NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

ePCT Quick Start Guide for Project Managers

This Quick Start Guide is designed to provide some resources to project managers (PMs) to support the conduct of an embedded pragmatic clinical trial (ePCT) within their healthcare system. It provides tips and tools from the NIH Pragmatic Trials Collaboratory for managing an ePCT from planning through completion.

1. IMPORTANT THINGS TO KNOW

This section introduces PMs to information for understanding ePCTs and assisting the study team in the planning phase. PMs should have working knowledge of the general principles and procedures for managing clinical trials; those foundational resources are not included here but are readily available.

Key Knowledge	Recommended Reading
Understanding how **ePCTs are different** from traditional clinical trials	The *Living Textbook* chapter, What is a Pragmatic Clinical Trial, introduces the key elements that make a trial pragmatic.
Using a **single IRB** for multisite ePCTs	With few exceptions, most NIH-supported studies conducting multisite or cooperative research will need to use a single IRB (sIRB). The Clinical Trials Transformation Initiative (CTTI) has sIRB resources that can help streamline and optimize study execution.
Assembling the ePCT **study team** including project **stakeholders**	Although the research team typically designs a pragmatic study, it is the healthcare system partners who actually deliver the intervention. Because ePCTs are embedded in health systems, individuals from both the research team and health system must understand and respect each other's workflow, culture, priorities, and responsibilities. The *Living Textbook* chapter, Building Partnerships and Teams to Ensure a Successful Trial, describes who to engage, and how, as well as how to assemble the ideal study team. This guidance document or this worksheet can help you consider potential staffing needs or training approaches.

2. DOCUMENTATION CHECKLIST

During the planning and implementation of an ePCT, PMs will be responsible for managing a large amount of documentation. This section includes a sample checklist of potential trial documents with links to templates and samples where available. Specific requirements will vary based on the trial, institution, and funder.

Study Documents	Examples from Research Toolkits
Protocol	Regulatory Binder Checklist Protocol Template DSMB Charter Template Study Protocol Template
Staffing plan, including multisite organization chart	Considerations for Training Front-Line Staff and Clinicians on Pragmatic Clinical Trial Procedures

Study Documents	Examples from Research Toolkits
Recruitment plan	Planning Recruitment (CTTI Presentation)
Statistical analysis plan	COVID-19 Checklist for Statistical Analysis Plans in Pragmatic Trials
Budget	
Contractual documents (e.g., memorandum of understanding [MOU], reliance agreement)	
Electronic health record use plan and IT-facilitated updates as needed	*Living Textbook* Chapter: Using Electronic Health Record Data in Pragmatic Clinical Trials Acquiring and Using Electronic Health Record Data
Study plan and timeline	
Communication plan	*Living Textbook* chapter: Dissemination Approaches for Different Stakeholders Designing with Implementation and Dissemination in Mind
Committee membership and meeting plan, including advisory and steering committees	
Manual of procedures	Manual of Procedures (MOP) Outline – Multi-Site Manual of Procedures (MOP) Guidelines – Multi-Site Manual of Procedures (MOP) Outline – Single-Site Manual of Procedures (MOP) Guidelines – Single-Site
Data coordinating activities (e.g., data dictionary, data quality assessment, data harmonization across sites)	REDCap (tool for clinical study management and data capture)
Patient recruitment and intervention materials	*Living Textbook* chapter: Participant Recruitment
Clinical staff training and intervention materials	ePCT Training Resources
Interviewer/research staff training	
Vendor contracts	
Specimen management plan	
Site initiation plan	
Dissemination and sustainability plan	Reporting Pragmatic Clinical Trials

Study Documents	Examples from Research Toolkits
Regulatory	Resources listed below
REGULATORY DOCUMENTS	
Data sharing plan including data use agreements between parties	Data and Resource Sharing
IRB review and approval	NCATS SMART IRB Platform
Registry in ClinicalTrials.gov	
Informing participants; consent process and documentation	Good Documentation Practice Informed Consent Checklist Informed Consent Template TiME Trial Consent Info Sheets for Study Sites TSOS Consent Form
OVERSIGHT DOCUMENTS	
Data and safety monitoring plan/committee	Data Monitoring Committee Charter Template
Data management plan	Data Management and Sharing
Quality management plan	Assessing Data Quality (video)

NIH WEBSITES

PMs are encouraged to visit NIH-specific websites to find helpful guidance, templates, and sample forms.

ADDITIONAL RESOURCES

National Center for Complementary and Integrative Health

National Institute on Aging

National Institute of Dental and Craniofacial Research

HHS.gov Guidance Portal

National Center for Advancing Translational Sciences

NIH Collaboratory *Living Textbook*

Visit the *Living Textbook*:
www.rethinkingclinicaltrials.org