Next Generation Surveillance: FDA's Sentinel Program

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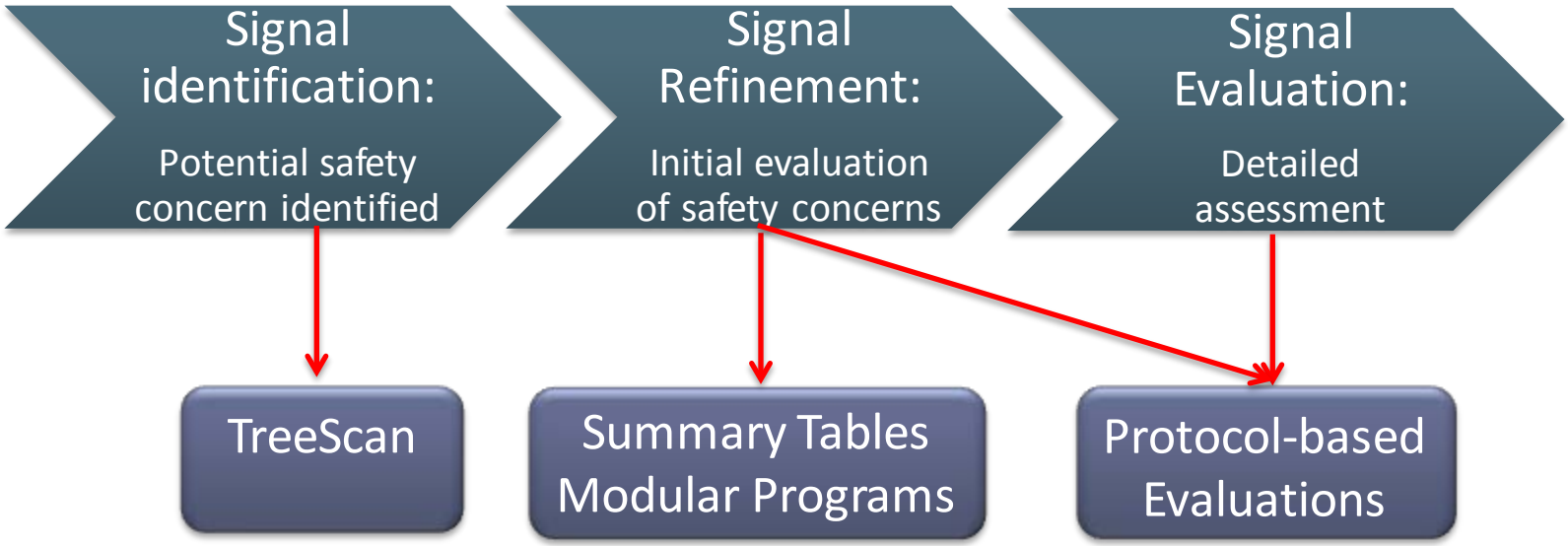
Impetus

- FDA Amendment Act of 2007 required FDA to create the capability to use electronic health data from at least 100 million people to assess the safety of marketed medical products

Post-Market Safety Surveillance



Mini-Sentinel Partner Organizations

Lead – HPHC Institute

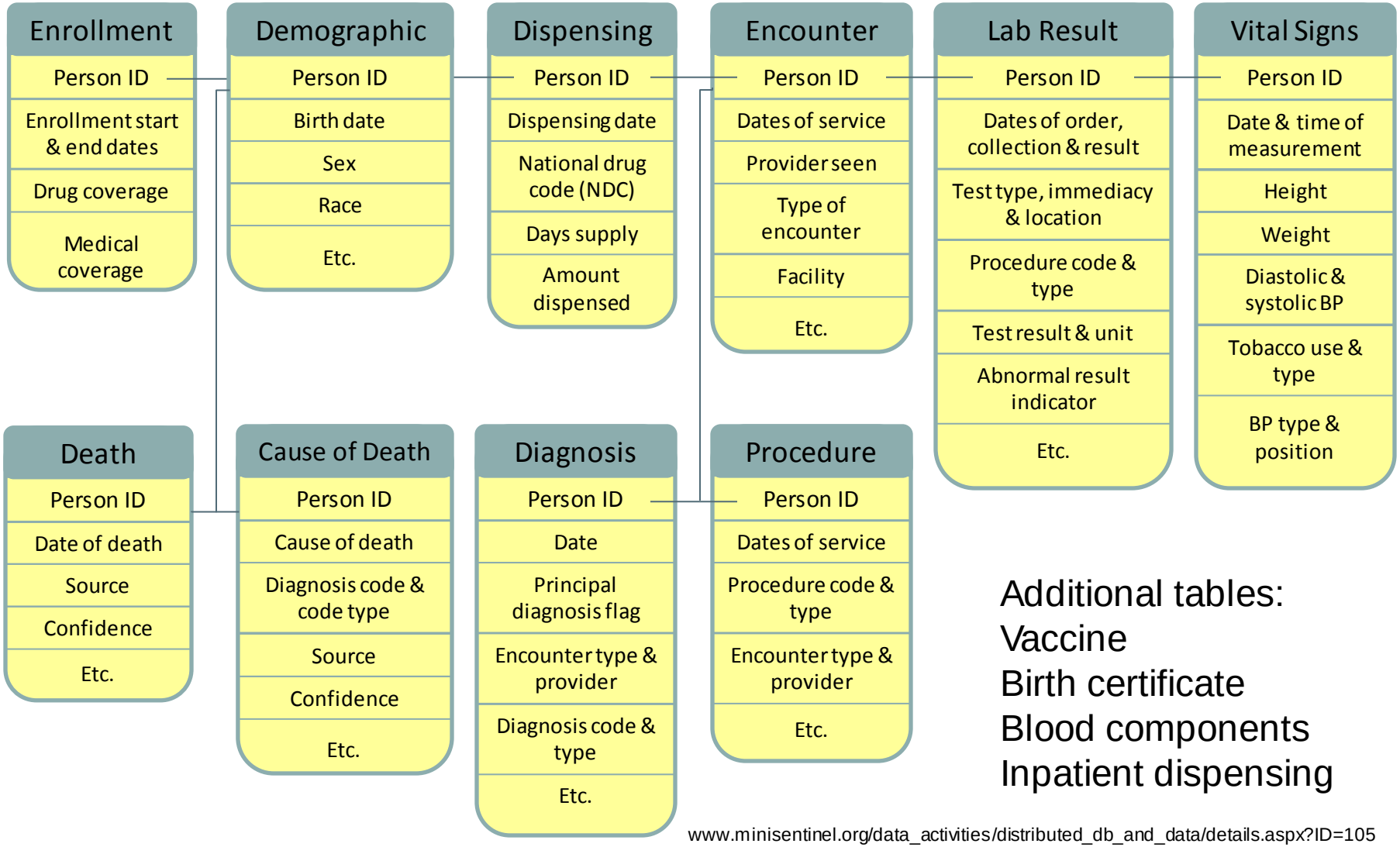
Data and scientific partners

Scientific partners

Mini-Sentinel's Data Sources

- Administrative data
  - Enrollment
  - Demographics
  - Outpatient pharmacy dispensing
  - Utilization (encounters, diagnoses, procedures)
- EHR and laboratory test result data for 10%
  - Height, weight, blood pressure, temperature
  - Laboratory test results (selected tests)
- Registries
  - Immunization
  - Birth certificates
- **Full text records** (small number to confirm selected exposures and outcomes – names, etc. redacted)

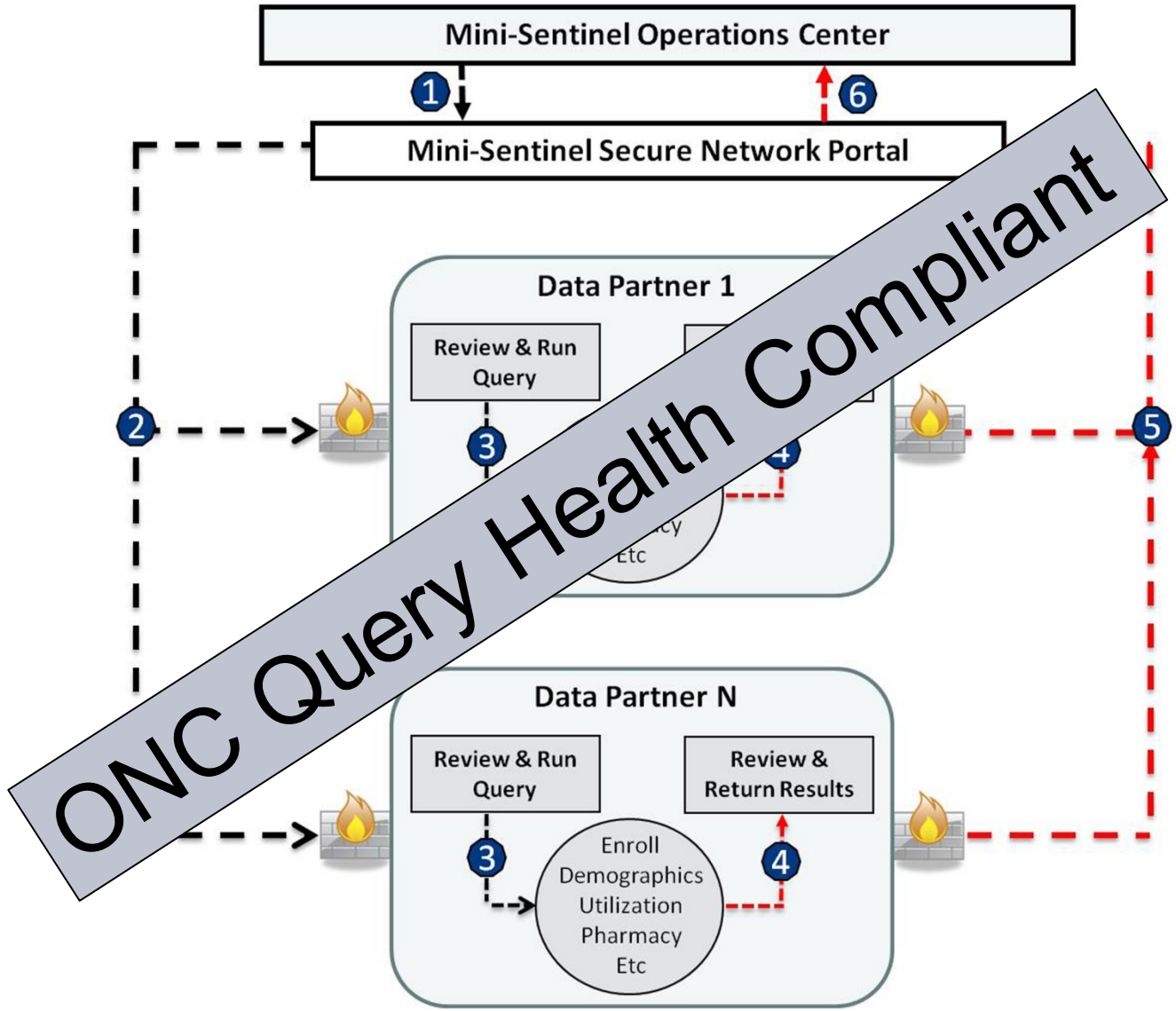
Mini-Sentinel's Common Data Model



Additional tables:
Vaccine
Birth certificate
Blood components
Inpatient dispensing

www.minisentinel.org/data_activities/distributed_db_and_data/details.aspx?ID=105

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

Sentinel Captures the Healthcare Experience of Many People

- Populations with well-defined person-time for which most medically-attended events are known
- 182 million members*, 2000-2015
  - 120 million* with medical and pharmacy benefits
  - 334 million person-years of observation time
- 40 million people currently accruing new data
- 4.4 billion dispensings
- 5.1 billion unique encounters
- 31 million people with >1 laboratory test result

*Counts distinct "PatID" values in the database, 2000-2015

Impact / Dissemination

- 4 FDA drug safety communications
  - Tri-valent inactivated flu vaccine and febrile seizures (no increased risk)
  - RotaTeq, Rotarix and intussusception (label change for RotaTeq, no label change for Rotarix)
  - Dabigatran and bleeding (no increased risk)
  - Olmesartan and sprue-like enteropathy (label change)
- 26 Presentations by FDA
- 48 Methods reports / white papers
- 70 Peer-reviewed articles
- 137 Assessments of products, conditions, product-outcome pairs

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intussusception Risk after Rotavirus Vaccination in U.S. Infants

W. Katherine Yih, Ph.D., M.P.H., Tracy A. Lieu, M.D., M.P.H., Martin Kulldorff, Ph.D., David Martin, M.D., M.P.H., Cheryl N. McMahill-Walraven, M.S.W., Ph.D., Richard Platt, M.D., Nandini Selvam, Ph.D., M.P.H., Mano Selvan, Ph.D., Grace M. Lee, M.D., M.P.H., and Michael Nguyen, M.D.

Yih, N Engl J Med. 2014;370:503

The NEW ENGLAND JOURNAL of MEDICINE

Mini-Sentinel and Regulatory Science — Big Data Rendered Fit and Functional

Bruce M. Psaty, M.D., Ph.D., and Alasdair M. Breckenridge, M.D.

In medicine, "big data" come in many forms. With the financial incentives provided by Medicare and Medicaid for the "meaningful

functions of billing and clinical care. If, as Nate Silver suggests in *The Signal and the Noise*, "Most of

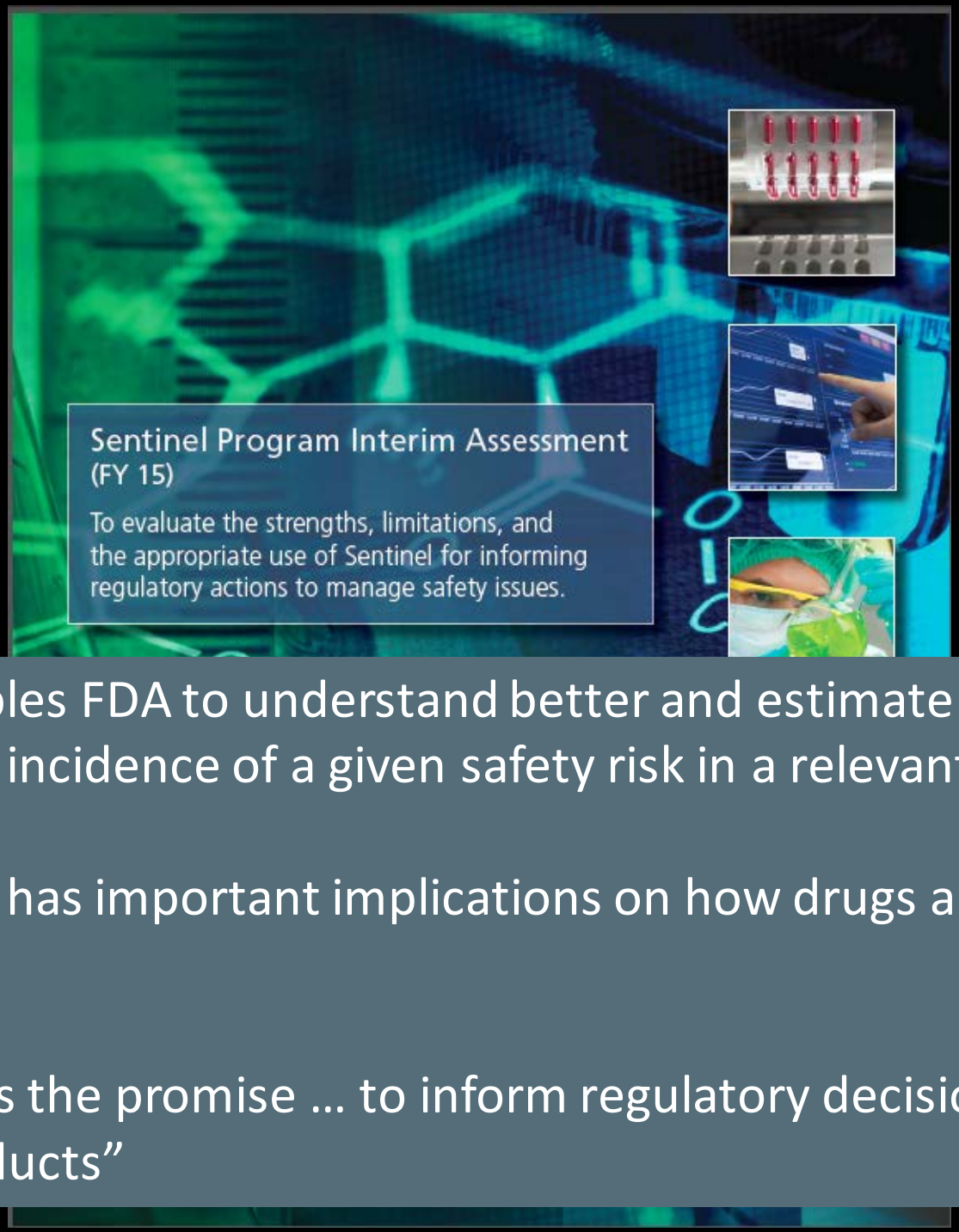
tional Heart, Lung, and Blood Institute have produced data sets with millions of genetic variants for each participant, encouraged the development of consortia with hundreds of thousands of study participants, and resulted in discoveries about the genetic origins

that can contribute meaningfully to the health of the public.

One model is the Mini-Sentinel. A pilot project of the Sentinel Initiative of the Food and Drug Administration (FDA), the Mini-Sentinel has created a nationwide system that uses electronic data

"The Mini-Sentinel ' provides an essential public health service. The current configuration — the data model, the methods development, and the investigative team — represents an impressive achievement..

Psaty. N Engl J Med 2014;370:2165



"Sentinel enables FDA to understand better and estimate more accurately the incidence of a given safety risk in a relevant population"

"Sentinel data has important implications on how drugs and biologics are used…"

"Sentinel holds the promise … to inform regulatory decisions regarding approved products"

New FDA medical product safety interests

- FDA's Active Risk Identification and Analysis (ARIA) program
- More blood / blood product evaluation

New Data Resources

- In progress
  - CMS data
  - Inpatient EHR data (Hospital Corporation of America)
- Active discussion
  - Dept of Defense and VA data
  - Linkage to PCORnet EHR data

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Advancing Regulatory Science for Public Health

The IMEDS program is offered by the Reagan-Udall Foundation for the FDA through the FDA Amendments Act of 2007. IMEDS serves to advance the science and tools necessary to support post-market 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 post-market settings.

Biologics & Biosimilars Collective Intelligence Consortium

Biosimilars represent an opportunity to bend the cost curve for specialty drugs. AMCP believes the public and health care community's adoption of biosimilars will be enhanced if we can assure them that biosimilars are being actively monitored for safety and effectiveness.

NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

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NIH Collaboratory › NIH Collaboratory Distributed Research Network

NIH Collaboratory Distributed Research Network

Millions of people. Strong collaborations. Privacy first.

The NIH Collaboratory Distributed Research Network enables investigators to collaborate with each other in the use of electronic health data, wh multisite research programs.

The Network's querying capabilities reduce the need to share confidential or proprietary data by enabling authorized researchers to send queries partners). In some cases, queries can take the form of computer programs that a data partner can execute on a preexisting dataset. The data pa aggregated (count) data, rather than the data itself. This form of remote querying reduces legal, regulatory, privacy, proprietary, and technical ba research.

The network seeks to build strong and trusted collaborations to support the research that will lead to improved health for millions of people around the world.

To learn Distribu

support

What does the NIH Collaboratory Distributed Research Network do?

- Provides infrastructure and mechanisms to facilitate multicenter studies using electronic clinical, administrative, and research data
- Allows searchable discovery of available data resources, health systems, researchers, and re-usable analytic tools
- Enables authorized investigators to identify clinical, administrative, and research datasets of interest
- Facilitates multisite distributed querying of data resources, while allowing the data to remain in the control of the data owners
- Serves as a repository of tools to leverage EHRs to support clinical research across multiple health systems

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Thank you