What is the Most Effective Use of the 1-Year Planning Phase?

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Objective

- Discuss how to optimize the planning phase to increase successful completion of the pragmatic trial
- Provide examples from pragmatic trials and resources for developing a planning phase or start up period for a pragmatic trials

Key Considerations for Planning Activities

- Focus on your pain points
- Determine how you will merge and aggregate data
- Fail fast: make sure it works, try different things
- Maximize and evaluate for diversity and equity
- Start with the sites that will be the most challenging
- What do you need to figure out before the trial starts?

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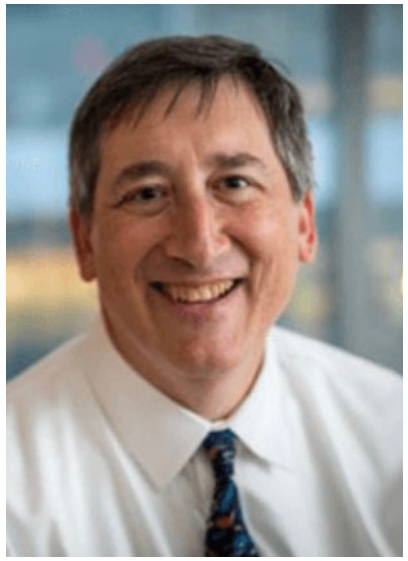
Albert E. Kent Professor of Emergency Medicine
Yale School of Medicine,
Professor of Medicine and Public Health



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Questions for the Panel

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1. What is one thing you did during the planning phase that set your trial up for success?

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2. If you had it to do over, are there any activities you would add to your planning phase? If you piloted elements, would you change what you piloted?

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3. What advice do you have for working with health care system partners during the planning phase? How can the planning phase be used to enhance diversity of participants?

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4. What activites in your planning phase were helpful to determine the quality of data or how you merged/aggregated data?

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Resource: The Living Textbook

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org

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Quick Start Guides

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ePCT QUICK START GUIDE FOR INVESTIGATORS

This Quick Start Guide is designed for clinical investigators interested in learning how to conduct an embedded pragm 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
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.

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Provide Step by Step recommendations for

- Chapters with information
- Important things to do or know

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Implementation Readiness Checklist

Milestone	Completed
Recruitment plans are finalized	
All sites identified (documentation of site commitment)	
Methods for accurately identifying participants validated	
All agreements for necessary subcontracts in place	
Ethical/regulatory aspects are addressed	
Coordinated IRB oversight in place	
Finalized plans for informed consent or waiver of informed consent	
Finalized data and safety monitoring plan	
Intervention is fully developed and finalized	
Finalized intervention (including materials and training at sites) ready for site implementation	
Finalized protocol is IRB approved (informed consent and data collection forms, if applicable)	
Data collection methods are adequately tested	
Validated methods for the electronic health record information	
Validated study surveys, interviews, or other data collection modes	
Demonstrated quality assurance and harmonization of data elements across healthcare systems/sites	
Statistical and data analysis methods have been adequately developed	
Budget is realistic, feasible, and accounts for potential changes	

https://rethinkingclinicaltrials.org/chapters/conduct/startup/startup-implementation/

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