NIH Collaboratory
Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

EPCT QUICK START GUIDE FOR RESEARCHER AND HEALTHCARE SYSTEMS LEADER PARTNERSHIPS

This Quick Start Guide is designed to help clinical investigators successfully partner with healthcare system leaders to support the successful conduct of an embedded pragmatic clinical trial (ePCT) within their healthcare system. It provides advice from the Collaboratory and serves as an annotated Table of Contents, pointing readers to essential content in the *Living Textbook* regarding partnering to conduct an ePCT.

	Considerations	Advice	IMPORTANT THINGS to KNOW or DO
1	Learn what makes an ePCT different	*"For healthcare system partners, the idea of improvement through systematic and scientific thinking is part of the value of participating."* —from Advice From Healthcare System Leadership *"Pragmatic clinical trials offer an opportunity to combine the work of caring for patients with the generation of real-world evidence that could improve the quality of care for patients in a reliable way. This may help create a cycle that leads to continual learning, i.e., the learning health system."* —from Advice From Healthcare System Leadership	• Understand how an ePCT contrasts with a traditional explanatory trial. • Understand different experimental designs and randomizations schemes, such as stepped wedge and cluster designs because this may affect timing.
2	Build partnerships to ensure a successful trial	*"The best way to create engagement is for partners to commit to it at the outset so that they learn to trust each other and address problems collaboratively... Such collaborations are the key to solving the unforeseen and inevitable challenges of conducting clinical trials in large healthcare systems."* —Ellen Tambor, MA, see full interview.	• Talk to the healthcare system leader about how to engage key stakeholders at the participating healthcare system areas to ensure they understand their role in the delivery of the embedded intervention. • Ensure you have a local champion.
3	Select research topics of mutual interest	*"A research question that will interest a healthcare system must be clinically, operationally, or strategically important and provide value to the healthcare system, such as providing an adoptable solution to a problem or clarifying alternatives between different treatments or therapies."* —from Advice From Healthcare System Leadership	• Consider who will use the evidence generated by the study.
4	Plan for sustainability from the beginning	*"Ideally, ePCT study teams will establish ongoing, bidirectional health system partnerships throughout the lifecycle of the trial and will plan their intervention with "implementation in mind."* —from Dissemination to Health System Leaders	• Understand the key considerations for implementing and sustaining the interventions from the trial and discuss them with your healthcare system leader. • Discuss and understand potential needs for intervention staffing and flexibility. • Consider the training needs for the frontline personnel delivering the intervention.

5	Discuss data security and data sharing considerations	*"In the end, the right answer is not the same for every trial, it depends on the particular data that might be shared, the level of detail about healthcare systems, and the uses to which those data might be put."* —Greg Simon, MD, MPH (PI of SPOT) in Data Sharing and Embedded Research	• Discuss the data sharing plan and the privacy needs of the institution with the healthcare system leaders. • Prepare for data sharing.
6	Build data systems for learning healthcare	*"Using electronic health record (EHR) data for research is fundamentally different than collecting the research data prospectively, as is traditional for controlled clinical trials."* —From Using Electronic Health Record Data in Pragmatic Trials	• Consider standards that promote interoperability and aggregation of data. • Ensure adequate IT staff is available at the institution.
7	Prepare for Implementation	*"To help speed implementation and translation of research findings into practice across the nation, tools, such as online materials, training videos, etc., can be created. Materials developed to train the sites participating in the PCT are good starting places for materials for a broader audience. But again, a health system leader must first recognize the need for the tool, then champion its implementation (pointing to the need to involve these stakeholders in study design)."* —From Dissemination and Implementation	• Discuss who will help ensure the study is implemented as seamlessly as possible. • Work with healthcare system leaders to develop the most appropriate, useable, leave-behind tools for sustaining or de-implementing the intervention.

Additional Resources

Advice from Healthcare System Leaders	Get expert advice from experienced healthcare system leaders and learn the 5 principles of good partnership
Download ePCT training resources	Learn from a variety of materials that reflect the knowledge, insight, and best practices acquired by the NIH Collaboratory program 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.
Read more about the NIH Collaboratory and the Core Working Groups	The NIH Collaboratory aims to improve the way clinical trials are conducted by creating a new infrastructure for collaborative research with healthcare systems. The Collaboratory has 5 Core Working Groups of experts that help research teams address challenges of conducting research embedded in clinical care, and they collect and disseminate knowledge and best practices learned throughout the process. The ultimate goal is to ensure that healthcare providers and patients can make decisions based on the best available clinical evidence.