4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0049]

Promoting the Use of Complex Innovative Designs in Clinical Trials; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Promoting the Use of Complex Innovative Designs in Clinical Trials." The topic to be discussed is the use of complex innovative designs (CID) in clinical trials of drugs and biological products to inform regulatory decision making. This meeting will inform development of a guidance document as required by the 21st Century Cures Act (Cures Act) and is being conducted to meet the performance goal of convening a public workshop on CID included in the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA). This meeting will also inform the development of a CID pilot program. FDA is seeking comments on the use of CID to inform regulatory decision making and is also seeking input on the CID pilot program.

DATES: The public meeting will be held on March 20, 2018, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by April 20, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver

Spring, MD 20993-0002. Entrance for the public meeting 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/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of April 20, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2018-N-0049 for "Promoting the Use of Complex Innovative Designs in Clinical Trials; Public Meeting; 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Robyn Bent, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3541, Silver Spring, MD 20993-0002, 240-402-2572, robyn.bent@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to support FDA guidance development as required under section 3021 of the Cures Act. Section 3021 of the Cures Act directs FDA to develop a guidance

document to address several areas related to CID, including the use of complex innovative clinical trial designs, ways sponsors may obtain feedback on technical issues related to simulations, the submission of resulting information, the types of quantitative information that should be submitted for review, and recommended analysis methodologies. Before issuing the guidance, FDA is required to conduct a public meeting to gather input from the wider community of stakeholders, including academic and medical researchers, expert practitioners, drug developers, and other interested persons.

The public meeting is also intended to meet a performance goal FDA agreed to under FDARA, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 letter (PDUFA VI letter), which is available at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf. Specifically, Section J.4 of the PDUFA VI letter, "Enhancing Capacity to Review Complex Innovative Designs," (https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf) outlines commitments, including a public workshop to discuss various CIDs and a CID pilot program. The meeting will focus on clinical trial designs for which simulations are necessary to evaluate the operating characteristics of the trial and the acceptability of those designs in regulatory decision making.

II. Topics for Discussion at the Public Meeting

The purpose of this public meeting is to (1) facilitate discussion and information sharing about the use of CID in drug development and regulatory decision making and (2) obtain input from stakeholders about the CID pilot program.

The meeting will consist of four sessions. The sessions will focus on (1) complex adaptive designs; (2) other innovative designs such as use of external/historical control subjects, Bayesian designs, and master protocols; (3) clinical trial simulations for confirmatory trial design and planning; and (4) the CID pilot program. Following each session there will be an opportunity for public comment.

After this public meeting, FDA will consider the stakeholder input from the meeting and the public docket, launch the pilot program by the end of fiscal year 2018, and publish a draft guidance within 18 months of the meeting.

Meeting updates, the agenda, and background materials (if any) will be made available at: https://www.fda.gov/Drugs/NewsEvents/ucm587344.htm prior to the workshop.

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit https://ComplexInnovativeDesigns.eventbrite.com by March 13, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. 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 meeting must register by March 13, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability,

please contact Robyn Bent (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

FDA will also hold an open public comment period at the meeting to give the public an opportunity to present their comments. Registration for open public comment will occur at the registration desk on the day of the meeting on a first-come, first-served basis.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. To register for the webcast of this public meeting, visit https://ComplexInnovativeDesigns.eventbrite.com by March 13, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A link to the webcast will be provided following registration.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm587344.htm.

Dated: February 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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