



Embedding Clinical Trials into Clinical Practice

Multi-Stakeholder Expert Meeting Agenda

September 21, 2022

8:30 a.m. – 3:30 p.m. EDT

Hotel Washington, Grand Ballroom, Washington, D.C.

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

MEETING OBJECTIVES:

- ▶ Develop strategies for implementing at least 2 of CTTI's new recommendations into the planning of trials, including trials intended for regulatory review
- ▶ Identify 3 implementation barriers that trial designers and health systems have the power to mitigate
- ▶ Brainstorm relevant metrics to monitor and evaluate implementation of the selected recommendations

MEETING MATERIALS

- ▶ CTTI Recommendations
- ▶ 5 Case Examples of Trials with Embedded Elements

SEPTEMBER 21, 2022

7:30 a.m. **Breakfast** (*Provided*)

8:30 a.m. **Welcoming Remarks**

8:30 a.m. Introduction to the Clinical Trials Transformation Initiative (CTTI)
Sally Okun, CTTI

8:40 a.m. Opening Comments
Janet Woodcock, FDA

9:00 a.m. **Session I: Paving the Way**

Session Facilitator/Moderator: *Lindsay Kehoe, CTTI*

Session Objectives:

- ▶ Review rationale for embedding clinical trial elements into clinical practice
- ▶ Highlight initiatives that are demonstrating integration of research and practice is possible
- ▶ Provide overview of CTTI's project and related tools

9:00 a.m. Integrating Clinical Research and Practice: Perspectives from Groups Paving the Way
ACT@POC – Mark McClellan, Duke Margolis
NIH Collaboratory – Adrian Hernandez, Duke Clinical Research Institute
PROTAS – Martin Landray, University of Oxford
PCORnet – Neely Williams, Community Partners' Linked Network

9:40 a.m. Q&A

9:55 a.m. Trials in Clinical Practice Project Overview
Lindsay Kehoe, CTTI

10:15 a.m. **Break**

10:30 a.m. **Session II: Implementation Workshop**

Session Facilitator/Moderator: *Matthew Roe, AstraZeneca*

Session Objectives:

- ▶ Develop strategies for implementing at least 2 of CTTI's new recommendations into the planning of trials intended for regulatory review
- ▶ Identify 3 implementation barriers that trial designers and health systems have the power to mitigate

10:30 a.m. Break Out Group Workshop
For your trial scenario:

- *What elements of your trial are embedded into clinical practice and how feasible are they to embed?*
- *What are 2-3 pain points with embedding these elements?*
- *Which CTTI recommendation(s) help with embedding the trial elements? Why are they helpful? How would you use the recommendation(s) in planning a trial?*

- *Is there anything in your scenario that you'd change to make integrating elements of your trial more feasible? Explain.*

12:00 p.m. Lunch (Provided)

- 1:00 p.m. Session II Debrief
- *Recap the pain points identified in Session II and potential mitigation approaches*
 - *How can CTTI's recommendations help?*

1:25 p.m. Session III: Developing Metrics of Implementation

Session Facilitator/Moderator: *Morgan Hanger, CTTI*

Session Objectives:

- ▶ *Brainstorm relevant metrics to monitor and evaluate implementation of the design, operational, and cultural recommendations*
- ▶ *Identify ways to drive momentum for embedding trials into practice*

1:25 p.m. Level setting on what is meant by metrics and implementation
Morgan Hanger, CTTI

1:35 p.m. Metrics Development: Break Out Groups
What should CTTI be measuring to understand:
(a) whether change is happening?
(b) whether change is improving quality and efficiency of trials?

2:10 p.m. Afternoon Refreshments (Provided)

- 2:25 p.m. Gaining Momentum
- *What are the measure concepts break out groups identified?*
 - *Beyond our recommendations, dissemination, and measurement efforts, how else can CTTI drive momentum for embedding trials into practice?*
 - *Outside of CTTI, what are some other levers for change across the CTE?*
 - *Who is responsible for those additional levers?*

3:25 p.m. Closing Comments

3:25 p.m. Highlights and Next Steps
Lindsay Kehoe, CTTI

3:30 p.m. Adjourn

For more information, contact the Trials in Clinical Practice Project Manager, Lindsay Kehoe at Lindsay.kehoe@duke.edu, or visit <http://www.ctti-clinicaltrials.org>.