NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Steering Committee Meeting

May 16-17, 2023

Congressional Ballroom, Bethesda Marriott

Agenda

Meeting Purpose

Day 1: Learn about key issues in health equity and implementation science; hear about and foster cross-Core collaboration; provide time for networking; hear from the newest Demonstration Projects; share challenges and lessons learned from the UH3 Demonstration Projects. Day 2: Hear from the FDA; have a rich discussion on data sharing and practices; share challenges and lessons learned from the UH3 Demonstration Projects; and learn about the next steps for the NIH Pragmatic Trials Collaboratory.

DAY 1 MAY 16, 2023 CONGRESSIONAL BALLROOM, BETHESDA MARRIOTT			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:15 a.m.	**Welcome** **Opening Remarks** **Introductions**	Helene Langevin Lesley Curtis	*Meeting goals and expectations* *Introductions*
8:15 – 8:35 a.m.	**Keynote: Implementation Science**	David Chambers	*Hear about the role of implementation science in ePCTs.*
8:35 – 9:20 a.m.	**Focus on Implementation Science: Insights From Trials**	**Moderator** Devon Check **Panel** Hayden Bosworth Lynn DeBar Vince Mor	*Hear from the Demonstration Projects about intervention implementation/ delivery challenges. Discuss pitfalls and barriers in the delivery of the intervention.* *Understand how the Implementation Science Core can help mitigate some of the challenges and facilitate next steps.*
9:20 – 10:05 a.m.	**Focus on Implementation Science: Intervention Delivery Complexity and the Collaboratory Tool**	**Moderator** Steven George **Speaker** Lindsay Ballengee **Panel** Angelo Volandes Vince Mor	*Introduce the intervention complexity tool. Understand how intervention complexity can impact the ability to get results.* *Identify what can be done differently to reduce complexity and the next steps in tool development.* *Hear from Projects (ACP COVID and PROVEN) that have used the tool and lessons learned.*

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10:05 – 10:35 a.m.	**Cross-Core Collaborations**	**Moderator** Kevin Weinfurt **Panel** Rosa Gonzalez-Guarda Keith Marsolo Emily O'Brien Greg Simon Jeremy Sugarman	*Learn about the cross-Core collaborations among the Ethics & Regulatory, Electronic Health Records, Biostatistics and Study Design, Patient-Centered Outcomes, Health Care Systems Interactions, Implementation Science, and Health Equity Cores.*
10:35 a.m. – 12:00 p.m.	**Breakout and Networking Time**		
12:00 – 12:30 p.m.	**Lunch and Report Back**		*During lunch there will be an opportunity for participants to report back from the networking sessions.*
12:30 – 1:15 p.m.	**Keynote: Focus on Health Equity**	Eliseo J. Pérez-Stable	*Discuss national priorities for improving health equity. Describe principles and opportunities for integrating a health equity lens throughout the research life cycle.*
1:15 – 2:00 p.m.	**Panel Discussion**	**Moderator** Rosa Gonzalez-Guarda **Panel** Julie Fritz Mike Ho Corita Grudzen	*Discuss experiences bringing a health equity lens into ePCTS.*
2:00 – 3:00 p.m.	**Focus on Health Equity: The ePCT Landscape/Ecosystem (5-8 min presentations)** **Overview From:** • Patient-Centered Outcomes Research Institute (PCORI) • Pain Management Collaboratory (PMC) • IMPACT Collaboratory • Mental Health Research Network (MHRN) **Moderated Discussion (25 min)**	**Moderator** Cherise Harrington **Panel** Anne Trontell Diana Burgess Ana Quiñones Greg Simon	*Identify what national programs and initiatives are doing to improve health equity.* *Discuss best practices for engaging minoritized and other underrepresented communities to improve health equity.* *Examine the impact of these initiatives and how lessons are disseminated across different stakeholder groups.*
3:00 – 3:15 p.m.	**Break**		*Core leaders are available for one-on-one discussions to follow up on any issues or topics from the Demonstration Projects.*
3:15 – 3:40 p.m.	**Discussion From New Demonstration Project (25 min including Q&A)** INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for	Shruti Gohil Rich Platt	*Project abstracts, data sharing plans, and barriers scorecards are in the meeting e-binder.* *Update on lessons learned from Year 1, ongoing transition issues, sustainability for the UH3 phase, and any challenges (6-8 slides). Discussion of data sharing*

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	Patients (INSPIRE)		*plans (2-4 slides).*
3:40 – 4:50 p.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned From the UH3s** **10 min per project including Q&A:** • Improving Chronic Disease Management with Pieces (ICD-Pieces) • Primary Palliative Care for Emergency Medicine (PRIM-ER) • Guiding Good Choices for Health (GGC4H): Testing Feasibility and Effectiveness of Universal Parent-Focused Prevention in Three Healthcare Systems • Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly (ACP PEACE) • Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis (HiLo) • Implementation of the American College of Physicians Guideline for Low Back Pain (IMPACt-LBP) • Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)	Miguel Vazquez Corita Grudzen Stacy Sterling James Tulsky Angelo Volandes Hrishikesh Chakraborty Christine Goertz Adam Goode Jon Lurie Hrishikesh Chakraborty Mike Ho Sheana Bull	*Project abstracts, data sharing plans, and barriers scorecards are in the meeting e-binder.* ***Each UH3 Demonstration Project presentation should focus on the following:*** 1. *Brief overview/status update (1-2 slides)* 2. *Discuss the top barriers/challenges (1-2 slides)* 3. *Provide a recent generalizable lesson learned (1-2 slides)* 4. *Plan for data sharing (1-2 slides)*
4:50 – 5:05 p.m.	**Closing Remarks/Adjourn**	Wendy Weber Lesley Curtis	*Summary of Day 1*
5:30 – 7:00 p.m.	**Reception** **Location: *Dirksen***		*Networking* *Team-building activities*

DAY 2 MAY 17, 2023 CONGRESSIONAL BALLROOM, BETHESDA MARRIOTT			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:15 – 8:30 a.m.	**Welcome** **Opening Remarks** **Introductions**	Wendy Weber Lesley Curtis	*Meeting goals and expectations* *Introductions*
8:30 – 10:00 a.m.	**Clinical Decision Support Software in ePCTs—FDA and Regulatory Perspectives**	**Setting the Stage** Adrian Hernandez **FDA** Matt Diamond Sonja Fulmer **Ethics/Regulatory Perspective** Pearl O'Rourke Jeremy Sugarman **Moderator** Greg Simon	*Describe case studies from the Collaboratory and beyond illustrating challenges with clinical decision support software.* *Hear from the FDA about the newly released guidance on clinical decision support software and the associated considerations and opportunities for ePCTs.* *Hear about regulatory, ethical, and IRB considerations related to evaluation of clinical decision support tools.* *Hear about considerations related to evaluation of clinical decision support tools from the perspective of ePCT trialists.*
10:00 – 10:15 a.m.	**Break**		*Core leaders are available for one-on-one discussions to follow up on any issues or topics from the Demonstration Projects.*
10:15 – 10:35 a.m.	**NIH and Other Requirements for ClinicalTrials.gov Reporting**	Stacey Arnold	*Learn about requirements for registering and reporting the results of clinical trials to ClinicalTrials.gov.* *Hear about efforts to modernize the ClinicalTrials.gov and Protocol Registration and Results System (PRS) databases.* *Review PRS options for data entry for ePCTs and discuss ways to address issues that arise in reporting.*
10:35 – 11:00 a.m.	**What's New With Data Sharing and Repositories**	Taunton Paine	*Hear from the NIH about the new data sharing policy that was released in January 2023. Learn the changes and exceptions, noting that all new NIH Pragmatic Trials Collaboratory and all PRISM projects will be required to share data.* *Learn from the NIH various data sharing options and suggested criteria for identifying a data repository for your study.*

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11:00 – 11:25 a.m.	**Clarifying Different Scientific Goals and Resources Needed for Data Sharing Based on Collaboratory Experiences**	Keith Marsolo	*Discuss the different scientific goals that motivate data sharing.* *Discuss the resources needed to achieve each of the goals.* *Describe early Collaboratory experiences in the use of shared data.*
11:25 – 11:50 a.m.	**Lightning Round—Sharing Results With Patients and Participants**	**Moderator** Kevin Weinfurt **Panel** Emily O'Brien Lynn DeBar Natalia Morone	*Hear about approaches to sharing results with participants and community stakeholders.*
11:50 a.m. – 1:00 p.m.	**Lunch**		
1:00 – 1:20 p.m.	**Lessons on Data Sharing From the HEAL Bioethics Supplement**	Stephanie Morain	*Discuss ethical issues associated with data sharing, including lessons learned from the Bioethics Supplement.*
1:20 – 1:45 p.m.	**How Do We Drive Change in the Incentive Structure to Promote Data Sharing?**	Adrian Hernandez	*Discuss incentives for data sharing including those for researchers, clinicians, and healthcare system leaders.* *Discuss how to improve patient understanding of the importance of data sharing and encourage participation.*
1:45 – 2:30 p.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned From the UH3s** **15 min per project including Q&A:** • Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction) • Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics (BeatPain Utah) • Fibromyalgia TENS in Physical Therapy Study (FM-TIPS)	Lynn DeBar Andrea Cook Julie Fritz Kathleen Sluka	*Project abstracts, data sharing plans, and barriers scorecards are in the meeting e-binder.* ***Each UH3 Demonstration Project presentation should focus on the following:*** 1. *Brief overview/status update (1-2 slides)* 2. *Discuss the top barriers/ challenges (1-2 slides)* 3. *Provide a recent generalizable lesson learned (1-2 slides)* 4. *Plan for data sharing (1-2 slides)*

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2:30 – 2:45 p.m.	**Break**		
2:45 – 3:30 p.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned from the UH3s** **15 min per project including Q&A:** • Non-pharmacological Options in postoperative Hospital-based And Rehabilitation pain Management (NOHARM) • Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting (OPTIMUM) • Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain (GRACE)	Andrea Cheville Jon Tilburt Natalia Morone Ardith Doorenbos	*Project abstracts, data sharing plans, and barriers scorecards are in the meeting e-binder.* ***Each UH3 Demonstration Project presentation should focus on the following:*** 1. *Brief overview/status update (1-2 slides)* 2. *Discuss the top barriers/ challenges (1-2 slides)* 3. *Provide a recent generalizable lesson learned (1-2 slides)* 4. *Plan for data sharing (1-2 slides)*
3:30 – 4:00 p.m.	**Closing Remarks/Adjourn**	Wendy Weber Lesley Curtis	*Summarize the meeting and highlight key lessons learned. Discuss next steps for the Collaboratory.*