

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Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Steven Lemery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2374, Silver Spring, MD 20993-0002, 301-796-2276; or Stephen Ripley, 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FDA is announcing the availability of a draft guidance for industry entitled “Tissue Agnostic Drug Development in Oncology.” This draft guidance

provides recommendations to sponsors regarding considerations for tissue agnostic drug development in oncology. For the purpose of this guidance, the term “tissue agnostic oncology drug” refers to a drug that targets a specific molecular alteration(s) (a kind of biomarker) across multiple cancer types as defined, for example by organ, tissue, or tumor type. A tissue agnostic oncology drug can therefore be used to treat multiple types of cancer (e.g., colorectal, thyroid, and breast cancers) with the targeted molecular alteration (e.g., either the same targeted molecular alteration or targeted molecular alterations affecting a single pathway). The guidance discusses the need in tissue agnostic drug development to generalize treatment effects based on data observed in some cancer types to other cancer types with the same targeted molecular alteration, when no subjects (or a limited number of subjects) with the other cancer types were included in the clinical trial(s). Such an approach may expedite or enable the development of new therapies for patients with rare cancer types when it may not be feasible to test the drug in an adequate number of subjects for every cancer type.

The draft guidance describes factors that sponsors should consider when determining whether a tissue agnostic oncology drug development program may be scientifically and clinically appropriate, such as biology, subject population, clinical pharmacology, and clinical safety and efficacy. In addition, the draft guidance describes issues to be addressed in a tissue agnostic drug development program, such as nonclinical assessment, subject selection, study designs, statistical considerations, endpoints, pediatrics, diagnostic considerations, postapproval data and information, and labeling.

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 “Tissue Agnostic Drug Development in Oncology.” 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–

3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

##### **III. Electronic Access**

Persons with access to the internet may obtain an electronic version of 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: October 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-22616 Filed 10-17-22; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2022-D-1744]

#### **Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials; 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 “Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials.” This guidance is intended for sponsors of cancer immunotherapeutic drugs that modulate the endogenous immune system and may break immunologic tolerance to normal organs and tissues; it provides recommendations regarding the data that should be collected and evaluated

to assess whether adverse events are immune-mediated adverse reactions (imARs) and the data on imARs that should be included in a new drug application (NDA) or biologics license application (BLA) for a cancer immunotherapeutic drug.

**DATES:** Submit either electronic or written comments on the draft guidance by December 19, 2022 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-2022-D-1744 for "Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer

Immunotherapeutic Clinical Trials." 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>.

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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. 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:**

Marc Theoret, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993-0002, 301-796-4099; or Stephen Ripley, Center for Biologics Evaluation and Research, Office of Communication, Outreach, and Development, 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 "Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials." This guidance is intended for sponsors of cancer immunotherapeutic drugs that modulate the endogenous immune system and may break immunologic tolerance to normal organs and tissues; it provides recommendations regarding the data that should be collected and evaluated to assess whether adverse events are imARs and the data on imARs that should be included in an NDA or BLA for a cancer immunotherapeutic drug.

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 "Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials." 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 including the submission of labeling, 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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: October 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–22617 Filed 10–17–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Tick-Borne Disease Working Group

**AGENCY:** Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice; addendum to 87 FR 56964 published on September 16, 2022.

**SUMMARY:** The Office of the Assistant Secretary for Health published a notice of an upcoming meeting of the Tick-Borne Disease Working Group (TBDWG) in the **Federal Register** on September 16, 2022. This addendum provides notice of an additional day added to the October 25, 2022 meeting. The 24th meeting of the TBDWG will now take place from October 24–25, 2022. The September 16th **Federal Register** notice can be accessed at <https://www.federalregister.gov/documents/2022/09/16/2022-20088/meeting-of-the-tick-borne-disease-working-group>.

**DATES:** The public can view the meeting online via webcast on October 24 and 25, 2022 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change) each day. The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2022-10-25/index.html> when this information becomes available.

**SUPPLEMENTARY INFORMATION:** As stated in the **Federal Register** notice dated September 16th, the public will have an opportunity to present their views to the TBDWG orally during the meeting's

public comment session or by submitting a written public comment. Persons who wish to provide verbal or written public comment should review instructions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2022-10-25/index.html> and respond by midnight October 17, 2022 ET.

#### FOR FURTHER INFORMATION CONTACT:

James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Rockville, MD 20852. Email: [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov). Phone: 202–795–7608.

Dated: September 30, 2022.

**James Berger,**

*Designated Federal Officer, HHS Tick-Borne Disease Working Group, Office of HIV/AIDS and Infectious Disease Policy.*

[FR Doc. 2022–22589 Filed 10–17–22; 8:45 am]

**BILLING CODE 4150–28–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) 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:** Population Sciences and Epidemiology Integrated Review Group; Cardiovascular and Respiratory Diseases Study Section.

**Date:** November 8–9, 2022.

**Time:** 9 a.m. to 8 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:** Mohammed F A Elfaramawi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive,

Room 1007F, Bethesda, MD 20892, (301) 480–1142, [elfaramawimf@csr.nih.gov](mailto:elfaramawimf@csr.nih.gov).

**Name of Committee:** Population Sciences and Epidemiology Integrated Review Group; Cancer and Hematologic Disorders Study Section.

**Date:** November 9–10, 2022.

**Time:** 8:30 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

**Contact Person:** Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, [wieschd@csr.nih.gov](mailto:wieschd@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Small Business: Renal and Urological Sciences.

**Date:** November 10, 2022.

**Time:** 8 a.m. to 6 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:** Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182 MSC 7818, Bethesda, MD 20892, (301) 827–5467, [ganesan.ramesh@nih.gov](mailto:ganesan.ramesh@nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; RFA–OD–22–002: Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (U01 Clinical Trial Not Allowed).

**Date:** November 10, 2022.

**Time:** 1 p.m. to 4 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:** Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4097, [maureen.shuh@nih.gov](mailto:maureen.shuh@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 12, 2022.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–22585 Filed 10–17–22; 8:45 am]

**BILLING CODE 4140–01–P**