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).*

TUESDAY, AUGUST 25

10:30 a.m. Welcoming Remarks, Context, & Objectives

Leanne Madre and Zachary Hallinan, CTTI

10:40 a.m. Session I: Regulatory Perspectives & DCT Implementation Post-Pandemic

Session Facilitator: Pamela Tenaerts, Medable
Session Objectives:

- Understand how regulatory changes during the COVID-19 pandemic supported increased usage of DCT solutions
- Discuss challenges and opportunities for sustaining and supporting increased usage moving forward

10:45 a.m. Panelists:

Lola Fashoyin-Aje, FDA, CDER
Elizabeth Kunkoski, FDA, CDER
Kirstine Moll Harboe, Danish Medicines Agency
Fergus Sweeney, European Medicines Agency

11:25 a.m. Q&A and General Discussion

12:10 p.m. Break

12:25 p.m. Session II: DCTs & Changing Stakeholder Roles

Session Facilitator: Linda Coleman, Yale University
Session Objectives:

- 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)
- Identify considerations for operationalizing DCT solutions from the patient, site, DCT provider, and health system perspectives
- Discuss challenges and opportunities for future trials

12:25 p.m. Panelists:

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

12:55 p.m. Q&A and General Discussion

1:25 p.m. Transition to Breakout Discussions

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

WEDNESDAY, AUGUST 26

10:30 a.m. Welcome: Review Day 1 & Look Ahead to Day 2

Zachary Hallinan, CTTI

10:40 a.m. 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

10:40 a.m. Case Study Presentations
Robert "Joe" Mather, Pfizer
Alma Chavez, Duke Clinical Research Institute
Scott Askin, Novartis

11:15 a.m. Panel Discussion and Q&A
All case study presenters, joined by:
Adam Hartman, National Institute of Neurological Disorders & Stroke
Isaac Rodriguez-Chavez, ICON

12:15 p.m. Break *(15 minutes)*

12:30 p.m. 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

1:55 p.m. Break

2:00 p.m. Closing Plenary

Session Facilitator: Zachary Hallinan, CTTI

2:30 p.m. Adjourn