ICH M11 EWG Work Plan
14 February 2025

Topic Adoption date: *November 2018*

Rapporteur: *Dr. Ron Fitzmartin, FDA, United States*

Regulatory Chair: *Dr. Noemie Manent, EC, Europe*

Last Face-to-Face Meeting: *Montreal, Canada, November 2024*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2018	*Concept Paper Outline endorsed at Kobe meeting by ICH Assembly*
Sep. 2018	*Establishment of Informal Working Group*
Nov. 2018	• *Endorsement of Final Concept Paper, Business Plan, and Work Plan by ICH MC* • *Establishment of formal Expert Working Group (EWG)*
Sep. 2022	• *Step 1 Signoff draft Guideline, Template, and Technical Specification*
Sep. 2022	• *Step 2a/2b Signoff and endorsement of draft Guideline, Template, and Technical Specification*
Oct. 2022	• *Step 3 Public Consultation*
Mar. 2023	• *Closure of Step 3 Public Consultation period*

1.b. Key Deliverables

Approval Date	Deliverable
Nov. 2018	*Guideline that explains the need for a harmonized clinical protocol template and outlines the development process of the template and technical specification.*
Nov. 2018	*Clinical protocol template that specifies headers, common text, instructions, data fields, and terminologies.*
Nov. 2018	*Technical specification that aligns with the guideline and template to enable electronic exchange of the clinical protocol information.*
Jun. 2023	*ICH Technical Implementation Guide (IG) for Fast Healthcare Interoperability Resources (FHIR) was added to the M11 deliverables at an*

	interim EWG meeting in Berlin and reported to the MC. The IG will be completed after the guideline, template and technical specification are adopted at Step 4.
Oct. 2023	*Development of training materials approved by the Assembly in Prague.*

1.c. Future anticipated key milestones

Expected future completion date	Milestone
Feb. 2025	*Step 2 approval of the draft updated Technical Specification*
Apr. 2025	*Regional Public Consultation on the draft updated Technical Specification*
Jul. 2025	*Adjudication of Public Comments on the Technical Specification*
Oct. 2025	*Updated Guideline, Template and Technical Specification*
Nov. 2025	*Step 3 Sign-off & Step 4 adoption of the Guideline, Template and Technical Specification*
Jan. 2026	*Final versioned training materials*
Feb. 2026	*Step 2 (Testing) of the ICH Technical Implementation Guide for Fast Healthcare Interoperability Resources (FHIR)*
May 2026	*Step 4 adoption of ICH Technical Implementation Guide for FHIR*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2025	*Feb 2025*	• *Prepare draft updated Technical Specification for Step 1 and Step 2 approval.* • *Submit draft updated Technical Specification to the ICH Secretariat*	• *Step 1 sign-off.* • *Step 2 approval of the draft updated Technical Specification by the Assembly.*
Feb. 2025	*Apr 2025*	• *Regional Public Consultation of draft updated Technical Specification*	• *Conduct regional public consultation of technical specification.*
May. 2025	*Jul 2025*	• *Compilation and adjudication of public comments* • *Update draft Guideline, Template and Technical Specification*	• *Compilation and integration of public comments.* • *Adjudication of comments.*

		• *Continue development of training materials*	• *Consultation with M2 on updates to the technical specification.* • *Revise draft Guideline, Template, and Technical Specification, as needed.*
July 2025	*October 2025*	• *Quality Control (QC) the draft updated Guideline, Template, and Technical Specification.* • *As needed, update the draft Guideline, Template and Technical Specification.* • *Complete development of training materials* • *Prepare for Step 3 Sign off.*	• *Conduct final independent QC of deliverables.* • *Reconcile QC findings and apply edits to the documents.* • *EWG review and consensus on final training materials.* • *Coordination with Secretariat to prepare for Step 3 signoff.*
Nov 2025	*Nov 2025*	• *Step 3 Sign off.* • *Step 4 Adoption of Guideline, Template and Technical Specification.*	