



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0734]

Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies." The purpose of this document is to outline FDA's proposed recommendations and expectations for the evaluation and reporting of age, race, and ethnicity data in medical device clinical studies. The primary intent of these recommendations is to improve the quality, consistency, and transparency of data regarding the performance of medical devices within specific age, race, and ethnic groups. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-0734 for "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies" to the Office of the Center Director, 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 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 request.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5428, Silver Spring, MD 20993-0002, 301-796-6349; 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

Section 907 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA) directed the Agency to publish and provide to Congress a report describing the extent to which clinical trial participation and safety and effectiveness data by demographic subgroups, including sex, age, race, and ethnicity, is included in applications submitted to FDA (Ref 1). Section 907 also directed FDA to publish and provide to Congress an action plan outlining recommendations for improving the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling; on the inclusion of such data, or the lack of availability of such data, in labeling; and on improving the public availability of such data to patients health care providers and researchers, and to indicate the applicability of these recommendations to the types of medical products addressed in section 907. In the Action Plan, FDA committed to developing this draft guidance as part of the strategy to fulfill FDASIA requirements (Ref. 2).

This guidance outlines FDA's recommendations and expectations for patient enrollment, data analysis, and reporting of age, race, and ethnicity data in medical device clinical studies. Specific objectives of this guidance are to (1) encourage the collection and consideration of age, race, ethnicity, and associated covariates (e.g., body size, biomarkers, bone density) during the study design stage; (2) outline recommended analyses of study subgroup data with a framework for considering demographic data when interpreting overall study outcomes; and (3) specify FDA's recommendations for reporting age, race, and ethnicity-specific information in summaries and labeling for approved or cleared medical devices. FDA believes these recommendations will help improve the quality, consistency, and transparency of data regarding the performance of medical devices within specific age, race, and ethnic groups as well as encourage appropriate enrollment of diverse populations including relevant age, race, and ethnic groups. Proper

evaluation and reporting of these data can benefit patients, clinicians, researchers, regulators, and other stakeholders.

This document extends the policy established in FDA's guidance entitled "Evaluation of Sex-Specific Data in Medical Device Clinical Studies" to additional demographic subgroups of age, race, and ethnicity (Ref. 3). Upon finalization of this draft guidance, FDA intends to integrate the content of both guidances into one document.

II. Significance of Guidance

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 the evaluation and reporting of age, race, and ethnicity data in medical device clinical studies. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BioLogicsBloodVaccines/GuidanceComplianceRegulatoryinformation/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic

copy of the document. Please use the document number 1500026 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). These 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 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Report: Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products, issued August 2013, required under FDASIA section 907, available at

<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsstotheFDCA/FDASIA/UCM365544.pdf>.

2. FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (August, 2014), available at

<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsstotheFDCA/FDASIA/UCM410474.pdf>.

3. FDA's guidance entitled "Evaluation of Sex-Specific Data in Medical Device Clinical Studies" (August 22, 2014), available at

<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm283707.pdf>.

Dated: June 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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