Master Protocol Studies: Charting Multi-Stakeholder Pathways to Success

October 22 – 23, 2019
Westin Crystal City I 1800 Richmond Highway, Arlington, VA 22202

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- Map the pre-planning, planning, and execution processes of a master protocol trial.
- Strategize solutions to common roadblocks related to the pre-planning, planning, and execution of a master protocol study.
- Identify and prioritize the creation of tools to support the adoption of emerging best practices outlined by CTTI’s roadmap.
8:30 a.m.  Breakfast *(provided)*

9:00 a.m.  Welcoming Remarks & Meeting Overview

9:00 a.m.  Introduction to the Clinical Trials Transformation Initiative (CTTI)  
*Annemarie Forrest, CTTI*

9:10 a.m.  VeloCTTI Master Protocol Project Overview  
*Kimberly Fisher, CTTI*

9:30 a.m.  **Session I: Landscape Review**

*Session Facilitator/Moderator: Kimberly Fisher, CTTI*

*Session Objectives:*

- Review master protocol study landscape review findings
- Discuss multi-stakeholder capacity building efforts

9:30 a.m.  Landscape Review Findings  
*Nicholas Richardson, FDA, CDER*

10:00 a.m.  Multi-Stakeholder, Cross-Institutional Strategies for Change  
*Daniel Millar, Janssen Pharmaceuticals*

10:15 a.m.  Leveraging Master Protocols to Build Local Infrastructure & Technical Capacity for Low & Middle Income Countries  
*Jay Park, MTEK Sciences*

10:30 a.m.  Large Group Discussion

11:00 a.m.  **Break**

11:10 a.m.  **Session II: Building Capacity for Innovation**

11:10 a.m.  *Session Moderator: Abby Bronson, Parent Project Muscular Dystrophy*

*Session Objectives:*

- Explore key lessons learned from established studies that can inform the emerging efforts
- Highlight emerging master protocol efforts in diverse therapeutic areas
- Explore enterprise-level infrastructure development needs to drive the efficient and appropriate use of master protocol studies

Panelists:

-Stacey Adam, FNIH
-Mary Redman, Fred Hutchinson Cancer Center
-Mika Newton, xCures
-Michelle Detry, Berry Consultants, LLC
-Ed Connor, I-ACT for Children

12:15 p.m.  Large Group Discussion

1:00 p.m.  **Lunch (provided)**
1:45 p.m.  **Session III: Small Group Breakout Sessions**

*Session Facilitator/Moderator: Kim Fisher, CTTI*

**Session Objectives:**
- Provide critical feedback on high-level roadmap
- Brainstorm strategies to address common roadblocks outlined in roadmap

2:00 p.m.  **Breakout Session Facilitators**

- Pre-Planning: Jane Perlmutter & Annemarie Forrest, CTTI
- Planning: Marianne Chase, Massachusetts General Hospital & Kimberly Fisher, CTTI
- Execution: Roger J. Lewis, Berry Consultants, LLC & Laura Shannon, CTTI

3:15 p.m.  **Break**

4:45 p.m.  **Large Group Discussion:***

*Facilitator/Moderator: Kimberly Fisher, CTTI*

Quick recap of pre-planning, planning, and execution breakout discussion sessions (5-7 minutes per group)

- Guiding Questions:
  - What are the goals that CTTI should focus on that could advance the development of master protocol studies?
    - Study-level goals
    - Enterprise-level goals
  - What are the strategies to achieve these goals?

5:30 p.m.  **Day 1 Adjourned**

5:30 p.m.  **Cocktails & Hors D'oeuvres**
8:30 a.m.  Session IV: Tool Identification

Session Facilitator/Moderator: Kimberly Fisher, CTTI
Session Objectives:
► Brainstorm and prioritize tools related to challenges and potential strategies discussed during Day 1
► Discuss next steps

Roadmap Strategy Session Instructions
Kimberly Fisher, CTTI

Breakout Session Facilitators
Pre-Planning: Karen Dimick, Genentech & Annemarie Forrest, CTTI
Planning: Gene Vinson, Syneos Health & Kimberly Fisher, CTTI
Execution: Rajeshwari Sridhara, FDA, CDER, & Laura Shannon, CTTI

11:00 a.m.  Large Group Strategy Session:
Facilitator/Moderator: Nicholas Richardson, FDA, CDER
► Quick recap of pre-planning, planning, and execution strategy sessions (5-7 minutes per group)
► Guiding Questions: How well do the tools brainstormed by each breakout group address the considerations discussed in Day 1 of the meeting?
  o Are we on target?
  o What is missing?

11:45 a.m.  Lunch

12:15 p.m.  Session VI: Next Steps & Closing Comments

Session Facilitator/Moderator: Kimberly Fisher, CTTI
Session Objectives:
► Recap of stretch goals:
  o Suggestions for future expert meeting topics
  o Strategies to engage organizations at the pre-planning and planning stages for feedback

1:00 p.m.  Highlights, Next Steps, & Adjourn
Kimberly Fisher, CTTI

For more information, contact the Master Protocol Project Manager, Kimberly Fisher at kimberly.a.fisher@duke.edu, or visit http://www.ctti-clinicaltrials.org.