Twelfth Annual Sentinel Initiative Public Workshop
Washington Plaza Hotel
10 Thomas Cir NW, Washington, DC 20005
April 20, 2020

Agenda

9:00 a.m. Welcome and Overview
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

9:10 a.m. Keynote Address
Patrizia Cavazzoni, U.S. Food and Drug Administration

9:25 a.m. The Sentinel Initiative: Enhancing FDA’s Flagship Active Surveillance Program and Evidence Generation Platform
Objective: 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 describe center specific actions to advance Sentinel’s data, tools, and methods, and introduce key themes for discussion throughout the workshop.
Moderator: Mark McClellan
Speakers:
- Gerald Dal Pan, U.S. Food and Drug Administration
- Steven Anderson, U.S. Food and Drug Administration
- Danica Marinac-Dabic, U.S. Food and Drug Administration

10:00 a.m. A Robust Sentinel System for the 21st Century
Objective: In response to legislative mandates and evidentiary needs to diversify scientific expertise and enhance core key capabilities in the Sentinel System, the Center for Drug Evaluation and Research (CDER) has awarded a new five-year contract that establishes a new organizational structure for the Sentinel Coordinating Center. This new contract builds on FDA successes integrating active, post-market safety surveillance into regulatory decision-making. Presently, CDER is routinely using the Active Risk Identification and Analysis (ARIA) component of the Sentinel System to inform sufficiency analysis, and this session will highlight important milestones achieved and plans for the future.
Moderator: Mark McClellan
Speakers:
- Michael Nguyen, U.S. Food and Drug Administration
- Chesley Richards, U.S. Centers for Disease Control and Prevention
- Brian Bradbury, Amgen

10:30 a.m. Break

10:45 a.m. The BEST and CMS Partnership: Updates on CBER’s Biologic Product and RWE-generation Systems
Objective: Launched in 2017, the BEST Initiative enacts the Agency’s mandate to

Join the conversation with #sentinelinitiative
implement active safety surveillance for biologic products. This session will overview the portfolio of activities under the BEST Initiative and collaborative partnership between the Center for Biologic Evaluation and Research (CBER) and Centers for Medicare & Medicaid Services (CMS). Representatives of CBER will highlight key achievements over the last year, and discuss the development of automated approaches using innovative technologies such as artificial intelligence to execute safety surveillance reporting and inform regulatory decision making.

**Moderator:** Mark McClellan  
**Speakers:**  
- Azadeh Shoaibi, U.S. Food and Drug Administration  
- Alan Williams, U.S. Food and Drug Administration  
- Richard Forshee, U.S. Food and Drug Administration  

11:45 a.m.  
**Lunch Break**

12:45 p.m.  
**Building the BEST Network and Establishing New Capabilities for the Surveillance of Biologics**  
**Objective:** Collaborating partners will discuss ongoing work to support the expansion of the BEST data infrastructure to include a broad range of electronic health data on diverse populations. BEST continues to evolve its tools and methods such as the use of ‘On Demand’ analytics and is leveraging innovative technologies such as artificial intelligence and automation to enhance key areas such as adverse event detection, medical chart review, and automated reporting. Together, these efforts continue to improve the quality of information available for safety and effectiveness evaluations to enhance regulatory decision making for biologic products.

**Moderator:** Mark McClellan  
**Speakers:**  
- Jay Bhattacharya, Acumen  
- Keran Moll, IBM  
- Christian Reich, IQVIA  
- Jon Duke, Georgia Institute of Technology

1:30 p.m.  
**Supporting Innovation in Real-World Evidence of Patient Input through use of FHIR and Digital Health Technologies**  
**Objective:** CBER is collaborating with the National Organization for Rare Disorders (NORD) and IBM to develop approaches to collect patient history data and potentially reduce control group sizes in randomized trials. Working directly with patient groups has expanded participation and access to many more patients with rare conditions in addition to the patients identified through healthcare provider databases. A Fast Healthcare Interoperability Resources (FHIR) based platform is being leveraged in combination with the power of digital health technologies, such as mobile apps, to collect relevant, high-quality EHR and patient history information in a patient-centric manner.

**Moderator:** Mark McClellan  
**Speakers:**  
- Telba Irony, U.S. Food and Drug Administration  
- Pamela Gavin, National Organization for Rare Disorders  
- Shayan Hobbi, IBM

Join the conversation with #sentinelinitiative
2:15 p.m.  Break

2:30 p.m.  Developing New Distributed Data Sources and Computable Phenotypes for Rapid Querying

Objective: Building on the morning discussion of ARIA sufficiency analysis, this session will consider key projects underway to expand the Sentinel Common Data Model (CDM) with new data elements and validated outcomes. The expanded CDM will support efficient analytic processes requiring new data infrastructure to scale use of these new data elements within a distributed production environment for rapid querying. Panelists will share current work and lessons learned developing data sources and opportunities to improve the overall quality and reliability of outcome data in the CDM.

Moderator: Mark McClellan

Speakers:
- David Carrell, Kaiser Permanente
- Jeffrey Brown, Harvard Pilgrim Health Care Institute
- David Martin, U.S. Food and Drug Administration
- Carla Rodriguez-Watson, IMEDS
- Teresa Gibson, IBM Watson Health

3:45 p.m.  The New Coordinating Centers: Key Perspectives of Center Leads about the Future of the Sentinel System

Objective: This session will feature key leads from each center who will discuss plans on how to advance and transform Sentinel’s data infrastructure into a national resource for evidence generation. Panelists will also discuss opportunities for collaboration to broaden stakeholder involvement, improve access to new data sources and analytic tools, and ensure more efficient and effective safety surveillance activities.

Moderator: Mark McClellan

Speakers:
- Richard Platt, Harvard Pilgrim Health Care Institute
- Sebastian Schneeweiss, Harvard Medical School
- Asif Dhar, Deloitte

4:45 p.m.  Closing Remarks and Adjournment

Mark McClellan

Funding for this conference was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written conference 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.

Join the conversation with #sentinelinitiative