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FDA Publishes Guidance Snapshot on Conducting Clinical Trials with Decentralized Elements

Alert

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By Theodore Thompson

A decentralized clinical trial (DCT) includes clinical trials where trial-related activities occur at locations other than traditional clinical trial sites such as hospitals and clinics. The Food and Drug Administration (FDA) published a Guidance Snapshot on Friday, October 17, 2025, which highlights elements from a full FDA guidance document for companies conducting DCTs.

Although the full guidance document should be relied upon when drafting clinical trial protocols with decentralized elements, the Guidance Snapshot provides a helpful overview of the key elements, including:

- DCTs should be designed to reduce variability in the data collected by dispersed health care providers by including specific instructions in the protocols to perform data collection activities.
- DCTs that permit data collection or tests to be performed independently by trial participants in their homes should provide clear instructions to participants (e.g., in the form of telehealth visits or pre-recorded videos with clear instructions).
- Study-specific activities that may be unique to the clinical trial should be performed by qualified and well-trained trial personnel who understand the study protocol.
- Medical device and pharmaceutical companies should ensure that any digital health technology relied upon to transfer data collected at remote locations is secure and suitable for use by the trial participants.

Further information is available at the full guidance document.

For counsel on clinical trial agreements regardless of whether the trial is a DCT or single-site trial, please contact Theodore Thompson or the Stinson LLP contact with whom you regularly work.

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