ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)

Step 2

Step 2 document – to be released for comments

27 September 2022

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Legal Notice

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Background

- **This document has been signed off as a *Step 2* document (27 September 2022) to be issued by the ICH Regulatory Members for public consultation**
- **This document was developed based on a Concept Paper (15 November 2018) and a Business Plan (15 November 2018)**
- **Anticipating finalization as a *Step 4* document to be implemented in the local regional regulatory system: October / 2024**

Key Principles – ICH M11 Deliverables

- **ICH M11 is a new harmonised guideline on the clinical protocol that specifies comprehensive organization with standardized content (including both required and optional components).**
- **Deliverables**
  - A Template to include identification of headers, common text and a set of data fields and terminologies which will be the basis for efficiencies in data exchange
  - A Technical Specification that uses an open, nonproprietary standard to enable electronic exchange of clinical protocol information

Key Principles - Template

- **The Template was designed based on general principles that would 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.**
- **Principles**
  - Build common core content - The template design represents a core set of information for a clinical trial of any medicinal product(s).

Key Principles - Template

- Serve the needs of stakeholders - 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.
- Define content for electronic exchange - The protocol content can be electronically exchanged among parties, including sponsors and regulators, using current (for example, electronic common technical document) and other future technologies.

Key Principles - Template

- Design for content re-use - The clinical protocol is a rich source of information that can be re-used as part of the clinical trial management and review process, and, for example, published on clinical trial registries to promote clinical trial transparency and used in standardised clinical trial data capture.
- Maintain flexibility - The template incorporates both recommended and optional text and data fields to maintain flexibility. Higher-level heading structure is conserved, while lower-level sections can be added, removed, or modified as needed.

Key Principles – Technical Specification

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

Key Principles – Technical Specification

- **Principles**
  - Promote structured common core content
  - Define content specifications for electronic exchange
  - Develop a data model based on specifications
  - Focus on relevant content use and re-use
  - Use an open, non-proprietary exchange message standard
  - Maintain flexibility for technical innovation and region-specific use

ICH M11 Objectives and Benefits

- **A clinical protocol describes the processes and procedures directing the conduct and analysis of a clinical trial of medicinal product(s) in humans. To date, no internationally adopted harmonised standard has been established for the format and content of the clinical protocol to support consistency across sponsors and for the electronic exchange of protocol information.**

ICH M11 Objectives and Benefits - Guideline

- **The purpose of the 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.**

ICH M11 Objectives and Benefits - Template

- **The Template presents the format and structure of the protocol, including the table of contents, common headers, and contents.**
- **Use of the clinical trial protocol Template aids the sponsor or sponsor-investigator in the development of a protocol that is complete, free from ambiguity, well organised, and aligned with quality by design principles as set forth in other ICH guidelines.**

ICH M11 Objectives and Benefits - Template

- **By conveying information consistently and in the same location across clinical trial protocols, the protocol Template is intended to provide value to parties that include sponsors, investigators, clinical site personnel, trial participants, ethics committees, and regulators.**

ICH M11 Objectives and Benefits – Technical Specification

- **The Technical Specification presents the conformance, cardinality, and other technical attributes that enable the electronic exchange of protocol content.**
- **The Technical Specification presenting the business requirements and common structured protocol content components and an open, non-proprietary standard for electronic exchange enables development of interoperable electronic tools to facilitate exchange, review, and execution of protocols.**

ICH M11 Scope

- **The Template and Technical Specification are applicable to interventional clinical trials of medicinal products across all phases and therapeutic areas of clinical research.**

ICH M11 Out of Scope

- **Neither the 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 do not provide instruction on the development of a well-designed trial or characterise a well-crafted final protocol.**

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Summary of Guideline Content - Template

- **The Template is designed with the most vital information for execution (for example, Synopsis, Schema, Schedule of Activities) near the front.**
- **Trial-specific information appears earlier in the protocol template, while reference details and more general (non-trial specific) information is in the General Considerations and Appendices. This organisational construct was adopted for its utility during execution. All sections carry equal weight and rigor.**

Summary of Guideline Content – Technical Specification

- **The Technical Specification serves as a technical representation of the Template. This Technical Specification is to be aligned with the latest version of the Guideline and Template, but with flexibility in addressing data exchange needs per ICH and those of regional authorities.**
- **The Technical Specification contains detailed descriptions of information components of the Template.**

Summary of Guideline Content – Technical Specification

- **Example**

12 **Overall Rules**

Term (Variable)	Overall rules
Data Type	Text
Topic, Value or Header	H
Definition	
User Guidance	
Conformance	Rules
Cardinality	
Relationship content from ToC representing the protocol hierarchy	All document
Relationship (reference to high level conceptual model)	
Value	REQUIRED Level 1 and Level 2 headings
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Considerations

- **The Technical Specification is at an early stage of maturity as certain terms (variables) in this version (e.g., Cardinality, Definition, Relationship to Conceptual Model) are to be addressed post-public consultation as ICH M11 progresses through the formal ICH procedure.**
- **The Template and Technical Specification are versioned documents. As clinical protocol requirements evolve and technology advances, they may be revised subject to a change control process.**

Conclusions

- **A harmonised clinical protocol Template and Technical Specification for electronic exchange of protocol information will enhance the ability of sponsors, regulators, investigators, and other stakeholders to initiate, review, and conduct clinical research, resulting in more efficient drug development and delivery of medicines to patients.**
- **Additional training materials will be developed to complement the Guideline.**

Contact

- **For any questions please contact the ICH Secretariat:**

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