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.

[FR Doc. 2024–21078 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–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.

ADDRESSES: You may submit comments on any guidance 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–2024–D–2052 for ''Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice.'' 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 the draft 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; or 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Heather Stone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3348, Silver Spring, MD 20993–0002, 301–796–2274, *Heather.Stone@fda.hhs.gov;* or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice.'' This draft guidance is intended to support the conduct of randomized controlled drug trials with streamlined protocols and procedures that focus on essential data, allowing integration of research into routine clinical practice. Depending on the condition and the intervention to be studied, the spectrum of trial designs may range from those that are almost completely reliant on data acquired by the participant's local healthcare providers during routine clinical practice visits to those that require significant supplementation with dedicated, research-specific activities for data collection conducted by trial staff.

Traditional randomized controlled drug trials typically capture a large amount of protocol-specified patient information (*e.g.,* patient characteristics, medical history, concomitant medications, vital signs, adverse events, laboratory results, measures of drug response, clinical status) at baseline and over the course of the trial. Some of these data are also collected in routine clinical practice, although the specific procedures and methods, timing of collection, and documentation formats typically differ from those in a clinical trial. Given the potential overlap in information collected, data for clinical research can, under appropriate circumstances, be obtained from routine clinical practice interactions, reducing the need for dedicated trial sites.

This draft guidance applies to studies involving FDA-approved drugs being studied for new indications, populations, or doses; drug safety studies for FDA-approved drugs; other postmarketing studies; comparative effectiveness studies; and trials of unapproved drugs in later development when the safety profile is sufficiently characterized and the drug is appropriate to be administered and managed in the setting of routine clinical practice. This guidance does not address non-interventional (observational) studies.

Among other things, the draft guidance provides considerations

regarding the roles and responsibilities of sponsors, investigators, healthcare institutions, and local healthcare providers and addresses using a quality by design approach to facilitate the conduct of trials in the clinical practice setting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice.'' 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 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: September 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21077 Filed 9–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Cohort Studies of HIV/AIDS and Substance Use.

Date: November 4, 2024.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Soyoun Cho, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 594–9460, *Soyoun.cho@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Engaging Survivors of Sexual Violence and Trafficking in HIV and Substance Use Disorder Services.

Date: November 6, 2024.

Time: 11:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435–1258, *marisa.srivareerat@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Harnessing Artificial Intelligence and Polypharmacology to Discover Pharmacotherapeutics for Substance Use Disorders.

Date: November 13, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Devon Rene Oskvig, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 402–6965, *devon.oskvig@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 12, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21152 Filed 9–17–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Basic Mechanisms of Cancer Health Disparities Study Section.

Date: October 15–16, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Amy L Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, email: *rubinsteinal@csr.nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review