NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Steering Committee Meeting
May 1, 2019
Doubletree Bethesda

Design & Analysis of Embedded Pragmatic Clinical Trials Workshop
May 2, 2019
Lister Hill Auditorium, NIH Campus

Agenda

Meeting Purpose

Day 1: Discuss progress and sustainability of the NIH Collaboratory, hear perspectives on the landscape of ePCTs and the need for real-world evidence, hear about challenges and lessons learned from the UH3 Demonstration Projects, get updates on progress and transition plans from the UG3 Demonstration Projects, discuss data sharing policy and planning, and conduct one-on-one consultations with representatives from the Core Working Groups. Day2: Intensive workshop to start discussions on statistical issues with ePCTs.

DAY 1 MAY 1, 2019			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:15 – 8:30 a.m.	**Welcome** **Opening Remarks** **Introductions**	David Shurtleff Helene Langevin Richard Hodes Lesley Curtis	*Meeting goals and expectations* *Introductions*
8:30 – 9:10 a.m.	**KEYNOTE PANEL**	**Moderator** Catherine Meyers **Panel** NIH: Richard Hodes FDA: Jacqueline Corrigan-Curay CMS: Joseph Chin Implementation Science: Danny Almirall	*Stakeholders discuss perspectives on generating real-world evidence and the importance of conducting ePCTs for knowledge dissemination and implementation* ***Includes time for Q&A***
9:10 – 10:10 a.m.	**Looking at the Landscape of ePCTs**	PCORI: Anne Trontell, PCORI NIH-DoD-VA Pain Management Collaboratory: Robert Kerns HEAL Initiative: Wendy Weber	*Learn about the work of other ongoing pragmatic trial programs* ***Includes time for Q&A***

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DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
10:10 – 10:40 a.m.	**Break/Core Representative Consultations**	Eric Larson Liz DeLong Rachel Richesson Judith Carrithers	*Core Leaders are available for one-on-one discussions to follow up on any issues or topics from the Demonstration Projects.*
10:40 – 11:30 a.m.	**Top Barriers/Challenges and Recent Generalizable Lessons Learned from the UH3s** **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) • Suicide Prevention Outreach Trial (SPOT) • Lumbar Imaging with Reporting of Epidemiology (LIRE)	Doug Zatzick Miguel Vazquez Vincent Mor Susan Mitchell Angelo Volandes Greg Simon Jerry Jarvik	*Project abstracts and updated barrier scorecards are in the meeting packet* ***Each UH3 Demonstration Project presentation will identify the following:*** *1. The current top barriers/ challenges* *2. A recent generalizable lesson learned*
11:30 – 11:45 a.m.	**Collaboratory's Review of Experiences with Manuscript Submissions**	Devon Check	*Hear about issues encountered by the Demonstration Projects during journal peer review and share the Collaboratory's plan for investigating these empirically*
11:45 a.m. – 12:30 p.m.	**Data Sharing Plans**	Adrian Hernandez Wendy Weber	*Briefly discuss the current data sharing policy of the NIH Collaboratory and review the data and resource sharing information created by the CC to assist with the development of data sharing plans*
12:30 – 1:30 p.m.	**Lunch**		

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DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
1:30 – 2:15 p.m.	**Lessons Learned Completed ePCTs**	Lynn DeBar Laura Dember Susan Huang Bev Green	*Celebrate the completion of some of the Demonstration Projects and hear about lessons learned and experiences from the full lifecycle of an ePCT* ***Includes time for Q&A***
2:15 – 3:45 p.m.	**Discussion From New UG3 Demonstration Projects** **15 min per project** • Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge) • Primary Palliative Care for Emergency Medicine (PRIM-ER) • Pragmatic Trial of Parent-Focused Prevention in Pediatric Primary Care: Implementation and Adolescent Health Outcomes in Three Health Systems (GGC4H: Guiding Good Choices for Health) • 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	Michael Ho Corita Grudzen Rico Catalano Stacy Sterling Margaret Kuklinski Ted Melnick Gail D'Onofrio James Tulsky Angelo Volandes Myles Wolf	*Project abstracts, data sharing plans and barrier scorecards are in the meeting packet* *Update on lessons learned from Year 1, ongoing transition issues, sustainability for the UH3 phase and any challenges* *Discussion about the current data sharing plans for the UG3s, addressing the following:* 1. *What is your current data sharing plan and do you foresee any obstacles?* 2. *What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent?* 3. *How will you put the policy from the data sharing work group into practice in your study?* 4. *What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?*

DAY 1 MAY 1, 2019			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
	Patients Undergoing Hemodialysis (HiLo)		
3:45 – 4:15 p.m.	**Break/Core Representative Consultations**	Eric Larson Liz DeLong Rachel Richesson Judith Carrithers	*Core Leaders are available for one-on-one discussions to follow up on any issues/topics from the Demonstration Projects.*
4:15 – 4:45 p.m.	**Review of Lessons Learned/ Milestones from the Collaboratory and Sustainability of the Collaboratory**	Adrian Hernandez	*Update on lessons learned/milestones from the Coordinating Center and start discussion on the long-term sustainability of the Collaboratory*
4:45 – 5:00 p.m.	**Closing Remarks/Adjourn**	David Shurtleff Helene Langevin Richard Hodes Lesley Curtis	*Summary of Day 1 meeting*

DAY 2 MAY 2, 2019 Design & Analysis of Embedded Pragmatic Clinical Trials Workshop NIH Lister Hill Auditorium			
DURATION	**AGENDA TOPIC**	**WHO**	**GOAL/DELIVERABLE**
8:00 – 8:10 a.m.	**Welcome and Introductions**	Helene Langevin Richard Hodes Catherine Meyers Wendy Weber	*Workshop goals and expectations* *Introductions*
8:10 – 8:40 a.m.	**Keynote**	David Murray	
8:40 – 10:15 a.m.	**Panel 1** **Measurement and Data: Outcomes, Exposures, and Subgroups Based on EHR Data**	**Moderator** Rui Wang **Panel** • PROVEN: Vince Mor/ Roee Gutman • STRIDE: Nancy Latham/Dave Ganz /Peter Peduzzi • ABATE: Susan Huang/ Ken Kleinman	*Discussion of issues in how to measure the outcome variable and whether the error in measuring the outcome variable is correlated with the true response to the intervention. This is particularly important if the source of outcome measurement is from extant data systems, like the EMR or patient ratings made by the staff. in some cases, exposure to the intervention could even sensitize the staff recording diagnoses or symptoms such that they are recorded more assiduously and completely, resulting in more symptoms or problems among the experimental patients relative to the controls. There are many nuances to these issues that will be explored in case examples. Also discussion of outcome measures in the EHR.*
10:15 – 10:30 a.m.	**Break**		
10:30 a.m. – 12:00 p.m.	**Panel 2** **To Cluster or Not to Cluster?**	**Moderator** Keith Goldfeld **Panel** • ICD-Pieces: Miguel Vazquez/Chul Ahn • PPACT: Lynn DeBar/William Vollmer • SPOT: Greg Simon/Susan Shortreed	*Pragmatic trials embedded in health care delivery systems must consider the organizational structure where individual patients are typically nested within providers, clinics, and higher level organizational units. Research design must consider trade-offs associated with elements of intervention delivery and analytical approaches that address the multi-level structure.*

DAY 2
MAY 2, 2019
Design & Analysis of Embedded Pragmatic Clinical Trials Workshop
NIH Lister Hill Auditorium

DURATION	AGENDA TOPIC	WHO	GOAL/DELIVERABLE
12:00 – 1:00 p.m.	**Lunch**		
1:00 – 2:30 p.m.	**Panel 3** **Choosing a Parallel Group or Stepped-Wedge Design**	**Moderator** Fan Li **Panel** • LIRE: Jerry Jarvik/Patrick Heagerty • EMBED: Ted Melnick/Jim Dziura • TSOS: Doug Zatzick/Patrick Heagerty	*Cluster-randomized trials are often limited in the number of clusters available for study, and therefore a variety of design alternatives are considered. One contemporary design is the stepped-wedge that leverages longitudinal follow-up of clusters and allows each cluster to be observed in both intervention and control states.*
2:30 – 4:00 p.m.	**Panel 4** **Unique Complications**	**Moderator** Andrea Cook **Panel** • HiLo: Myles Wolf/Hrishikesh Chakraborty • STOP-CRC: Bev Green/William Vollmer • TiME: Laura Dember/ J. Richard Landis and Jesse Hsu	*Embedded pragmatic clinical trials often encounter challenges that are associated with research embedded in a dynamic delivery system environment. Issues include questions about appropriate consent, strategies for monitoring trials for conduct quality and patient safety, and plans for handling unplanned changes in the research environment.*
4:00 p.m.	**Summary & Concluding Remarks**	Elizabeth Delong Patrick Heagerty Catherine Meyers	