Embedding Clinical Trials in Health Care Settings

Multi-Stakeholder Expert Meeting Agenda
May 11, 2022
10:30 a.m. – 2:30 p.m. EST
Virtual Event

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

MEETING OBJECTIVES:

► Present findings from project’s evidence generation: in-depth interviews with study designers and implementers
► Refine operational recommendations and resources
► Begin to strategize implementation of operational recommendations and resources

MEETING MATERIALS
► Draft CTTI Recommendations
► 5 Case Examples of Trials with Embedded Elements
10:30 a.m. Welcoming Remarks

10:30 a.m. Introduction to the Clinical Trials Transformation Initiative (CTTI)
Sally Okun, CTTI

10:35 a.m. Session I: Project Overview and Results

10:35 a.m. Trials in Health Care Settings Project Overview and Meeting Objectives
Lindsay Kehoe, CTTI

10:40 a.m. Review of Project’s In-depth Interview Results
Amy Corneli, CTTI

11:00 a.m. Q&A about Interview results

11:15 a.m. Session II: Leveraging Examples to Refine Recommendations

Session Facilitator/Moderator: Lindsay Kehoe, CTTI
Session Objectives:
► Learn from examples of embedded trials
► Identify gaps and refine recommendations

11:15 a.m. Review of Project’s Draft Recommendations
Mark Stewart, Friends of Cancer Research

11:30 a.m. Open Group Discussion about Recommendations
- Are these recommendations clear?
- Where is there too much or not enough information?
- Is there a place where a tool (e.g., a flowchart or checklist) would help to provide needed detail?

11:50 a.m. Break

12:00 p.m. Case Example #1: Recovery
Martin Landray, University of Oxford

12:10 p.m. Case Example #2: I-SPY
Laura Esserman, University of California San Francisco

12:20 p.m. Case Example #3: VA Diuretic Comparison Project
Ryan Ferguson, Department of Veteran’s Affairs

12:30 p.m. Break Out Groups
Each group will help refine the recommendations with a focus on operations, data, technology implementation, or future directions

1:30 p.m. Break

1:40 p.m. Break Out Group Debrief
<table>
<thead>
<tr>
<th>Time</th>
<th>Session III: Strategizing Implementation of Recommendations</th>
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<tbody>
<tr>
<td>1:55 p.m.</td>
<td>Implementation Opportunities</td>
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<td>Kraig Kinchen, Eli Lilly and Company</td>
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<td><strong>Session Objectives:</strong></td>
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<td>▶ Review purpose of recommendations and target audience</td>
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<td>▶ Discuss how best to implement the recommendations</td>
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<td>▶ Explore desired outcome for implementation</td>
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<td>2:00 p.m.</td>
<td>Open Discussion and Poll</td>
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<td>- <em>How do we best communicate the rationale for embedding trials?</em></td>
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<td>- <em>What does success look like?</em></td>
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<td>- <em>Are there trials, in early planning phases, that might benefit from implementation of the recommendations?</em></td>
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**2:25 p.m.**  
**Closing Comments**

**Next Steps and Adjourn**
Lindsay Kehoe, CTTI

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