Innovation in Medical Evidence Development and Surveillance

Research Areas

- Tool Development
  - Data Sharing
- Data-Sharing Enabler

At a Glance

- Status: Active Consortium
- Year Launched: 2013
- Initiating Organization: Reagan-Udall Foundation
- Initiator Type: Nonprofit foundation
- Location: North America

Abstract

The Innovation in Medical Evidence Development and Surveillance (IMEDS) program is offered by the Reagan-Udall Foundation (RUF) for the U.S. Food and Drug Administration (FDA) through the FDA Amendments Act of 2007. IMEDS serves to advance the science and tools necessary to support postmarket evidence generation on regulated products and to facilitate utilization of a robust secondary electronic healthcare data platform for generating better evidence on regulated products in the postmarket settings.

Mission

IMEDS serves to advance the science and tools necessary to support postmarket evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust secondary electronic healthcare data platform for generating better evidence on regulated products in the postmarket settings. IMEDS includes three components:
Structure & Governance

The IMEDS governance structure establishes the strategic, operational, and technical decision-making process required to excel in its mission. It provides strategic leadership, establishes priorities and policies, and is accountable and transparent to the community.

The following are the defined roles and responsibilities for IMEDS governing bodies:

Financing

Given that other organizations solicit funding from many of the same institutions with whom IMEDS will interact through its research responsibilities (including regulated industry, which currently funds academic institutions, payer research units, contract research organizations, and others), a clearly articulated funding strategy is necessary to ensure the long-term sustainability of IMEDS. Guiding principles for the funding strategy include the following:

Intellectual Property

For the most part, the standard vocabularies used by IMEDS have been adapted from public or proprietary sources. There are very few vocabularies created de novo by IMEDS. All publicly available vocabularies are called “unrestricted” and are distributed in a file that is open source and licensed under the Apache License Version 2.0. Some third-party vocabularies (called “restricted”) are only available to be used for certain research purposes, and an end user license agreement has to be executed.

Impact/Accomplishment

IMEDS-Methods projects carried out in 2014 addressed three challenges to obtaining unbiased estimates of risks associated with the use of regulated medical products. The first focused on improved development of case-identifying algorithms to identify subjects who experienced adverse events. The second shed light on how to avoid potential pitfalls of a novel approach to calibrating p-values recently proposed in the literature. The third examined potential sources of bias and heterogeneity in study
results stemming from the use of different data sources, study designs, and common data models. These projects and additional investigations in collaboration with investigators from the FDA and Mini-Sentinel are helping to inform the best uses and limitations of the FDA's Sentinel System. They also provide value to manufacturers, researchers, patients, and clinicians by supplying a valid framework for assessing and interpreting risks associated with the use of regulated products. The IMEDS Research Lab continues to be a vital resource for advancing the development of cutting-edge technologies in support of public health needs. Software, tools, and datasets formatted in the OMOP and Mini-Sentinel Common Data Models support FDA, academic, and industry activities throughout the United States and internationally.

Links/Social Media Feed

Homepage
http://imeds.reaganudall.org/
LinkedIn
https://www.linkedin.com/groups/Observational-Medical-Outcomes-Partnership-OMOP-5053705/about

Points of Contact

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