committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: September 12, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21241 Filed 9–17–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–2870]**

### Conducting Clinical Trials With Decentralized Elements; Guidance for Industry, Investigators, and Other Interested Parties Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry, investigators, and other interested parties entitled ''Conducting Clinical Trials With Decentralized Elements.'' This guidance provides recommendations regarding the implementation of decentralized elements in clinical trials for drugs, biological products, and devices. Decentralized elements allow trial-related activities to occur remotely at locations convenient for trial participants (*e.g.,* telehealth visits with investigators or visits with local healthcare providers (HCPs)). FDA's regulatory requirements are the same for trials that include decentralized elements and trials that do not include decentralized elements. To help ensure the appropriate oversight trials with decentralized elements, the integrity of trial data, and the safety of trial participants, this guidance covers the responsibilities of sponsors and investigators. This guidance finalizes the draft guidance entitled ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices'' issued on May 3, 2023.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 18, 2024.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2022–D–2870 for ''Conducting Clinical Trials With Decentralized Elements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ryan Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993, 240–402–9756; James Myers, Center for Biologics Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G318, Silver Spring, MD 20993–0002, 301–796–6359; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Conducting Clinical Trials With Decentralized Elements.'' Section 3606(a) of the Consolidated Appropriations Act, 2023 directs FDA to issue a final guidance that includes recommendations to clarify and advance the use of DCTs to support the development of drugs and devices. This guidance fulfills the requirements set forth in section 3606(a)(2) of the Consolidated Appropriations Act, 2023. The content described in section 3606(b) of the Consolidated Appropriations Act, 2023 is further addressed through this guidance's reference to FDA's guidance for industry, investigators, and other stakeholders entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations'' (December 2023).

In this guidance, a decentralized clinical trial (DCT) refers to a clinical trial that includes decentralized elements where trial-related activities occur at locations other than traditional clinical trial sites. These trial-related activities may take place at the location of trial participants (*e.g.,* their homes) or in local healthcare facilities that are close to trial participants' locations. FDA's regulatory requirements are the same for trials that include decentralized elements and trials that do not include decentralized elements.

DCTs may include the use of local healthcare providers and local clinical laboratory facilities in the management of trial participants and the use of telehealth and digital health technologies to acquire data remotely. By allowing remote participation and reducing the need to travel for face-to-face visits, DCTs may enhance convenience for study participants, facilitate research on diseases affecting populations with limited mobility, and reduce the burden on caregivers.

This guidance provides recommendations related to the incorporation of decentralized elements into clinical trials, including: (1) DCT design, conduct, and oversight; (2) conduct of remote clinical trial visits and activities including the use of local HCPs; (3) use of digital health technologies in DCTs; (4) the roles of sponsors and investigators in DCTs; (5) informed consent and institutional review board oversight of DCTs; (6) types of investigational products appropriate for study in DCTs; (7) packaging and shipping of investigational products in DCTs; (8) processes and procedures to ensure participant safety; and (9) use of software in DCTs.

This guidance finalizes the draft guidance entitled ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices'' issued on May 3, 2023 (88 FR 27900). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) removal of language regarding the requirement to maintain a task log of local HCPs, (2) clarification about challenges related to data variability in DCTs, (3) updates to responsibilities for ensuring qualifications of local HCPs, and (4) clarifications on the need for a physical location for inspections. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Conducting Clinical Trials With Decentralized Elements.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications, including Form FDA 1572, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 812 pertaining to investigational device exemption applications have been approved under OMB control number 0910–0078. The collections of information in 21 CFR parts 50 and 56 pertaining to the protection of human subjects, informed consent, and institutional review boards have been approved under OMB control number 0910–0130.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: September 12, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–D–2052]**

### Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice.'' FDA is publishing this draft guidance as part of a series of guidance documents under its Real-World Evidence (RWE) Program and to satisfy, in part, a mandate under the Federal Food, Drug, and Cosmetic Act to issue guidance about the use of RWE in regulatory decision-making. This draft guidance is intended to support the conduct of randomized controlled drug trials with streamlined protocols and procedures that can integrate research into routine clinical practice.

**DATES:** Submit either electronic or written comments on the draft guidance by December 17, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.