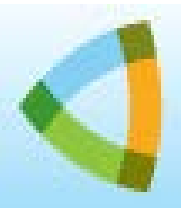


# Perspectives from the NIH Healthcare Systems Research Collaboratory

**FDA/UMD CERSI Workshop - March 24, 2016**  
**Developing a National Resource for Evidence Generation**

**Wendy Weber, ND, PhD, MPH**  
**NIH/NCCIH**  
**Chief, Division of Extramural Clinical Research Branch**





# NIH Health Care Systems Research Collaboratory Common Fund Program

- **Goal:** To strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners.
- **Aim:** To provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research. Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to health practice.



# ■ NIH Collaboratory Distributed Research Network

**Millions of people. Strong collaborations. Privacy first.**

The NIH Collaboratory Distributed Research Network (DRN) enables investigators to collaborate with each other in the use of electronic health data, while also safeguarding protected health information and proprietary data. It supports both single- and multisite research programs.

The Network's querying capabilities reduce the need to share confidential or proprietary data by enabling authorized researchers to send queries to collaborators holding data (i.e., data partners). In some cases, queries can take the form of computer programs that a data partner can execute on a pre-existing dataset. The data partner can return the query result, typically aggregated (count) data, rather than the data itself. This form of remote querying reduces legal, regulatory, privacy, proprietary, and technical barriers associated with data sharing for 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.

## On this page

[What does the NIH Collaboratory Distributed Research Network do?](#)

[How does the network operate?](#)

[Who can submit a query/data request?](#)

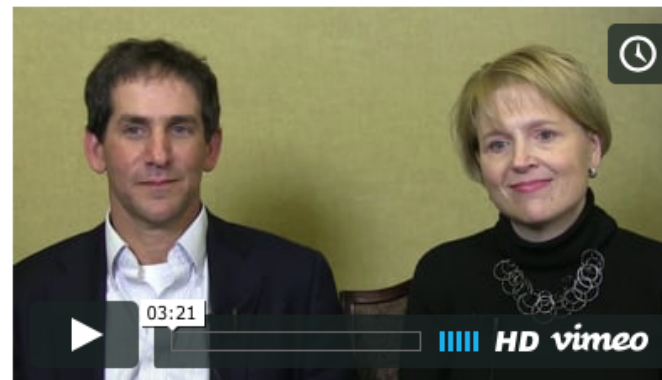
[How do I submit a query/data request?](#)

[What datasets are available in the NIH Collaboratory Distributed Research Network?](#)

[How can my organization/network become a data partner?](#)

[What software platform does the network use?](#)

[What are the confidentiality and nondisclosure rules for data partners and DRN Coordinating Center staff?](#)



**Drs. Jeff Brown and Lesley Curtis explain the NIH Collaboratory Distributed Research Network.**

## Documents

[NIH Collaboratory Distributed Research Network User's Guide](#)

[NIH Collaboratory DRN Request Form](#)

[DRN Governance](#)

## Recent Presentations

6/5/2015: Grand Rounds Presentation: NIH Collaboratory Distributed Research Network ([Video](#); [Slides](#))

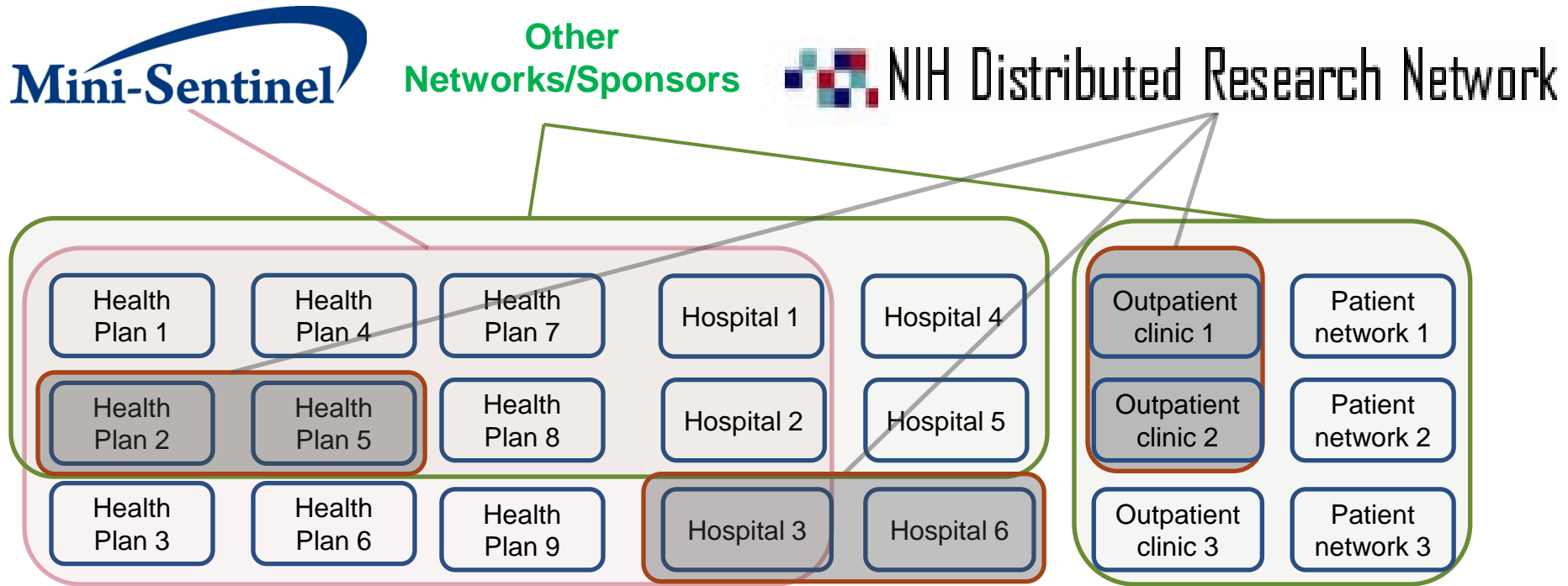
11/14/2014: Grand Rounds Presentation: Using the NIH

# Collaboratory DRN Data Partners

- **Aetna**
- **Group Health Research Institutes**
- **Harvard Pilgrim Health Care Institute**
- **HealthCore, Inc.**
- **HealthPartners Institute for Education and Research**
- **Humana: Comprehensive Health Insights, Inc.**
- **Meyers Primary Care Institute**
- **The MURDOCK Study**
- **OptumInsight, Inc.**
- **Ochsner Health Systems**



# Sharing of Infrastructure



- Each organization can participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development

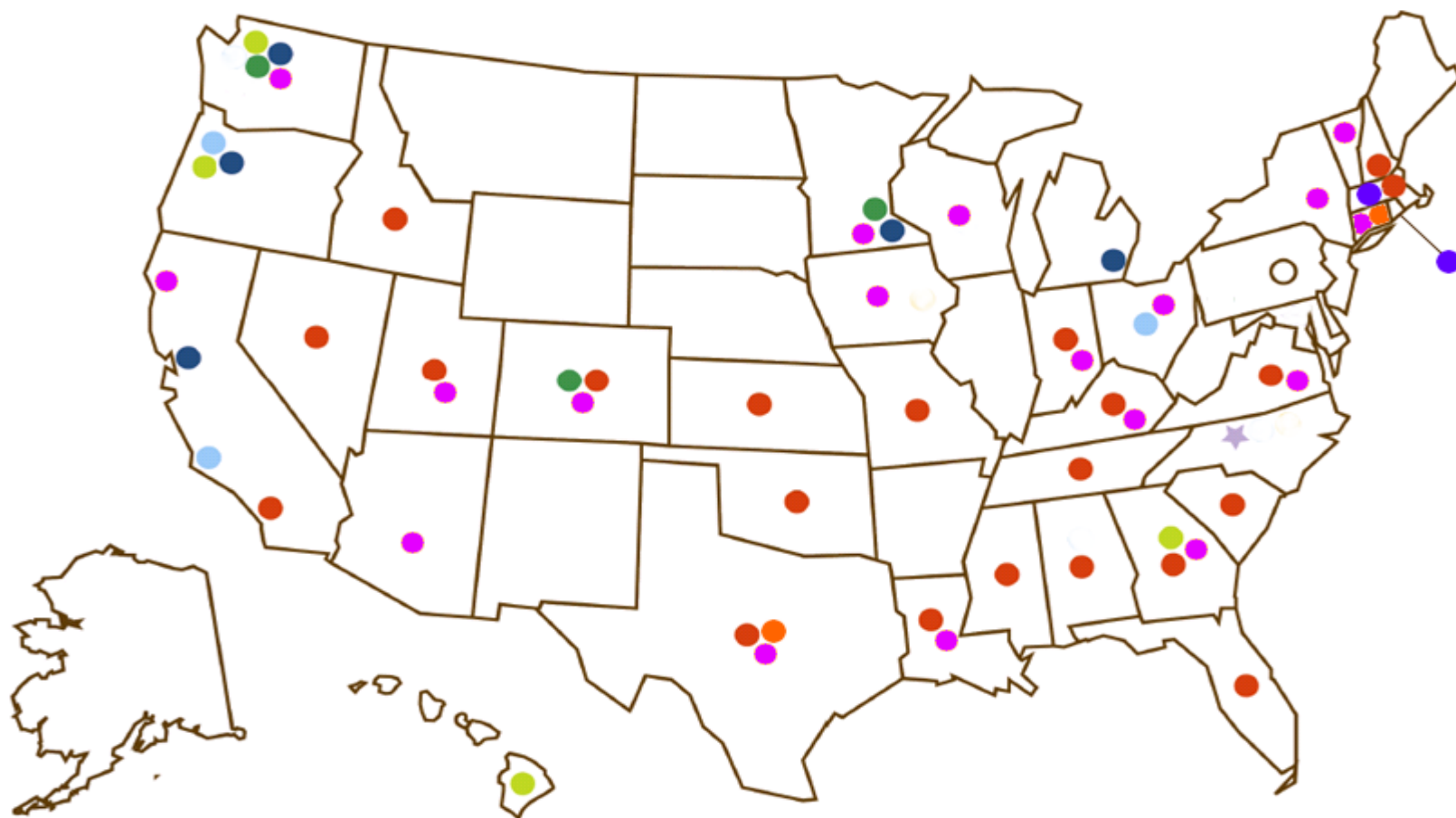


# **NIH Collaboratory Coordinating Center (CCC)**

- **Provide national leadership and technical expertise in all aspects of research with health care systems**
- **Support the design and rapid execution of a set of high impact Pragmatic Trial Demonstration Projects conducted in partnerships with health care systems**
- **Make available data, tools and resources from these, and other, projects to facilitate a broadened base of research partnerships with health care systems**



# NIH Health Care Systems Research Collaboratory



- ★ Collaboratory Coordinating Center
- Suicide Prevention Outreach Trial (SPOT)
- Time to Reduce Mortality in End-Stage Renal Disease (TIME) (sites in dialysis units across the US)
- Trauma Survivors Outcomes & Support (TSOS)
- Lumbar Image Reporting and Epidemiology
- Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)
- Collaborative Care for Chronic Pain in Primary Care (PPACT)
- Active Bathing to Eliminate Infections (ABATE)
- Improving Chronic Disease Management with Pieces (ICD-Pieces)
- Pragmatic Trial of Video Education in Nursing Homes (PROVEN) (sites in nursing homes across the US)



# NIH Collaboratory Demonstration Project HCS

- **Group Health Cooperative**
- **Kaiser Permanente**
- **Mayo Clinic**
- **Henry Ford Health System**
- **HealthPartners Institute**
- **Parkland Health System**
- **Texas Health Resources**
- **ProHealth CT**
- **Fresenius and DaVita Dialysis Corporations**
- **Hospital Corporation of America**
- **US Level 1 Trauma Care Centers**
- **Genesis Healthcare**
- **UHS Pruitt Corporation**
- **Oregon Community Health Information Network (FQHCs)**
- **North Texas VA**





# NIH Collaboratory

## Demonstration Project Interventions

- Organizational change to patient care (e.g. dialysis time or new bathing protocol)
- Enhancing information available to providers in EHR to change care delivery
- Direct to patient screening kits, video education, or online intervention
- Enhanced coordination of care delivered to complex patients



# Pragmatic Trial Demonstration Projects

- **Time to Reduce Mortality in End-Stage Renal Disease Trial - NIDDK**
- Laura Dember, University of Pennsylvania
  - Fresenius Medical Care North America
  - DaVita
- CRT – 402 HD units, ~6,400 patients



# Pragmatic Trial Demonstration Projects

- **A Pragmatic Trial of Lumbar Image Reporting with Epidemiology – NIAMS & NCCIH**
- **Jeffrey Jarvik, University of Washington**
  - Kaiser Permanente of Northern California
  - Group Health Cooperative, Seattle, WA
  - Mayo Clinic, Rochester, MN
  - Henry Ford Health System, Detroit, MI
- **CRT (stepped wedge design) – 100 sites, practitioners, ~270,000 patients**
- **Began April 2014 (currently with 98 sites/150,000 patients)**



# Pragmatic Trial Demonstration Projects

- **Strategies and Opportunities to Stop Colon Cancer in Priority Populations - NCI**
- Gloria Coronado, Kaiser Foundation Hospitals
- Oregon Community Health Information Network (OCHIN)
  - Federally Qualified Health Center Clinics in OR & CA
- CRT – 26 clinics, ~32,000 patients



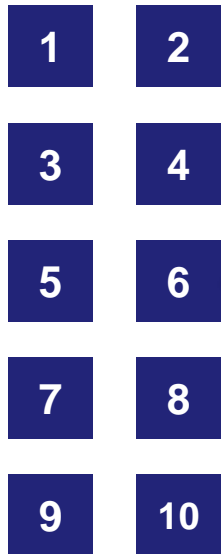
# **NIH Collaboratory Coordinating Center (CCC)**

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# Collaboratory Overview of Activities

## Demonstration Projects



## Other

PCORnet

Other

Steering Committee Meetings

Teleconferences

Issue Tracker

## Cores/Working Groups

Electronic Health Records

Stakeholder Engagement

Health Care Systems Interactions

Phenotypes, Data Standards, and Data Quality

Regulatory/Ethics

Biostatistics and Study Design

Patient-Reported Outcomes

## Lessons

Knowledge Repository & Living Textbook

Grand Rounds & Presentations

Guidance Documents & Manuscripts



The screenshot shows the NIH Collaboratory website homepage. The browser address bar displays the URL <https://www.nihcollaboratory.org/Pages/>. The website header features the NIH Collaboratory logo with the tagline "Rethinking Clinical Trials®" and the subtitle "Health Care Systems Research Collaboratory". A search bar is located on the right side of the header. Below the header, a navigation menu includes links for "NIH Collaboratory", "About Us", "Demonstration Projects", "Cores", "News", "Collaboration Spaces", and "The Living Textbook". A secondary navigation bar includes "Grand Rounds" and "Home".

The main content area is divided into several sections:

- Upcoming Events:** Announces the "July 10: Grand Rounds Special Series: Central IRBs - Cynthia Hahn" and describes the "The Clinical Trials Transformation Initiative's Recommendations: Advancing the Use of Central IRBs for Multicenter Clinical Trials".
- View Calendar:** A link to view the calendar.
- Subscribe to our mailing list:** Provides the email address [nih-collaboratory@dm.duke.edu](mailto:nih-collaboratory@dm.duke.edu).
- News & Announcements:** Features a PCORnet announcement about the ADAPTABLE Aspirin Study Protocol for Public Review and Comment, dated July 1, 2015.
- Stakeholder Interviews:** Two interviews are featured: one with Adrian Hernandez, Kevin Weinfurt, and Lesley Curtis discussing the future of the NIH Collaboratory (June 18, 2015), and another with Gloria Coronado, PhD, and Beverly Green, MD, MPH, discussing lessons learned in the STOP CRC UH3 Demonstration Project (June 17, 2015).
- Transformative:** A large banner with the text "Transforming the way clinical trials are conducted." and a "Learn more >" link, accompanied by an image of researchers in a lab.
- Knowledge Repository:** A section for viewing Collaboratory products, resources, and publication references.
- Distributed Research Network:** A section describing the NIH Collaboratory Distributed Research Network, which enables investigators to collaborate with each other in the use of electronic health data, while also safeguarding protected health information and proprietary data.
- Featured Topics:** A list of articles, presentations, and other products related to specific topics of interest, including presentations from the April 2015 Steering Committee Face-to-Face Meeting, a regulatory update related to SUPPORT Trial, demonstration projects - regulatory and ethics discussions, and the NIH Collaboratory Communication Channels Chart (Updated 5/14/2015).
- Grand Rounds Portal Page:** A link to the Grand Rounds Portal Page.
- Recent Presentations:** A list of recent presentations, including one by Pamela Duncan, Cheryl Bushnell, and Wayne Rosamond titled "A Pragmatic Trial for Comprehensive Stroke Services Funded by PCORI" (06/26/15), and another by Andrea J. Cook and Liz DeLong titled "Improving Pragmatic Clinical Trials: Lessons Learned from the NIH Collaboratory Biostatistics Core" (06/19/15).

Browser address bar: <https://www.nihcollaboratory.org/Pages/Knowledge-Repository.aspx>

Browser tabs: NIH QVR- Hlist, Pages - Knowledge-Rep..., Rethinking Clinical Trials..., How to Take Screenshots i...

Browser menu: File, Edit, View, Favorites, Tools, Help

Browser toolbar: Home - OCRA, Suggested Sites, Grants Considered for Fun..., Web Slice Gallery

Browser status bar: Convert, Select

Page header: Distributed Research Network


Page title: NIH Collaboratory > Knowledge-Repository

Home

# Welcome to the Knowledge Repository


A collection of Collaboratory documents and resources.

### Stakeholder Interviews




Interviews with NIH Collaboratory leaders, researchers, and other stakeholders.

### Collaboratory Products




NIH Collaboratory articles, whitepapers, tools for research, guidance, policy documents, and more.

### Grand Rounds Archives




Collected videos and slide presentations from weekly joint Collaboratory/PCORnet Grand Rounds educational sessions.

### External Resources



Journal articles, presentations, news articles, and more from beyond the NIH Collaboratory, with a focus on pragmatic clinical research.

### Living Textbook

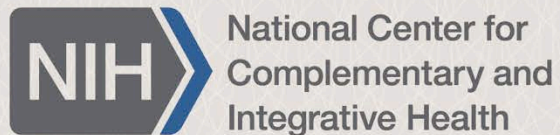


Information and tools for understanding, designing, conducting, analyzing, and disseminating pragmatic clinical research.

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