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

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

Visit the Living Textbook: www.rethinkingclinicaltrials.org

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

22 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

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
How is a Clinical Trial Considered Pragmatic?

An Exploratory 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:

<table>
<thead>
<tr>
<th>Exploratory</th>
<th>Pragmatic</th>
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<tbody>
<tr>
<td>Eligibility: Who is selected to participate in the trial?</td>
<td>Typical patients, minimal inclusion criteria</td>
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<tr>
<td>Recruitment: How are participants recruited into the trial?</td>
<td>Recruited in usual healthcare settings; participants may include patients, providers, or health systems</td>
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<td>Setting: Where is the trial being done?</td>
<td>Primary care clinic or setting where the trials results will be applied</td>
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<td>Organization: What expertise and resources are needed to deliver the intervention?</td>
<td>Changes to clinical delivery and resources are minimal, easy to implement in usual care after the trial</td>
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<td>Flexibility—delivery: How should the intervention be delivered?</td>
<td>Details of intervention delivery left to the care provider</td>
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<td>Flexibility—adherence: What measures are in place to ensure participants adhere to the intervention?</td>
<td>No special measures to enforce intervention engagement or compliance</td>
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<td>Follow-up: How closely are participants followed up?</td>
<td>Few follow-up visits, outcome data obtained through EHR, questionnaires, or other data sources</td>
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<tr>
<td>Primary outcome: How relevant is it to participants?</td>
<td>Outcomes of importance to patients, measured as they would be in usual care</td>
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<tr>
<td>Primary analysis: To what extent are all data included?</td>
<td>Intention-to-treat analysis</td>
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