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Committee for Medicinal Products for Human Use

## ICH M11 Guideline on clinical electronic structured harmonised protocol (CeSHarP)

### Step 5

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## M11 Guideline

### Document history

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M11	Endorsement by the Members of the ICH Assembly under <i>Step 2</i> and release for public consultation.	27 September 2022
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# 1. Introduction

## 1.1. Background

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 harmonised 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 organised, and aligned with quality by design principles, as set forth in other ICH guidelines. 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.

## 1.2. Purpose

The purpose of this guideline is to describe the general protocol design principles and approach used to develop the separate associated documents, the ICH M11 Clinical Electronic Structured Harmonised Protocol Template [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 harmonised 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.

## 1.3. Scope

The Template and Technical Specification documents supported by this guideline 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 postapproval studies (see ICH E8 [R1] General Considerations for Clinical Studies). The term “medicinal product” in this guideline, 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 guideline 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 guidelines that establish requirements for protocol content. They neither provide instruction on the development of a well-designed trial nor do they characterise a well-crafted final protocol. Rather, the M11 Guideline, Template, and Technical Specification establish common instructions for placement of content, as reflected in other prevailing guidelines, as well as the technical attributes for interoperable electronic exchange of that content.

## 2. General design principles

### 2.1. *Clinical Electronic Structured Harmonised Protocol - Template*

The Template was designed based on general principles that support a harmonised 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 re-use** - The protocol is a rich source of information that can be re-used as a part of the clinical trial management and review process, for publishing on clinical trial registries to promote clinical trial transparency, or for standardised 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 guidelines relevant to the conduct of clinical trials.

### 2.2. *Clinical Electronic Structured Harmonised Protocol - Technical Specification*

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

### 3. Template conventions and design

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 organised 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.