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

Day 1

1:00 p.m. Welcome and Overview

1:10 p.m. Keynote Address

1:25 p.m. Fireside Chat with Sentinel Initiative Leadership
FDA Center 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 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.

Moderated Discussion and Q&A

2:10 p.m. Reflections on PDUFA VI Commitments and Looking Ahead to PDUFA VII
This session will highlight recent PDUFA commitments for improving the Sentinel Initiative. The presentation will overview the FDA’s progress made towards fulfilling the Prescription Drug User Fee Act (PDUFA) VI commitments, and also consider the upcoming strategic goals for the Sentinel Initiative under the PDUFA VII commitment letter.

2:20 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 and Monkeypox response efforts. Discussion will include how quantitative estimates were established and informed FDA’s risk benefit framework on potential risks associated with myocarditis and pericarditis following COVID-19 vaccination. Effectiveness studies on COVID-19 vaccinations in nursing homes as well as results from a feasibility analysis identifying potential Monkeypox cases will also be examined.

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 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.

Moderated Discussion and Q&A

4:50 p.m.  Day 1 Closing Remarks

5:00 p.m.  Adjourn Day 1
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Day 2

12:00 p.m.  Day 2 Opening Remarks and Day 1 Summary

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. Discussion will also consider how these data infrastructure improvements are supporting methodological advances in signal detection.

Moderated Discussion and Q&A

1:25 p.m.  BEST Innovations in Data Infrastructure and Analytic Methods
In this session, participants will explore how linkages across real-world data (RWD) sources are being developed between immunization systems and claims data to improve data on COVID-19 vaccine exposures. Additionally, this session will showcase near, real-time surveillance work and highlight CBER’s efforts towards conducting more robust analyses.

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 working to expand partnerships and build the stakeholder community. Session topics include highlighting 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.

Moderated Discussion and Q&A

4:05 p.m.  Day 2 Closing Remarks

4:15 p.m.  Adjourn Day 2

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