U.S. FOOD & DRUG ADMINISTRATION

Guidance Snapshot

Conducting Clinical Trials With Decentralized Elements

Guidance for Industry, Investigators, and Other Interested Parties

What Is Recommended in This Guidance?

This guidance provides FDA's recommendations for sponsors, investigators, and other interested parties regarding the implementation of decentralized elements in clinical trials.

Why Is This Guidance Important?

By enabling remote participation, decentralized clinical trials (DCTs) may enhance convenience for trial participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or limited access to traditional clinical trial sites. This may help improve trial participant engagement, recruitment, enrollment, and retention—and may help produce clinical trials that are representative of the target population.

What Are DCTs?

In this guidance, a DCT refers to a clinical trial that includes decentralized elements where trial-related activities occur at locations other than traditional clinical trial sites. Decentralized elements allow trial-related activities to occur remotely at locations convenient for trial participants. They can include, among other things, telehealth visits with trial personnel, in-home visits with remote trial personnel, or visits with local health care providers (HCPs), such as doctors or nurses.

Guidance Snapshots are a communication tool and are not a substitute for the guidance document.
To learn more about conducting clinical trials with decentralized elements, **read the guidance**.
To see additional Guidance Snapshots, **check out the pilot program**.

Key Recommendations for Implementing DCTs

DCT Design and Conduct

- Whether trial-related activities are performed by local HCPs or trial personnel, the clinical trial should be designed to limit variability in the data collected by including, as applicable, specific instructions in the protocol for performing these activities.
- DCTs that permit tests to be performed independently by participants at home (e.g., spirometry) may introduce variability. Training or video supervision (i.e., during a telehealth visit) may reduce such variability.
- To limit bias, the protocol should specify which visits will be conducted at traditional clinical trial sites, which visits will be conducted remotely, and which visits can be left to participants' choice.

Remote Clinical Trial Visits and Clinical Trial-Related Activities

The following should be considered when planning remote clinical trial visits or remote clinical trial-related activities:

- Sponsors should consider the investigational product (IP) and the medical condition of the anticipated trial population when determining whether telehealth visits are appropriate, and the protocol should specify when telehealth visits will occur.
- Investigators may use local HCPs to perform certain trial-related activities remotely.
  - The trial-related activities local HCPs perform should not differ from those that they are qualified to perform in clinical practice and should not require a detailed knowledge of the protocol, investigator's brochure, or IP (e.g., performing physical examinations or obtaining vital signs).
- Trial-related activities that are unique to a research study (i.e., not routine in clinical practice) and/or require a detailed knowledge of the protocol, investigator's brochure, or IP should be performed by qualified trial personnel who have been appropriately trained on the protocol.

Digital Health Technologies

- Digital health technologies (DHTs) may allow transmission of data remotely and securely from trial participants wherever they are located. Sponsors should ensure that DHTs used in a DCT are available and suitable for use by all trial participants.

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Roles and Responsibilities

The Sponsor

- Sponsor responsibilities are the same for trials that include decentralized elements and trials that do not include decentralized elements.
- Contracted services used by sponsors may include networks of local HCPs, and sponsors should ensure they are qualified to perform any activities for which they are contracted.
- Sponsors should describe in the trial protocol or other trial-related documents how operational aspects of the DCT will be implemented.
- Sponsors must ensure proper monitoring of an investigation and should note any unique aspects related to the decentralized elements.

The Investigator and Delegation of Trial-Related Activities

- Investigators are responsible for the conduct of the DCT and for protecting the rights, safety, and welfare of subjects under their care. Additional training, coordination, and standard operating procedures may be needed for decentralized elements to ensure consistent implementation.
- When permitted by the protocol, investigators can delegate trial-related activities to local HCPs. Investigators must ensure such activities are conducted according to the investigational plan and applicable regulations and remain responsible for the adequate supervision of those to whom they have delegated these activities.
- Investigators should review data by other trial personnel and local HCPs, as applicable, and follow up on any data that are missing, concerning, or appear to be in error.

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FDA Oversight

For FDA inspections, the investigator should identify a physical location where a responsible person is available to facilitate the FDA inspectors' access to trial-related records (either paper or electronic access) for participants under the clinical investigator's care and to facilitate interviews with trial personnel (either in person or remotely).

Informed Consent and Institutional Review Board Oversight

- A DCT may include obtaining informed consent remotely.
- Obtaining informed consent is an investigator responsibility, which may be delegated to trial personnel. Obtaining informed consent is not an appropriate activity for local HCPs to perform.

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Investigational Products in a DCT

Drugs and Biological Products

- Sponsors should consider the nature of the IP when determining whether administration outside of a traditional clinical trial site is appropriate.
- Administration of an IP that has a high-risk safety profile; that is in early stages of development such that the safety profile is not well defined; or that requires complex preparation, administration, or medical assessments may need in-person supervision by the investigator at a traditional clinical trial site.
- It may be appropriate for local HCPs or trial personnel working remotely to administer an IP if the safety profile of the IP is well characterized and specialized monitoring during the immediate period following administration is not needed.

Medical Devices

- When determining the appropriate use or administration of an investigational device in a DCT, sponsors should consider the type of medical device, its intended use, its instructions for use, and the potential risks of the device for participants.
- Investigational devices intended for home use may be appropriate for use by trial participants without the investigator's direct oversight when such direct oversight is not needed to mitigate potential serious risks to trial participants.
- Investigational devices that are not intended for self-use (i.e., devices used in hospital or ambulatory care settings) should be used or administered by qualified trial personnel with investigator oversight.

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Packaging and Shipping Investigational Products

- DCTs may involve the direct distribution of IPs to trial participants or local HCPs. In these cases, investigators must remain responsible for supervising the supply of IP to trial participants or local HCPs.
- Sponsors should address the following in trial-related documents:
  - Maintaining physical integrity and stability of the IP.
  - Tracking receipt of IPs by participants and local HCPs.
  - Disposition of unused IPs.

Safety Monitoring in DCTs

- The safety monitoring plan should take the decentralized nature of the clinical trial into account and ensure that adverse events and medication errors are appropriately collected and adequately addressed.
  This includes describing how local HCPs will be instructed to report any concerning signs, symptoms, or clinical events they become aware of when performing trial-related activities.
- The safety monitoring plan should describe how participants are expected to respond to and report adverse events, including where to seek medical assistance.

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