



July 31, 2023

Submitted at: <https://www.regulations.gov>

Re: **Docket No. FDA-2022-D-2870** Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders.

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Association of Clinical
Research Professionals

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To Whom It May Concern:

The Association of Clinical Research Professionals (ACRP) submits the following comments on the Food and Drug Administration's (FDA_ Draft Guidance: Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders (Draft Guidance). ACRP appreciated the opportunity to provide comments on this valuable guidance.

The Association of Clinical Research (ACRP) supports clinical research professionals through membership, training and development, and certification. Founded in 1976, ACRP is a non-profit organization with more than 12,000 members who work in clinical research.

At ACRP, we are improving the quality of clinical research by directly impacting the professionals conducting clinical trials. We are leading innovation in clinical research workforce development by setting standards for professional competence and building and validating competence in the workforce.

INTRODUCTION (I)

- No comments

BACKGROUND (II)

- [49-52] Please consider a different example of a DCT, as this example conflates study participant activity (on-site) with processing lab tests (off-site) at the lab facility. The subject is still seen at the site, and labs drawn at the site are then shipped to the lab. That is not a good example of a DCT process and has already been addressed in the 2009 Inv. Guidance doc.

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- [54] regarding 'Telehealth' - the subject is 'home,' and the Investigator is in their 'office' interacting via a call/video. There is still a connection between the Investigator and the subject. This is not a good premise to draw a conclusion about third-party vendor home visits. Please consider an example of a Nurse or Physician with a third-party vendor who is seeing the patient via Telehealth and the connection between the vendor and the Investigator.

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

- [88-91] To paraphrase... "trial activities occur off-site, may use a network of locations, with local HCPs, ALL under the oversight of the investigator." This is the crux of the issue: how and if an investigator can provide adequate oversight??
- [93-96] Even though in lines 22-23 in fully, DCTs trial activities occur at locations other than a traditional clinical trial site. The FDA is requiring a physical location where 'all clinical trial-related records' are accessible and where trial personnel can be interviewed. Does that mean that off-site trial personnel are required to be physically present for a potential interview? They would have to be available in person from a study with potential sites from a wide geographical area over the days of the inspection. Why can't an off-site study staff be interviewed virtually if the study can be conducted off-site with virtual visits? This process contradicts their earlier definition of a fully DCT where ALL activities (and FDA inspection is an activity) take place at locations other than traditional trial sites.
- [93-96] The requirement for localization of records is problematic in the context of a fully-decentralized trial. If data collection occurs in "locations other than traditional sites" like patients' homes, does this become a sponsor's responsibility to facilitate? If all data is collected remotely and stored on cloud-based systems, the FDA should consider remote inspections rather than traditional on-site inspections.

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Remote Clinical Trial Visits and Clinical Trial-Related Activities (B)

- Bullet 3 may need clarification '...by HCPs who are located close to trial participants' homes but are not part of the trial personnel.'

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Should not all personnel involved in the conduction of the trial (or at a minimum, all clinical personnel conducting protocol-required tasks) be considered part of the trial team and under the oversight of the PI by being listed on the 1572?

- Section B, Bullet 3: When referring to local healthcare providers conducting trial-related activities, they shall be listed as key personnel in a DOA. Also, if performing activities like point of care testing or height/weight, are these staff members held to machine calibration records as study staff would be? Will 1572s be updated to include Telehealth as an optional means in lieu of "location?"
- [128-130], The statement that 'local HCPs may be used by sponsors or investigators' is too vague since all studies require PI oversight. What is meant by 'used by sponsors'? Does this bypass the PI's oversight, or is this a process that the PI has no connection to but will still be held responsible for?
- [119-120] Consider adjusting the wording to "the protocol should specify [criteria for deciding] when a telehealth visit is appropriate." It is important to PI discretion on what is most appropriate for their patient while providing flexibility for patient preference. The protocol should clarify the parameters in which the decision is to be made and not dictate one way or another.

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Digital Health Technologies (C)

- No comments

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Roles and Responsibilities (D)

- [213-214] The Sponsor should also address the liability a site may have with sending staff for a home visit and provide indemnification. And be careful to address the safety concerns that site staff may have to do a home visit.
- [264-265] With the additional time DCTs require, I believe the number of study participants a PI can 'adequately supervise' will be less than in a traditional trial.
- [293-294] Should the quality control measures put in place be defined by the Sponsor instead of the Investigator?



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- [293-296] Please clarify the statement, "Quality control measures should be in place to help reduce variability, including regular review by investigators of participant data entered by local HCPs, to assess consistency and completeness of the required procedures." Is this section intended to cover Data entry only? Suggest modifying the language to "Quality control measures should be in place to help reduce variability [in participant data], including regular review by investigators of participant data entered into the [eCRF] by local HCPs, to assess consistency and completeness of the required [data]."

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Informed Consent and Institutional Review Board Oversight (E)

- Please address the consent/assent of minors.

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Investigational Products in a DCT (F)

- [369-370] How does one comply with the requirement for administering IP only to participants under the Investigator's personal supervision with having an IP administered by local HCP or trial personnel working remotely?
- [370-372] "The nature of the IP should be considered when determining whether administration outside of a clinical trial site in a DCT is appropriate." Please clarify if this is a Sponsor or Investigator decision and where it should be documented (i.e., protocol, pharmacy manual, source record). Would assume it should align with [396-398], which states it is the Sponsor's responsibility for devices.

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Packaging and Shipping of Investigational Products (G)

- [428] documenting and managing direct shipment of IP to participants, receipt and use and return, and compliance and destruction will be very challenging - if it can be done at all.
- [419-421] Consider modifying the statement to read, "The protocol [and pharmacy manual] should describe how the physical integrity and stability of the IP will be maintained during shipment to trial



participants, including appropriate packaging materials and methods (e.g., temperature control)."

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Safety Monitoring Plan (H)

- No comments

RECOMMENDATIONS FOR IMPLEMENTING DCTS (III)

Software Used in Conducting DCTs (I)

- No comments

ADDITIONAL FEEDBACK:

- The 2009 Guidance document on Investigator Responsibilities makes the central lab responsible for the results generated from blood samples sent to them from the site. They are a 3rd party vendor that we have little to no control over. Can we not look at that process to make 3rd party vendors performing activities off-site as not the responsibility of the Investigator since we do not have fiduciary control and cannot adequately provide oversight?
- Perhaps there would be value in addressing how the investigator/sponsor should address subject reimbursement if the visits are done remotely. Compensation is sometimes considered to cover time and travel, but if travel is not done. Is there any direction that could be given for this?

The Association of Clinical Research Professionals is grateful for the FDA's consideration of this feedback. Please feel free to contact Bridget Gonzales at bridget.gonzales@acrpnnet.org.

Respectfully submitted on behalf of the members of ACRP,

Bridget Gonzales, CCRC
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