

- autografts) Humanitarian Device Exemption (HDE)
- b. Quelimmune (HDE)
2. Center for Devices and Radiological Health
 - a. Enterra Therapy System (HDE)
 - b. Liposorber LA-15 System (HDE)
 - c. Medtronic Activa Neurostimulator for Dystonia Treatment (HDE)
 - d. Medtronic Contegra Pulmonary Valved Conduit (HDE)
 - e. Minimally Invasive Deformity Correction (MID-C) System (HDE)
 - f. nAbCyte Anti-AAVRh74var HB-FE Assay (HDE)
 - g. Pleximmune (HDE)
 - h. Reflect Scoliosis Correction System (HDE)
 - i. Sonallevé MR-HIFU (HDE)
 - j. The Tether—Vertebral Body Tethering System (HDE)
 3. Center for Drug Evaluation and Research
 - a. Aranesp (darbepoetin alfa)
 - b. Dalvance (dalbavancin)
 - c. Fragmin (dalteparin sodium)
 - d. Isopto Atropine (atropine sulfate)
 - e. Kloxado nasal spray, Zimhi injection, Naloxone Hydrochloride Autoinjector, Naloxone hydrochloride nasal spray, RiVive nasal spray, Rezenopy nasal spray (naloxone hydrochloride)
 - f. Lymphoseek (technetium Tc 99m tilmanocept)
 - g. Nextstellis (drospirenone/estetrol)
 - h. Sprycel (dasatinib)
 - i. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate)
 - j. Tecentriq (atezolizumab)
 - k. Veklury (remdesivir)
 - l. Vemlidy (tenofovir alafenamide)
 - m. Zelsuvmi (berdazimer)
 - n. Zevtera (ceftobiprole medocartil sodium)
 - o. Zinplava (bezlotoxumab)

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before September 9, 2026, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. ET on September 16, 2026. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or comments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 1, 2026. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 2, 2026.

For press inquiries, please contact the FDA Newsroom at <https://www.fda.gov/news-events/fda-newsroom>.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Shivana Srivastava (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers.

The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-15149 Filed 7-27-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-1402]

Cancer Clinical Trial Eligibility Criteria: Laboratory Values; Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry, institutional review boards (IRBs), and clinical investigators entitled “Cancer Clinical Trial Eligibility Criteria: Laboratory Values.” This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations for selecting appropriate laboratory values as trial eligibility criteria to avoid unjustified exclusions of trial participants. This guidance finalizes the draft guidance of the same title issued on April 26, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on July 28, 2026.

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-2024-D-1402 for "Cancer Clinical Trial Eligibility Criteria: Laboratory Values." 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, or to 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 guidance document.

FOR FURTHER INFORMATION CONTACT:
LCDR Michael Gu, Oncology Center of Excellence, Food and Drug Administration, 301-796-2031, OCE-Guidances@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, IRBs, and clinical investigators entitled "Cancer Clinical Trial Eligibility Criteria: Laboratory Values." The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context.

Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this guidance includes recommendations to consider appropriate use of laboratory values as trial eligibility criteria and intends to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

This guidance finalizes the draft guidance entitled "Cancer Clinical Trial Eligibility Criteria: Laboratory Values" issued on April 26, 2024 (89 FR 32450). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include minor revisions for clarification.

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 "Cancer Clinical Trial Eligibility Criteria: Laboratory Values." 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. This guidance is also being issued consistent with FDA regulations in 21 CFR 312.145, 314.445, and 601.29, which provide that FDA will make guidance documents available to facilitate compliance with certain requirements in 21 CFR parts 312, 314, and 601, respectively.

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 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 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 guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15187 Filed 7–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1376]

Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications; Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry, institutional review boards (IRBs), and clinical investigators entitled “Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.” This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding the appropriate use of washout periods and concomitant medication exclusions. This guidance finalizes the draft guidance of the same title issued on April 26, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on July 28, 2026.

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

Electronic Submissions

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- **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”).

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- 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–1376 for “Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.” 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. 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: LCDR Michael Gu, Oncology Center of Excellence, Food and Drug Administration, 301–796–2031, OCE-Guidances@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.” The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template