

Innovation in Medical Evidence Development and Surveillance Program (IMEDS)

Overview of IMEDS Charter

August 2013

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

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 and improves upon the methods for secondary use of data (the OMOP 3-Year research agenda will serve as a starting point).
- Build an inclusive, educated community of methods researchers
- Establish fully transparent governance to oversee implementation of research agenda
- Establish a data environment needed for methods research
 - Internal data laboratory
 - Establish partnerships with Data Partners

IMEDS Overview

IMEDS Charter

- With guidance from the IMEDS Organizing Committee, RUF created a draft IMEDS Charter which details the business strategy, operating model and governance plan for IMEDS-Methods.
- This IMEDS Charter was modeled on the *OMOP Charter* and *Mini-Sentinel Principles & Policies* documents.
- This IMEDS Charter details the principles and policies governing all projects within the IMEDS program: IMEDS-Methods, IMEDS-Education, and IMEDS-Evaluation. Given that RUF has prioritized the design and implementation of IMEDS-Methods as the first IMEDS project, the bulk of the document outlines principles and policies specifically governing IMEDS-Methods.
- The Charter will inform the general public about how IMEDS will operate, and can be used as background material for potential IMEDS funders, data partners, and other key contributors.
- The draft Charter was approved the RUF Board on 4/2/13, and a modified version was approved by the IMEDS Steering Committee on 8/19/13.

IMEDS Overview

IMEDS Key Features (as outlined in IMEDS Charter)

A process for creating and refining the IMEDS-Methods Research Agenda

- 2013: All OMOP methods research will continue as planned
- IMEDS will then create a 2014-2016 3-Year IMEDS Research Agenda which uses the OMOP 3-Year Research Agenda as a starting point
 - IMEDS will work with FDA to identify, articulate, and prioritize methodological needs that FDA views as important for conducting safety surveillance activities and potentially research areas beyond safety surveillance, as necessary
 - IMEDS will then solicit input from the general public on methodological needs of other stakeholders (including patients, consumers, industry)
 - IMEDS will confirm that the IMEDS Research Agenda addresses the FDA's needs, and then deliver the Research Agenda to the IMEDS Steering Committee for review and approval
 - IMEDS will review and revise the Research Agenda, with input from the FDA and other stakeholders, as necessary

The IMEDS Research Agenda will be created in a transparent manner that engages key stakeholders in an open and ongoing dialogue.

IMEDS Overview

IMEDS Key Features (as outlined in IMEDS Charter)

Several approaches by which IMEDS can choose to initiate research

- 1. Intramural Research:** Investigators who have committed some amount of time to IMEDS, and may be paid by either RUF (as an RUF employee, contractor, or detailee/seconded individual) or their employer. Individuals will be required to apply for these positions (which will be limited in number)
- 2. Request for Task Order Proposal (RFTOP):** A limited number of individuals and institutions will be notified of certain research opportunities, likely when the research is specific to evaluating, improving, or refining tools specific to Sentinel operations. Current OMOP and Mini-Sentinel investigators are eligible to participate in this research.
- 3. Grants Open for Competition:** Any members of the at-large research community may develop proposals in response to publically stated grant needs.
- 4. Unsolicited/Independent Research:** The at-large research community may make unsolicited proposals to complete research in alignment with IMEDS-Methods' mission.

This process is intended to create broad participation among the research community and also leverage the expertise of those with prior experience in OMOP and Mini-Sentinel research.

IMEDS Overview

IMEDS Key Features (as outlined in IMEDS Charter)

A data environment to support IMEDS's research needs

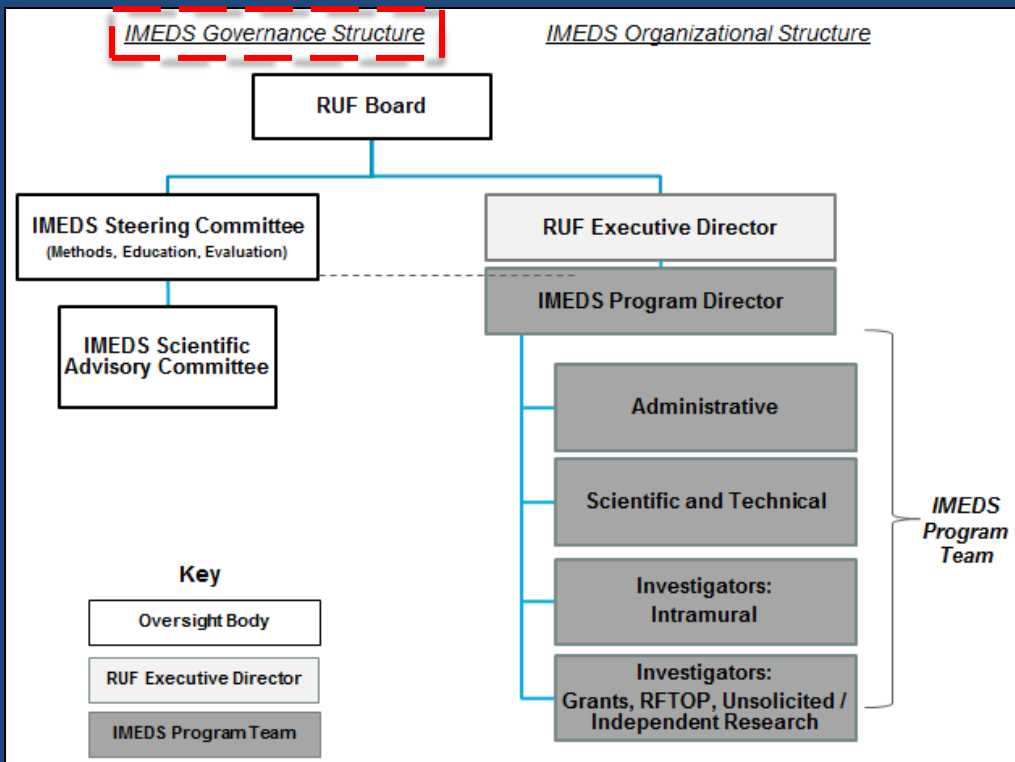
- 1. IMEDS Lab:** uses the OMOP Research Lab as a starting point and provides investigators with resources to conduct experiments through cloud-based computing software. The IMEDS Lab will also be made available to the at-large research community (in accordance with data use agreements, and pending approval by IMEDS), and IMEDS will supplement and update the existing OMOP data, as necessary.
- 2. IMEDS Distributed Network:** modeled on the Mini-Sentinel Distributed Network, this IMEDS Distributed Network would allow IMEDS to conduct experiments against data partners' data while still allowing data partners to retain control and security of that data.

This data environment will encourage broad participation by data partners and investigators in IMEDS-Methods research, helping to increase overall expertise of and collaboration within the research community.

IMEDS Overview

IMEDS Key Features (as outlined in IMEDS Charter)

Defined roles and responsibilities for IMEDS Governing Bodies

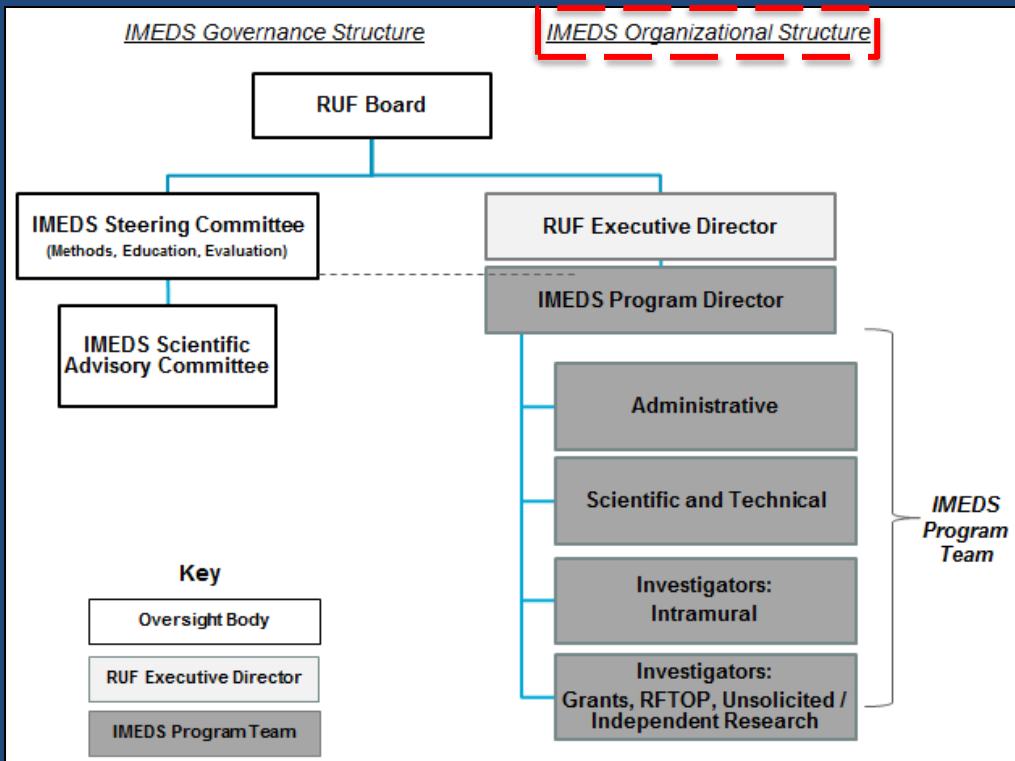


- **RUF Board:** selects IMEDS Steering Committee members; reviews and approves IMEDS partnerships, budget; evaluates effectiveness of IMEDS; assists with IMEDS fundraising
- **IMEDS Steering Committee:** reviews and approves IMEDS Research Agenda; provides guidance on IMEDS partnerships, external communications; selects IMEDS Scientific Advisory Committee members
- **IMEDS Scientific Advisory Committee:** provides input on IMEDS Research Agenda, research proposals, and research work products
- **IMEDS Privacy Panel:** provides expertise on IMEDS privacy and ethics issues; reports to RUF Board

IMEDS Overview

IMEDS Key Features (as outlined in IMEDS Charter)

Defined roles and responsibilities for IMEDS Program Team



- **RUF Executive Director:** hires IMEDS Program Director; ensures alignment between RUF and IMEDS missions
- **IMEDS Program Director:** day-to-day oversight of IMEDS activities; manages creation of IMEDS Research Agenda and completion of research
- **Administrative:** support the IMEDS Program Director in project and contract management for all IMEDS investigators and contractors
- **Scientific and Technical:** provide support and expertise regarding the IMEDS Research Agenda, and IMEDS Lab
- **Investigators:** complete IMEDS research (as assigned by IMEDS Program Director); evaluate research proposals and work products