

GOAL

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

NIH Pragmatic Trials Collaboratory

WHAT ARE EMBEDDED PRAGMATIC CLINICAL TRIALS (ePCTS)?

Trials conducted within healthcare systems that use streamlined procedures and existing infrastructure to answer important medical questions. These trials have the potential to inform policy and practice with high-quality evidence at a reduced cost and increased efficiency compared with traditional clinical trials.

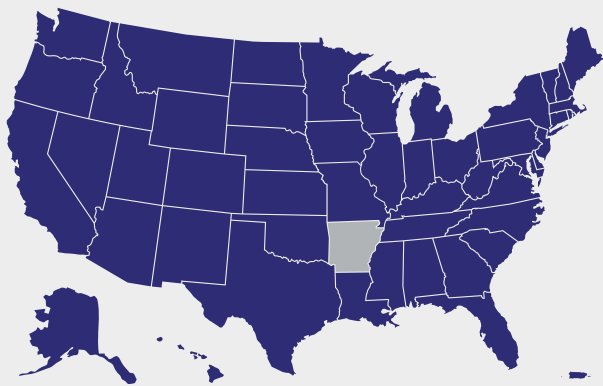
PROGRAM

NIH COLLABORATORY TRIALS: ePCTs that address questions of major public health importance and provide proof of concept for innovative pragmatic research designs

CORES: Working groups that support the conduct of NIH Collaboratory Trials and generate guidance addressing implementation challenges

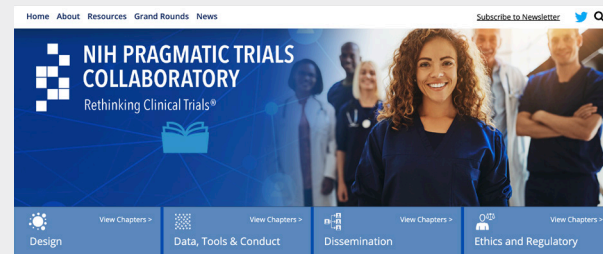
32 NIH COLLABORATORY TRIALS

- Conducted in partnership with healthcare systems
- Studying diverse clinical areas spanning 14 NIH Institutes and Centers
- >1100 clinical sites across 49 US States and Puerto Rico; >940,000 active subjects



RESOURCES

Living Textbook of Pragmatic Clinical Trials
Comprehensive resource on ePCTs



DESIGN describes how to plan an ePCT, including biostatistical and study design considerations, using electronic health record data, and building study teams and partnerships

DATA, TOOLS & CONDUCT describes tips for study startup, participant recruitment, data collection, and intervention delivery and monitoring

DISSEMINATION describes data sharing, dissemination, and implementation approaches

ETHICS AND REGULATORY describes issues related to privacy, informed consent, collateral findings, data and safety monitoring, and more

Plus:

- Grand Rounds webinars and podcasts
- Monthly NIH Collaboratory newsletter

Visit the Living Textbook:

www.rethinkingclinicaltrials.org

This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health, the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, the National Institute on Aging, the National Heart, Lung, and Blood Institute, the National Institute of Nursing Research, the National Institute of Minority Health and Health Disparities, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the NIH Office of Behavioral and Social Sciences Research, and the NIH Office of Disease Prevention. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961.

HOW IS A CLINICAL TRIAL CONSIDERED PRAGMATIC?

An **EXPLANATORY** approach answers the question, “Can this intervention work under ideal conditions?”

A **PRAGMATIC** approach answers the question, “Does this intervention work under usual conditions?”

A trial’s degree of pragmatism will vary along this spectrum:

