NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

ePCT QUICK START GUIDE FOR INVESTIGATORS

This Quick Start Guide is designed for clinical investigators interested in learning how to conduct an embedded pragmatic clinical trial (ePCT). It serves as an annotated Table of Contents, pointing readers to essential content in the *Living Textbook* needed to plan and launch an ePCT.

	STEP	IMPORTANT THINGS to KNOW or DO	NOTES and PLANNED ACTIONS
1	Learn what makes an ePCT different	• Understand how an ePCT contrasts with a traditional explanatory trial. • Determine which elements of an ePCT make sense to be more or less pragmatic, considering tradeoffs in flexibility, adherence, and generalizability of the intervention.	
2	Build partnerships to ensure a successful trial	• Discover how healthcare system engagement and support at all levels is essential from beginning to end. • Determine the key stakeholders to engage with at your partner healthcare system and their role in the delivery of your embedded intervention. • Identify the actions to take to engage stakeholders for the duration of your trial. • Learn how to assemble the ideal study team.	
3	Plan for sustainability from the beginning	• Understand the key considerations for implementing, disseminating, and sustaining your trial before you begin the design. • Learn how to select the best experimental design to answer your research question. • Develop your data sharing plan.	
4	Choose the right outcomes	• Learn how to develop meaningful endpoints relevant to participants, funders, communities, and healthcare providers. • Determine how your trial will ascertain the intervention outcome within the routine healthcare setting; for example, using the electronic health record. • Understand different approaches to measuring outcomes. • Consider benefit cost and cost-effectiveness measures.	
5	Plan the study design and analysis	• Learn about whether cluster randomization is suited to your research question. • Understand your trial's statistical approach and develop the statistical analysis plan. • Plan for changes to happen as the trial progresses and consider whether and how you will adapt the intervention.	

6	Consider oversight and monitoring	• Determine how your trial's participants should be protected. • Understand informed consent and alternative approaches to disclosure. • Consider whether your trial should have a data monitoring committee (DMC). • Learn about special training and resources for DMCs specific to ePCTs.	
7	Test trial feasibility	• Understand the importance of pilot testing to assess how your intervention will be integrated into the clinical setting as well as the readiness of your health system partner. • Identify the study documentation to assemble in the planning phase. • Consider training needs for the frontline personnel delivering your intervention. • Plan how you will track, document, and accommodate intervention modifications, implementation measures (fidelity, exposure, participant engagement, and satisfaction), and health system changes during the trial.	
8	Prepare to launch	• Determine the readiness of your trial and whether any adjustments are needed before launch. • Plan the participant recruitment activities.	
9	Prepare for dissemination and implementation	• Understand implementation frameworks and the differences between implementation in the trial versus the real world. • Develop a plan for communicating to different stakeholders, including health system leaders, the scientific community, and patients. • Understand the reporting requirements for PCTs (PDF document).	

Additional Resources

Submit a compelling ePCT grant application	Get expert advice from NIH Program Officers on how to develop a strong ePCT proposal. Understand the importance of a clearly defined research question and a testable hypothesis. Learn how to find the right program official and funding opportunity to fit your research question.
Download ePCT training resources	Learn from a variety of materials that reflect the knowledge, insight, and best practices acquired by the NIH Collaboratory program (PDF) and its Demonstration Projects.
Learn about the NIH Collaboratory Demonstration Projects	Read about these novel trials that address questions of major public health importance and engage healthcare delivery systems in research partnerships. Learn about challenges and solutions from the PIs and study teams.

The Coordinating Center of the National Institutes of Health (NIH) Health Care Systems Research Collaboratory is supported by the NIH Common Fund through a cooperative agreement from the Office of Strategic Coordination within the Office of the NIH Director.