

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.

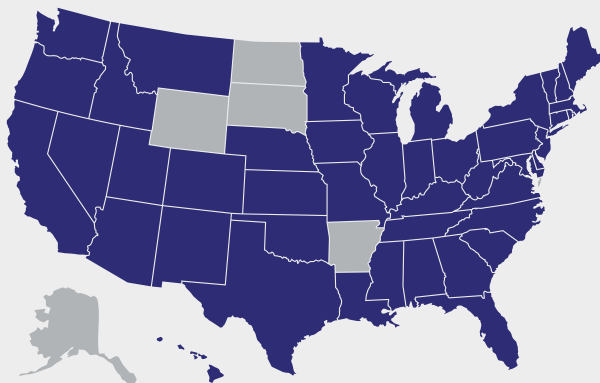
PROGRAM

DEMONSTRATION PROJECTS: 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 Demonstration Projects and generate guidance addressing implementation challenges

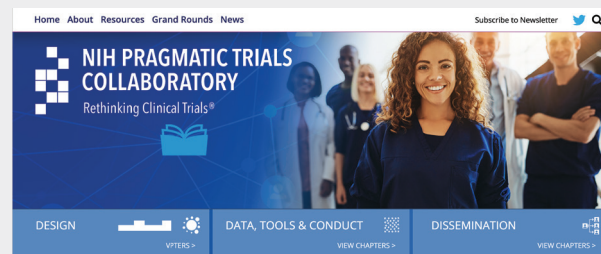
23 DEMONSTRATION PROJECTS

- Conducted in partnership with healthcare systems
- Studying diverse clinical areas spanning 12 NIH Institutes and Centers
- >1100 clinical sites across 90% of United States;
>940,000 active subjects



RESOURCES

Living Textbook of Pragmatic Clinical Trials
Comprehensive resource expanding on lessons from the Demonstration Projects and Cores



DESIGN describes how to plan the trial, including randomization schemes, endpoints and outcomes, analysis, informed consent, using electronic health record data, designing with implementation in mind, and feasibility studies

DATA, TOOLS & CONDUCT describes considerations for study startup and participant recruitment

DISSEMINATION describes data sharing and embedded research and dissemination and implementation approaches

Plus:

- Grand Rounds webinars and podcasts on ePCT topics
- Monthly NIH Collaboratory newsletter

Visit the Living Textbook:
www.rethinkingclinicaltrials.org

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:

