U.S. Department of Health & Human Services • National Institutes of Health

National Center for Complementary and Integrative Health

# Lessons Learned from Virtual Clinical Trials: NIH Health Care Systems Research Collaboratory

Wendy Weber, ND, PhD, MPH

November 28, 2018

# NIH Health Care System Research Collaboratory

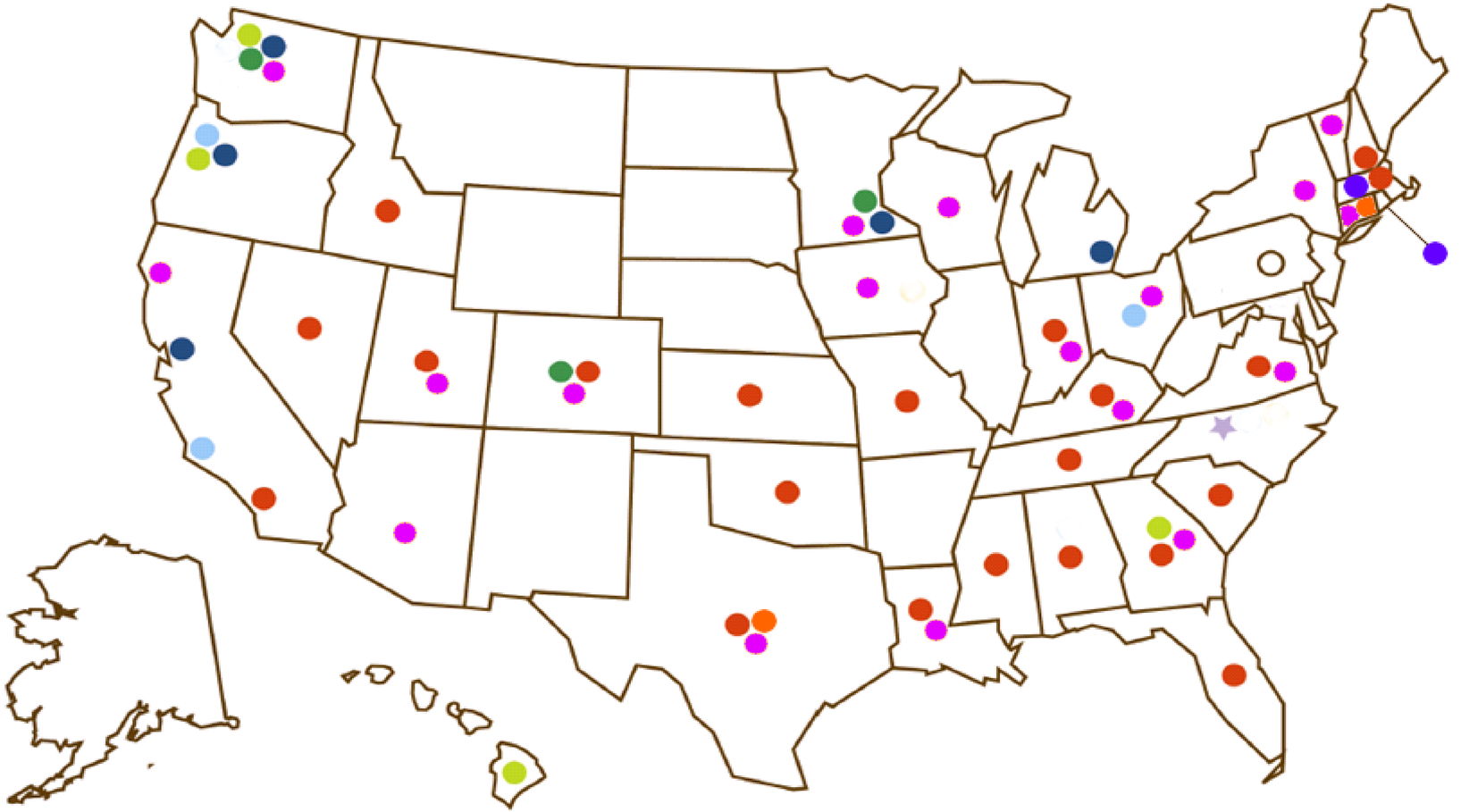
- **Mission:** Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners.
  - Leverage electronic health record data for clinical research

# “Embedded Pragmatic Clinical Trials”

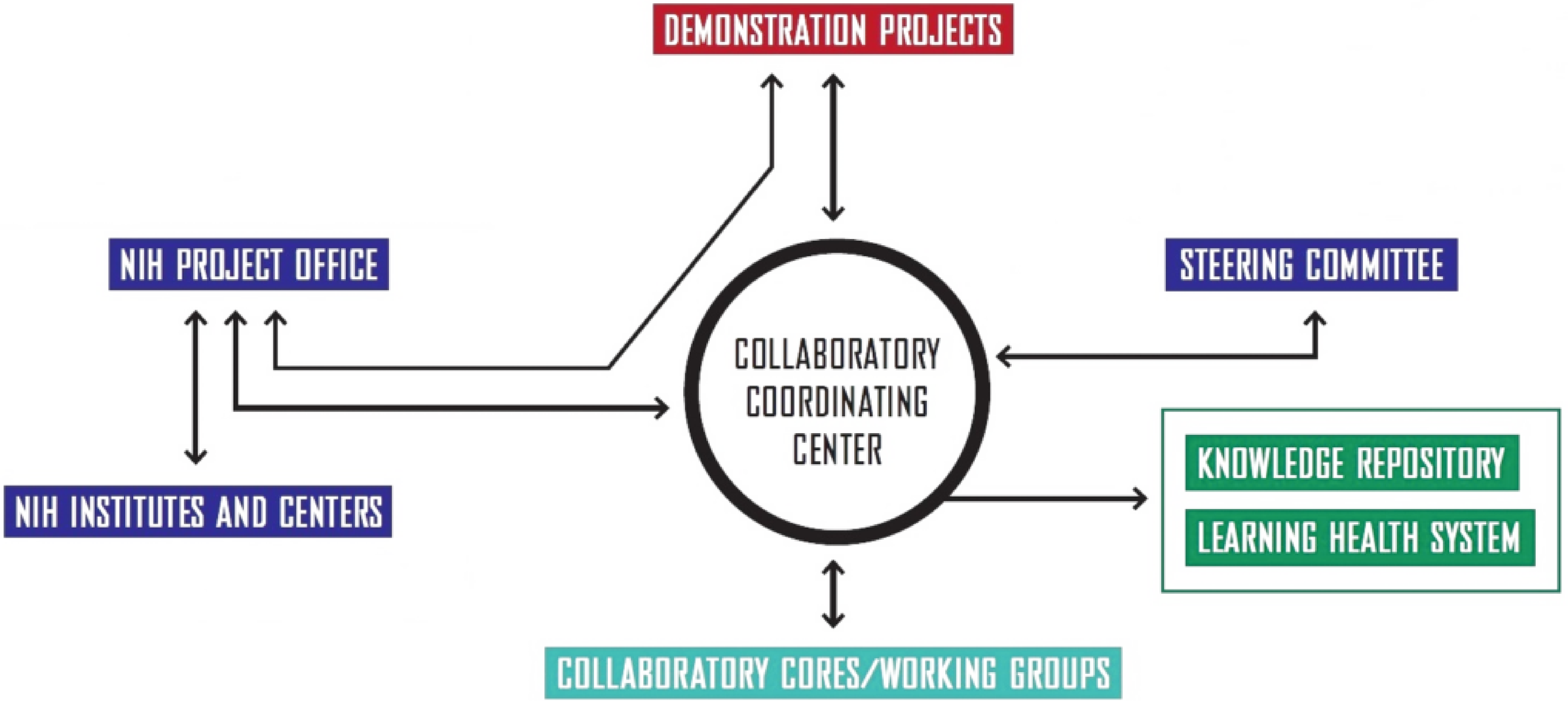

# Overview

- Background NIH HCS Collaboratory
- Leveraging the EHR
- Lessons learned – expected and unexpected

# 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)


DEMONSTRATION PROJECTS
NIH PROJECT OFFICE
STEERING COMMITTEE
COLLABORATORY COORDINATING CENTER
NIH INSTITUTES AND CENTERS
KNOWLEDGE REPOSITORY
LEARNING HEALTH SYSTEM
COLLABORATORY CORES/WORKING GROUPS

# Rethinkingclinicaltrials.org

NIH Collaboratory Rethi

rethinkingclinicaltrials.org

NIH COLLABORATORY
# LIVING TEXTBOOK
*of Pragmatic Clinical Trials*

HOME WELCOME GRAND ROUNDS NEWS

- How to Use This Site
- About NIH Collaboratory
- Demonstration Projects
- Core Working Groups
- Distributed Research Network
- Calendar

CONDUCT

DISSEMINATION

## s: A Living Textbook of

gmatic clinical trials, a collection of
ystems Research Collaboratory. Pragmatic
ld clinical settings with highly generalizable
ical evidence at a fraction of the typical cost
al clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than are typically encountered with traditional clinical trials. The Living Textbook reflects a collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of pragmatic clinical trials. Given the rapid pace of change in this field, this electronic textbook will continue to be added to and updated.

GET STARTED

What is a
**PRAGMATIC CLINICAL TRIAL?**

**ENGAGING STAKEHOLDERS**
and building partnerships to ensure a successful trial

What is the
**NIH COLLABORATORY?**

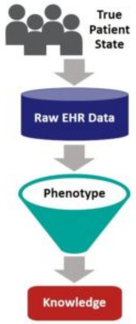
**TRAINING RESOURCES**

# Electronic Health Records

**Co-Chairs:** Rachel Richesson, Greg Simon
**NIH Representatives:** Jerry Sheehan, Barbara Wells
**Members:** Nick Anderson, Alan Bauck, Arne Beck, Denise Cifelli, Lesley Curtis, Pedro Gozalo, Beverly Green, Ed Hammond, Susan Huang, Lauren Heim, Michael Kahn, Andrea Kline-Simon, Josh Lakin, Reesa Laws, Julie Lima, Charles Lu, Rosemary Madigan, David Magid, Devin Mann, Meghan Mayhew, Vincent Mor, Brett Moran, George "Holt" Oliver, Jon Puro, Jerry Sheehan, Kari Stephens, Stacy Sterling, Erik Van Eaton, Ferdinand Velasco, Angelo Volandes, Wolfgang Winkelmayer
**Project Manager:** Jesse Hickerson

Products and Publications | Presentations

The ability to harness electronic health data is transforming the way clinical research is conducted. The Electronic Health Records (EHR) Core's goal is to facilitate multisite research collaborations between investigators and data stewards. Core members have expertise in data models, data standards and quality, algorithms, and approaches to define clinical phenotypes, extract information, define endpoints, and discover errors in data from healthcare systems.




The secondary use of electronic health record (EHR) data for clinical research requires not only an understanding of data representation, exchange standards, and the influence of workflows, but also the development and implementation of valid approaches for identifying cohorts with clinical conditions. This involves collaboration among clinicians, EHR experts, and informaticians to develop algorithms, or computable phenotypes, for identifying patients with clinical conditions being studied by researchers.

There are many ways to identify patients who have been diagnosed with a specific condition, and understanding the pros and cons of the various approaches is essential for using EHRs effectively in pragmatic clinical trials. Also, comprehensive data characterization and data quality assessment enable investigators to match a research question with data of appropriate quality in order to conduct the research. The EHR Core supports these efforts across the Collaboratory and makes tools available to the wider research community.

## Areas of Focus

***Develop and test phenotype algorithms for use within and across projects***

- Demonstration Projects
- Existing literature
- Mini-Sentinel

***Use standards organizations to move these measures into practice***

- Contribute to a learning healthcare system
- Develop a suite of standards

## Presentation


Rachel Richesson, PhD, Duke University School of Nursing, describes recent updates from the Collaboratory's EHR Core (formerly the Phenotypes, Data Standards, and Data Quality Core).

## Special Topics

- Learning healthcare systems
- ICD-9 to ICD-10 Mapping
- Phenotype Case Study: LIRE Trial
- Phenotype Case Study: MURDOCK Trial

## Interviews

- 10/11/2017: Reflections on the First 5 Years of the Phenotypes, Data Standards, and Data Quality Core

## Supplementary Material

- 7/19/2018: ADAPTABLE Supplement Patient-Reported Health Data Standards-2018-07-19 (PDF)

# Leveraging the EHR

- Great resource of information that is collected as part of routine care
  - No Cost!
- What data is consistently collected
  - Billed services – procedures, hospital stays, medical visits, laboratory measures, medication fills (some)
- *Are these outcomes useful for your study?*

# Challenges Faced when using EHR

- Missing data – field may exist, but may be empty
- Services received outside of the system
  - Free clinics, discounted medications, urgent care
- Most patient reported outcomes are not routinely collected (depression, pain, sleep, fatigue, etc)
- Adverse event reporting is scarce
- Follow up is not routine or on a schedule

# Potential Solutions to Challenges

- Augment data collection with email link to web, IVR phone calls, mobile app, live person calls
  - Patient reported outcomes and adverse events
- Use creative analytic methods – trends over time and not exact time point analysis
- During planning period
  - Assess data sample for completeness
  - Identify other sources of care in the community

# *EXPECT THE UNEXPECTED*

# Lessons Learned

- Expected
  - Missing data
  - Staff turnover
  - Decreased fidelity to intervention
  - Evolving HCS
  - ICD9 to ICD10
- Unexpected
  - Frequency of staff turnover
  - New EHR launched
  - Systemic changes in HCS – stepped wedge
  - **Time to get the data out of the EHR and clean it!**

# Embedded Pragmatic Clinical Trials

- Primary intent is to answer the question
  - "Does "it" work in this setting?"
  - Not evaluating how does it work, or what mediates effect
- Cost can be much less
  - Collaboratory trials $4.5 million direct over 5 years with 200-200,000 patients in each trial

# When are Embedded PCTs good design choice?

- Outcome of interest is captured in the EHR
- Have a HCS partner interested in study outcome
- Familiar intervention
  - New indication for approved drug/biologic/device
- Few competing interventions or trials in the HCS
- Don’t need data collected at study visits

National Center for Complementary and Integrative Health

## Contact

1-888-644-6226
info@nccih.nih.gov

nccih.nih.gov

## Connect

nccih.nih.gov/connect