

# **Better Science, Better Health: New Healthcare Models**

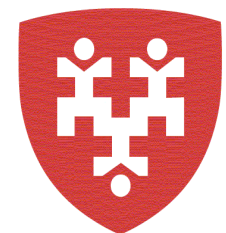
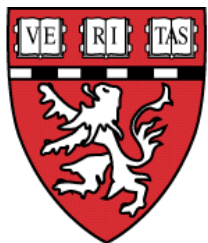
## ***Real World Evidence: Moving Beyond the Hype***

### **Sentinel Overview**

Jeffrey Brown, PhD

Washington D.C., October 28, 2015

Department of Population Medicine  
Harvard Pilgrim Health Care Institute/ Harvard Medical  
School



# Barriers to Using Real-World Data

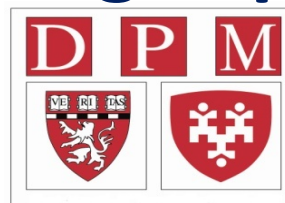
- Patient privacy and data security
- Regulations
  - Research versus public health surveillance
- Fragmented health care system
- Health system confidentiality and competition
- Competition among research groups
- Data quality, characteristics, interoperability
- Observation research methods
- Appropriate use
  - Match **methods** and **data** to the **question** and **purpose**

# Sentinel History

- 2007: FDA Amendments Act
  - A mandate to create an active surveillance system
  - Access data from **100 million** individuals by July 2012
- 2008: FDA launched the Sentinel Initiative
- 2009: Mini-Sentinel funded under Sentinel Initiative
  - 5-year pilot to create active surveillance system and develop policies, infrastructure, collaboration
- 2014: Funding awarded for Sentinel
- Today: Functional network with extensive capabilities
  - Analytic tools for rapid response to simple and complex (eg, matched and self-controlled designs) questions
  - Ability to review full-text medical records

# Scientific Partners Bring Expertise

Lead – HPHC Institute



Data and  
scientific  
partners



Scientific  
partners



# Impact / Dissemination

- 4 FDA drug safety communications
  - Tri-valent inactivated flu vaccine and febrile seizures (no increased risk)
  - Rotarix and intussusception (label change)
  - Dabigatran and bleeding (no increased risk)
  - Olmesartan and sprue-like enteropathy (label change)
- 70 peer-reviewed articles
- 48 methods reports / white papers
- Thousands of unique queries and comparisons contributing to over 140 formal assessments

[www.mini-sentinel.org](http://www.mini-sentinel.org)

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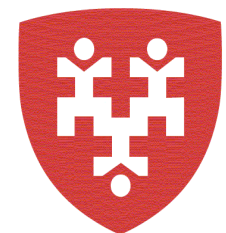
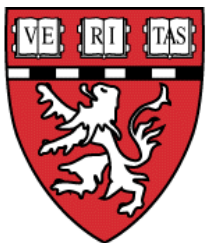
[Jeff\\_brown@hphc.org](mailto:Jeff_brown@hphc.org)

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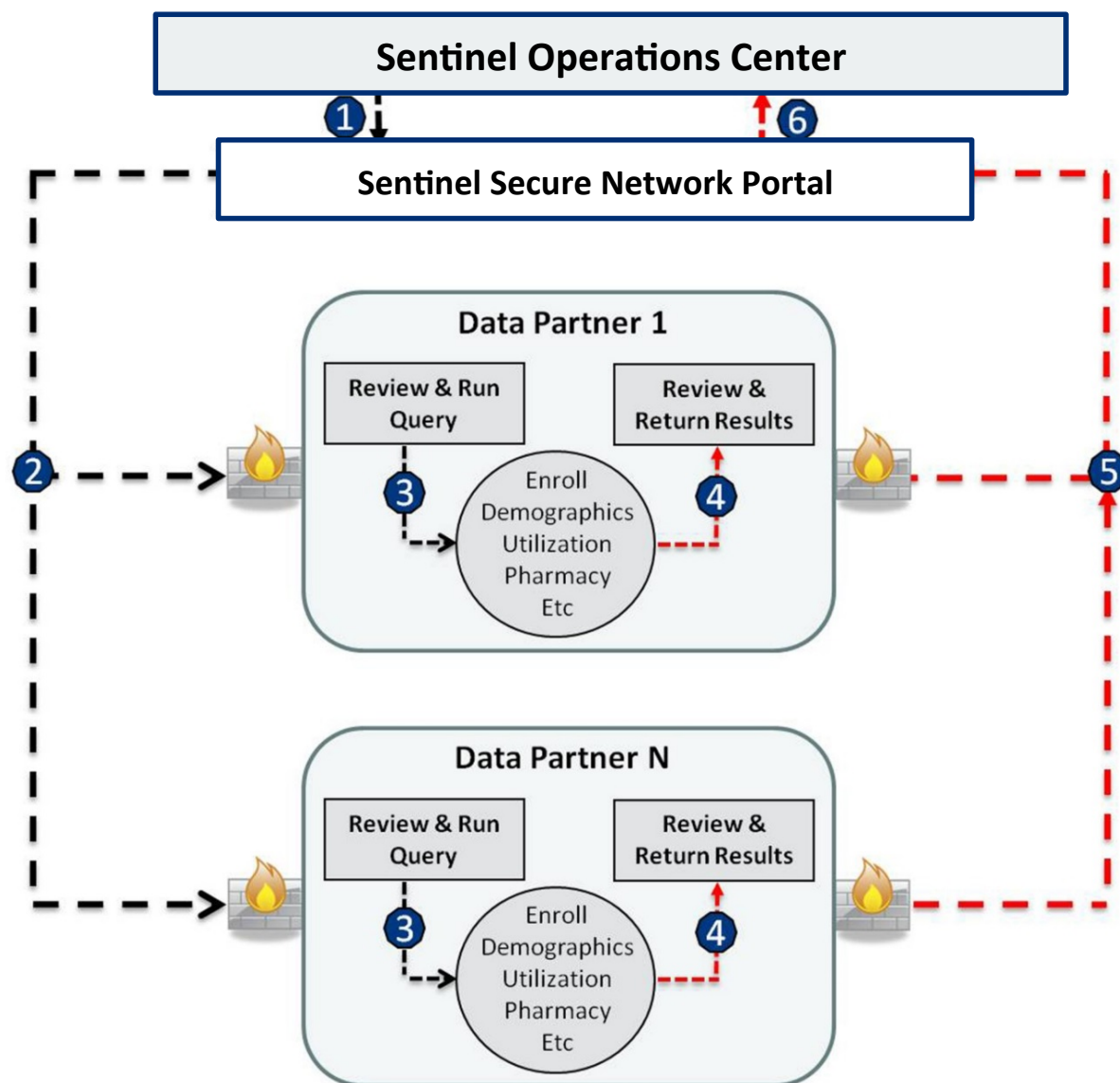
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# Distributed Data Networks



1- User creates and submits query for FDA (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 to SOC via secure network

6- Results aggregated and sent to FDA Team



# Common Data Model

## Administrative

Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure
<b>Person ID</b>	<b>Person ID</b>	<b>Person ID</b>	<b>Person ID</b>	<b>Person ID</b>	<b>Person ID</b>
Enrollment start & end dates	Birth date	Dispensing date	Service date(s)	Service date(s)	Service date(s)
Drug coverage	Sex	National drug code (NDC)	Encounter ID	Encounter ID	Encounter ID
Medical coverage	ZIP code	Days supply	Encounter type & provider	Encounter type & provider	Encounter type & provider
Medical record availability	Etc.	Amount dispensed	Facility	Diagnosis code & type	Procedure code & type
			Etc.	Principal discharge diagnosis	Etc.

## Clinical

Lab Result	Vital Signs
<b>Person ID</b>	<b>Person ID</b>
Result and specimen collection dates	Measurement date and time
Test type, immediacy & location	Height and weight
Logical Observation Identifiers Names and Codes (LOINC ®)	Diastolic & systolic BP
Test result & unit	Tobacco use & type
Etc.	Etc.

## Registry

Death	Cause of Death	State Vaccine
<b>Person ID</b>	<b>Person ID</b>	<b>Person ID</b>
Death date	Cause of death	Vaccination date
Source	Source	Admission Type
Confidence	Confidence	Vaccine code & type
Etc.	Etc.	Provider
		Etc.