

## Collaboratory ePCT Training Workshop

February 20-21, 2018

JB Duke Hotel

230 Science Dr.

Durham, North Carolina 27708

# Agenda

### Workshop Purpose

*The purpose of this workshop is to (1) train investigators in the design and conduct of embedded pragmatic clinical trials (ePCTs) and (2) pilot the educational materials and collect feedback on their quality and appropriateness from both the attendees and the subject matter experts.*

DAY 1			
DURATION	AGENDA TOPIC	WHO	GOAL
7:00 – 8:00 a.m.	<b>Breakfast</b> <i>The Marketplace</i>		
8:00 – 8:15 a.m.	<b>Welcome and opening remarks</b>	Kevin Weinfurt and Wendy Weber	<i>Learning objectives and goals for workshop</i>
8:15 – 9:00 a.m.	<b>Introduction exercise</b> (30 mins) <b>Introduction to the 2 case studies</b> (15 mins)	Facilitator: Kevin Weinfurt  Gloria Coronado and Doug Zatzick	<i>Introductions</i>
9:00 – 9:45 a.m.	<b>Topic 1: What are Embedded Pragmatic Clinical Trials?</b> (Part 1)	Instructor: Lesley Curtis	<i>Identify key considerations in the design and conduct of ePCTs and how they differ from explanatory trials</i>
9:45 – 10:00 a.m.	<b>Break</b>		
10:00 – 10:45 a.m.	<b>Topic 1: What are Embedded Pragmatic Clinical Trials?</b> (Part 2)	Facilitators: Gloria Coronado and Doug Zatzick	<i>Demonstrate understanding of ePCTs and how they differ from explanatory trials as illustrated by the 2 case studies</i>

DAY 1

DURATION	AGENDA TOPIC	WHO	GOAL
10:45 – 12:15 p.m.	<b>Topic 2: Engaging All Stakeholders &amp; Aligning with Healthcare System Partners</b>	Instructor: Leah Tuzzio	<p><i>Describe the breadth of stakeholders to engage as partners in an ePCT and approaches for engaging them through all phases of a research study</i></p> <p><i>Understand the real-world priorities and perspectives of health system leaders and how to obtain their support</i></p>
12:15 – 1:15 p.m.	<b>Lunch - <i>The Marketplace</i></b>		
1:15 – 1:45 p.m.	<b>Topic 3: Designing with Implementation in Mind</b>	Instructor: Doug Zatzick	<i>Consider how to design ePCTs so that findings can be successfully implemented and sustained in real-world healthcare settings</i>
1:45 – 2:45 p.m.	<b>Topic 4: Design and Analytic Considerations (Part 1)</b>	Instructor: Liz Turner Consultant: Liz DeLong	<i>Recognize analytical challenges of cluster-randomized and stepped-wedge study designs</i>
2:45 – 3:00 p.m.	<b>Break</b>		
3:00 – 4:00 p.m.	<b>Topic 4: Design and Analytic Considerations (Part 2)</b>	Instructor: Liz Turner Consultant: Liz DeLong	<i>Recognize analytical challenges of cluster-randomized and stepped-wedge study designs</i>
4:00 – 5:00 p.m.	<b>Topic 5: Regulatory and Ethical Challenges of ePCTs</b>	Instructor: Kevin Weinfurt	<i>Learn about the regulatory and ethics considerations specific to ePCTs</i>
5:00 – 5:15 p.m.	<b>Closing remarks</b>	Kevin Weinfurt and Wendy Weber	<i>Summary of Day 1</i>
	<b>Dinner - <i>The Marketplace</i></b>		

DAY 2			
DURATION	AGENDA TOPIC	WHO	GOAL
7:00 – 8:00 a.m.	<b>Breakfast</b> <i>The Marketplace</i>		
8:00 – 8:15 a.m.	<b>Announcements</b>	Kevin Weinfurt and Wendy Weber	<i>Summary of Day 1</i> <i>Meeting goals for Day 2</i>
8:15 – 9:15 a.m.	<b>Topic 6: Measuring Outcomes</b>	Instructors: Lesley Curtis and Rachel Richesson	<i>Describe methods for measuring outcomes using data sources such as electronic health records (EHRs) and patient-reported outcomes (PROs)</i>
9:15 – 10:15 a.m.	<b>Topic 7: Pilot and Feasibility Testing</b>	Instructor: Wendy Weber	<i>Identify approaches to evaluate the capabilities and challenges of partner healthcare system and test key elements of various types of interventions</i>
10:15 – 10:30 a.m.	<b>Break</b>		
10:30 – 11:00 a.m.	<b>Topic 8: Dissemination</b>	Instructor: Doug Zatzick	<i>Identify considerations for dissemination of study results</i>
11:00 – 11:15 a.m.	<b>Topic 9: ePCT Team Composition</b>	Instructor: Lesley Curtis	<i>Identify ideal composition and skills needed in an ePCT study team</i>
11:15 – 11:45 a.m.	<b>Topic 10: Developing a Compelling Application (Part 1)</b>	Instructor: Marcel Salive	<i>Provide participants information on how to develop a compelling ePCT application</i>
11:45 – 1:00 p.m.	<b>Lunch - <i>The Marketplace</i></b>		
1:00 – 2:30 p.m.	<b>Topic 10: Developing a Compelling Application (Part 2)</b>	Facilitator: Kevin Weinfurt	<i>Demonstrate learning around how to develop specific aims and study plans for an ePCT</i>
2:30 – 3:00 p.m.	<b>Q&amp;A</b>	Facilitator: Kevin Weinfurt	<i>Opportunity for additional questions that may not have been previously addressed</i>
3:00 – 3:15 p.m.	<b>Closing remarks and evaluation</b>	Kevin Weinfurt, Wendy Weber, Gloria Coronado, and Doug Zatzick	<i>Summarize the workshop and offer parting advice from SMEs</i>  <i>Complete the evaluation</i>