



# Master Protocol Studies: Charting Multi-Stakeholder Pathways to Success

October 22 – 23, 2019

Westin Crystal City | 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.

## TUESDAY, OCTOBER 22, 2019

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**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**

## WEDNESDAY, OCTOBER 23, 2019

8:00 a.m. **Breakfast** *(provided)*

### 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?
  - Are we on target?
  - 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:
  - Suggestions for future expert meeting topics
  - Strategies to engage organizations at the pre-planning and planning stages for feedback

1:00 p.m. **Highlights, Next Steps, & Adjourn**

*Kimberly Fisher, CTTI*

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*For more information, contact the Master Protocol Project Manager, Kimberly Fisher at [kimberly.a.fisher@duke.edu](mailto:kimberly.a.fisher@duke.edu), or visit <http://www.ctti-clinicaltrials.org>.*