

responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

j. To compare such records to other agencies' systems of records or to non-Federal records, in coordination with an Office of Inspector General (OIG) in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the Inspector General Act.

k. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records are stored electronically in a database. Information is encrypted in transit and at rest.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information on individuals contained in Pegasys records are retrievable by name or other identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in the system to support transactional integrity and will be retained according to the National Archives and Records Administration (NARA) General Records Schedule 1.1—Financial Management and Reporting Recording Records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access is limited to authorized individuals with passwords, and the database is maintained behind a certified firewall. Information on individuals is released only to authorized persons with a lawful government purpose and in accordance with the provisions of routine use. Additionally, vulnerability scanning, real-time intrusion detection, firewall monitoring and alerts, database monitoring, site protection monitoring, identity management monitoring, virus

and compliance scans are performed on a scheduled basis to ensure adequate security measures are in place to prevent unauthorized access.

RECORD ACCESS PROCEDURES:

If an individual wishes to access any data or record pertaining to him or her in the system after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.2.

CONTESTING RECORD PROCEDURES:

If an individual wishes to contest the content of any record pertaining to him or her in the system after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.4.

NOTIFICATION PROCEDURES:

If an individual wishes to be notified at his or her request if the system contains a record pertaining to him or her after it has been submitted, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The initial Notice in connection with this system of records was published on October 16, 2006 (71 FR 60710). Under GSA, a first updated Notice was published on April 25, 2008 (73 FR 22396) and a second updated Notice was published on December 31, 2013 (78 FR 79694). These records were then transferred to the US Department of Agriculture and administered under USDA/OCFO–10, which was previously published in the **Federal Register** on December 19, 2018 (83 FR 67712).

Richard Speidel,

Chief Privacy Officer, Office of Enterprise Data & Privacy Management, General Services Administration.

[FR Doc. 2026–00358 Filed 1–9–26; 8:45 am]

BILLING CODE 6820–AB–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–3217]

Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products; 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 “Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products.” This document provides guidance on the appropriate use of Bayesian methods in clinical trials. The primary focus is on the use of Bayesian methods to support primary inference in pivotal clinical trials designed to support the effectiveness and safety of drug and biological products.

DATES: Submit either electronic or written comments on the draft guidance by March 13, 2026 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–2025–D–3217 for “Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products.” 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 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:

Scott N. Goldie, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055, Scott.Goldie@fda.hhs.gov, or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products.” This document provides guidance to sponsors and applicants submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics licensing applications (BLAs) or supplemental applications on the appropriate use of Bayesian methods in clinical trials. The primary focus of this guidance is on the use of Bayesian methods to support primary inference in pivotal clinical trials designed to support the effectiveness and safety of drug and biological products. This draft guidance is being issued to satisfy a commitment under the sixth reauthorization of the Prescription Drug User Fee Act to publish draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products.

Bayesian statistics is an approach to estimation and inference based on the use of Bayes’ theorem. In a Bayesian analysis, data collected in a study are combined with a prior distribution that expresses a pre-study position about a parameter of interest to form a posterior distribution that expresses the updated, post-study position about the parameter of interest. The prior distribution often represents a summary of data or information available before the study begins. The posterior distribution is used for inference and to draw conclusions about the study results.

The draft guidance addresses relevant considerations on how to appropriately design clinical trials using Bayesian approaches. The document describes settings where Bayesian methods have been used and provides recommendations related to the choice of success criteria, evaluation of trial operating characteristics, and

determination of the prior distribution. It includes detailed considerations for use of an informative prior to borrow external information in the primary analysis of a prospective trial. The document also discusses estimands and missing data, software and computation, and documentation and reporting considerations for trials that use Bayesian methods.

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 “Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products.” 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 312 pertaining to the submissions of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314 and 21 CFR 601 pertaining to the submission of new drug applications and biologic licensing applications have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

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>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-00325 Filed 1-9-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: February 11, 2026.

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

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments; and Overview of the BRAIN program.

Meeting is virtual and will be videocast from this link: <https://videocast.nih.gov>.

Place: National Institutes of Health, 6001 Executive Boulevard, Room 1131, Rockville, Maryland 20852, (Virtual Meeting).

Contact Person: Andrea Meredith Ph.D., Director, Extramural Activities, National Institute of Neurological, Disorders and Stroke, NIH, 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, (301) 496-9248, andrea.meredith@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.ninds.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: January 7, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-00302 Filed 1-9-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: March 16-17, 2026.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: DLM Presentations, Interviews, and Preliminary Discussions.

Address: National Institutes of Health, Clinical Center, 10 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ronald Neumann, M.D., Deputy Scientific Director, National Institutes of Health, Clinical Center, 10 Center Drive, Bethesda, MD 20892, 301-496-6455, rneumann@cc.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: January 7, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-00300 Filed 1-9-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received by March 13, 2026.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact Melissa Park, PRA Liaison, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2E196, Bethesda, MD 20892 or call non-toll-free number (240) 276-5717 or email your request, including your address to: melissa.park@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological