4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-3054]

M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol; International Council for Harmonisation; Draft Technical Specification; and Template; 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 revised draft technical specification entitled "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP)" and a supplemental document entitled "M11 Template." The revised draft technical specification and template were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The revised draft technical specification recommends the use of an open, nonproprietary standard to enable electronic exchange of clinical protocol information. The template identifies headers, common text, and a set of data fields and terminologies that will be the basis for efficiencies in data exchange. These ICH documents create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. This revised draft technical specification and updated template revise and replace the draft versions of the same titles issued in December 2022.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-3054 for "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol

(CeSHarP)." 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 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 (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance*: Veronica Pei, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5338, Silver Spring, MD 20993-0002, 240-402-7091, Veronica.Pei@fda.hhs.gov; or James Myers, 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.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993-0002, 301-348-1967, Brooke.DalSanto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the revised draft technical specification entitled "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP)" and a supplemental document entitled "M11 Template." The revised draft technical specification and template were prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing

the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to https://www.ich.org/).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In March 2025, the ICH Assembly endorsed the revised draft technical specification entitled "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP)" and a supplemental document entitled "M11 Template" and agreed that the materials should be made available for public comment. The revised draft technical specification and template are the products of the Multidisciplinary Expert Working Group of the ICH. To

support the review and public comment on the completed technical specification, the updated template is being provided as a reference document to aid in the review and understanding of the technical specification, but FDA is not seeking comment on the template. Comments about the technical specification will be considered by FDA and the Multidisciplinary Expert Working Group.

This technical specification revises the draft technical specification entitled "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol (CeSHarP)" and the supplemental document entitled "M11 Template" that were issued on December 22, 2022 (87 FR 78696), along with the draft guidance for industry entitled "M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP)" (available at https://www.fda.gov/media/164112/download).

The technical specification recommends the use of an open, nonproprietary standard to enable electronic exchange of clinical protocol information. Revisions to the technical specification include cardinality, definitions, and terminology alignment, reflecting both prior public feedback and expert working group discussions. The template's structure and content provide a framework for relevant stakeholders to develop, review and use protocols that consistently and unambiguously include a uniform table of contents, common section headers and content, as well as common terminologies. Revisions to the template include the table of contents, instructions, content, and specifications for universal and optional text, reflection both prior public feedback and expert working group discussions. The intent of the draft guidance for industry and these supporting documents is to create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders.

The revised draft technical specification and template have been left in the original ICH format. The final technical specification and template will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication.

The technical specification and template, when finalized, will represent the current thinking of FDA on the topics they address. They do not establish any rights for any person and are 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 any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M-25-20, and in particular, on any costs or cost savings.

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 part 312 pertaining to clinical trial design and protocols have been approved under OMB control number 0910-0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance, template, and technical specification at https://www.regulations.gov, 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, or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Dated: June 2, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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