Recipients are required to submit their Post-Expenditure Report within 6 months of the end of the period covered by the report.

The law governing the programs at Title XX of the Social Security Act [42 U.S.C. 1397c] mandates states and territories submit to the federal administering office an Intended Use Plan and Pre-Expenditure report. These materials are to detail the planned use of funds. At the end of the fiscal year, the law also requires states to provide the federal agency with a reconciliation of the actual use of grant funds in the Post-Expenditure Report [42 U.S.C. 1397e].

The forms and model plans support the states and territories in meeting the statutory requirement and provide a consistent set of tools for information collection on the grants' use for each state, as well as grant wide. The state and territory reports are congregated and analyzed and, in turn, comprise the SSBG Annual Report. The data informs the program's performance and efficiency measures for program impact and efficacy. OCS is proposing to make minor editorial modifications to some column titles in the Pre- and Post-Expenditure Reports, for clarification.

Respondents: Agencies that administer the SSBG at the state or territory level, including the 50 states; the District of Columbia; the Commonwealth of Puerto Rico; Massachusetts Commission for the Blind (M–CFB); and the territories of American Samoa, Guam, the U.S. Virgin Islands, and the Commonwealth of Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Pre-Expenditure Report Form	57	1	2	114
Intended Use Plan	57	1	40	2,280
Post-Expenditure Reporting Form	57	1	110	6,270
Estimated Total Annual Burden Hours:				8,664

Authority: 42 U.S.C. 1397–1397e.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–02851 Filed 2–12–24; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0219]

Use of Data Monitoring Committees in Clinical Trials; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Use of Data Monitoring Committees in Clinical Trials.'' This guidance is intended to assist sponsors of clinical trials in determining when a data monitoring committee (DMC) (also known as a data and safety monitoring board (DSMB), a data and safety monitoring committee (DSMC), or an independent data monitoring committee (IDMC)) would be useful for trial monitoring and what procedures and practices should be considered to guide their operation. When finalized, this guidance will supersede the final guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees,'' issued in March 2006. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 15, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 15, 2024.

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–2001–D–0219 for ''Use of Data Monitoring Committees in 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.*

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 to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, or to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334 Silver Spring, MD 20993, 240–402–8926; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993–0002, 240–402–7911; or Ouided Rouabhi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G221, Silver Spring, MD 20993–0002, 301–796–6359.

With regard to the proposed collection of information: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Use of Data Monitoring Committees in Clinical Trials.'' This guidance pertains primarily to the sponsor's responsibility for clinical trial management and decision making, but may also be relevant to any individual or group to whom the sponsor has delegated applicable trial management responsibilities. This guidance provides recommendations to help sponsors of clinical trials determine: (1) when a DMC (also known as a DSMB, a DSMC, or an IDMC) would be useful for trial monitoring and (2) what procedures and practices should be considered to guide their operation. Under FDA regulations, sponsors are not required to use DMCs in clinical trials except under 21 CFR 50.24(a)(7)(iv), where an institutional review board can approve a clinical trial without requiring informed consent from all research subjects, provided certain requirements are met, including the establishment of an independent DMC.

Although the use of DMCs initially was more common in disease areas associated with significant morbidity or mortality, since 2006, there has been an increase in the use of DMCs in many disease areas not involving serious morbidity or mortality. For example, DMCs can provide the specialized expertise to evaluate emerging efficacy and safety data for trials in rare diseases (*e.g.,* certain genetic disorders), for trials in vulnerable populations (*e.g.,* neonates), and for oncologic therapies with highly specific targets and potential serious risks (*e.g.,* biological products for genetic targets, immunotherapies). DMCs are also being used in early phase trials in serious diseases or conditions. With this growth of DMC use, a variety of approaches to DMC operations has been developed.

This draft guidance revises the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' issued on March 28, 2006. Changes to the guidance reflect changes in DMC structure and practice since FDA issued the 2006 version. When finalized, this guidance will replace the 2006 guidance.

Sponsors may be required to monitor clinical studies evaluating investigational drugs, biological products, and devices (see 21 CFR 312.50 and 312.56 (for drugs and biological products) and 21 CFR 812.2(b)(1)(iv), 812.40, and 812.46 (for devices)). Various groups and/or individuals play different roles in clinical trial monitoring and oversight. One such group is a DMC. A clinical trial DMC is established by a sponsor and is composed of a group of individuals with relevant expertise that reviews accumulating data on a regular basis from one or more clinical trials and recommends to the sponsor whether to continue, modify, or stop a trial or trials.

Consistent with § 312.32(d)(1) (21 CFR 312.32(d)(1)), the sponsor must investigate a DMC's recommendation relating to an increased rate of serious unanticipated adverse events as potentially reportable to FDA under § 312.32. If the sponsor concludes that there is a ''reasonable possibility'' that the increased rate of serious unanticipated adverse events was associated with use of the drug, the finding, and support for it (which could include the DMC report, any analyses, and pertinent data) must be submitted to FDA as a serious unexpected suspected adverse reaction. Similar considerations would also apply if the sponsor concludes that an increased rate of adverse events constitutes an unanticipated adverse device effect under 21 CFR 812.46(b) and 812.150(b)(1).

In the guidance (section VI.B), FDA recommends that sponsors establish a charter describing DMC obligations, responsibilities, and standard operating procedures. The charter should address, for example, the following:

1. Procedures for assessing financial and intellectual conflicts of interest of proposed DMC members, including identifying any concurrent service of any DMC member on other DMCs for trials of the same, related, or competing product;

2. how unblinded analyses will be prepared (*e.g.,* by an independent statistician) for the DMC and at what frequency; and

3. procedures to maintain the confidentiality of interim comparative data in communications between the DMC, the sponsor, and (if applicable) outside parties to ensure that such data available to the DMC are not inappropriately disclosed or disclosed without appropriate protections.

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 Data Monitoring Committees in 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

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Use of Data Monitoring Committees in Clinical Trials

OMB Control Number 0910–0581—Revision

This collection of information supports recommendations found in the Agency guidance. The draft guidance document entitled ''Use of Data Monitoring Committees in Clinical Trials'' addresses the roles, responsibilities, and operating procedures of DMCs and describes certain reporting and recordkeeping responsibilities, including the following: (1) sponsor reporting to FDA on DMC recommendations related to safety; (2) standard operating procedures (SOPs) for DMCs; (3) DMC meeting records; and (4) DMC reports based on meeting minutes to the sponsor. The submission of the requested information provides the appropriate parties with essential information regarding the clinical trial upon which they may base their recommendations.

1. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

FDA recommends that sponsors inform FDA about all DMC recommendations related to the safety of the investigational product, whether or not the adverse events that led to the recommendation meet the definition of serious.

2. Charters and SOPs for DMCs

In section VI.B of the guidance, we outline recommendations for establishing a DMC charter describing SOPs. The SOPs ensure that established written procedures are followed and proper recordkeeping is performed.

In section VII of the guidance, we outline the relationships of the DMC members and the sponsors to address the independence of the DMC from the sponsor.

3. DMC Meeting Records

FDA recommends that the DMC keep minutes of all meetings but use separate minutes for open and closed sessions.

4. DMC Reports of Meeting Minutes to the Sponsor

The Agency recommends in the guidance that DMCs should issue a written report to the sponsor based on the DMC meeting minutes. This report should include sufficient information to explain the rationale for any recommended changes. Sponsors should establish procedures to minimize bias, such as requiring that reports to the sponsor include only those data generally available to the sponsor (*e.g.,* number screened, number enrolled at each site) (see 21 CFR 314.126(b)(5) and 860.7(f)(1)). FDA may request copies of DMC meeting records when the trial is completed (21 CFR 312.58 and 812.150(b)(10)) and may also request access to the electronic data sets used for each set of interim analysis. FDA therefore recommends that sponsors arrange for archiving such electronic data sets.

Description of the Respondents: The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of guidance; reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section VIII; Sponsor reporting to FDA on DMC recommendations related to safety.	74	1	74	0.5 (30 minutes)	37
Total					37

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Section of guidance; recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Sections VI and VII; Charters and SOPs for DMCs	74	1	74	8	592
Section VI.6.C.4.b.; DMC meeting records	740	1	740	2	1,480
Total					2,072

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Section of guidance; disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Section VI.C.4.; DMC reports of meeting minutes to the sponsor	740	2	1,480	1	1,480

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

Reporting, Recordkeeping, and Third-Party Disclosure Burdens: Based on our experience and the anticipated increase in DMC use, FDA estimates that there are approximately 1,480 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 740 clinical trials. For the purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 74 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends using a DMC, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial, resulting in the issuance of two DMC reports of meeting minutes (closed and open meeting sessions) to the sponsor. One set of both of the meeting records should be maintained per clinical trial.

Based on a review of the information collection since our last request for OMB approval, our estimated burden for the information collection reflects an overall increase in burden of 1,183 hours and a corresponding increase of 1,794 responses. We attribute this increase generally to an adjustment in respondents based on our experience and the anticipated increase in DMC use. In table 3, since we removed the language in this draft guidance regarding waivers, we removed the ''sponsor notification to the DMC regarding waivers'' task from the burden table, resulting in a decrease of 1 response. In addition, the sections in the draft guidance were changed; therefore, we updated the section numbers in the burden tables in accordance with the draft guidance.

This draft guidance also refers to previously approved FDA collections of information found in FDA regulations. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. 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 pertaining to good clinical practice have been approved under OMB control number 0910–0843. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 54 pertaining to financial disclosure by clinical investigators have been approved under OMB control number 0910–0396.

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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02849 Filed 2–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents; Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notices; correction.

SUMMARY: HRSA published documents in the **Federal Register** of October 24,