NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Kick-Off/Steering Committee Meeting
May 14-15, 2018
Congressional Ballroom, Bethesda Marriott
Pooks Hill Road

Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions Workshop
May 16, 2018
Congressional Ballroom, Bethesda Marriott
Pooks Hill Road

Agenda

Meeting Purpose

Day 1: Welcome the new UG3 Demonstration Projects; provide introductions, an overview of the Collaboratory, and an understanding of the Core Working Groups; and discuss lessons learned, data sharing, and current ethics and regulatory issues. Day 2: Celebrate the Collaboratory's progress; kick off the next 5 years; receive updates from the Core Working Groups; and hear about the top barriers/challenges and lessons learned from the UH3s. Day 3: Intensive workshop to start discussions on embedded A vs. B pragmatic clinical trials.

DAY 1 MAY 14, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:20 a.m.	**Welcome** **Opening Remarks** **Introductions**	*David Shurtleff* *Richard Hodes* *Lesley Curtis*	*Meeting goals and expectations* *Introductions*
8:20 – 8:30 a.m.	**Overview of a Cooperative Agreement**	*Wendy Weber*	*Discuss what it means to be part of a cooperative agreement. Reinforce the idea of identifying and openly discussing issues and challenges with this community.*

DAY 1 MAY 14, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:30 – 9:15 a.m.	**Overview of the NIH HCS Research Collaboratory Program**	*David Shurtleff* *and* *Panel of Directors* *Richard Hodes* *Wilson Compton* *David Murray* *Bill Riley* *Gary Gibbons* *Rob Star*	*Learn about the NIH HCS Research Collaboratory.* *Look at innovative thinking about embedded pragmatic clinical trials (ePCTs).* *Panel discussion with new Institute and Center Directors and Leadership on how the new projects fit within the portfolio.*
9:15 – 9:45 a.m.	**Questions and Answer Session**		
9:45 – 10:30 a.m.	**Collaboratory Coordinating Center Overview and Goals**	*Adrian Hernandez*	*Overview of the coordination of the Coordinating Center* *How do projects work with the Coordinating Center?* *Lessons learned*
10:30 – 10:45 a.m.	**Break**		
10:45 – 11:15 a.m.	**Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials**	*Jonathan McCall*	*Overview of the Living Textbook, participation in the content development, and sustainability of the resource.*
11:15 a.m. – 12:00 p.m.	**Policies and Guidance Documents** • NIH Collaboratory Data Sharing Policy and Considerations • Publications and Products Process • Data Quality	*Adrian Hernandez* *Eric Larson* *Rachel Richesson*	*Provide a review of the Collaboratory policies and guidance documents.*
12:00 – 12:30 p.m.	**Brief High-Level Overview From New UG3 Demonstration Projects** • 6 projects **5 min each**	*Michael Ho* *Corita Grudzen* *Rico Catalano* *Ted Melnick* *James Tulsky* *Myles Wolf*	*Provide a brief overview of the projects in preparation for the breakout sessions.* *More detailed review of the projects with discussion on Day 2.* *Project abstracts are in the packets.*
12:30 – 1:30 p.m.	**Lunch**		

DAY 1 MAY 14, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
1:30 – 4:45 p.m.	**Breakout Sessions** **25 min for discussion and 5 min for rotation**	*See breakout schedule*	*One-on-one discussions with the new UG3 projects and the Collaboratory Core teams.* *Discuss engagement with the UG3 PIs and identified areas of focus for the project.*
4:45 – 5:00 p.m.	**NIH and Other Requirements for ClinicalTrials.gov Reporting**	*Deborah Zarin*	*Discuss data sharing from the NIH's perspective.*
5:00 – 5:30 p.m.	**Results Reporting of ePCTs**	*Adrian Hernandez*	*Discuss what information should be reported in an ePCT results publication, including details about the health systems data and analytic methods used. Discuss getting results out.*
5:30 – 6:00 p.m.	**Distributed Research Network Query Capabilities**	*Rich Platt* *Lesley Curtis*	*Provide a brief update on the history of the DRN, discuss the current and planned capabilities and use of the DRN.*
6:00 – 6:15 p.m.	**Closing Remarks**	*David Shurtleff* *Richard Hodes* *Lesley Curtis*	*Summarize Day 1*
6:15 – 8:30 p.m.	**Reception and Dinner** **Location: Hart/Dirksen/Russell Rooms** **Directly across from the Main Ballroom**	*Collaboratory Family Feud and Activities* *Timeline Slides*	

DAY 2 MAY 15, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:20 a.m.	**Welcome** **Opening Remarks**	*David Shurtleff* *Richard Hodes* *Lesley Curtis*	*Meeting goals and expectations* *Review from Day 1*
8:20 – 8:30 a.m.	**Common Fund Discussion**	*James Anderson*	*Provide an overview of the Common Fund with Phase 2 impressions from Common Fund colleagues.*

DAY 2 MAY 15, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**

8:30 – 9:15 a.m.	**Landscape of National ePCT Initiative**
	10 min per initiative
	• Overview from:
	  ○ Patient-Centered Outcomes Research Institute (PCORI)
	  ○ National Institutes of Health (NIH)
	  ○ Veterans Affairs (VA)
	• Q&A (15 min)
		Anne Trontell
		Cathy Meyers
		Ryan Ferguson
			Hear from representatives from PCORI, NIH, and the VA on how these initiatives are promoting ePCTs and future directions.

9:15 – 9:30 a.m.	**Health Systems Engagement Issues and Lessons Learned from the Health Care Systems Interactions Core**	*Eric Larson*	*Present unique issues for ePCTs working in dynamic delivery systems where research may not be first priority, lessons learned, and how to achieve shared aspirations of true learning health systems.* *Examples include: changes in leadership, challenges involving electronic health records, and constancy of changes in strategy and local markets.*
9:30 – 10:00 a.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned** **10 min per project** • A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS]) • Improving Chronic Disease Management with Pieces (ICD-Pieces™) • Pragmatic Trial of Video Education in Nursing Homes (PROVEN)	*Doug Zatzick* *Miguel Vazquez* *Vincent Mor*	*Project abstracts and updated barriers scorecards are in the packets.* *<u>Each UH3 Demonstration Project presentation will identify the following</u>:* 1. *The current top barriers/ challenges* 2. *A recent generalizable lesson learned* 3. *One thing you know now that you wish you knew when you started your project* 4. *What advice would you give to the new UG3 projects?* 5. *What have you learned or gained through the Collaboratory program that you would not have gotten elsewhere?*

DAY 2 MAY 15, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
10:00 – 10:15 a.m.	**Break**		
10:15 – 11:15 a.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned** **10 min per project** • Collaborative Care for Chronic Pain in Primary Care (PPACT) • Strategies and Opportunities to Stop Colon Cancer in Priority Populations (STOP CRC) • Active Bathing to Eliminate (ABATE) Infection • Suicide Prevention Outreach Trial (SPOT) • Lumbar Imaging with Reporting of Epidemiology (LIRE) • Time to Reduce Mortality in End-Stage Renal Disease (TiME)	*Lynn DeBar* *Bev Green* *Susan Huang* *Greg Simon* *Jerry Jarvik* *Laura Dember*	*Project abstracts and updated barriers scorecards are in the packets.* *<u>Each UH3 Demonstration Project presentation will identify the following</u>:* 1. *The current top barriers/ challenges* 2. *A recent generalizable lesson learned* 3. *One thing you know now that you wish you knew when you started your project* 4. *What advice would you give to the new UG3 projects?* 5. *What have you learned or gained through the Collaboratory program that you would not have gotten elsewhere?*
11:15 a.m. – 12:15 p.m.	**Discussion From New UG3 Demonstration Projects** • 2 projects **30 min each** *(15-min overview/status and 15-min discussion)* • Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge) • Primary Palliative Care for Emergency Medicine (PRIM-ER)	*Michael Ho* *Sheana Bull* *Corita Grudzen*	*Provide an overview of the project followed by Q&A.* • *Barriers Scorecard* • *Data Sharing Barriers* *Project abstracts and data sharing plans are in the packets.*
12:15 – 1:30 p.m.	**Lunch**		

DAY 2 MAY 15, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
1:30 – 3:30 p.m.	**Discussion From New UG3 Demonstration Projects** • 4 projects **30 min each** *(15-min overview/status and 15-min discussion)* • Parents, Pediatricians, and Prevention: Pathways to Adolescent Health (P4TH) • Pragmatic Trial of User-Centered Clinical Decision Support to Implement EMergency Department-Initiated BuprenorphinE for Opioid Use Disorder (EMBED) • 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)	*Rico Catalano* *Stacy Sterling* *Margaret Kuklinski* *Ted Melnick* *James Tulsky* *Angelo Volandes* *Myles Wolf*	*Provide an overview of the project followed by Q&A.* • *Barriers Scorecard* • *Data Sharing Barriers* *Project abstracts and data sharing plans are in the packets.*
3:30 – 3:45 p.m.	**Break**		
3:45 – 4:15 p.m.	**CMS Quality Measures**	*Reena Duseja*	*Discuss how the intersection of CMS measures would work with ePCTs.*
4:15 – 5:00 p.m.	**Lessons Learned From Core Groups** **15 min per Core Group** • Biostatistics and Study Design • Electronic Health Records • Regulatory/Ethics	*Liz DeLong* *Greg Simon* *Rachel Richesson* *Adrian Hernandez*	*Discuss generalizable knowledge created out of the Cores, how it can be used, and future work of the Cores.* *Provide lessons learned from the Core Working Groups* *Each Core Working Group will discuss the following:* 1. *What do you view as the biggest impact of your Core to date?* 2. *What do you view as important for the Core to tackle going forward?*

DAY 2 MAY 15, 2018 Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
5:00 – 5:45 p.m.	**Data Sharing Principles and Lessons Learned**	*Greg Simon*	*Discuss Collaboratory principles for data sharing across the Demonstration Projects.* *Discuss lessons learned around data sharing.*
5:45 – 6:00 p.m.	**Closing Remarks/Adjourn**	*David Shurtleff* *Richard Hodes* *Lesley Curtis*	*Summarize the meeting.*
6:00 – 8:00 p.m.	*Dinner on your own*		

DAY 3 MAY 16, 2018 Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions Workshop Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:10 a.m.	**Welcome and Introduction**	*David Shurtleff* *Richard Hodes* *Catherine Meyers* *Wendy Weber*	*Meeting goals and expectations* *An intensive workshop to start discussions on embedded A vs. B pragmatic clinical trials. The workshop aims to inform research funders and investigators on progress in NIH-funded ePCTs, and discuss strategies for planning future trials that can make a difference and readily bridge the gap between evidence, practice, and policy.*
8:10 – 8:30 a.m.	**KEYNOTE SPEAKER**	*Michael Lauer*	
8:30 – 9:30 a.m.	**Partnering With Stakeholders to Conduct Embedded A vs. B Trials: Keys to Success** **Responder**: *Michael Lauer*	*Moderator:* *Rich Platt* *Panelists:* *Steve Friedhoff* *Kenneth Sands* *Joseph Chin*	*Presenters will share approaches for overcoming local or system barriers to conducting embedded A vs. B trials (e.g., governance, formulary controls, supply chain, health system return on investment) and review strategies for effectively partnering with various stakeholders to conduct these trials.*

DAY 3 MAY 16, 2018 Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions Workshop Congressional Ballroom, Bethesda Marriott			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
9:30 – 10:30 a.m.	**Examples in Action: Embedded A vs. B Trials**	*Moderator:* *Beverly Green* *Panelists:* *Ryan Ferguson* *Susan Huang* *Michael Kappelman*	*Investigators will present examples of ongoing embedded A vs. B trials, including individually randomized trials, cluster randomized trials in which clinicians or practices agree to be randomized, and cluster randomized trials in which randomization of formularies or supply chains is used to effect randomization. Presenters will identify major challenges and suggestions for overcoming obstacles. The examples will highlight opportunities for ePCTs to occur successfully in various healthcare settings and within the current regulatory framework.*
10:30 – 10:45 a.m.	**Break**		
10:45 – 11:35 a.m.	**Maximizing the Pragmatic: Understanding Approaches to Design of Embedded A vs. B Trials**	*Moderator:* *Greg Simon* *Panelists:* *Scott Solomon* *Rachael Fleurence* *Kourtney Davis*	*The presentation will show examples of ePCTs that serve as examples for further integration within health systems leveraging methodologies and randomization schemes that can work for a variety of health plans or health systems such as individual, cluster practice, payer, formularies, or co-pays.*
11:35 a.m. – 12:45 p.m.	**Regulatory Aspects of Clinical Research and the Regulation of Products for Embedded A vs. B Pragmatic Trials**	*Moderator:* *Adrian Hernandez* *Panelists:* *Jacqueline Corrigan-Curay* *Owen Faris* *Julie Kaneshiro*	*What are the FDA considerations for assessing the ratio of benefits to risks? What are the approaches for embedded studies, especially around safety (knowns, unknowns)? What are the CDRH/CDER policy-level considerations for doing ePCTs?*
12:45 – 1:45 p.m.	**Lunch**		

DAY 3
MAY 16, 2018
Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions Workshop
Congressional Ballroom, Bethesda Marriott

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
1:45 – 3:00 p.m.	**Ethical and IRB Approaches for a Successful Embedded A vs. B Pragmatic Trials**	*Moderator:* *David Wendler* *Panelists:* *Barbara Bierer* *Spencer Hey* *Judith Carrithers*	*This session will focus on the changes to the Common Rule, IRB considerations, the use of a single IRB, and how these impact ePCTs.*
3:00 – 4:00 p.m.	**Summary Expert Panel Discussion**	*Moderator:* *Cathy Meyers* *Panelists:* *Adrian Hernandez* *Rich Platt* *Beverly Green* *Greg Simon* *Dave Wendler*	
4:00 – 4:15 p.m.	**Concluding Remarks**	*Adrian Hernandez* *Rich Platt*	