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Decentralized Clinical Trials Blog Series

Article By:

Jessa Boubker

Kyle Y. Faget

Monica R. Chmielewski

Nathan A. Beaver

Aaron T. Maguregui

Thomas B. Ferrante

DCT Blog Series: Introduction

Decentralized Clinical Trials (DCTs) are clinical trials where some or all trial-related activities occur at locations other than traditional clinical trial sites, such as via telemedicine or in a clinical trial participant's home. Access to telehealth providers, local laboratories and image centers, and innovative digital health technologies has resulted in a proliferation of opportunities to reimagine and restructure how clinical trials are conducted and provide a more patient-centric approach to clinical research.

In a press release announcing the U.S. Food and Drug Administration's (FDA) new draft guidance aimed at bolstering DCT adoption, FDA Commissioner Robert M. Califf, M.D. highlights the value of DCTs and states: "As we seek to improve our evidence generation system, decentralized clinical trials may enhance convenience for trial participants, reduce the burden on caregivers, expand access to more diverse populations, improve trial efficiencies, and facilitate research on rare diseases and diseases affecting populations with limited mobility."

Whether conducting a clinical trial for the first time or a veteran to clinical trials, those involved in clinical trials will need to firmly grasp the evolving legal and regulatory landscape when conducting virtual or hybrid clinical trials. In this six-part blog series, we will be addressing key considerations and common issues faced by clinical trial sponsors, investors, and clinical investigators embracing the DCT model.

FDA DCT Guidance – Sponsor and Investigator Responsibilities

This two-part edition will unpack FDA's new draft guidance released on May 2, 2023 regarding the implementation of DCTs for drugs, biological products, and devices. These editions will separately address the obligations of sponsors and investigators when creating, coordinating, facilitating, and conducting a clinical trial.

Regulation of Digital Health Technologies

This edition will address how FDA is regulating digital health technologies used to facilitate DCTs, which will include a discussion of what constitutes a regulated device, legislative actions aimed at spurring innovation, how FDA is approaching regulation of specific categories of digital health technologies, and FDA's current focus on cybersecurity issues impacting software.

Telemedicine Regulations Applicable to DCTs

This edition will explore the legal and regulatory considerations when conducting DCTs that employ telemedicine, such as the array of state law practice standards and guidelines that must be followed when conducting DCTs remotely and/or across state lines.

Diversity in Clinical Trials

This edition will cover FDA's commitment to expanding diversity in clinical trials and how DCTs contribute to this effort, such as by enhancing convenience for trial participants, reducing burdens on caregivers, expanding geographic access, and facilitating research on rare diseases and diseases affecting populations with limited mobility.

Research Misconduct Considerations for DCTs

This edition will discuss research misconduct concerns to consider when conducting DCTs, such as establishing strong systems to ensure the integrity of data, monitoring research conduct remotely, and effectively addressing allegations of misconduct.

Our goal is that this DCT Blog Series will serve as a helpful starting point for pharmaceutical and medical device companies, clinical research organizations, site management organizations, digital health companies, investors, innovators, and clinicians as each embraces the DCT model.

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