

FDA Guidance on Conducting Clinical Trials with Decentralized Elements

This document offers guidance from the FDA on how clinical trials can incorporate decentralized elements, which involve remote assessments, telemedicine, and digital health technologies. The purpose is to help sponsors, investigators, and other stakeholders effectively design and manage decentralized trials (DCTs).

Key Elements of Decentralized Clinical Trials (DCTs)

- **Definition:** DCTs utilize technology and telemedicine to allow participants to engage remotely in clinical trials. They can reduce participant burden and enhance diversity by enabling recruitment from a broader geographic area.
- **Remote Data Collection:** Digital health technologies (e.g., wearables, apps) are used to collect data remotely. This requires thorough planning to ensure data accuracy, validity, and compliance with regulatory standards.
- **Informed Consent:** In DCTs, informed consent may be obtained electronically (eConsent). This process must meet all regulatory standards to ensure participant understanding and voluntary participation.
- **Use of Telemedicine:** Telemedicine plays a critical role in patient assessments, replacing in-person visits with video conferencing when appropriate. This requires ensuring that the technology used is secure and maintains patient privacy.
- **Home Healthcare Visits:** Some aspects of clinical trials, such as administering treatments or collecting samples, can be conducted via home healthcare providers, reducing the need for site visits.
- **Site Responsibilities:** Investigators retain the same responsibilities in DCTs as in traditional trials. This includes maintaining oversight of trial procedures and ensuring that the study is conducted in compliance with all applicable regulations.
- **Participant Safety and Monitoring:** Safety monitoring in DCTs must be rigorous, with clear protocols for handling adverse events remotely. The use of remote monitoring technologies is emphasized to ensure timely identification of any issues.
- **Data Management and Security:** Data collected remotely should be secure, with protocols in place to ensure patient privacy and compliance with regulations like HIPAA. The integrity and quality of the data must be maintained to ensure valid trial outcomes.
- **Regulatory Considerations:** The FDA outlines specific regulatory considerations for DCTs, including how to handle protocol amendments, deviations, and the submission of study results. Ensuring compliance with these regulations is critical for the success of decentralized trials.

Challenges and Benefits

- **Challenges:** DCTs can encounter technical issues, data security concerns, and regulatory hurdles, as well as the need for adequate training for personnel and participants.
- **Benefits:** DCTs enable faster recruitment, improved participant retention, and greater demographic representation while reducing geographical and logistical barriers that often hinder traditional trials.

Conclusion

The FDA supports the use of decentralized elements in clinical trials, recognizing their potential to improve accessibility, efficiency, and diversity in clinical research. However, careful planning, clear communication, and adherence to regulatory standards are critical to the success of DCTs.