EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PP17

ICH M11: Shaping the future of clinical trial protocols

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Structured data is transforming the way **clinical trials** are planned, designed, conducted, and evaluated, leading to **greater efficiency and reliability**. By adopting standardised formats, researchers can streamline study processes, improve data quality, and enhance regulatory compliance.

The **ICH M11 template and its technical specification** are essential tools in this transition, providing a robust framework for data consistency, interoperability and exchange.

What is ICH M11?

The **ICH M11 Clinical Electronic Structured Harmonised Protocol Template** provides a comprehensive organisation with standardised content, including both required and optional components

Protocols:

The clinical protocol is an important document that describes the processes and procedures directing the conduct and analysis of a clinical trial.

Format and core content of protocols vary from sponsor to sponsor, making interpretation difficult for:

- Study Sites
- Institutional Review Boards (IRBs)
- Regulators
- Sponsors (project managers, medical writers)

Benefits of ICH M11

- Efficient search capability (content and metadata)
- Machine-readable
- Content reuse
- Makes documents easily accessible for years to come

M11 delivers 3 documents

Guideline

Provides background, purpose, and scope

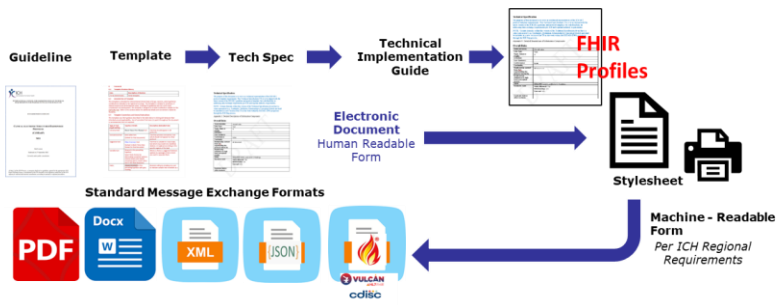
Protocol Template

Provides a comprehensive organisation with headers, common text, instructions, data fields, and terminologies

Technical Specification

Provides technical representation aligned with the guideline and template to enable the preparation of the data exchange implementation guide

M11 Template can be exchanged using many formats



ICH M11 sets the stage for global harmonisation and digital transformation of clinical trial protocols.

Get ready for the future!

Expert Working Group (EWG)