Thirteenth Annual Sentinel Initiative Public Workshop
November 8 and 9, 2021

Agenda

Day 1

10:00 am  Welcome and Overview
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

10:10 am  Keynote Presentation
Patrizia Cavazzoni, U.S. Food and Drug Administration

10:25 am  Fireside Chat with Sentinel Initiative Leadership
Sentinel Initiative leadership will provide remarks on major developments, milestones, and strategic aims to enhance and expand their distributed data networking systems including Sentinel and National Evaluation System for health Technology (NEST). Panelists will describe at a high-level the role of these systems in COVID-19 pandemic response and key lessons learned from the pandemic.

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

- Gerald Dal Pan, FDA
- Daniel Canos, FDA

10:50 am  Session I: Sentinel Coordinating Center Perspectives
Objective: This session will feature key leads from the Operations Center, Innovation Center, and the Community Building and Outreach Center who will discuss the broader work of the Sentinel Initiative. Panelists will discuss the implementation of Coordinating Center master plans as well as Sentinel’s impact as a regulatory resource over the past 15 years and new developments in the Sentinel common data model.

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

Panelists:
- Patricia Bright, FDA
- Richard Platt, Harvard Pilgrim Health Care Institute
- Sebastian Schneeweiss, Harvard Medical School
- Asif Dhar, Deloitte

11:50 am  Break
12:20 pm  
**Session II: Improving Causal Inference for RWE Generation**

Objective: Speakers will discuss the Sentinel Innovation Center’s work to support FDA’s real-world evidence (RWE) framework, with a particular focus on applications to causal inference methods. The panelists will also consider related international collaborations, including work with Europe’s Data Analytics and Real World Interrogation Network (DARWIN).

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

Speakers: **Robert Ball**, FDA

Panelists:
- **John Concato**, FDA, CDER
- **Josh Gagne**, Johnson & Johnson
- **Gianmario Candore**, EMA

1:20 pm  
**Session III: Fireside Chat on Building Robust Evidence Generation Systems**

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

Speaker: **Robert Califf**, Verily

1:40 pm  
**Day 1 Closing Remarks**

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

1:50 pm  
**Adjourn Day 1**
Day 2

10:00 am  Day 2 Opening Remarks and Day 1 Summary

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

10:10 am  Session IV: Sentinel Collaborations for COVID-19 Response

Objective: Presenters will describe work by Sentinel and its external partners in response to the COVID-19 pandemic. The session will cover how Sentinel tools were adapted to fit rapidly developing public health needs and support FDA’s work combating COVID-19, as well as unique international collaborative efforts necessitated by the global nature of the pandemic.

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

Speakers:

- Michael Blum, FDA
- Noelle Cocoros, Harvard Pilgrim Institute
- Susan Winckler, Reagan-Udall Foundation
- Catherine Cohet, EMA

11:10 am  Session V: BEST Spotlight

Objective: This session will highlight BEST’s work from the past year. Focus areas are TBA.

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

12:10 pm  Break

12:40 pm  Session VI: BEST Spotlight

Objective: This session will highlight BEST and their collaborating partners’ work from the past year. Focus areas are TBA.

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

1:40 pm  Closing Remarks

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

1:50 pm  Adjourn
Funding for this workshop was made possible in part by a cooperative agreement (U01FD006807) from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.