Master Protocol Expert Meeting

FINAL AGENDA
April 20 & 21, 2020

11:15 a.m. - 1:45 p.m. ET
Virtual Meeting

Day 1: CTTI Tool Overview and Follow-Up Activities

Monday, April 20, 11:15 a.m. - 1:45 p.m. ET

Session 1: Review CTTI's pre-planning and planning master protocol tools aimed at building collaboration and consensus across diverse stakeholders

Session 2: In light of COVID-19, discuss what recent master protocol efforts have revealed about the need for ongoing cross-institutional capacity building efforts

Day 2: Master Protocol Pre-Planning and Planning Case Studies

Tues., April 21, 11:15 a.m. - 1:45 p.m. ET

Two case studies will be presented to highlight challenges and lessons learned from two emerging master protocol efforts. **Meeting attendees will be engaged in discussion about strategies to address challenges related to stakeholder engagement, funding, and biomarker discovery and validation.**

Case Study 1: Adaptive Platform to Prevent Early Childhood Stunting in Rwanda: Efforts in Rwanda to combat early childhood stunting pushes experts to think creatively about how to leverage the framework of master protocols to build capacity and infrastructure for health systems in resource-limited countries. The proposed study seeks to assess multiple intervention modalities simultaneously to treat and prevent stunting-resulting in more nimble, comprehensive responses to this major public health challenge in sub-Saharan Africa. Presenters will tie lessons learned from their Rwanda case study to challenges and lessons learned to fight efforts of COVID-19 in LMIC settings.

Case Study 2: Department of Defense PTSD Adaptive Platform Trial: Targeted, efficacious treatments for PTSD are urgently needed for active duty, veteran, and civilian populations. The DOD's adaptive platform trial presents an exciting opportunity to apply a precision medicine approach to deliver optimized treatments to Warfighters, increasing the medical readiness of our Service Members. The rigorous identification and validation of multi-modal treatment-response biomarkers will be critical in this effort and may serve as a model for related psychiatric conditions.

MEETING AGENDA:

APRIL 20, 2020

11:15 a.m.	**Welcoming Remarks**
11:15 a.m.	Introduction to the Clinical Trials Transformation Initiative (CTTI) *Pamela Tenaerts, CTTI*
11:20 a.m.	VeloCTTI Master Protocol Project Overview *Kimberly Fisher, CTTI*
11:25 a.m.	**Session I: CTTI Tool Review**
	Session Facilitator/Moderator: *Kimberly Fisher, CTTI* *Session Objectives*: ▶ Describe core challenges that drove the development of CTTI master protocol project tools ▶ Provide critical feedback on CTTI project tools
11:25 a.m.	Business Development & Partnership Consolidation Strategies *Daniel Millar, Janssen & Abby Bronson, Parent Project Muscular Dystrophy*
11:40 a.m.	Master Protocol Trial Simulation: Components & Communications Considerations *Michelle Detry, Berry Consultants, LLC*
11:50 a.m.	Protocol Development & Vendor Assessment *Marianne Chase, Massachusetts General Hospital*
12:05 p.m.	Large Group Discussion: ▶ How well do CTTI's tools address early adopters' needs? ▶ Are there critical challenges in the pre-planning and planning stages of a master protocol study's development that CTTI's tools do not address? ▶ How should the clinical trials research community facilitate future opportunities for early adopters to collaborate and problem-solve with more experienced master protocol experts?
12:25 p.m.	**Break**

12:30 p.m. **Panel Discussion: Leveraging Master Protocol Studies to Combat COVID 19**

Session Facilitator/Moderator: Daniel Millar, Janssen

Session Objectives:

- Describe master protocol studies that are being conducted in response to COVID-19
- Identify study-level and enterprise-level resources that are needed to support the efficient use of master protocol studies to develop treatments for COVID-19

Panelists:

Louis Dron, Cytel
Nicholas Richardson, CDER, FDA
Kirsty Wydenbach, MHRA
Derek Angus, University of Pittsburgh
Christopher Butler, University of Oxford

1:15 p.m. Large Group Discussion

- How should master protocol studies be leveraged to combat COVID-19?
- What are specific resources that CTTI should develop to support the efficient development of master protocol studies in response to COVID-19

1:45 p.m. **Day 1 Adjourned**

April 21, 2020

11:15 a.m. Day 2 Overview

11:15 a.m. *Session Facilitator/Moderator: Kimberly Fisher, CTTI*

- Review key takeaways from Day 1
- Review Objectives of Day 2

11:20 a.m. Early Adopters Case Studies

Session Facilitator/Moderator: Abby Bronson, Parent Project Muscular Dystrophy

Session Objectives:

- Apply CTTI tools to the development of real-world master protocol that are at the pre-planning and planning stages of study development
  - Panelists who participated in the Early Adopters Panel will provide case material
- Identify necessary revisions to CTTI tools to make them more responsive to the unique design and operational challenges identified in diverse therapeutic areas.

11:20 a.m. **Case Study 1:** Adaptive Multi-Arm, Multi-Stage Platform Trial to Prevent Early Childhood Stunting in Rwanda
Jay Park, Cytel

11:50 a.m. Case Study 1 Large Group Discussion

12:20 p.m. Break

12:25 p.m. **Case Study 2:** Department of Defense PTSD Adaptive Platform Trial
Elyse Katz & Kim del Carmen, DoD

12:50 p.m. Case Study 2 Large Group Discussion

1:20 p.m. Closing Comments

Session Facilitator/Moderator : Kim Fisher, CTTI

Session Objectives :

- Review project next steps
- Discuss topics for follow-up May webinar

1:45 p.m. Meeting Adjourned