M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP)

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2026
ICH-Multidisciplinary

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FOREWORD

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory expectations in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized safety reporting and marketing application submissions, and contributed to many other improvements in the quality of global drug development and manufacturing and the products available to patients.

ICH is a consensus-driven process that involves technical experts from regulatory authorities and industry parties in detailed technical and science-based harmonization work that results in the development of ICH guidelines. The commitment to consistent adoption of these consensus-based guidelines by regulators around the globe is critical to realizing the benefits of safe, effective, and high-quality medicines for patients as well as for industry. As a Founding Regulatory Member of ICH, the Food and Drug Administration (FDA) plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance to industry.

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M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION (1)[2]

A. Background (1.1)

The clinical trial protocol provides details on trial purpose, objectives, design, and rationale, and describes the processes and procedures directing the conduct and analysis of a clinical trial of medicinal product(s) in humans. To date, ICH has not adopted a harmonized standard for the format and content of the protocol to facilitate consistency across sponsors and for the electronic exchange of protocol information.

Variability in format and core content among sponsors contributes to inefficiencies and difficulties in searching, reviewing, and assessing protocols. Use of the protocol template aids the sponsor or sponsor-investigator in the development of a protocol that is complete, unambiguous, well organized, and aligned with quality by design principles, as set forth in other ICH guidances. By conveying information consistently and in the same location across protocols, a protocol template is intended to provide value to parties that include sponsors, investigators, investigator site staff, trial participants, institutional review boards/ethics committees, and regulators.

A technical specification presenting the business requirements and common structured protocol content components will enable an open, nonproprietary interoperable standard for electronic exchange, aiding the review and execution of protocols.

[1] This guidance was developed within the Expert Working Group (Multidisciplinary) of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document has been endorsed by the ICH Assembly at *Step 4* of the ICH process, November 2025. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory bodies of the ICH regions.

[2] The numbers in parentheses reflect the organizational breakdown of the document endorsed by the ICH Assembly at *Step 4* of the ICH process, November 2025.

B. Purpose (1.2)

The purpose of this guidance is to describe the general protocol design principles and approach used to develop the separate associated documents, the ICH draft guidance for industry *M11 Template: Clinical Electronic Structured Harmonized Protocol (CeSHarP)* (June 2025)[3] (Template) and the Technical Specification that are acceptable to all regulatory authorities of the ICH regions. The Template presents the format and structure of the protocol, including table of contents, common headers, and instructions for content. The Technical Specification presents the data elements and technical attributes (e.g., definition, conformance, cardinality) that enable the interoperable electronic exchange of protocol content.

Use of this Template and Technical Specification should ensure that protocols are provided in a harmonized data exchange format acceptable to the regulatory authorities. The Template and Technical Specification have been developed with built-in flexibility and are versioned documents. As protocol requirements evolve and technology advances, they may be revised, subject to a change control process.

C. Scope (1.3)

The Template and Technical Specification documents supported by this guidance are intended to assist stakeholders (those who use and exchange protocol information, including sponsors, investigators, investigator site staff, trial participants, institutional review boards/ethics committees, and regulators) in the development, amendment, review, conduct, and closeout of a clinical trial. The Template and Technical Specification are applicable to interventional clinical trials of medicinal products across all phases and therapeutic areas of clinical research. Interventional trials may include but are not limited to human pharmacology, exploratory, confirmatory, and post approval studies (see the ICH guidance for industry *E8 (R1) General Considerations for Clinical Studies* (April 2022)).[4] The term "medicinal product" in this guidance, and the term "trial intervention" in the protocol Template refer to any therapeutic, prophylactic, or diagnostic agent including pharmaceuticals, biologics, vaccines, drug-device combination products when being developed as a drug, and when applicable, cell or gene therapy products.

Neither this guidance nor the Template or Technical Specification are intended to specify processes related to development and maintenance of a protocol. They do not supersede or negate other guidances that establish requirements for protocol content. They neither provide instruction on the development of a well-designed trial nor do they characterize a well-crafted final protocol. Rather, this guidance, Template, and Technical Specification establish common instructions for placement of content, as reflected in other prevailing guidances, as well as the technical attributes for interoperable electronic exchange of that content.

[3] When final, this guidance will represent the FDA's current thinking on this topic. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.
[4] See the Search for FDA Guidance Documents web page.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. GENERAL DESIGN PRINCIPLES (2)

A. Clinical Electronic Structured Harmonized Protocol – Template (2.1)

The Template was designed based on general principles that support a harmonized standard protocol to facilitate consistency and efficiency in the development, amendment, review, conduct, and closeout of a clinical trial and the exchange of protocol information. Specifically, the principles include:

- **Build common core content** – The Template design represents a core set of information for a clinical trial of any medicinal product(s).

- **Serve the needs of stakeholders** – The Template structure and content provide a framework for 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.

- **Define content for electronic exchange** – The protocol content can be electronically exchanged among parties, including sponsors and regulators, using current (e.g., electronic common technical document) and future technologies.

- **Design for content reuse** – The protocol is a rich source of information that can be reused as a part of the clinical trial management and review process, for publishing on clinical trial registries to promote clinical trial transparency, or for standardized clinical trial data capture.

- **Maintain flexibility** – The Template provides both universal and optional text to maintain flexibility. Higher-level heading structure is retained, while many lower-level sections can be added, removed, or modified as needed.

The Template should be used in conjunction with other ICH guidances relevant to the conduct of clinical trials.

B. Clinical Electronic Structured Harmonized Protocol – Technical Specification (2.2)

The Technical Specification includes detailed descriptions of the structured content components (e.g., specific data fields and blocks of text-based content), along with other defining attributes and business rules as established in the Template.

The Technical Specification is based on the following design principles:

- Promote structured common core content
- Define content specifications for electronic exchange
- Focus on relevant content use and reuse
- Enable development of a data model and an open, non-proprietary exchange message standard
- Maintain flexibility for technical innovation and region-specific use

III. TEMPLATE CONVENTIONS AND DESIGN (3)

The Template should enable a final protocol that meets the needs of its audience, which includes sponsors, investigators, investigator site staff, trial participants, institutional review boards/ethics committees, and regulators. To facilitate efficient and accurate execution, primary consideration was given to the needs of investigators and investigator site staff. Accordingly,

- The Template is designed with the most vital information for execution (e.g., Synopsis, Schema, Schedule of Activities) near the front.
- The Template is organized in a Main Body/Appendix framework, with reference details in the Appendix.
- Content in the Appendix carries equal weight and rigor as the content in the Main Body.
- Unnecessary repetition is eliminated wherever possible.