Opportunities to Expand the Public Health Impact of the Sentinel Initiative
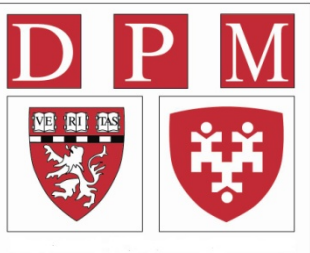
FDA Mini-Sentinel as a National Resource

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January 31, 2013

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
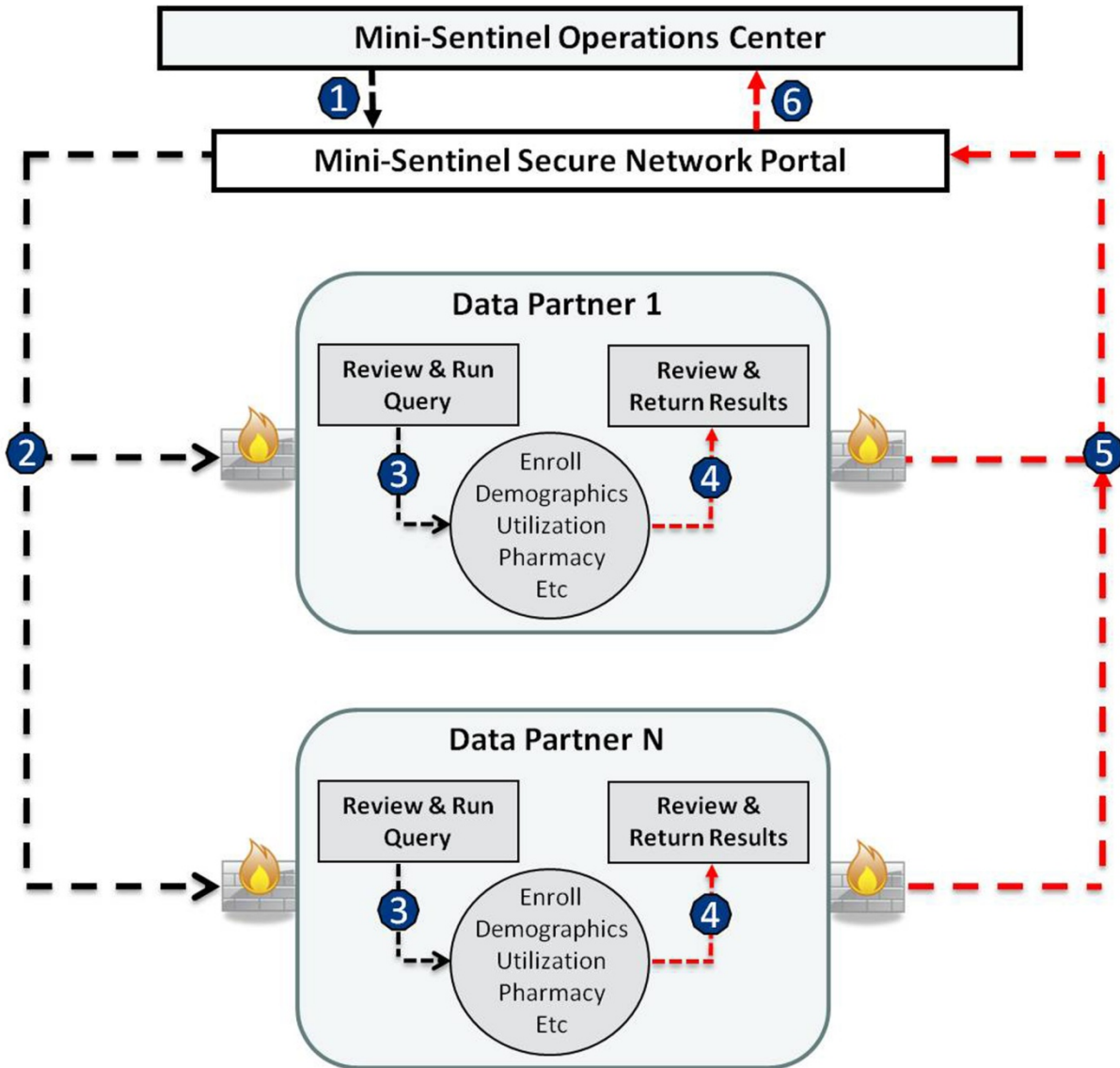
External engagements

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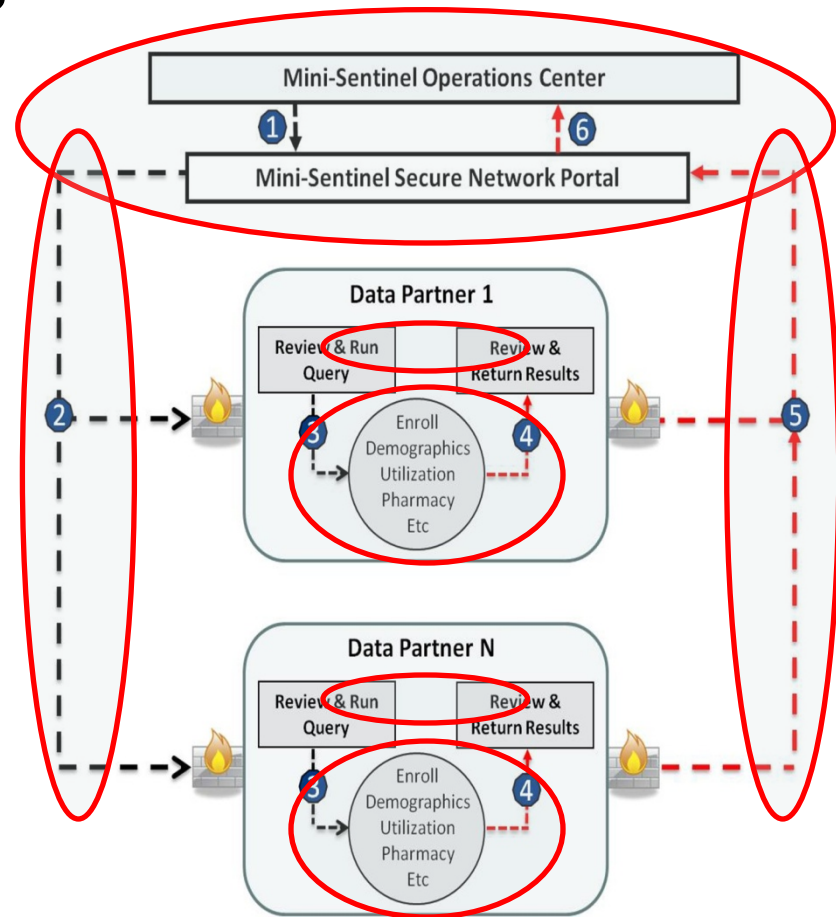
- ### Governance and Operations
  - ✓ Policies and contracting
  - ✓ Standard operating procedures
  - ✓ Legal and regulatory compliance
  - ✓ Internal and external engagement
  - ✓ Expectations for participation
  - ✓ Communications

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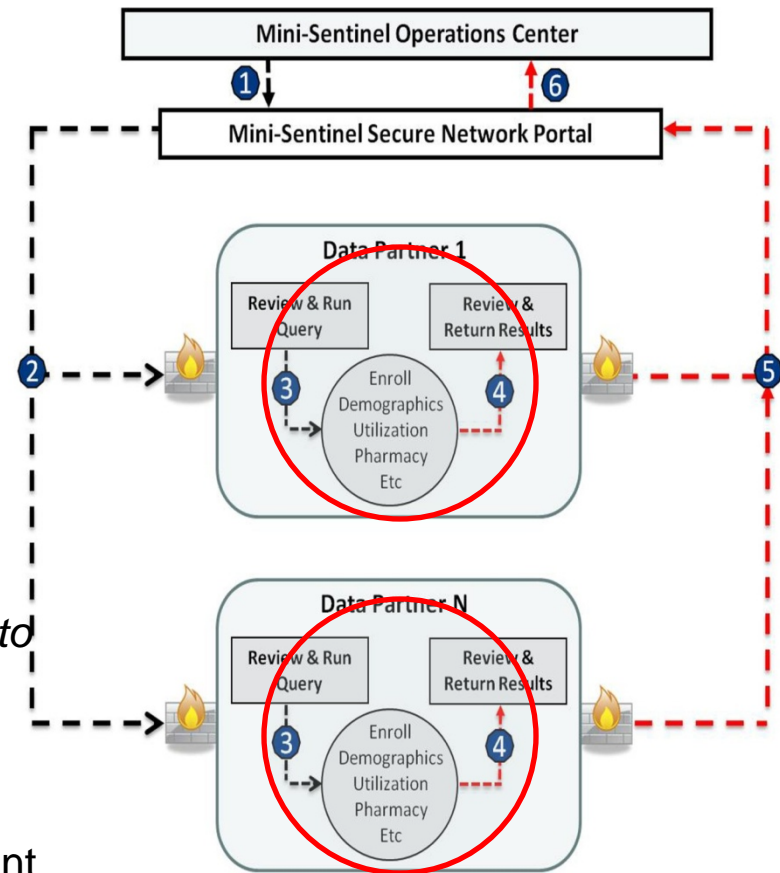- **Data Availability**
  - ✓ Data model and expansion
  - ✓ Data refreshes and integrity
  - ✓ *Immediate access to analysts and investigators to assist interpretation of findings*
- **Query Responsibilities**
  - ✓ Maintain infrastructure for rapid response
  - ✓ Rapid response based on service level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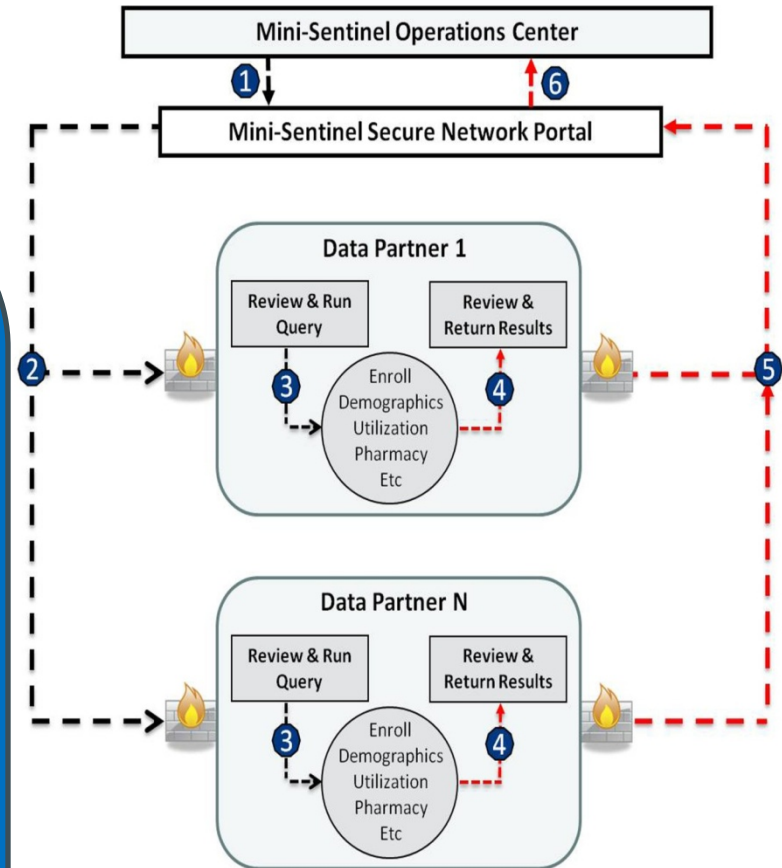 - ✓ Testing and review of querying tools
  - ✓ Query tool approval

Why it works for Mini-Sentinel

Coordinating Center Data Partners

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

Why it works for Mini-Sentinel
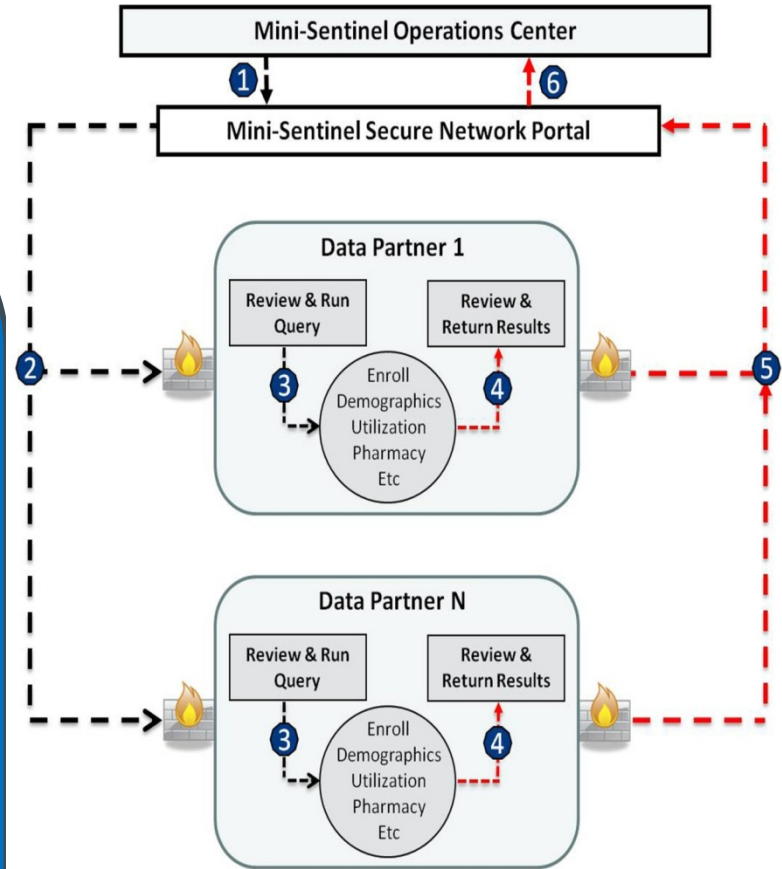
Coordinating Center Data Partners

Mini-Sentinel needs
- Responsiveness
- Data Partner Commitment

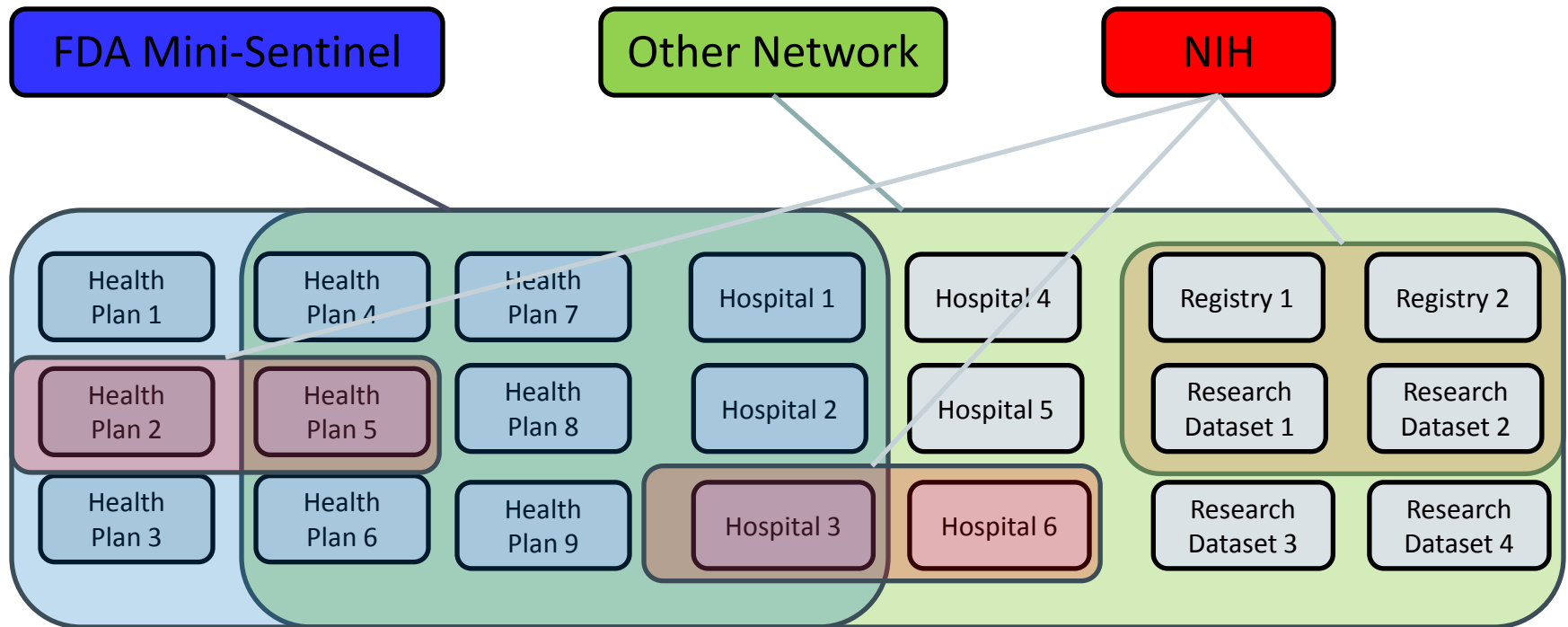**Tightly Coupled Network**

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

Multiple Networks Sharing Infrastructure

❑ **Partner Organizations** can choose to participate in multiple networks

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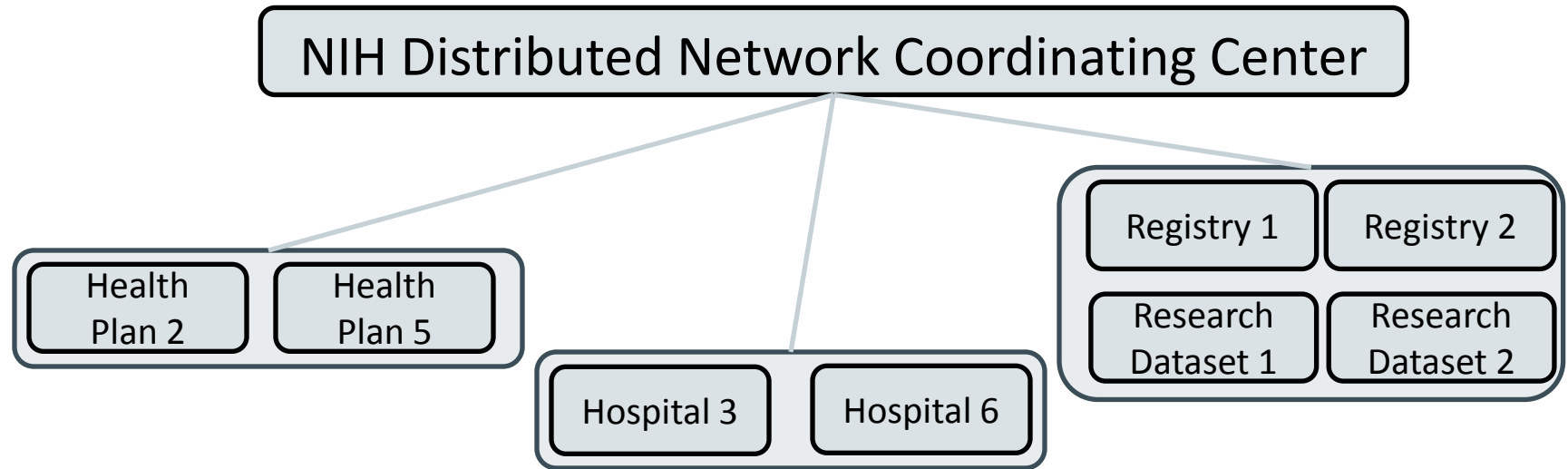
NIH Health Care Systems Collaboratory

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!