

NIH Pragmatic Trials Collaboratory

GOAL

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

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.

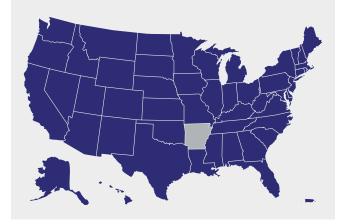
PROGRAM

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



Visit the Living Textbook: www.rethinkingclinicaltrials.org

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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

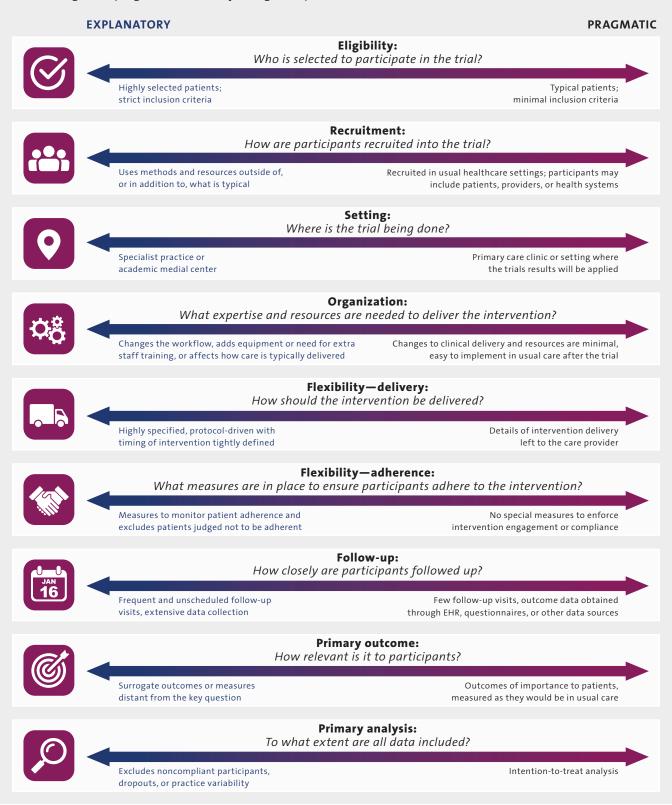
Plus:

- · Grand Rounds webinars and podcasts
- · Monthly NIH Collaboratory newsletter

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:



Source: The PRECIS-2 tool: designing trials that are fit for purpose. BMJ 2015;350:h2147. PMID:25956159. doi:10.1136/bmj.h2147.

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