Decentralized Clinical Trials Expert Meeting
Wednesday, August 25 & Thursday, August 26, 2021
10:30 a.m. – 2:30 p.m. EDT
Virtual Event

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

MEETING OBJECTIVES:
In order to update CTTI’s existing decentralized clinical trials (DCT)* recommendations, this expert meeting seeks to:

► Collect recent knowledge and insights – both what works and what doesn’t – from operationalizing DCT solutions (i.e., remote and virtual visits, using local labs and healthcare providers, and direct-to-participant shipping)

► Understand current practices for incorporating DCT solutions in clinical trials, including considerations for protocol design and safety monitoring

► Identify opportunities to increase adoption of DCT solutions moving forward

*For the purposes of this meeting, DCTs are defined as those executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product is shipped directly to the trial participant).
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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Facilitator</th>
<th>Objectives</th>
<th>Panelists</th>
<th>Discussion</th>
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<tr>
<td>10:30</td>
<td>Welcoming Remarks, Context, &amp; Objectives</td>
<td>Leanne Madre and Zachary Hallinan, CTTI</td>
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<td>10:40</td>
<td>Session I: Regulatory Perspectives &amp; DCT Implementation Post-Pandemic</td>
<td>Pamela Tenaerts, Medable</td>
<td>Understand how regulatory changes during the COVID-19 pandemic supported increased usage of DCT solutions</td>
<td>Lola Fashoyin-Aje, FDA, CDER, Elizabeth Kunkoski, FDA, CDER, Kirstine Moll Harboe, Danish Medicines Agency, Fergus Sweeney, European Medicines Agency</td>
<td>Q&amp;A and General Discussion</td>
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<td>10:45</td>
<td>Panelists:</td>
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<td>11:25</td>
<td>Q&amp;A and General Discussion</td>
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<td>12:10</td>
<td>Break</td>
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<td>12:25</td>
<td>Session II: DCTs &amp; Changing Stakeholder Roles</td>
<td>Linda Coleman, Yale University</td>
<td>Understand how stakeholder roles and experiences are changing in trials using decentralized solutions (telemedicine, direct-to-participant shipping, home health visits, and/or use of local labs and imaging centers)</td>
<td>Theresa Strong, Foundation for Prader-Willi Research, Patricia Larrabee, Rochester Clinical Research, Graham Wylie, Medical Research Network, Tassos Kyriakides, U.S. Department of Veterans Affairs</td>
<td>Q&amp;A and General Discussion</td>
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<td>12:55</td>
<td>Q&amp;A and General Discussion</td>
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<td>1:25</td>
<td>Transition to Breakout Discussions</td>
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1:30 p.m. Breakout Discussions

Session Objectives:
► Discuss considerations for operationalizing DCT solutions from patient, site, and mobile/local HCP perspectives
► Identify associated opportunities for more effectively implementing DCT solutions based on recent experiences, as well as opportunities for continuous feedback/improvement going forward
► Identify opportunities and challenges for the future

Breakout Group Discussions:
Considerations and opportunities for:
► Topic A: Tele-visits
► Topic B: Direct-to-participant shipping
► Topic C: Home health visits
► Topic D: Use of local labs and imaging centers
► Topic E: Safety monitoring in decentralized trials

2:30 p.m. Adjourn Day 1
Welcome: Review Day 1 & Look Ahead to Day 2
Zachary Hallinan, CTTI

Session III: Sponsor Perspectives – What’s Working Now?
Session Facilitator: Megan Doyle, Amgen
Session Objectives:
► Understand from sponsor perspective what works and what doesn’t for specific DCT solutions
► Discuss how to ensure DCT solutions are considered during study design, including as opportunities to streamline trials and reduce participant burden
► Identify considerations for effective and efficient safety monitoring in DCTs

Case Study Presentations
Robert “Joe” Mather, Pfizer
Alma Chavez, Duke Clinical Research Institute
Scott Askin, Novartis

Panel Discussion and Q&A
All case study presenters, joined by:
Adam Hartman, National Institute of Neurological Disorders & Stroke
Isaac Rodriguez-Chavez, ICON

Break (15 minutes)

Breakout Discussions: Designing & Implementing Better DCTs
Session Objectives:
► Collect additional multi-stakeholder input on three overarching questions related to planning trials incorporating DCT solutions

Breakout groups discuss how sponsors are, and should be:
Topic A: Evaluating the costs vs. benefits of DCT solutions given the current state of knowledge
Topic B: Ensuring DCT solutions are considered during the design of clinical trials and patient optionality is maintained
Topic C: Planning for effective and efficient remote study monitoring in trials using DCT solutions

Break

Closing Plenary
Session Facilitator: Zachary Hallinan, CTTI

Adjourn

For more information, contact CTTI’s DCT Update Project Manager, Zachary Hallinan, at zachary.hallinan@duke.edu, or visit http://www.ctti-clinicaltrials.org.