

requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options.

- Treatment information, including the investigational drug’s name and the name of the entity supplying the drug (generally the manufacturer), the applicable FDA review division (if known), and the treatment plan. This should include the planned dose, route and schedule of administration, planned duration of treatment, monitoring procedures, and planned modifications to the treatment plan in the event of toxicity.

- LOA, generally obtained from the entity that is the sponsor of the IND (e.g., commercial sponsor/drug manufacturer) being referenced, if applicable.

- Physician’s qualification statement. An appropriate statement includes medical school attended, year of graduation, medical specialty, State medical license number, current employment, and job title.

Alternatively, the relevant portion of the physician’s curriculum vitae may be attached.

- Physician’s contact information, including name, physical address, email

address, telephone number, facsimile number, and physician’s IND number, if previously issued by FDA.

- Contents of submission (for followup/additional submissions), including the type of submission being made. FDA accepts Form FDA 3926 for certain followup/additional submissions, which include the following: Initial written IND safety report (§ 312.32(c)); followup to a written IND safety report (§ 312.32(d)); annual report (§ 312.33); summary of expanded access use (treatment completed) (§ 312.310(c)(2)); change in treatment plan (§ 312.30); general correspondence or response to FDA request for information (§ 312.41); and response to clinical hold (§ 312.42(e)).

- Request for authorization to use Form FDA 3926 for individual patient expanded access application.

- Signature of the physician certifying that treatment will not begin until 30 days after FDA receives the completed application and all required material unless the submitting physician receives earlier notification from FDA that the treatment may proceed. The physician agrees not to

begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. The physician also certifies that informed consent will be obtained in compliance with Federal requirements (including FDA’s regulations in 21 CFR part 50) and that an institutional review board (IRB) that complies with all Federal requirements (including FDA’s regulations in 21 CFR part 56) will be responsible for initial and continuing review and approval of the expanded access use. The physician also acknowledges that in the case of an emergency request, treatment may begin without prior IRB approval, provided the IRB is notified of the emergency treatment within 5 working days of treatment. The physician agrees to conduct the investigation in accordance with all other applicable regulatory requirements.

In the **Federal Register** of November 7, 2018 (83 FR 55723), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Guidance on individual patient expanded access applications: Form FDA 3926	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Expanded access submission elements included in Form FDA 3926	790	3.03	2,394	0.75 (45 mins.)	1,795

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we are retaining the currently approved burden estimate. The estimates for “number of respondents,” “number of responses per respondent,” and “total annual responses” were obtained from reports and data management systems from the Center for Drug Evaluation and Research (CDER) and from other sources familiar with the number of submissions received for individual patient expanded access use under part 312. The estimates for “average burden per response” were based on information CDER provided and personnel of the U.S. Department of Health and Human Services familiar with preparing and reviewing expanded access submissions by practicing physicians.

Based on data from the Document Archiving, Reporting, and Regulatory Tracking System for the number of submissions to FDA using FDA Form 3926 during fiscal years 2015, 2016, and 2017, we estimate that approximately

790 licensed physicians would use FDA Form 3926 to submit 1.46 requests per physician (respondent) for individual patient expanded access, for a total of 1,153 responses annually. Based on these estimates, FDA calculates the total annual responses to be 2,394 (1,153 requests for individual patient expanded access and 1,241 followup submissions) by 790 physicians for an average of 3.03 responses per respondent. FDA estimates the average burden per response to be 45 minutes (0.75 hour). Based on this estimate, FDA calculates the total burden to be 1,795 hours.

Dated: April 11, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
 [FR Doc. 2019-07711 Filed 4-16-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0001]

Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities.” Convened by the Duke-Robert J. Margolis Center for Health Policy at Duke University in partnership with the Critical Path Institute and supported by a cooperative agreement

with FDA, the purpose of the public workshop is to bring the stakeholder community together to discuss challenges and opportunities to advance the development and application of analysis data standards in drug development and regulatory review. This public workshop is being organized to fulfill FDA's commitment in section (I)(j)(5)(c) of the Prescription Drug User Fee Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (PDUFA VI goals letter; available at <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>) to convene a public workshop to advance the development and application of analysis data standards. FDA will use the information from this public workshop to inform ongoing and future analysis data standards initiatives and strategic planning to improve the efficiency of regulatory review of electronic submissions.

DATES: The public workshop will be held on June 12, 2019, from 9 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. For more information, please check the following website: <https://www.tommydouglascenter.com/>. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Mary Jo Salerno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3541, Silver Spring, MD 20993-0002, 240-402-0420, MaryJo.Salerno@fda.hhs.gov. If contacting in writing, please use the subject line "Analysis Data Standards Public Workshop."

SUPPLEMENTARY INFORMATION:

I. Background

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables. Establishing common study data standards provides new opportunities to transform the vast, diverse, and continually increasing

amount of clinical study data into useful information to speed the delivery of new therapies to patients. Having standard, uniform study data enables FDA scientists to combine data from multiple studies to explore many new research questions and gain new insights. Data standards also help FDA receive, process, review, and archive submissions more efficiently and effectively by preventing submission reviewers from having to navigate a high volume of less-structured data, which allows reviewers more time to focus on the scientific review.

The Center for Drug Evaluation and Research (CDER) established the Data Standards Program in 2010. The program has led CDER's efforts to standardize data and has helped FDA meet its commitments in the Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 (PDUFA V). Accomplishments to date include the following: (1) Publication of a final guidance entitled "Providing Regulatory Submissions in Electronic Format—eCTD Specifications"; developing a repeatable test process to ensure data standards meet FDA needs; (2) working with FDA's Center for Biologics Evaluation and Research to compile a prioritized list of disease and therapeutic areas for which additional data standardization is needed; and (3) working with partners to develop a series of use cases for clinical study data related to Human Immunodeficiency Virus therapies, vaccines, and comparative clinical endpoint bioequivalence studies.

Standards models that span the data lifecycle from data collection (e.g., Clinical Data Acquisition Standards Harmonization (CDASH)) to tabulated representation (e.g., Standard for the Exchange of Nonclinical Data (SEND) and Study Data Tabulation Model (SDTM)) are foundational for analysis data standards (e.g., Analysis Data Model (ADaM)). FDA is conducting this public workshop to support the PDUFA VI goals to advance the development and application of analysis data standards.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will address a range of issues related to the development and implementation of analysis data standards. Items for discussion will include stakeholder experience implementing analysis data standards in electronic submissions. Input will be sought on the key challenges and opportunities to: (1) Improve the

efficiency, predictability, and quality of data submissions; (2) support data traceability; and (3) support optimal implementation of analysis data standards. Input will also be sought on approaches to reduce the variability of formats used to submit study data, improve the integration of data across studies, and enable the use of data from sources other than traditional clinical trials.

III. Participating in the Public Workshop

Registration: To register for the public workshop, visit the following website: <https://healthpolicy.duke.edu/events/analysis-data-standards-workshop>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by June 10, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Duke-Margolis will post on its website if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy, 202-791-9561, sarah.supsiri@duke.edu, no later than June 5, 2019.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Webcast participants will be able to submit questions and comments via the webcast portal. Following the workshop, archived video footage will be available on the Duke-Margolis website at <https://healthpolicy.duke.edu/events/analysis-data-standards-workshop>. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Before joining the streaming webcast of the public workshop, we recommend that you review these technical system requirements. 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 transcripts will not be available.

Workshop Materials: All event materials will be provided to registered attendees via email before the workshop

and will also be publicly available on the Duke-Margolis website at <https://healthpolicy.duke.edu/events/analysis-data-standards-workshop>.

Dated: April 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-07700 Filed 4-16-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee hearing.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Date and Times: Wednesday, June 5, 2019: 9:00 a.m.–5:00 p.m. (EST), Thursday, June 6, 2019: 8:30 a.m.–3:00 p.m. (EST)

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 505A, Washington, DC 20201.

Status: Open.

Purpose: At the June 5–6, 2019 meeting, the Committee will deliberate draft recommendations for the HHS Secretary, move forward on activities outlined in the NCVHS 2019 workplan, and hold discussions on several health data policy topics. Anticipated action items during this meeting include a letter that outlines recommendations to the Secretary and an accompanying report focused on a framework for health information privacy and security.

Specifically, the Privacy, Confidentiality and Security Subcommittee will provide an update to the full Committee regarding its working meeting held in March 2019 focused on health information privacy and security beyond the scope of HIPAA. This will include discussion of a draft report that will lay out a framework for extending basic protections for health information privacy and security, a result of two years of NCVHS hearings and deliberations, to understand the environment and consider what might be a workable framework that supports innovative use of health information to advance health and wellness and reduces administrative burden, while protecting the rights of information subjects. Together with this draft report, the Subcommittee plans to present a draft set of recommendations to the HHS Secretary based on the framework

put forth in the report for full Committee deliberation.

The Subcommittee on Standards will review the timeline of its ICD–11 evaluation project and discuss any refinements that result from exploration of existing research on the impact of the transition to ICD–10, ICD–10–CM, and ICD–10–PCS. The Subcommittee will update the full Committee regarding progress on plans for an August expert roundtable meeting, which will focus on identifying research questions HHS could address to evaluate benefit and cost of the upcoming transition from ICD–10 to ICD–11 for mortality and morbidity. The Subcommittee will report on continued progress on the elements of a Predictability Roadmap in follow up to its December 2018 hearing—the current focus will be on evaluating the function and purpose of the Designated Standards Maintenance Organizations (DSMOs) in light of changes in the health care standards environment and the need for harmonization of administrative and clinical standards. Finally, the Subcommittee anticipates continuing discussion and possible activities in collaboration with the Office of the National Coordinator for Health Information and Technology (ONC) regarding the opportunity for burden reduction through convergence of administrative and clinical data standards using the prior authorization transaction as a use-case.

The Subcommittee on Population Health will provide an update on its work to address community data needs, including use-cases, for the full Committee to consider providing as input to the Federal Data Strategy. The Committee will further refine the remainder of its 2019 workplan and discuss potential options moving into fiscal year 2020.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

Contact Persons For More

Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: www.ncvhs.hhs.gov, where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

Should you require reasonable accommodation, please contact the CDC

Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: April 11, 2019.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2019-07709 Filed 4-16-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Planning and Implementation Grant (R34 and U01).

Date: May 23, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Reed Solomon Shabman, Ph.D., Scientific Review Officer, Scientific Review Program DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823 Rockville, MD 20852, 240–292–0189, reed.shabman@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Planning and Implementation Grant (R34 and U01).

Date: June 6, 2019.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Reed Solomon Shabman, Ph.D., Scientific Review Officer Scientific Review Program DEA/NIAID/NIH/DHHS,