

## 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, Biologics Effectiveness and Safety (BEST), and National Evaluation System for health Technology (NEST). Panelists will also 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

Panelists:

- **Gerald Dal Pan**, U.S. Food and Drug Administration
- **Steven Anderson**, U.S. Food and Drug Administration
- **Daniel Caños**, U.S. Food and Drug Administration

**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, Sentinel's impact as a regulatory resource over the past 15 years, and new developments.

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

Panelists:

- **Patricia Bright**, U.S. Food and Drug Administration
- **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 and BEST’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: **Rachele Hendricks-Sturup**, Duke-Robert J. Margolis, MD, Center for Health Policy

Speaker: **Robert Ball**, FDA

Panelists:

- **Rich Forshee**, U.S. Food and Drug Administration
- **John Concato**, U.S. Food and Drug Administration
- **Josh Gagne**, Johnson & Johnson
- **Gianmario Candore**, European Medicines Agency

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

Panelists:

- **Michael Blum**, U.S. Food and Drug Administration
- **Noelle Cocoros**, Harvard Pilgrim Health Care Institute
- **Susan Winckler**, Reagan-Udall Foundation for the FDA
- **Catherine Cohet**, European Medicines Agency

**11:10 am Session V: BEST's COVID-19 Response**

Objective: Presenters will describe work by BEST to collaborate with CDC, CMS, and other government agencies in supporting pandemic response. Discussion will also explore how lessons from the pandemic will affect the development of BEST projects and potential inter-agency partnerships in the future.

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

Panelists:

- **Hui-Lee Wong**, U.S. Food and Drug Administration
- **Eric Weintraub**, Centers for Disease Control and Prevention
- **Fran Cunningham**, U.S. Department of Veterans Affairs

**12:10 pm Break**

**12:40 pm      Session VI: BEST Collaborator Perspectives**

Objective: Representatives from BEST and its collaborating partners will discuss ongoing work to support pandemic response, and the nimble, adaptable approaches that have allowed them to meet the pandemic's unique challenges. Panelists will discuss vaccine safety protocol development as well as the use of near-real-time data to forecast key health outcomes, and provider and health system burden associated with COVID-19.

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

Panelists:

- **Rich Forshee**, U.S. Food and Drug Administration
- **George Hripcsak**, Columbia University
- **John Seeger**, Optum
- **Tom MaCurdy**, Acumen LLC
- **Bradley Layton**, RTI Health Solutions

**1:40 pm      Closing Remarks**

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

**1:50 pm      Adjourn**

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