

***Changing Trials for Changing Times:
Essentials of Embedded Pragmatic Clinical Trials Workshop***

HCSRN 2023 Annual Conference
Sheraton Downtown Denver, Denver, Colorado
February 20, 2023
8 a.m.-4:45 p.m. MT

Join workshop by Zoom: <https://duke.zoom.us/j/93859922865?pwd=eIR4SUZTWw1yRWtWTUxmODJFTWRvdz09>
Meeting ID: 938 5992 2865; Passcode: 12345

DURATION	AGENDA TOPIC	SPEAKERS	GOALS
8:00-8:50 a.m.	What are Embedded Pragmatic Clinical Trials (ePCTs)?	Wendy Weber	<ul style="list-style-type: none"> • Welcome and introduction of agenda, objectives, and Living Textbook • 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
8:50-9:30 a.m.	Engaging Stakeholders & Aligning with Health System Partners	Emily O'Brien	<ul style="list-style-type: none"> • 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

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9:30-10:00 a.m.	Objectives and Trial Design: An Overview of Hybrid Designs	Patrick Heagerty	<ul style="list-style-type: none"> Overview of the 3 types of effectiveness-implementation hybrid trial designs and when they may be appropriate for ePCTs Q & A with attendees
10:00-10:30 a.m.	Measuring Outcomes	Emily O'Brien	<ul style="list-style-type: none"> 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
10:30-10:45 a.m.	Break		<ul style="list-style-type: none"> Networking among attendees and presenters
10:45-11:55 a.m.	ePCT Design and Analysis	Patrick Heagerty	<ul style="list-style-type: none"> Learn about cluster randomized and stepped-wedge study designs Recognize the analytical challenges and trade-offs of pragmatic study designs, focusing on what principal investigators (PIs) need to know Q & A with attendees
11:55 a.m.- 12:55 p.m.	ePCTs in Context: Panel Discussion with Collaboratory Demonstration Project PIs	<p>Moderator: Kevin Weinfurt</p> <p>Panel: Arne Beck (GGC4H) Michael Ho (Nudge) Miguel Vazquez (ICD-Pieces)</p>	<ul style="list-style-type: none"> Introduce PIs of 3 ongoing ePCTs to reflect on the morning topics and discuss challenges, solutions, lessons learned, and how they leveraged networks and resources to support trial success Q & A with attendees
12:55-1:40 p.m.	Lunch		<ul style="list-style-type: none"> Networking among attendees and presenters
1:40-2:10 p.m.	Pilot & Feasibility Testing	Wendy Weber	<ul style="list-style-type: none"> Identify approaches to evaluating the capabilities of the partner healthcare system and testing key elements of various types of interventions Q & A with attendees
2:10-2:40 p.m.	Ethical & Regulatory Oversight Considerations	Stephanie Morain	<ul style="list-style-type: none"> Learn about the regulatory and ethical challenges of conducting ePCTs Discuss unique needs of historically underrepresented and mistreated groups Q & A with attendees

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2:40-2:55 p.m.	Break		<ul style="list-style-type: none"> • Networking among attendees and presenters
2:55-3:35 p.m.	Writing a Compelling Grant Application	Beda Jean-Francois	<ul style="list-style-type: none"> • Learn how to develop a compelling ePCT application • Tips from Collaboratory PIs • Q & A with attendees
3:35-4:35 p.m.	ePCTs in Context: Panel Discussion with Collaboratory Demonstration Project PIs	<p>Moderator: Kevin Weinfurt</p> <p>Panel: Arne Beck (GGC4H) Michael Ho (Nudge) Miguel Vazquez (ICD-Pieces)</p>	<ul style="list-style-type: none"> • Hear our 3 PI panelists reflect on the afternoon topics and discuss challenges, solutions, lessons learned, and how they leveraged networks and resources to support trial success • Q & A with attendees
4:35-4:45 p.m.	Next Steps	Kevin Weinfurt	<ul style="list-style-type: none"> • Final thoughts from the panelists • Final Q & A • Wrap-up including identifying sources for further learning