EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Clinical electronic Structured Harmonised Protocol (CeSHarP)-ICH M11 EWG

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# Content

- What is ICH?
- Overview of ICH M11 deliverables
- ICH M11 Scope
- Why Clinical electronic Structured Harmonised Protocol?
- What is Structured Content?
- The Benefits of harmonized and structured data
- Conclusion

# What is ICH?

- **International Council on Harmonisation (ICH) was launched in 1990**
- **Purpose:**
  - To promote public health through international harmonization that contributes to:
    - Prevention of unnecessary duplication of clinical trials and post market clinical evaluations
    - Development and manufacturing of new medicines
    - Registration and supervision of new medicines
    - Reduction of unnecessary animal testing without compromising safety and effectiveness

Accomplished through **Technical Guidelines** that are implemented by the regulatory authorities

https://ich.org/

# Overview of the ICH M11 Deliverables

A new **harmonized guideline** on the clinical protocol that specifies comprehensive organization with standardized content for interventional clinical trials. Additional deliverables include:

- A **Template** that includes 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, non-proprietary standard to enable electronic exchange of clinical protocol information.

# ICH M11 Scope

## Scope:

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

## 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 or a clinical trial.
- 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 characterize a well-crafted final protocol.

# Why Clinical electronic Structured Harmonised Protocol (CeSHarP)?

## The Problem

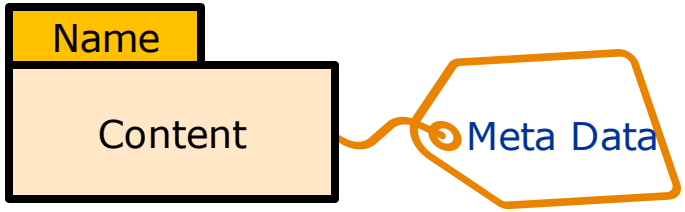
- No **internationally harmonized standard** template for the format and content to support consistency across sponsors and data exchange of protocol information
- Lack of harmonization **contributes to inefficiencies** and difficulties in reviewing and assessing clinical protocols by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. We receive protocols in many different formats
- **Format and core content** of study protocols vary from sponsor to sponsor with duplication of content, multiple terms for the same meaning, making interpretation difficult for researchers, sponsors, investigators, regulators and ethics bodies

# ICH M11: What is Structured Content?

*"**Structured content** is information or content that is organized in a predictable way and is usually classified with metadata."* https://en.wikipedia.org/wiki/Structured_content

*"**Metadata** (or metainformation) is "data that provides information about other data", but not the content of the data itself, such as the text of a message or the image itself."*

https://en.wikipedia.org/wiki/Metadata




Examples of metadata:

Creation date, update date, author, classification, keywords, associated projects, version, and permissions/security…

# Benefits of Harmonised and Structured Clinical Protocol

## Predictable

- Format and Structure – *Table of Contents*
- Core Content and Instructions - *common set of information unnecessary & avoiding repetition*
- Terms and Definitions – *uses controlled terminology to reduce v*ariability in data collection and analysis

**Provides flexibility where needed** – *recommended and optional text / sections*

**Consistency** with all other relevant ICH Guidelines, where possible

**Efficient Collaboration** - Enhance the ability of sponsors, regulators, investigators, and other stakeholders to collaborate effectively with streamlined communication and coordination

**Facilitate Review and Approval** - Ensures compliance with regulatory requirements and expedites the approval process

**Acceptable in all ICH regions**

# Conclusions

- ICH M11 deliverables:
  - Promote **harmonisation** across ICH regions
  - **Foundational step** toward a "digitized protocol"
  - Maintain **flexibility** for technical innovation and region-specific use
- 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

**Overall impact:** contributes to more efficient drug development and delivery of medicines to patients