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Decentralized Clinical Trials: Sponsor Responsibilities

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DCT Blog Series: Article 3

In the third edition of our blog series on decentralized clinical trials (DCTs), we address U.S. Food and Drug Administration's (FDA) expectations of Sponsors with respect to DTCs as articulated in the recently released draft guidance. While Sponsors' core responsibilities remain the same for DCTs as traditional, brick and mortar clinical trials when sponsoring a DTC, added sponsor responsibilities for DCTs include: ensuring proper coordination of decentralized activities, accounting for data from a variety of inputs, compliant shipping and administration of investigational products (IPs), and monitoring, including safety monitoring that accounts for the decentralized nature of the trial.

Key Considerations

Sponsors should describe in the protocol how operational aspects of the DCT will be implemented, including:

- Scheduled and unscheduled clinical trial visits (remote and in-person, as applicable);
- Transmission of reports on activities performed at different locations, (e.g., medical imaging; clinical laboratory tests; and procedures performed at trial participants' home, work, or other local facility);
- Delivery of IPs to trial participants, if applicable, and accountability for IPs; and
- Safety monitoring and management of adverse events.

FDA notes that Sponsors must account for multiple sources of data collection and recommends the following elements be addressed and included in a data management plan:

- Data origin and data flow from all sources to the sponsor, (e.g., a diagram that depicts the flow of data from creation to final storage);
- Methods used for remote data acquisition from trial participants, trial personnel, and contracted service providers, (e.g., local clinical laboratory facilities and local health care professionals (HCPs) who perform trial-related activities); and
- A list identifying vendors for data collection, handling, and management.

Sponsors should also ensure that the applicable case report forms identify where, when, and by whom data is collected.

Sponsors must also ensure proper monitoring of a trial via a monitoring plan, which should address the decentralized aspects of the trial and:

- Describe how monitoring will be implemented to assess protocol compliance and data quality and integrity;
- Specify the frequency with which trial records and source documents will be reviewed; and
- Note any unique aspects related to the DCT procedures and data capture.

FDA specifically encourages risk-based monitoring approaches and use of centralized monitoring to identify and proactively follow up on missing data, inconsistent data, data outliers, and potential protocol deviations that may be indicative of systemic or significant errors.

Sponsors of DTCs are encouraged to implement a safety monitoring plan, which:

- Takes into account the decentralized nature of the clinical trial and ensures that adverse events are appropriately captured and adequately addressed;
- Prespecifies if and when telehealth visits or in-person visits will be scheduled with trial personnel or local HCPs to collect safety data;
- Describes how trial participants are expected to respond to and report adverse events, including where to seek medical assistance locally when necessary and where to receive follow-up care;
- Describe the type of information that will be collected by digital health technology (DHT) when DHT is used to collect data in a DCT, how that information will be used and monitored, and what action trial participants or personnel should take in response to abnormal findings or electronic alerts; and
- Includes a mechanism whereby trial participants can contact trial personnel to report adverse events and have pertinent questions answered.

Importantly, Sponsors, in addition to compliance with FDA regulations, must comply with relevant local laws, regulations, and licensing requirements, governing the practice of medicine via telemedicine, including practice and trial performance using DHTs, and IP administration when conducting a DCT. Foley is an industry leader in the telehealth space and can assist sponsors to ensure compliance with these state laws and regulations.

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