Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: November 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25816 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4965]

Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice.'' The purpose of the public workshop is to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs. This workshop is being conducted to meet the performance goal of convening a public workshop on complex innovative design (CID) included in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The workshop may also inform a draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products. In conjunction with the workshop, FDA is seeking comments on the use of CID to inform regulatory decision making, including high-level case examples of CIDs and approaches that can advance the use of these designs. The public workshop will be held on March 5, 2024, from 9 a.m. to 3:30 p.m. Eastern Time.

DATES: Either electronic or written comments on this public workshop must be submitted by April 5, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.* The public workshop will use an online platform for the webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–4965 for ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Tuan Pham, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 3670, Silver Spring, MD 20993–0002, 301–348–1595, *CID.Meetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is intended to meet a performance goal FDA agreed to under the FDA User Fee Reauthorization Act of 2022, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, section I.4.e of the PDUFA VII letter outlines goals to enhance FDA's capacity to review complex innovative designs and convene a public workshop to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to facilitate discussion on the use of external data sources, Bayesian statistical methods, and simulations in complex innovative trial designs as well as trial implementation (*e.g.,* examples of defining and mitigating bias when using select trial design methods). Discussion topics will include considerations for external data sources, Bayesian statistical methods, simulations, and clinical trial implementation and will be based on FDA accumulated experience both within and outside of the Complex Innovative Trial Design Meeting Program (*https://www.fda.gov/drugs/development-resources/complex-innovative-trial-design-meeting-program*).

The workshop will consist of two sessions. The first session will focus on case studies that will illustrate various aspects of complex innovative designs and implementation. The second session will consist of panel discussions motivated by the case studies. There will be an opportunity for public comment.

Workshop updates, agenda, and background materials (if any) will be made available at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Registration will be available starting January 16, 2024. Please provide complete contact information for each attendee, including name, affiliation, and email. If you are unable to attend the workshop in person, you can register to view a live webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 27, 2024, 11:59 p.m. Eastern Time. Early registration is recommended because onsite seating is limited; therefore, FDA may limit the number of in-person participants from each organization. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Tuan Pham (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days before the workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be available on webcast. To register for the webcast of this public workshop, visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, affiliation, and email. A link to the webcast will be provided following registration. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25854 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meeting 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 of Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFA (EB–22–003) Review SEP.

Date: February 2, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Yoon-Young Jang, M.D., Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3397, *yoon-young.jang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: November 16, 2023.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–25847 Filed 11–21–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0041]

Establishment of Homeland Security Academic Partnership Council Subcommittees

AGENCY: The Office of Partnership and Engagement (OPE), The Department of Homeland Security (DHS).