

NIH Pragmatic Trials Collaboratory Virtual Onboarding Meeting

October 28, 2025



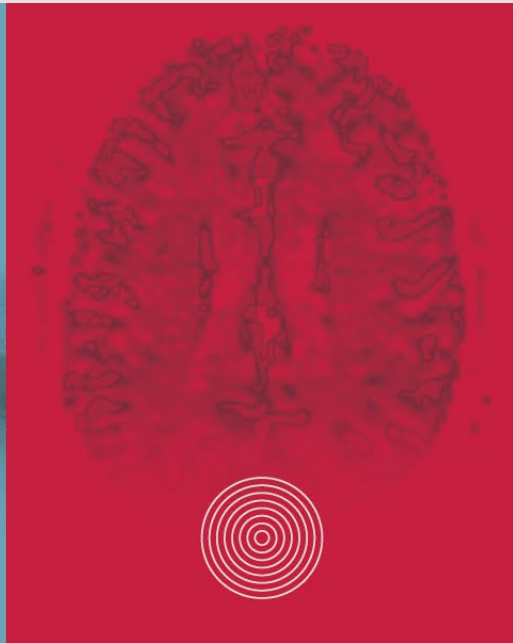
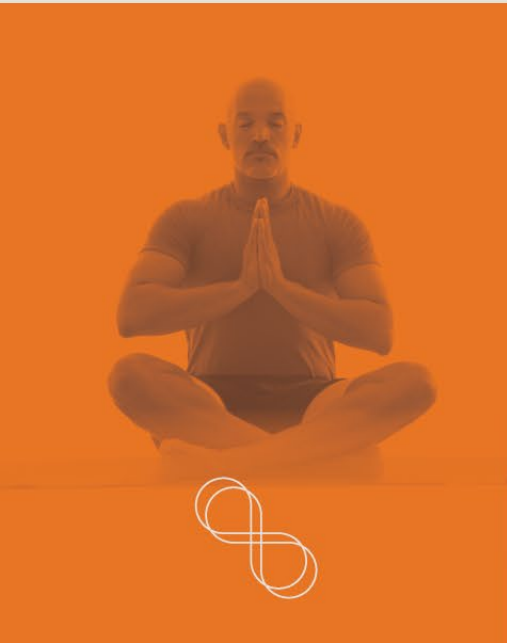
**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®



Overview of the NIH Pragmatic Trials Collaboratory

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Virtual Onboarding Meeting 2025





History: Initiated in 2012 via the NIH Common Fund, now transitioned to sustained funding from multiple NIH Institutes and Centers plus NIH HEAL Initiative



Goal: Strengthen the national capacity to implement cost-effective, large-scale research studies that engage healthcare delivery organizations as partners



Vision: Support the design and conduct of innovative embedded pragmatic clinical trials (ePCTs) to establish best practices and disseminate knowledge

Why Do an ePCT? The 5 Rs



Relevant Question

The question is pressing, and healthcare system leaders, patients, and front-line clinicians care about the answer.



Real-World Setting

Desire to test in diverse healthcare delivery settings with the hope of implementing findings widely.



Representative Population

Ability to recruit a population reflective of patients with the condition, including those from minoritized communities.



Routinely Collected Data

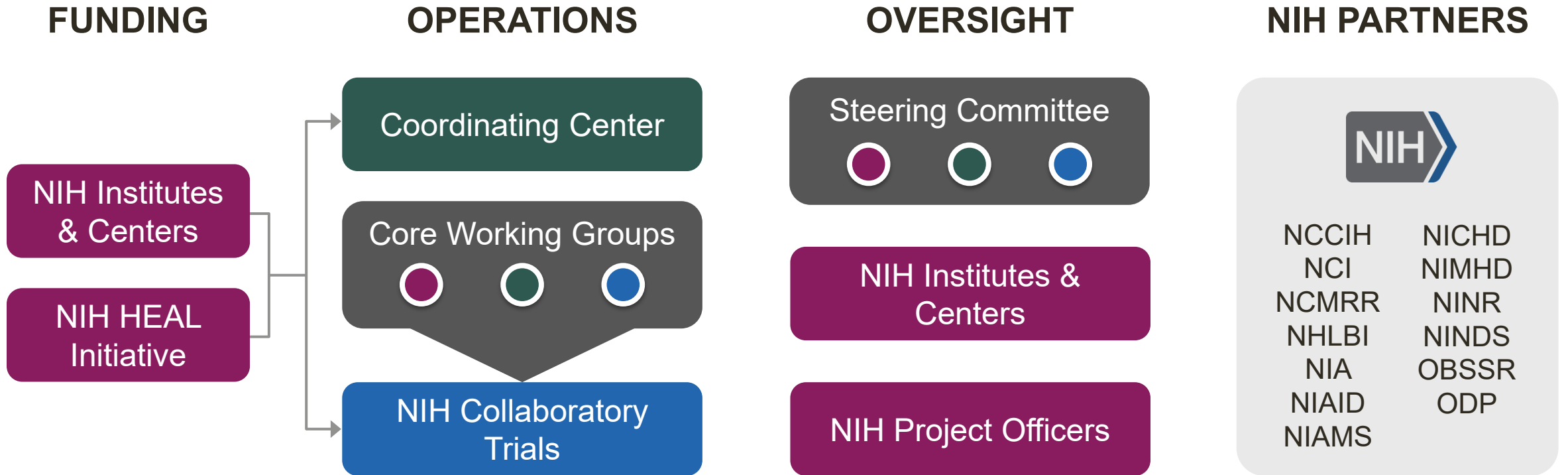
Can use data collected as part of healthcare delivery to answer the question, supplemented by data from other sources.



Rigorous Methods

Randomized research is needed to answer the question and inform changes in care, policy, or reimbursement.

Program Structure

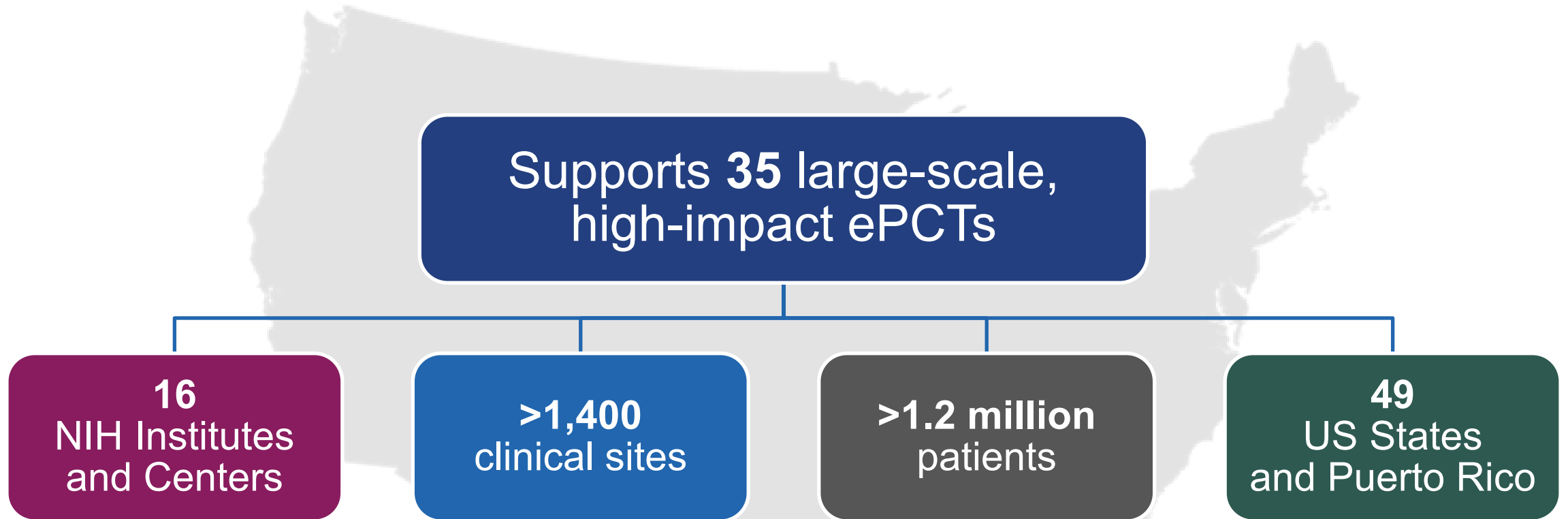


NIH Collaboratory Trials

- ePCTs addressing questions of major public health importance
 - Wide variety of therapeutic areas
 - Many have phased funding
 - Planning/startup phase
- ↓
- Implementation phase



Program Reach



No sites in Arkansas

Lessons Learned

▪ Expected

- Missing data
- Staff turnover
- Decreased fidelity to intervention
- Evolving HCS
- ICD9 to ICD10

▪ Unexpected

- Staff turnover frequency
- Impact of intervention fidelity/adherence
- New EHR launched
- Time effects (guidelines)– stepped wedge design
- Availability of data at end



Living Textbook of Pragmatic Clinical Trials

Website & Online Textbook



The screenshot shows the homepage of the NIH Pragmatic Trials Collaboratory. At the top, there is a navigation bar with links for Home, About, Resources, Grand Rounds, and News, along with a 'Subscribe to Newsletter' button and social media icons for Twitter and a search icon. The main header features the NIH Pragmatic Trials Collaboratory logo, the tagline 'Rethinking Clinical Trials®', and an image of a diverse group of healthcare professionals. Below the header is a navigation menu with four categories: Design, Data, Tools & Conduct, Dissemination, and Ethics and Regulatory, each with a 'View Chapters >' link. The main content area includes a video player with a play button and a 'GET STARTED' section with the text 'What is the NIH PRAGMATIC TRIALS COLLABORATORY?' and a right-pointing arrow.

rethinkingclinicaltrials.org

- Program information
- Comprehensive ePCT resource
- Continuously updated and expanded
- Internal and external contributors
- Reliable and citable

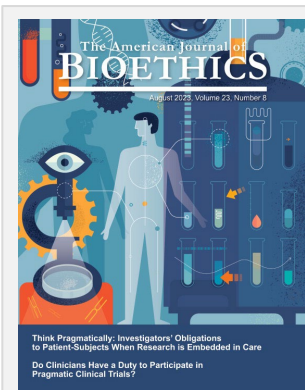
High-Profile Articles



The NEW ENGLAND
JOURNAL of MEDICINE

PERSPECTIVE

Is Learning Worth the Trouble? — Improving Health Care System Participation in Embedded Research



Think Pragmatically: Investigators' Obligations to Patient-Subjects When Research Is Embedded in Care

Do Clinicians Have a Duty to Participate in Pragmatic Clinical Trials?



Electronic health records based phenotyping in next-generation clinical trials: a perspective from the NIH Health Care Systems Collaboratory



Two weights make a wrong: Cluster randomized trials with variable cluster sizes and heterogeneous treatment effects

Annals of Internal Medicine

IDEAS AND OPINIONS

Data Sharing and Embedded Research



Benefits of a Cooperative Agreement with a Shared Coordinating Center

- Allows active partnership between NIH and Investigator Team
- More frequent communication
 - **Program Scientist is part of your team**
 - Tell us what is really going on so we can help
 - Connect you with resources across NIH to overcome barriers
- Coordinating Center
 - Has assisted many ePCTs
 - Working Groups/Cores set up to address the challenging areas
 - Additional scientific expertise to help your project



Transition Process

Letter from NIH on process

- Submit per instructions
2-3 months prior to transition time
- Planning “year” is really 9-10 months
- Document how you have met milestones
- Still need to submit progress report electronically on due date

Review considerations

- UG3 milestones met
- Potential for meeting UH3 milestones
- Participation in NIH Pragmatic Trials Collaboratory Activities
- Input from NIH Implementation Team (possible)
- Fit of UH3 milestones and NIH priorities
- Availability of funds

