Innovation in Medical Evidence Development and Surveillance Program (IMEDS)

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Overview

• High priority areas for Sentinel sustainability
• Overview of Reagan-Udall Foundation
• Introduction to IMEDS
• IMEDS next steps
Mini-Sentinel has made significant progress and is a useful tool for FDA.

Ensuring long-term sustainability and maximum impact on public health are essential.

High priority areas:
- Continued development of best methods for using electronic health data for safety assessments
- Train new scientists and equip them with the knowledge and expertise to conduct safety assessments
- Leverage the Sentinel tools to help answer other important questions about what works and doesn’t work in our health care system
The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress to:

- Advance the mission of the FDA by furthering regulatory science and research with the ultimate goal of improving public health
- Provide a unique opportunity to bring all stakeholders to the table to work on regulatory and development science
- Serve as home for a public-private partnership to provide a sustainable pathway to support the methodological, training, and other needs of the Sentinel Initiative

On July 25, 2012 the RUF Board approved the IMEDS planning process to create a new program area to fill this need
**Mission:** To support FDA’s mission by advancing the science and tools necessary to further post-market evidence generation for regulated medical products and to facilitate utilization of a robust secondary electronic healthcare data platform for generating such evidence.

**Starting point...**

**IMEDS-Methods:** Facilitate methodological research aimed at improving the tools for conducting safety surveillance using automated healthcare data.

**Soon to follow...**

**IMEDS-Education:** Train scientists in medical product safety surveillance using electronic health data.

**IMEDS-Evaluation:** Facilitate the use of Sentinel tools and capabilities to further understand the risks and benefits of medical products in the post-market setting.
IMEDS Overview
Progress to Date and Next Steps

Progress to Date

✓ Secured Accenture to support design
✓ Assembled and convened IMEDS Organizing Committee meetings to inform design of IMEDS-Methods
✓ Completed stakeholder interviews with stakeholders to supplement Organizing Committee perspectives
✓ Began development of IMEDS-Methods Charter document detailing IMEDS-Methods Business Strategy, Operating Model and Governance Plan

Next Steps

☑ Implement Communications Plan to inform key stakeholders about progress and to solicit input on design IMEDS-Methods
☑ Finalize IMEDS-Methods Charter (with guidance from Organizing Committee and others)
☑ Work with FNIH, FNIH Board, OMOP Executive Board, OMOP Investigators and Mini-Sentinel Planning Board to ensure alignment
<table>
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<th>Member</th>
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| Garry Neil, MD                 | • Apple Tree Partners, Apple Tree Pharmaceuticals, TransCelerate Biopharmaceuticals Inc.  
|                                | • Reagan-Udall Board Liaison                                                |
| Rachel Sherman, MD and Melissa Robb | • Food and Drug Administration                                               |
| Richard Platt, MD, MSc          | • Harvard Pilgrim Health Care Institute                                     
|                                | • Mini-Sentinel: Principal Investigator                                      |
|                                | • OMOP: Executive Board member                                               |
| Patrick Ryan, PhD               | • Janssen R&D                                                                |
|                                | • OMOP: Principal Investigator                                               |
| Lesley Curtis, PhD              | • Duke University                                                           |
|                                | • Mini-Sentinel: Leader, Data Core                                            |
| Alec Walker, MD, DrPH           | • World Health Information Science Consultants                               |
| Claire Spettell, PhD            | • Aetna                                                                     |
| John Santa, MD                  | • Consumer Reports                                                          |
| Lee Rucker, MS                  | • AARP                                                                      
|                                | • OMOP: Executive Board Member                                               |
**Initial Focus: IMEDS-Methods**

**Current Trends**

- Significant progress has been made on research methodology by both OMOP and Sentinel
- Electronic health data are constantly evolving; research methods must evolve accordingly to properly utilize this data
- Need exists for long-term, research agenda and corresponding governance structure to address methodological needs of Sentinel

**IMEDS-Methods Objectives:**

- Create a long-term methods research agenda that supports FDA safety activities
- Build an inclusive, educated community of methods researchers
- Establish fully transparent governance to oversee implementation of research agenda
- Identify and cultivate best research methods
- Establish a data environment needed for methods research
  - Internal data laboratory
  - Establish partnerships with Data Partners
Questions or Comments?

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