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
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<td>7:30 a.m.</td>
<td><strong>Breakfast</strong> <em>(Provided)</em></td>
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<td>8:30 a.m.</td>
<td><strong>Welcoming Remarks</strong></td>
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| 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**             |
| 9:00 a.m. | 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*  
*NII 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**    |
| 10:30 a.m. | 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](http://www.ctti-clinicaltrials.org).