NIH Pragmatic Trials Collaboratory Virtual Onboarding Meeting

October 29, 2025

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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

National Center for Complementary and Integrative Health

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

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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.

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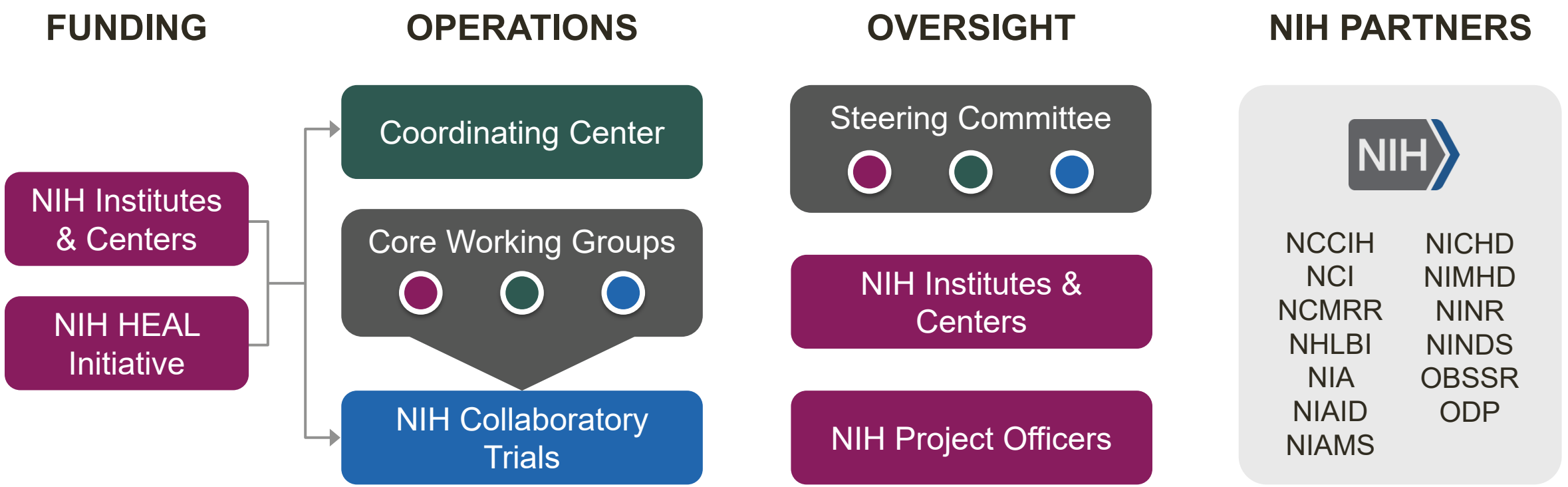
Program Structure



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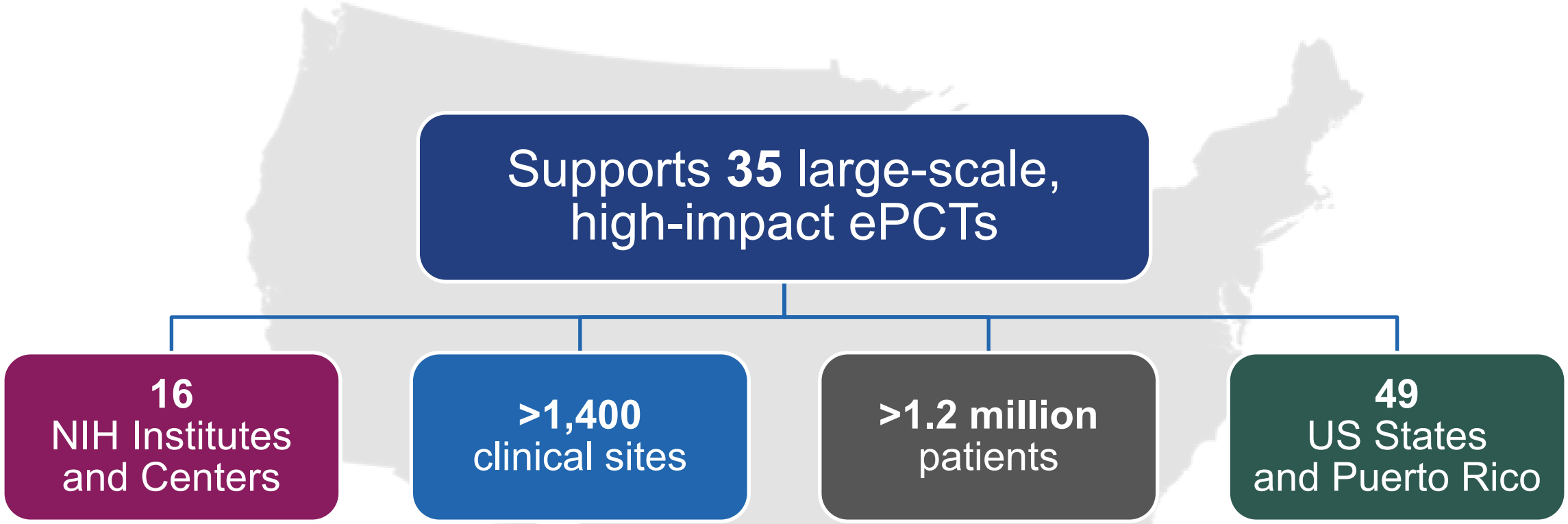
NIH Collaboratory Trials

- 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

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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

rethinkingclinicaltrials.org

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

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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

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

JAMIA
A SCHOLARLY JOURNAL OF INFORMATICS IN HEALTH AND BIOMEDICINE

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

Contemporary Clinical Trials

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

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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