

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

Background

- 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

Innovation in Medical Evidence Development and Surveillance Program (IMEDS)

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

IMEDS-Methods Organizing Committee

Member	Organization
Garry Neil, MD	<ul style="list-style-type: none"> • Apple Tree Partners, Apple Tree Pharmaceuticals, TransCelerate Biopharmaceuticals Inc. • Reagan-Udall Board Liaison
Rachel Sherman, MD and Melissa Robb	<ul style="list-style-type: none"> • Food and Drug Administration
Richard Platt, MD, MSc	<ul style="list-style-type: none"> • Harvard Pilgrim Health Care Institute • Mini-Sentinel: Principal Investigator • OMOP: Executive Board member
Patrick Ryan, PhD	<ul style="list-style-type: none"> • Janssen R&D • OMOP: Principal Investigator
Lesley Curtis, PhD	<ul style="list-style-type: none"> • Duke University • Mini-Sentinel: Leader, Data Core
Alec Walker, MD, DrPH	<ul style="list-style-type: none"> • World Health Information Science Consultants
Claire Spettell, PhD	<ul style="list-style-type: none"> • Aetna
John Santa, MD	<ul style="list-style-type: none"> • Consumer Reports
Lee Rucker, MS	<ul style="list-style-type: none"> • 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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