EMA
EUROPEAN MEDICINES AGENCY

ICH M11

Tools for clinical protocols

Presented by Noemie Manent, HTA Collaboration Specialist, Scientific Evidence Generation Department

Objectives and outline for today

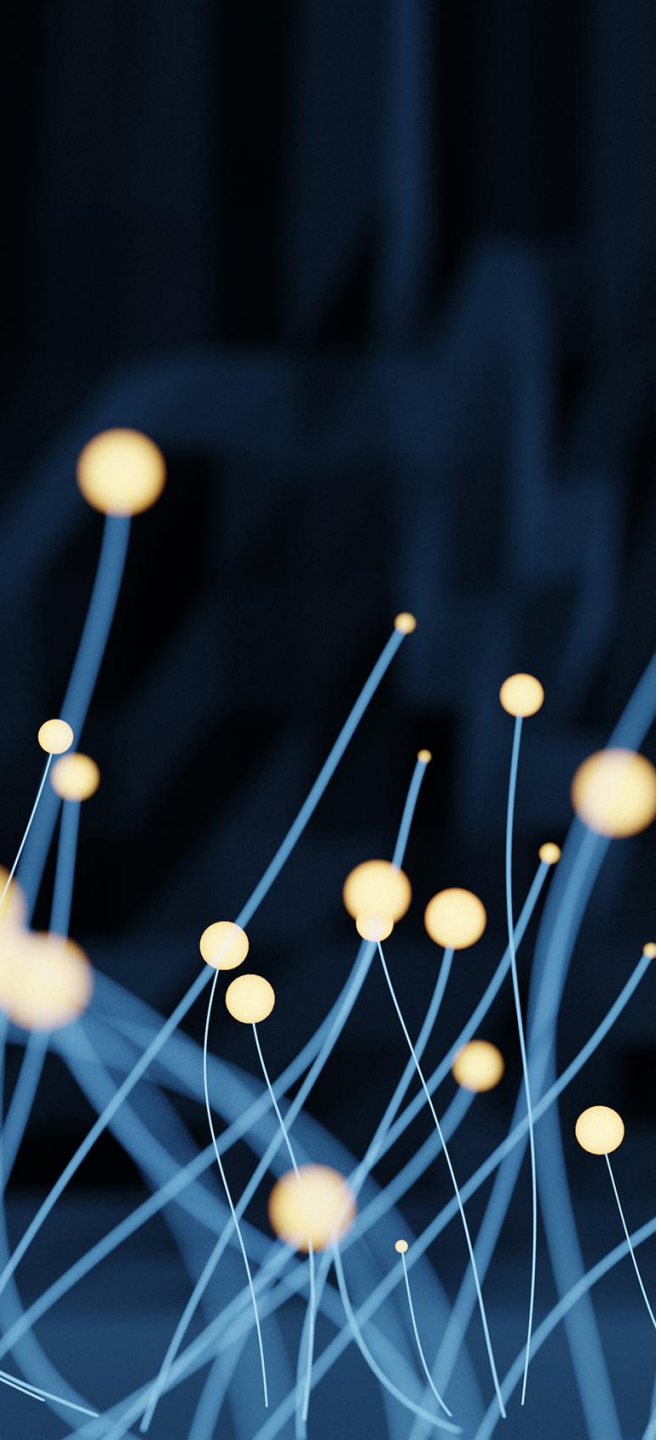
1. Providing the regular update on progress of ICH M11
2. Summarise the benefits for operation
3. Complementary work activities for ICH M11

ICH M11 Key Deliverables

Guideline: Describes the general protocol design principles and approach used to develop Protocol Template and the Technical Specification.

Protocol Template: Presents the format and structure of the protocol, including table of contents, universal headings and text, and instructions for content.

Technical Specification: List and describes the data elements and technical attributes (e.g., definition, conformance, cardinality) that will enable electronic exchange of protocol content.



Values of ICH M11 to Regulatory Agencies

Standardise protocol structure to improve quality, reduce ambiguity across regions and sponsors.

Establishes common data standards, including controlled terminology.

Streamlines the regulatory review process and accelerates study start-up timelines.

Strengthens collaboration and alignment across regulatory agencies and stakeholders.

Enables digital transformation toward data-driven clinical research.

Enabling advanced AI use cases.

How to use the deliverables?

Protocol Template

11 December 2025
EMA/CHMP/ICH/778801/2022
Committee for Medicinal Products for Human Use

ICH M11 Clinical electronic structured harmonised protocol (CeSHarP) – Template

Step 5

Transmission to CHMP	3 October 2022
Adoption by CHMP	13 October 2022
Release for public consultation	26 October 2022
Deadline for comments	26 February 2023
Final adoption by CHMP	11 December 2025
Date for coming into effect	11 June 2026

Technical Specification

ICH harmonisation for better health

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11 December 2025
EMA/CHMP/ICH/778800/2022
Committee for Medicinal Products for Human Use

ICH M11 Clinical electronic structured harmonised protocol (CeSHarP) - Technical specification

Step 5

M11 Terms and Definitions

Subset C217023 - ICH M11 Terminology

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The terminology subset that includes terms pertaining to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) M11 protocol template.

Subset Download Link: https://evs.nci.nih.gov/ftp1/ICH/M11

Enter at least 3 letters of a term. | Search | Reset

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CDISC Code	Codelist Code	Codelist Extensible	Codelist Name	ICH Preferred Term	ICH Synonyms(s)	ICH Definition	NCIt Preferred Term
C217023						The terminology subset that includes terms pertaining to the ICH M11 protocol template.	ICH M11 Terminology

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Complementary work activities for ICH M11

ICH M11 Expert Working Group work plan 2026

ICH M11 collaborates with M2 on the publication of Technical Implementation Group (TIG) for FHIR* to be published on M2 ESTRI page

Electronic Standards (ESTRI)

- Recommendation for a non-proprietary Electronic Standards for the Transfer of Regulatory Information (ESTRI)
- Recommendation of a standard that create measurable time and resource savings for both industry and regulators

* FHIR , Fast Healthcare Interoperability Resources developed by HL7 (Standards Development Organization (SDO))

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Thank you

name.surname@ema.europa.eu

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