Our Role
Pragmatic trials are foundational to the learning health model where ongoing evidence generation improves care. The NIH Pragmatic Trials Collaboratory is the nation’s leading resource on how to conduct randomized trials embedded in healthcare delivery.

About
Since 2012, the NIH Pragmatic Trials Collaboratory has helped rigorous trials be successful in real-world settings, creating standards for more efficient, large-scale clinical research.

What Are Embedded Pragmatic Clinical Trials?
- Conducted in healthcare systems
- Use existing infrastructure and streamlined procedures
- Provide high-quality evidence
- More efficient and cost effective than traditional trials

Our Reach
Support >30 high-impact, embedded pragmatic trials
14 NIH Institutes and Centers
>1400 clinical sites
>1.2 million patients
49 US States, Puerto Rico

Our Impact
We learn and share knowledge from each trial we support to advance pragmatic research methods.

NIH Partners, Past and Present
NCCIH  NCI  NCMRR  NHLBI  NIA  NIAID  NIAMS  NICHD  NIDA  NIDDK  NIMH  NIMHD  NINR  NINDS  OBSSR  ODP
Bold denotes current partners; Grants U24AT009676 and U24AT010961

Our Support
As a Resource Coordinating Center, we provide comprehensive expertise and technical assistance to researchers conducting pragmatic trials.

Consult and provide guidance on:
- Study design and analysis
- Regulatory issues and consent practices
- Use of real-word data sources
- Translating results into practice

Offer strategies to:
- Improve diversity, equity, and inclusion
- Engage health system partners

Assist with:
- Defining study endpoints
- Measuring patient-centered outcomes
- Assessing feasibility of clinical workflows
- Addressing challenges that arise

Wide Influence
The success of the NIH Pragmatic Trials Collaboratory and its extensive resources have informed subsequent NIH initiatives for pain management and dementia care, as well as research programs in Canada and Japan.

*LAST UPDATED JUNE 28, 2024*
Why Do an Embedded Pragmatic Clinical Trial? 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.

About NIH Collaboratory Trials

**SETTINGS**
- Academic health centers
- Community clinics
- Federally qualified health centers
- For-profit health systems
- Hospitals
- Managed care organizations
- Primary care
- Specialty care

**CHARACTERISTICS**
- Trials in multiple therapeutic areas
- Each works across multiple health systems
- Use electronic health records, administrative, and claims data
- Strong partnerships with health systems
- Committed to sharing lessons and data

How We Learn and Share

Pragmatic research poses unique challenges that the NIH Pragmatic Trials Collaboratory has a wealth of experience navigating. Through the program’s Core Working Groups, research teams are part of a community of scientists with a shared mission to help each other be successful and create generalizable knowledge about the design, conduct, and dissemination of pragmatic research.

**BEST PRACTICES**
NIH Collaboratory Trials
Core Working Groups
Coordinating Center

**DISSEMINATION**

- **Grand Rounds**
  Weekly webinar with >83,600 all-time attendees and >40 podcast episodes with >19,200 total plays

- **Living Textbook**
  Free online textbook, continually updated and expanded, with 30+ chapters, >1800 pages, and >100 contributors

- **Resources and Tools**
  Publications, guidance documents, Quick Start Guides, checklists, etc—over 90 study tools available

- **Education**
  Provided >70 hours of presenter-led training at 11 workshops, plus video modules, self-paced learning, fellowships, and more

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