

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

Information collection activity; guidance document section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total .....	.....	.....	247	.....	3,054

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

**Burden Estimate:** Table 1 provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

**Notification for a Carcinogenicity Protocol:** Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 92 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 98 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

**Requests for Special Protocol Assessment:** Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 152 requests for special protocol assessment per year from approximately 98 sponsors. CBER estimates that it will receive approximately two requests from approximately two sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on our experience with these submissions, we estimate approximately 15 hours on average would be needed per response.

The information collection reflects an adjustment decrease in burden by 196 hours. We attribute this adjustment to a decrease in the number of notifications for carcinogenicity protocols and an increase in the number of requests for

special protocol assessment reports we received over the last few years.

Dated: October 25, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–D–0760]

#### Measuring Growth and Evaluating Pubertal Development in Pediatric 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 “Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials.” The purpose of this draft guidance is to outline the most appropriate methods for measuring and recording growth and evaluating pubertal development for drugs or biological products in development for pediatric use when such an assessment is necessary to support safety. This draft guidance is intended to encourage a consistent approach to collecting interpretable and accurate growth and pubertal development data. This draft guidance does not address use of growth or pubertal development data to support primary evidence of efficacy in growth disorders and does not address evaluation of nutritional status.

**DATES:** Submit either electronic or written comments on the draft guidance by January 3, 2023 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–0760 for “Measuring Growth and Evaluating Pubertal Development in Pediatric 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 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; 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** George Greeley, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6406, Silver Spring, MD 20993-002, 301-796-4025; 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 "Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials." The purpose of this draft guidance is to assist sponsors in monitoring growth and pubertal development in clinical trials that enroll pediatric patients with both rare and common diseases. This draft guidance is focused on the most appropriate methods for measuring and recording growth and evaluating pubertal development for evaluation of safety.

If an investigational drug or biological product may affect growth or pubertal development, then accurate, serial measurement and recording of growth parameters are essential for data interpretation in pediatric clinical trials. In general, growth is assessed using measurements of weight, linear growth (length and height), and when appropriate, head circumference. Additional measurements and calculations may be needed in certain pediatric age groups and disease populations. In general, pubertal development is assessed using clinical phenotyping. Identifying the onset and progression of puberty are essential for accurate interpretation of growth data.

This draft guidance addresses measurement of growth, evaluation of pubertal development, and other measurements. The discussion of growth measurements consists of general considerations to ensure accurate, reproducible measurements followed by specific suggestions about how to measure weight, linear growth (length and height), and head circumference in the entire pediatric population starting at birth. The recommendations for pubertal development focus on use of the sexual maturity rating. The draft guidance also provides recommendations on other measurements, specifically use of skeletal age and dual-energy X-ray absorptiometry.

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 "Measuring Growth and Evaluating

Pubertal Development in Pediatric 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 new 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 collection of information in 21 CFR part 314 has been approved under OMB control number 0910-0001.

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

Dated: October 27, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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

### **National Committee on Vital and Health Statistics; Meeting and RFC**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Notice of meeting, notice of request for comment (RFC).

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting and related Request for Comment (RFC). The meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/>