Improving the Efficiency of Outcome Validation in the Sentinel System

Duke-Robert J. Margolis, MD, Center for Health Policy
1201 Pennsylvania Ave, NW Suite 500 • Washington, DC 20004
May 17, 2018

8:30 a.m.   **Registration**

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

9:10 a.m.   **Defining the Problem: Insufficiency in the Active Risk Identification and Analysis (ARIA) component of the Sentinel System**
Objective: The Active Risk Identification and Analysis (ARIA) component of the Sentinel System consists of the data in the Sentinel Common Data Model and automated tools available in the Sentinel System. The FDA Amendments Act of 2007 requires FDA to determine whether ARIA is sufficient for answering questions of regulatory interest before requiring a post-marketing study. Agency analyses have identified key reasons for ARIA insufficiency and one example of this is outcome validation. This presentation will highlight key challenges with validating outcomes, and will serve as a springboard for discussion in subsequent sessions on how underlying governance, processes, and technologies could support more efficient outcome validation as a starting point for greater sufficiency of ARIA, a stronger Sentinel System, and a more rigorous evidence generation enterprise.

Robert Ball, U.S. Food and Drug Administration

9:25 a.m.   **Sentinel System Efforts to Improve Chart Review and Outcome Validation**
Objective: This session will explore ongoing efforts the Sentinel Coordinating Center is undertaking to address key gaps in ARIA sufficiency. The first presentation will focus on key governance and technical challenges being addressed as part of the chart review process to improve ARIA sufficiency, and the second presentation will highlight survey results of novel technologies that could accelerate Sentinel's ability to access and extract information from medical record data. Following presentations, reactors from the FDA and Sentinel Coordinating Center will consider findings and next steps for improving chart review and outcome validation within Sentinel's distributed data infrastructure.

Moderator: Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

Presentation: Key Opportunities to Improve Chart Review in the Sentinel System
Judith Maro, Harvard Medical School & Harvard Pilgrim Health Care Institute

Presentation: Emerging Technologies for Automating Classification of Medical Charts
Shirley Wang, Harvard Medical School & Brigham and Women's Hospital

Commentators:
Jeffrey Brown, Harvard Medical School & Harvard Pilgrim Health Care Institute
Robert Ball, U.S. Food and Drug Administration
Steven Anderson, U.S. Food and Drug Administration

10:25 a.m.   **Break**

10:40 a.m.   **Improving Outcome Validation: Identifying Best Practices for Extracting Standardized Data from Medical Records**
Objective: This session will explore opportunities to efficiently extract standardized data from medical records for use in multi-site distributed analytics. Discussion topics will include novel tools and methods for improved chart review processes and will also consider the implementation requirements needed for these different approaches.

Moderator: Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
Debbie Dean, General Dynamics Information Technology
Amy Abernethy, Flatiron Health
Jon Duke, Georgia Tech University
David Carrell, Kaiser Permanente Washington Health Research Institute

12:00 p.m.   **Lunch**

1:00 p.m.   **Improving Outcome Validation: Novel Technologies and Methods for Identifying Cohorts and Outcomes**
Objective: This session will focus on best practices for applying novel technologies and methods such as natural language processing and machine learning to standardized data to improve outcome validation and rapid identification of cohorts. Discussion will center on how these tools and methods are being incorporated into computable phenotypes and opportunities to scale their use.

Moderator: Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
Joshua Denny, Vanderbilt University Medical Center
Nigam Shah, Stanford University
Jonathan Silverstein, University of Pittsburgh School of Medicine
Nicolle Gatto, Pfizer

2:15 p.m.   **Break**

2:30 p.m.   **Applications to the Sentinel System: National Health Insurers and Integrated Delivery Health Systems**
Objective: This session will feature Sentinel national health insurer and integrated delivery system Data Partners who will consider key opportunities highlighted in morning discussion to improve tools and methods in the short, medium, and longer term.

Moderator: Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:
Stephan Lanes, HealthCore
Vinit Nair, CHI
Jennifer Nelson, Kaiser Permanente Washington Health Research Institute
Lisa Herrinton, Kaiser Permanente Northern California
Robert Greenlee, Marshfield Clinic Research Institute

3:30 p.m.   **Developing a Strategic Plan and Prioritizing Pilots for Implementation**
Objective: Building on the previous session, Data Partners will consider and comment on the following key questions to begin outlining a strategic implementation plan in Sentinel for improving chart review and outcome validation activities:

- Is fundamental change to the Sentinel data infrastructure needed to implement the types of technologies and analytic approaches we discussed today?
- What changes and technologies might be considered high priority? Given the legal and policy implications of distributed governance in Sentinel, would certain technologies be better suited to support this approach?
- What might high priority pilots or approaches look like to test these capabilities in Sentinel?

Moderator: Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

4:15 p.m.   **Closing Remarks**
Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

4:30 p.m.   **Adjournment**