REAGAN - UDALL FOUNDATION FOR THE Food and Drug Administration

Innovation in Medical Evidence Development and Surveillance (IMEDS)

Reagan-Udall Foundation

June 6, 2013

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IMEDS Program

Why does IMEDS need to exist?

What is "methods research", and why is it necessary?

- Electronic healthcare data, including data from health insurance claims and electronic health records, are routinely captured across the health care system
- For the context of IMEDS, "methods research" includes the study and development of analytical tools to identify knowledge from electronic healthcare data. The tools and knowledge are then used to develop a better understanding of what the data shows about the benefits, risks, and outcomes of medical products

Who uses the findings from methods research, and why do they use them?

- **FDA:** to monitor safety of marketed medical products it regulates
- **Regulated Industry:** to monitor safety of medical products (e.g., drugs) it manufactures
- *All* stakeholders could potentially use methods research findings for broader purposes beyond medical product safety (e.g., compare the effectiveness of two medical products)

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IMEDS Program

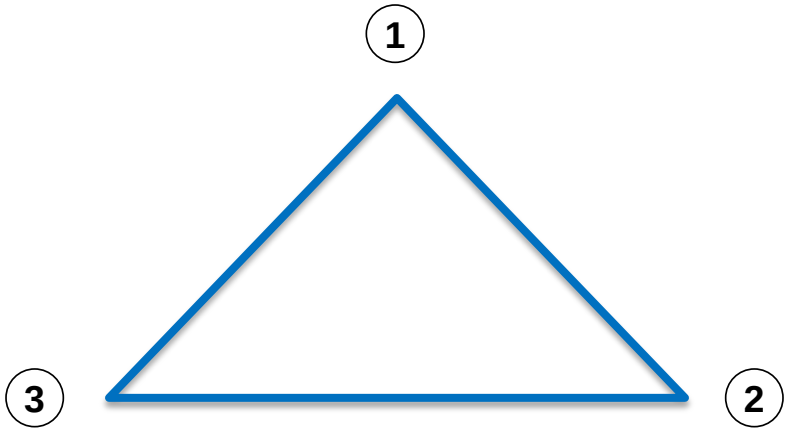
What are IMEDS' key areas?

IMEDS will help the FDA, regulated industry and clinicians improve patient care and the safety of medical products by focusing on three areas.

IMEDS-Methods

Facilitate methods research aimed at monitoring safety of marketed medical products.

Initial Focus for IMEDS Program



IMEDS-Evaluation

Use research findings to help understand the risks and benefits of marketed medical products.

IMEDS-Education

Train scientists in how to conduct methods research using electronic healthcare data.

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IMEDS Program

How will IMEDS compare to similar, existing programs?

Mini-Sentinel, OMOP and IMEDS

- IMEDS will build upon the considerable progress of two pilot projects launched after the signing of the FDA Amendments Act of 2007
  1. Mini-Sentinel: an initiative focused on the conduct of active medical product safety surveillance, supporting the FDA's regulatory decisions
  2. Observational Medical Outcomes Partnership (OMOP): a separate initiative focused on the study of how electronic healthcare data can be used to evaluate the safety of medical products

- OMOP has been managed by the Foundation for the National Institutes of Health (FNIH) and, as originally planned, is in the process of being transitioned to the Reagan-Udall Foundation for the FDA (RUF)

- OMOP will become a central component of the work IMEDS will complete

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IMEDS Program

What are examples of IMEDS methods research?

- Improve upon and create methods and tools that will advance the ability to identify potential medical product safety issues from electronic health data
- Support FDA's public health mission by establishing empirically-based scientific best practices that could be directly applied within the national Sentinel system
- Establishing a framework for evaluating how and when observational electronic health data can be used appropriately to "rule out" false safety signals
- Continue to explore, evaluate, and enhance the use of common data models that support the use of electronic health data from disparate sources for the assessment of medical product safety and effectiveness

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IMEDS Steering Committee

- **Marcus D. Wilson, PharmD**: President, HealthCore [Data Partner Representative, and **IMEDS Steering Committee Chair**]
- **Elizabeth B. Andrews, PhD**: Vice President of Pharmacoepidemiology and Risk Management, RTI [Research / Academic Institute Representative, and **IMEDS Steering Committee Vice-Chair**]
- **Robert M. Califf, MD**: Vice Chancellor for Clinical and Translational Research, Duke University [Provider / Clinician Representative]
- **Patrizia A. Cavazzoni, MD**: Senior Vice President for Worldwide Safety and Established Products Regulatory, Pfizer [Pharmaceutical Industry Representative]
- **Karen Midthun, MD**: Director, Center for Biologics Evaluation and Research, FDA [FDA Representative (non-voting member)]
- **Jane Perlmutter, PhD**: Founder, Gemini Group [Patient Advocate Representative]
- **Michael Rosenblatt, MD**: Executive Vice President and Chief Medical Officer, Merck [Pharmaceutical Industry Representative]
- **John S. Santa, MD, MPH**: Director, Health Ratings Center, Consumer Reports [Consumer Advocate Representative]
- **Janet Woodcock, MD**: Director, Center for Drug Evaluation and Research, FDA [FDA Representative (non-voting member)]
- [The Reagan-Udall Board will select a Liaison to serve as a non-voting member on the IMEDS Steering Committee]

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IMEDS Program

What benefits will IMEDS produce?

1. Research findings, governance decisions, funds received and program activities are shared with the general public with **full transparency**
2. **IMEDS research laboratory** provides researchers with access to numerous and diverse data sources, increasing the quantity and quality of methods research
3. Opportunities to **collaborate with data partners** through a distributed network
4. **Engagement with diverse research participants** helps ensure the most innovative, accurate research methods are developed
5. **RUF's affiliation with FDA** enables alignment between FDA needs and IMEDS research

FDA: more reliable data insights, enabling quicker responses to patient health issues

Regulated Industry: opportunity to play role in helping develop tools to evaluate safety of medical products

Patients: faster, more accurate insights to improve patient safety and health

Data Partners, Payers: better understanding of data and methods for evaluating safety among beneficiaries

Academia: additional training, research opportunities for faculty and graduate students

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IMEDS Program

Where can I access additional information?

Web: http://www.reaganudall.org/

(includes IMEDS Charter)

Web: http://omop.org/

Email: IMEDS@ReaganUdall.org