ICH M11: Clinical Electronic Structured Harmonised Protocol (CeSHarP)

Overview

ICH M11: Clinical Electronic Structured Harmonised Protocol (CeSHarP) is a harmonised guideline that was developed by the M11 Expert Working Group and adopted for implementation on 19 November 2025.

ICH M11 is a comprehensive initiative that addresses a longstanding gap in ICH standards by providing, for the first time, a harmonised approach to clinical trial protocol structure, content and transition toward electronic exchange.

Three elements

ICH M11 consists of three interconnected documents that work together to standardise protocol development and exchange:

1. The **Guideline** describes the general protocol design principles and approach used to develop the Protocol Template and Technical Specification.
2. The **Protocol Template** presents the format and structure of the protocol, including a standardised table of contents, universal headings and text, and detailed instructions for content placement.
3. The **Technical Specification** lists and describes the data elements and technical attributes – such as definitions, conformance requirements and cardinality – that will enable the electronic exchange of protocol contents.

These documents are applicable to interventional clinical trials of medicinal products across all phases and therapeutic areas, covering pharmaceuticals, biologics, vaccines, drug-device combinations and cell or gene therapy products.

The problem ICH M11 solves

Prior to this guideline, there was no globally harmonised standard for protocol format and content, leading to significant variability across sponsors and regions. These inconsistencies created inefficiencies and difficulties in searching, reviewing and assessing protocols. There was no interoperable standard for common terminologies to allow for electronic protocol exchange.

ICH M11 brings several important benefits to the clinical trial ecosystem. It establishes a standardised protocol structure and content through a harmonised framework that ensures consistent organisation, terminology and content across all ICH regions. This standardisation enhances protocol quality and clarity by providing detailed guidance on essential protocol elements, presentation of scientific rationale, and risk-based approaches to protocol design.

ICH M11 facilitates electronic implementation and data exchange by supporting the transition toward electronic protocol formats with structured data elements. This enables automated processing, improved data quality and seamless integration with electronic systems used in regulatory review and drug development.

Most importantly, ICH M11 improves efficiency for all stakeholders by reducing variability in protocol development and review, making it easier for sponsors to prepare protocols, investigators to execute them, and ethics committees and regulators to review them.

Relationship to other ESTRI elements

ICH M11 is a foundational element of ICH's **Electronic Standards for the Transfer of Regulatory Information (ESTRI) initiative** and integrates closely with other ESTRI components through several mechanisms.

The ICH M11 Technical Specification provides the business requirements and common structured protocol content components needed for electronic exchange between sponsors and regulators. Each data element in the specification includes a corresponding Object Identifier (OID) linked to its code list, enabling unambiguous identification in electronic systems. For example, the Trial Phase data element is identified as Code List C217045 with ICH OID 2.16.840.1.113883.3.989.2.3.1.18.

ICH is a Registration Authority under the arc of **HL7** with responsibility to assign its own OIDs. The **ICH M2 ESTRI Expert Working Group**, which is responsible for the technical aspects of ICH information transmission standards, assigns and maintains OID values in partnership with any ICH Expert Working Groups developing standards that require code lists or namespaces. The **ICH E2B** standard for individual case safety reports was the first ICH technical messaging standard to utilise this OID system for clear identification of coding values.

The ESTRI website publishes the **complete OID lists for ICH M11**, providing global access to all stakeholders. This publication fulfils key ICH M2 ESTRI objectives: to recommend technologies and standards that create measurable time and resource savings for both industry and regulators, and to recommend non-proprietary electronic standards that allow for international transmission of information between industry and regulators, regardless of their technical infrastructure.

Summary

ICH M11 includes built-in flexibility through its use of both universal and optional content, and the documents are versioned to allow updates as protocol requirements evolve and technology advances. This ensures that ICH M11 will remain relevant and useful as the clinical trial landscape continues to develop. By establishing a common foundation for protocol structure, content and electronic exchange, ICH M11 represents a significant step forward in harmonising clinical trial standards across regions and enabling more efficient, transparent and high-quality clinical research.