

DECENTRALIZED CLINICAL TRIALS UPDATE EXPERT MEETING



EXPERT MEETING SUMMARY | AUGUST 25–26, 2021



BACKGROUND

The Clinical Trials Transformation Initiative (CTTI) recently launched work to ensure its 2018 **Decentralized Clinical Trials (DCT) recommendations** reflect emerging best practices from conducting research in remote and virtual settings, including lessons learned from the COVID-19 pandemic. The revised recommendations will offer current information to the stakeholders across the clinical trials ecosystem on how best to plan and operationalize DCT solutions (i.e., remote and virtual visits, using local labs and healthcare providers, and direct-to-participant shipping).



MEETING OBJECTIVES

During a meeting with relevant experts and key stakeholders—including investigators, patients, regulators, technology experts, sponsor representatives, and other groups—CTTI and attendees:

- Collected recent knowledge and insights—both what works and what doesn't—from operationalizing DCT solutions
- Discussed current practices for incorporating DCT solutions in clinical trials, including considerations for protocol design and safety monitoring
- Identified opportunities to increase adoption of DCT solutions moving forward



MEETING THEMES

- **Design with Purpose.** The design of DCTs must prioritize patient safety and data quality. DCT elements should only be incorporated into study design where they are appropriate to the purpose of the study.
- **Engage Everyone.** It's important to engage all stakeholders in DCT protocol design and implementation.
- **Think Ahead, Early On.** Careful planning and consideration from the earliest stages of study and program design is essential.
- **Invest in Quality.** DCTs are often not the cheapest or easiest solution, but they can be the most impactful in terms of making trials more patient-centered and getting the best data.
- **Where to Focus Next.** Communication, collaboration, and regulatory guidance are critical for broader adoption of DCT solutions.



NEXT STEPS

Meeting participants identified distinct and actionable suggestions that the CTTI project team can use as the foundation for its next step—revising recommendations that will help accelerate the adoption of DCT solutions in clinical trials going forward.



ADDITIONAL RESOURCES

- [View](#) the meeting materials, including agenda, participant list, and presentations.
- For more information, please contact Zachary Hallinan at Zachary.Hallinan@duke.edu.



ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

The Clinical Trials Transformation Initiative ([CTTI](#)), a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges.



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