.   **Sentinel System Operations and Coordinating Center Perspectives**
This session will provide an update on Sentinel System operations over the past year. Topics will include research examining the natural history of COVID-19 and recent assessments of treatments, surveillance studies, additions of new data resources and infrastructure enhancements, as well as an update on implementation of signal detection capabilities.

Moderator: **Mark McClellan,** Duke-Robert J. Margolis, MD, Center for Health Policy
Co-moderator: **Rachele Hendricks-Sturrup,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **Darren Toh**, Harvard Pilgrim Health Care Institute
- **Judith Maro**, Harvard Pilgrim Health Care Institute
- **Efe Eworuke**, US Food and Drug Administration
- **Yandong Qiang**, US Food and Drug Administration

Moderated Discussion and Q&A

4:50 p.m.   **Day 1 Closing Remarks**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

5:00 p.m.   **Adjourn Day 1**

Day 2

12:00 p.m.   **Day 2 Opening Remarks and Day 1 Summary**
Rachele Hendricks-Sturrup, Duke-Robert J. Margolis, MD, Center for Health Policy

12:10 p.m.   **Sentinel System Innovations in Data Infrastructure and Analytic Methods**
Discussion will highlight the continued maturation of the Sentinel Initiative as well as important data and methodological advancements that are facilitating studies and supporting the robust development of real-world evidence (RWE) for safety and effectiveness. This session will explore the development of computable phenotypes including the use of structured and unstructured data to automate aspects of adverse event assessments. Panelists will also consider how these data infrastructure improvements are supporting methodological advances in signal detection.

Moderator: **Rachele Hendricks-Sturrup,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **Sebastian Schneeweiss**, Brigham and Women's Hospital
- **Rishi Desai**, Brigham and Women's Hospital
- **David Carrell**, Kaiser Permanente Washington
- **Colin Walsh**, Vanderbilt University Medical Center
- **Richie Wyss**, Brigham and Women's Hospital
- **Keith Marsolo,** Duke University
- **Shirley Wang**, Brigham and Women's Hospital

Moderated Discussion and Q & A

1:25 p.m.   **BEST Innovations in Data Infrastructure and Analytic Methods**
In this session, participants will explore linkages across real-world data sources to improve COVID-19 vaccine exposure and an application of the linked data in a COVID-19 study. Additionally, this session will showcase a COVID-19 vaccine effectiveness study in nursing homes and a benefit-risk assessment framework on potential risks associated with myocarditis/pericarditis following COVID-19 vaccination.

Moderator: **Rachele Hendricks-Sturrup,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **John Seeger,** Optum
- **Bradley Layton,** RTI Health Solutions
- **Yun Lu,** US Food and Drug Administration
- **Richard Forshee**, US Food and Drug Administration

Moderated Discussion and Q&A

2:40 p.m.   **Break**

2:50 p.m.   **Key Collaborations with Stakeholders and Development of New Partnerships in the Sentinel Initiative**
This session will discuss how the Sentinel Initiative is expanding partnerships and building the stakeholder community. Session topics will include ongoing work by the Sentinel System's Community Building and Outreach Center to engage with stakeholder community. Additionally, discussion will consider new partnerships being developed through the Sentinel System and BEST to improve public health disease surveillance and support analytic capabilities for automating adverse event reporting.

Moderator: **Tanisha Carino,** Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
- **Margaret Anderson**, Deloitte
- **Grace Marx**, Centers for Disease Control and Prevention
- **Lance Jones**, IBM Consulting
- **Eric Heflin,** eHealth Exchange

Moderated Discussion and Q&A

4:05 p.m.   **Day 2 Closing Remarks**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

4:15 p.m.   **Adjourn Day 2**