

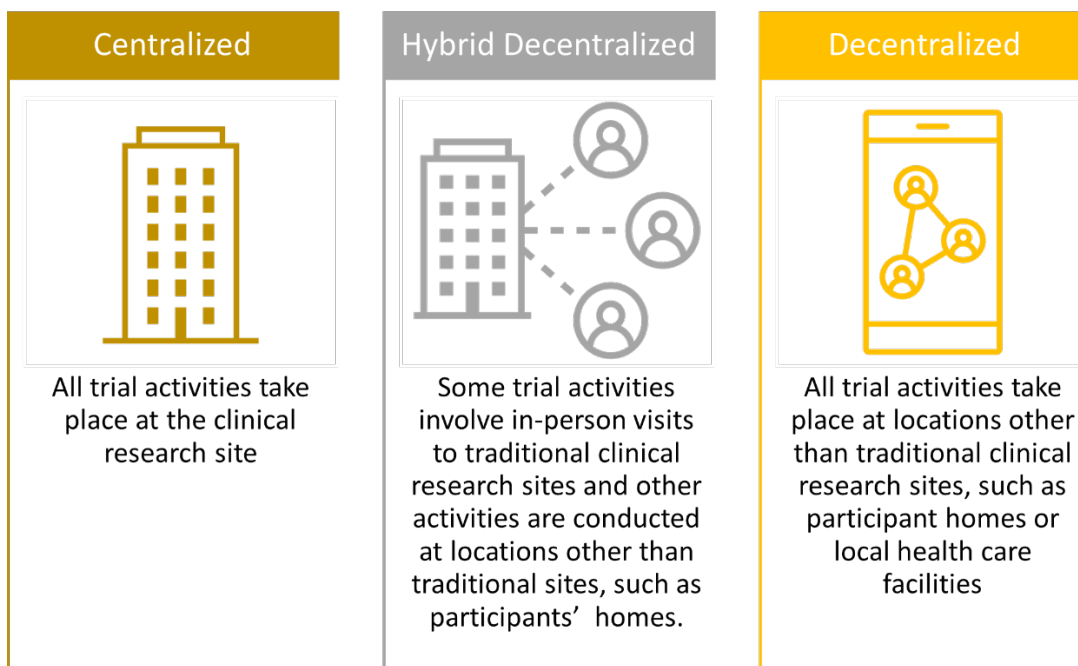


# CRSO Insightalyst

May 17, 2023

## FDA Draft Guidance on Decentralized Clinical Trials for Drugs, Biological Products, and Devices

Building on recommendations to facilitate decentralization of clinical trials during the COVID-19 public health emergency, the U.S. Food and Drug Administration (FDA or the Agency) issued the draft guidance titled, [Decentralized Clinical Trials for Drugs, Biological Products, and Devices](#) on May 2, 2023. A decentralized clinical trial (DCT) is a clinical trial where some or all trial-related activities occur at locations other than traditional clinical research sites.



FDA's regulatory requirements for DCTs are the same as those for traditional site-based clinical trials but DCTs can present unique challenges. The DCT draft guidance provides various recommendations regarding how sponsors, investigators, and other stakeholders can satisfy regulatory obligations in the context of DCTs and advance the use of such studies in the future.

[Click here](#) to explore each of the following topics covered in the guidance:

- ➡ DCT design
- ➡ Remote clinical trial visits and clinical trial-related activities

- ➔ Use of Digital Health Technologies (DHTs)
- ➔ Sponsor and investigator roles and responsibilities
- ➔ Informed consent and institutional review board (IRB) oversight
  - ➔ Investigational products in DCTs
- ➔ Packaging and shipping investigational products
  - ➔ Safety monitoring plans
  - ➔ Use of software in DCTs

## What does it mean for me?

If you are a UNC-Chapel Hill investigator or sponsor-investigator, consider the recommendations in the DCT draft guidance. Many clinical trials conducted at UNC-Chapel Hill include decentralized elements (i.e., they are hybrid DCTs). For example, laboratory tests are often conducted by clinical laboratory facilities located close to participants' homes.

**DCTs have the potential to enhance convenience for participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or access to traditional clinical research sites. They may also help improve participant engagement, recruitment, enrollment, and retention of a meaningfully diverse study population.**

You may also consider submitting comments to the draft guidance ([Docket No. FDA-2022-D-2870](#)) before the close date on August 1, 2023.

## More Available Information

The FDA will provide an overview of the draft guidance on June 20, 2023. Register for this virtual webinar [here](#).

The DCT draft guidance should be considered along with FDA's December 2021 draft guidance on [Digital Health Technologies for Remote Data Acquisition in Clinical Investigations](#).

If you have questions about the information presented in this issue of the Insightalyst, please contact the CRSO at [crso@med.unc.edu](mailto:crso@med.unc.edu).



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