

Driving Tomorrow's Outcomes Through Clinical Research in Real-World Settings: Essentials of Embedded Pragmatic Clinical Trials Workshop

2023 AcademyHealth Annual Research Meeting Seattle, WA June 23-24, 2023

DURATION	AGENDA TOPIC	SPEAKERS	GOALS
8:15 - 8:30 a.m.	Welcome Opening Remarks	Kevin Weinfurt	 Welcome and introduction of agenda, objectives, and Living Textbook
8:30 - 9:15 a.m.	What are Embedded Pragmatic Clinical Trials (ePCTs)?	Wendy Weber	 Identify key considerations in the design and conduct of ePCTs and how they differ from explanatory trials
			 Learn about the advantages and disadvantages of ePCTs, when a pragmatic approach can be used to answer the research question.
			Q & A with attendees
9:15 - 10:15 a.m.	Engaging Stakeholders & Aligning with Health System Partners	Emily O'Brien	 Describe the breadth of stakeholders to engage as partners and approaches for engaging them through all phases of the study
			 Identify skills needed for a strong study team and consider the diversity of the team, including inclusive practices
			 Understand the real-world priorities and perspectives of healthcare system leaders and how to obtain their support
			 Identify engagement practices to obtain patient and community perspectives
			Highlight challenges of partnering with diverse healthcare systems
			Q & A with attendees
10:15 - 10:30 a.m.	Break		Networking among attendees and presenters

JUNE 23, 2023					
DURATION	AGENDA TOPIC	SPEAKERS	GOALS		
10:30 - 11:15 a.m.	Objectives and Trial Design: An Overview of Hybrid Designs	Hayden Bosworth	 Overview of the 3 types of effectiveness-implementation hybrid trial designs and when they may be appropriate for ePCTs 		
			Q & A with attendees		
11:15 a.m 12:00 p.m.	Measuring Outcomes	Emily O'Brien	 Describe methods for measuring outcomes using data sources such as electronic health records (EHRs) and patient-reported outcomes (PROs) 		
			 Discuss the integration of a health equity lens in evaluating outcomes 		
			Q & A with attendees		
12:00 - 1:00 p.m.	Lunch		 Networking among attendees and presenters 		
1:00 - 1:45 p.m.	ePCT Design	Patrick Heagerty	Learn about cluster randomized and stepped-wedge study designs		
			Q & A with attendees		
1:45 - 2:30 p.m.	ePCT Analysis	Patrick Heagerty	 Recognize the analytical challenges and trade-offs of pragmatic study designs, focusing on what principal investigators (PIs) need to know 		
			Q & A with attendees		
2:30 - 2:45 p.m.	Break		 Networking among attendees and presenters 		
2:45 - 4:15 p.m.	ePCTs in Context: Small Group Work Followed by Panel Discussion with Collaboratory	Moderator: Kevin Weinfurt Panel:	 Have attendees work in small groups to discuss challenges faced by ongoing ePCTs 		
	Demonstration Project Pls	Margaret Kuklinski Angelo Volandes Michael Parchman	 Introduce PIs of ongoing ePCTs to discuss how they handled the challenges from attendees' discussion, reflect on the morning topics, and discuss lessons learned 		
			Q & A with attendees		
4:15 - 4:25 p.m.	Closing Remarks/Adjourn	Kevin Weinfurt	Summary of Day 1.		
			What to expect on Day 2		

JUNE 24, 2023					
DURATION	AGENDA TOPIC	SPEAKERS	GOALS		
8:00 - 8:15 a.m.	Welcome Opening Remarks Introductions	Kevin Weinfurt	Review of Day 1.		
			Meeting goals and expectations		
8:15 - 9:00 a.m.	Pilot & Feasibility Testing	Wendy Weber	 Identify approaches to evaluating the capabilities of the partner healthcare system and testing key elements of various types of interventions 		
			Q & A with attendees		
9:00 - 9:45 a.m.	Ethical & Regulatory Oversight Considerations	Stephanie Morain	 Learn about the regulatory and ethical challenges of conducting ePCTs 		
			 Discuss unique needs of historically underrepresented and mistreated groups 		
			Q & A with attendees		
9:45 – 9:55 a.m.	Break		Networking among attendees and presenters		
9:55 - 10:40 a.m.	Writing a Compelling Grant Application	Beda Jean-Francois	Learn how to develop a compelling ePCT application		
			Tips from Collaboratory PIs		
			Q & A with attendees		
10:40 - 11:55 a.m. 75 min	ePCTs in Context: Small Group Work Followed by Panel Discussion with Collaboratory Demonstration Project PIs	Moderator: Vince Mor Panel: Margaret Kuklinski Ardith Doorenbos	Have attendees work in small groups to discuss challenges faced by ongoing ePCTs		
			 Introduce PIs of ongoing ePCTs to discuss how they handled the challenges from attendees' discussion, reflect on the morning topics, and discuss lessons learned 		
			Q & A with attendees		
11:55 a.m 12:00 p.m. 5 mins	Closing Remarks	Kevin Weinfurt	Wrap-up including identifying sources for further learning		