4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2368]

Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data; 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, the Agency, or we) is announcing the following public workshop entitled "Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data." The purpose of the public workshop is to discuss methodological challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.

DATES: The public workshop will be held virtually on September 18, 2025, from 12:30 p.m. to 5 p.m. Eastern Time, and September 19, 2025, from 12:30 p.m. to 4 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by November 18, 2025. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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 November 18, 2025. 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-2025-N-2368 for " Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data." 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: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301-796-8112, Ethan.Gabbour@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments to elicit public input on methodologic challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments was published on December 12, 2023, and is available at https://www.regulations.gov by entering the following docket number: FDA-2023-N-1506. The input received in response to the RFI helped inform the topics for the first public workshop in this series, *Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data*, held on December 13, 2024. The discussions from the first workshop helped to inform the topics for this second workshop. These workshops, together with the input received in response to the RFI, will help FDA identify priorities for future work.

II. Topics for Discussion at the Public Workshop

The purpose of this virtual public workshop is to highlight and discuss methodological issues related to patient experience data, including the submission and evaluation of patient

[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114-255) and the FDA Reauthorization Act of 2017 (Pub. L. 115-52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.

experience data in the context of the benefit-risk assessment and product labeling, as well as other areas of greatest interest or concern to stakeholders. This workshop will build upon the previous workshop and will feature presentations and panel discussions with experts on selected methodologies and the challenges and opportunities they present. In addition, this workshop will present a draft version of an updated evidence dossier template to facilitate the submission of evidence to FDA to support a Clinical Outcome Assessment.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://fda.zoomgov.com/webinar/register/WN_8FiAJfirS3W2WpC_8K0Zww#/registration. Please provide complete contact information for each attendee, including name, organization, email, and affiliation.

Registration is free. Persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Ethan.Gabbour@fda.hhs.gov no later than September 11, 2025. Please note, closed captioning will be available automatically.

Transcript: 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 also be viewed at the Dockets Management Staff (see ADDRESSES).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16514 Filed: 8/27/2025 8:45 am; Publication Date: 8/28/2025]