Opportunities to Expand the Public Health Impact of the Sentinel Initiative

FDA Mini-Sentinel as a National Resource

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Outline

- External engagement
- How Mini-Sentinel operates
  - The pieces that make the whole
- Leverage the pieces to accelerate research
  - Example of the NIH Health Care System Collaboratory
External engagements

- OMOP
- Clinical Trials Transformation Initiative
- ONC Standards & Interoperability Framework (Query Health)
- NIH Health Care System Collaboratory
- IOM Roundtable on Value and Science-Driven Health Care
- Academy Health EDM Forum
- Other new partners as opportunities present
Goals of the external engagements

- Know what others are doing to inform our activities
- Describe what we are doing to inform their activities
- Build resources consistent with national standards
  - Data standards
  - Security
  - Distributed querying
- Inform others of our approaches and lessons learned
  - IOM, AcademyHealth, AMIA, ad-hoc
- Find shared needs across stakeholders
  - PCORI, NIH, CDC, ONC, etc
How Mini-Sentinel Works
Mini-Sentinel distributed analysis

1- User creates and submits query (a computer program)
2- Data partners retrieve query
3- Data partners review and run query against their local data
4- Data partners review results
5- Data partners return results via secure network
6- Results are aggregated
How it works: Coordinating Center

Coordinating Center

• Governance and Operations
  ✓ Policies and contracting
  ✓ Standard operating procedures
  ✓ Legal and regulatory compliance
  ✓ Internal and external engagement
  ✓ Expectations for participation
  ✓ Communications

• Data Integrity and Availability
  ✓ Data model management
  ✓ Data integrity: Fitness for purpose
  ✓ Refresh management and approval
  ✓ Data, methods, and use expertise
  ✓ Immediate information and Data Partner access

• Query Tools
  ✓ Data security and privacy
  ✓ Querying capabilities
  ✓ Querying processing and reporting
How it works: Data resources

Coordinating Center
- Governance and Operations
- Data Integrity and Availability
- Query Tools

Data Partners
- Data Availability
  - Data model and expansion
  - Data refreshes and integrity
  - Immediate access to analysts and investigators to assist interpretation of findings
- Query Responsibilities
  - Maintain infrastructure for rapid response
  - Rapid response based on service level agreement
- Query Tools
  - Testing and review of querying tools
  - Query tool approval
Why it works for Mini-Sentinel

Mini-Sentinel needs

• Responsiveness
  ✓ Frequent rapid response queries
  ✓ Quickly modify existing query types
  ✓ Design / test new query types
  ✓ Design / test new data resources
  ✓ Determine fitness of data for new uses
  ✓ Investigate unanticipated results

• Data Partner Commitment
  ✓ Data always available for use
  ✓ Guaranteed response times

Coordinating Center
Data Partners
Why it works for Mini-Sentinel

Mini-Sentinel needs
• Responsiveness
• Data Partner Commitment

Tightly Coupled Network

Daily interaction between Coordinating Center and Data Partners
How (and Why) to Leverage It To Build Other Networks
It’s really hard to build a network from scratch
Partner Organizations can choose to participate in multiple networks

Networks can leverage existing data, query tools, program libraries
NIH Health Care Systems Collaboratory

Home of the NIH Distributed Research Network

Millions of lives. Strong collaborations. Privacy first.

A Virtual Home for Knowledge about Pragmatic Clinical Trials using Health Systems

The Collaboratory
NIH Distributed Research Network (as envisioned)

- Designed to allow use of existing Mini-Sentinel and others tools
  - Can use many data types, e.g., EHR, claims, registries
  - Can use many data models, e.g., Mini-Sentinel, i2b2, OMOP
  - Can use existing querying tools, e.g., Mini-Sentinel modular programs
- Studies involve negotiation, planning, and investigation of data’s fitness for purpose

The Collaboratory
Thank you!