



Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Essentials of Embedded Pragmatic Clinical Trials

AcademyHealth 2019 Annual Research Meeting
Pre-Conference Seminar
Washington, D.C.
June 1, 2019

Embedded Pragmatic Clinical Trials (ePCTs) Seminar

- Lessons learned from the NIH Health Care Systems Research Collaboratory – the “NIH Collaboratory”
- Seminar overview
 - Topics
 - Speakers

The NIH Health Care Systems Research Collaboratory Coordinating Center is supported by the **NIH Common Fund**, through a cooperative agreement from the Office of Strategic Coordination within the Office of the NIH Director (Grant #U24AT009676-01)

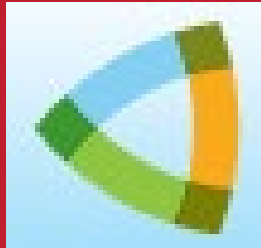
The NIH Collaboratory story



Initiated by the NIH Common Fund in 2012

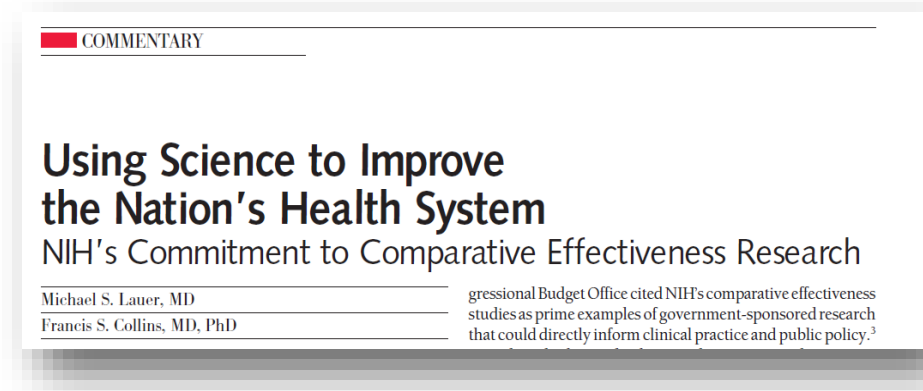


Goal: To strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners



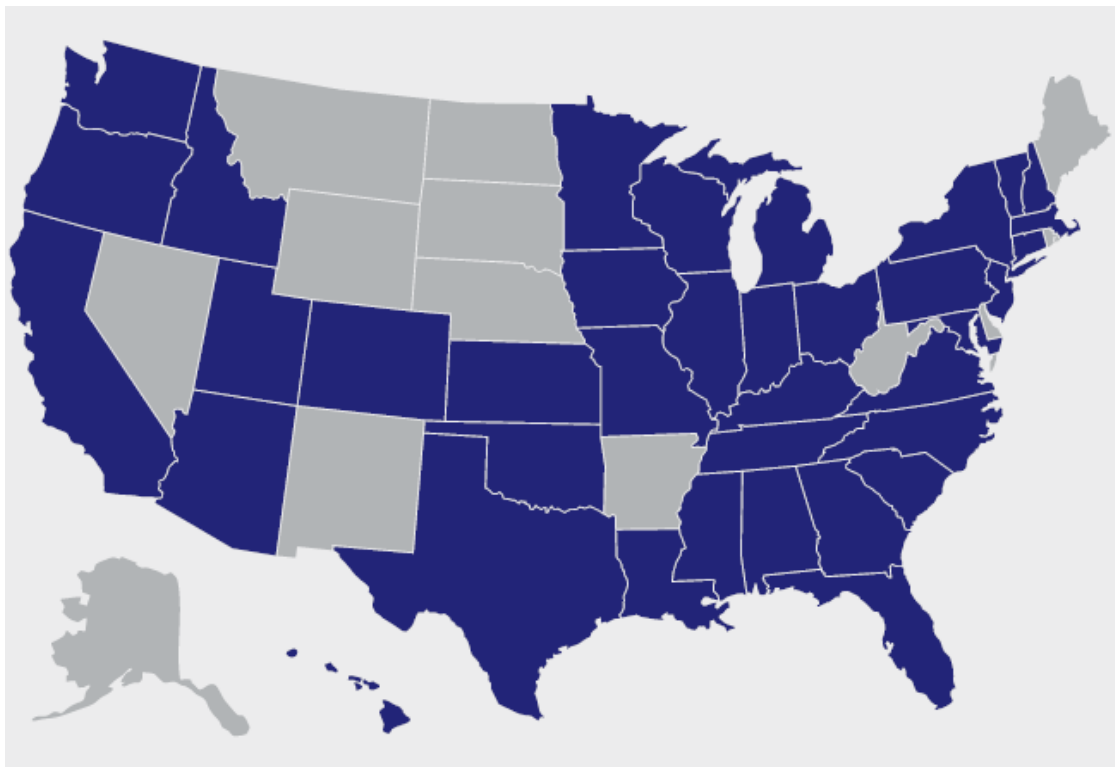
Aim: To provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research

Contemporary challenges for clinical research



- New approaches and strategies for the clinical trials enterprise
 - Stakeholder interactions and leveraging multidisciplinary expertise
 - Methods for preserving randomized trial design and optimizing use of available data
 - Dissemination and implementation

NIH Collaboratory ePCTs



- 15 embedded Demonstration Projects
- Diverse clinical settings, across 12 NIH Institutes
- >850 clinical sites, >80% of the US, >800,000 participants



Morning sessions

What are ePCTs?

Catherine Meyers

Engaging Stakeholders

Leah Tuzzio

Measuring Outcomes

Emily O'Brien

ePCT Design

David Murray

ePCT Analysis

David Murray

ePCTs in Context

PI Panel

Afternoon sessions

Pilot & Feasibility Testing

Wendy Weber

Ethics & Regulatory Oversight

Kevin Weinfurt
Julie Kaneshiro

Dissemination & Implementation

Wynne Norton

ePCTs in Context

PI Panel

Assembling an ePCT Team &
Writing a Grant Application

Robin Boineau
Marcel Salive