



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Steering Committee Meeting Agenda May 9-10, 2024 Congressional Ballroom, Bethesda Marriott

Meeting Purpose

Day 1: Hear from the newest NIH Collaboratory Trials; share challenges and lessons learned to promote successful trial conduct; discuss the evolution and current state of the NIH Collaboratory ecosystem; identify gaps and areas of opportunity for expanding the ecosystem of embedded pragmatic clinical trials (ePCTs).

Day 2: Have rich discussions on overcoming challenges in ePCTs, fostering patient engagement, and creating reusable infrastructure; share insights from seasoned NIH Collaboratory Trials on posttrial activities and moving to the next ePCT.

Meeting Participation Quick Reference Guide

Day 1 Morning	Day 1 Afternoon	Day 2 Morning	Day 2 Afternoon
New Trials	New + Seasoned Trials	New + Seasoned Trials	Seasoned Trials
Coordinating Center, Core Leadership, and NIH			

DAY 1: MAY 9, 2024

WHEN	TOPIC	WHO	GOALS
MORNING SESSION: FOCUS ON NEW TRIALS – NAVIGATING THE PLANNING PHASE			
8:30 – 8:40 a.m.	Welcome Opening Remarks	Wendy Weber Lesley Curtis	<i>Welcome participants; review meeting goals and expectations</i>
8:40 – 8:50 a.m.	Highlights of the NIH Pragmatic Trials Collaboratory	Wendy Weber	<i>Feature major accomplishments of the program; review specific requirements for the new trials; offer guidance and answer questions</i>
8:50 – 9:40 a.m.	Ethical and Regulatory Challenges/ Lessons Learned	Moderator Stephanie Morain Panel Michele Balas Diana Burgess Richard Skolasky	<i>Hear from the NIH Collaboratory Trials about ethical and regulatory challenges encountered</i> <i>Discuss strategies for navigating ethical and regulatory complexities of ePCTs</i>
9:40 – 10:30 a.m.	Study Design Challenges/ Lessons Learned	Moderator Patrick Heagerty Panel Sheana Bull Stephanie Fitzpatrick Chenchen Wang	<i>Learn about study design issues faced by the NIH Collaboratory Trials</i> <i>Share statistical and methodological considerations important for the planning phase and beyond</i>
10:30 – 10:40 a.m.	Break		
10:40 – 11:30 a.m.	Data Access and Management Challenges/ Lessons Learned	Moderator Rachel Richesson Panel Richard Skolasky Ed Vasilevskis	<i>Hear from the NIH Collaboratory Trials about challenges with data access, planning for data management, and data sharing</i> <i>Review methods for addressing issues related to data security, privacy, and approval for data use</i>
11:30 a.m. – 12:30 p.m.	Lessons and Challenges Engaging Rural Populations	Moderator Karen Kehl Panel Julie Fritz Richard Skolasky Sebastian Tong Katie Hadlandsmyth	<i>Share progress on ePCTs for the prevention and management of chronic pain in rural populations, describing challenges and lessons learned</i> <i>Begin communication that may lead to joint publications on methods and strategies, and/or future collaborations</i>
12:30 – 1:25 p.m.	Lunch		<i>Seasoned trial investigators arrive</i>

DAY 1: MAY 9, 2024

WHEN	TOPIC	WHO	GOALS
AFTERNOON SESSION: TOPICS FOR ALL TRIALS – EXPLORING THE ePCT ECOSYSTEM			
1:25 – 1:30 p.m.	Welcome Introduction of the Fireside Chat	Helene Langevin Richard Hodes David Shurtleff	<i>Welcome participants, introduce the Fireside Chat, and kick off the afternoon session for all NIH Collaboratory Trials</i>
1:30 – 2:30 p.m.	Fireside Chat: Pragmatic Research and National Health Priorities	Moderator Wendy Weber Guests Monica Bertagnolli Robert Califf	<i>Hear thoughts on how pragmatic research can help address the nation’s top health priorities Discuss how to maximize evidence generation from ePCTs and achieve the greatest benefits for the U.S. population</i>
2:30 – 3:00 p.m.	State of the NIH Pragmatic Trials Collaboratory Ecosystem	Kevin Weinfurt	<i>Share an overview of the characteristics of trials in the NIH Collaboratory, such as populations, partner types (e.g., hospitals, primary care, community clinics, FQHCs) Discuss the evolution of the program and identify gaps and areas of opportunity</i>
3:00 – 3:10 p.m.	Break		
3:10 – 4:15 p.m.	Addressing Barriers to ePCTs Involving Approved Drugs	Moderator Adrian Hernandez Panel Pearl O’Rourke Kevin Bugin Leonard Sacks Tracy Wang	<i>Describe barriers to conducting ePCTs involving approved drugs, including trials with repurposed drugs and A vs B trials Explore potential ways to overcome these barriers, including how the NIH Collaboratory might contribute</i>
4:15 – 5:00 p.m.	Promoting Patient Engagement in ePCTs	Moderator Steven George Panel Natalia Morone Chenchen Wang	<i>Review the Coordinating Center’s efforts to support patient engagement Hear from NIH Collaboratory Trials on challenges and methods for engaging patients in ePCTs Highlight a trial example from Pain Management Collaboratory to show cross-collaboratory efforts in patient engagement</i>
5:00 – 5:25 p.m.	Fostering Development of Up-and-Coming ePCT Investigators	Moderator Emily O’Brien Presenters Lindsay Ballangee Kaitlyn McLeod	<i>Hear flash talks from NIH Collaboratory fellows</i>
5:25 – 5:30 p.m.	Closing Remarks/Adjourn	Wendy Weber Lesley Curtis	<i>Summarize Day 1 and highlight key lessons learned; preview of Day 2</i>
5:45 – 7:30 p.m.	Networking Reception and Dinner Location: Dirksen		<i>Networking Team-building activities</i>

DAY 2: MAY 10, 2024

WHEN	TOPIC	WHO	GOALS
MORNING SESSION: TOPICS FOR ALL TRIALS – EXPLORING THE ePCT ECOSYSTEM			
8:15 – 8:20 a.m.	Opening Remarks	Wendy Weber Lesley Curtis	<i>Meeting goals and expectations; introductions</i>
8:20 – 8:30 a.m.	BackInAction Results	Lynn DeBar Andrea Cook	<i>Hear preliminary main outcomes</i>
8:30 – 9:15 a.m.	Clinician and Health System Engagement Challenges/ Lessons Learned	Moderator Greg Simon Panel Andrea Cheville Christine Goertz James Tulskey	<i>Hear about challenges engaging clinicians and health systems; discuss ways to strengthen these relationships to support ePCTs</i> <i>Share how trials are planning for retraining of clinical staff when there is turnover</i>
9:15 – 10:00 a.m.	Data Extraction and Quality Challenges/ Lessons Learned	Moderator Keith Marsolo Panel Dana Dailey Shruti Gohil Corita Grudzen	<i>Learn about issues encountered with EHR integration, data extraction, and data quality</i> <i>Share ways to mitigate data-related challenges, such as cleaning as you go and strong investigator–analytic team collaborations</i>
10:00 – 11:00 a.m.	Networking		<i>Core leaders available for 1:1 discussions</i>
11:00 a.m. – 12:00 p.m.	Expanding the ePCT Ecosystem to Better Serve Minoritized Communities	Moderator Cherise Harrington Panel Eliseo Pérez-Stable Stephanie Fitzpatrick Sebastian Tong	<i>Discuss the increasing burden on minoritized communities and health systems serving them</i> <i>Review the makeup of NIH Collaboratory Trial sites (academic medical centers, community hospitals, etc.) and explore how to expand the types</i>
AFTERNOON SESSION: FOCUS ON SEASONED TRIALS – PLANNING FOR THE FUTURE			
12:00 – 12:15 p.m.	Box Lunch		<i>New trial investigators may depart</i>
12:15 – 1:00 p.m.	Building and Sustaining Reusable Infrastructure for ePCTs	Moderator Christine Goertz Panel Julie Fritz Greg Simon Lynn DeBar	<i>Describe reusable infrastructure being used to promote ePCTs outside the NIH Collaboratory</i> <i>Explore different models for sustaining infrastructure for ePCTs</i>
1:00 – 1:30 p.m.	Exploring the Generative Investment of an ePCT for Catalyzing Research	Moderator Greg Simon Panel Susan Huang Natalia Morone Jon Tilburt	<i>Discuss elements of research platforms in NIH Collaboratory Trials most at risk of dissipating and needing to be rebuilt for future research</i> <i>Describe which elements could be reused (e.g., relationships, teams, interventions, EHR/IT systems)</i>
1:30 – 2:00 p.m.	Planning Effectively for Posttrial Activities	Moderator Hayden Bosworth Panel Shruti Gohil Corita Grudzen Stacy Sterling	<i>Discuss preparing for dissemination and sustainment or de-implementation before results are known; describe considerations for when and how to share results with partners and the public</i> <i>Learn ways to share trial tools more widely, and explore Dissemination and Implementation RO1s</i>
2:00 – 2:30 p.m.	How to Transition to the Next Research Opportunity	Moderator Rich Platt Panel Lynn DeBar Mike Ho Angelo Volandes	<i>Share insights from NIH Collaboratory Trials that informed subsequent pragmatic trials</i> <i>Learn which aspects investigators preserved in subsequent trials, and which aspects they discontinued or added</i>

DAY 2: MAY 10, 2024

WHEN	TOPIC	WHO	GOALS
2:30 – 2:40 p.m.	Closing Remarks Adjourn	Wendy Weber Lesley Curtis	<i>Highlight key lessons learned and describe next steps for the program</i>