

ICH M2 EWG Work Plan

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1. Key Milestones

1.1 Current Status of Key Milestones

Past completion date	Milestone
Nov. 2024	Assembly Approval of the ICH-CIOMS Agreement operationalized in January 2025
Jan. 2025	Updated ICH Object ID (OID) Registration Scheme; Revised ICH Best Practice Maintenance Document (v2.1)
Jan. 2025	Updated ESTRI M2 Recommendations Table Region Status
Jun. 2025	ICH M2 Proof of Concept: Step 3 Public Consultation Comments AI Management
Jul. 2025	Standard Developing Organization (SDO) Process Alignment Document
Nov. 2025	ICH M2/M11 Collaboration (Support for Step 3/4 finalization for M11 Guideline, M11 Template and M11 Technical Specification)

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Jun. 2023	ICH M2 Proof of Concept: Step 3 Public Consultation Comments AI Management A proof-of-concept evaluation for processing comments received during Step 3 public consultation using multiple AI platforms to support regulatory review processes by effectively processing large volumes of stakeholder feedback.
Dec. 2024	SDO Process Alignment Document Conduct comprehensive process mapping comparing ICH's five-step harmonization process with SDO (HL7 FHIR, CDISC, and ISO) frameworks, identifying overlaps, gaps, and alignment opportunities to avoid duplication.
May. 2025	Revision and Update of ICH M2 Concept Paper Revise the M2 Concept Paper (1994) incorporating recommendations from the ICH MC ensuring further proposed activities have a planned timely delivery and rapid turnaround of outputs to accommodate for the changing technology landscape.

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Sep. 2025	ICH M2 review of ICH Concept Papers – currently no new Concept Papers available for review
Mar. 2026	Finalize updates to established M2 terminology list management process to align with ongoing work on M11
May 2026	Revision and Update of ICH M2 Concept Paper (Revise 1994 Paper)
Sep. 2026	Complete joint M11/M2 review of draft HL7 UDP FHIR Implementation Guide for M11 clinical trial protocol (Two-month review period)
Dec. 2026	Revision and update of the SDO Engagement Process document
TBD. 2026	Draft Business Case: ICH M4Q Terminology Harmonization – ongoing support for M4Q identified issues per MC direction in May 2025 Madrid meeting

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Nov. 2024	Dec. 2026	Draft the M2 SDO Process document to incorporate the latest M2 advancements and ensure alignment with the current streamlined SDO engagement and process model.	Revise the old ICH SDO working practice v.1.0 document (2011) based on the advances of the current ICH M2 SDO engagement process analysis and document to reflect current process and include detailed process flow diagram outlining the requirements and considerations at each step.
Jan. 2025	Mar. 2026	M2/M11 collaboration: Update ESTR1 website to include M11 section and make Terms and definitions available for download in OASIS Genericcode format	M2/M11 collaboration: M11 is reviewing the M2 proposed text for the ESTR1 website updates before publication.
Jun. 2025	Sep. 2025	M2 Review of ICH Concept Papers	M2 Review of ICH Concept Papers for opportunities in harmonization of data exchange
Oct. 2025	May. 2026	M2 Annual Report 2025	Annual Report summarizes M2's work completed in 2025 to provide transparency to MC and other EWGs to prioritize and increase its involvement with other EWGs to enhance awareness of developments across working groups that would benefit from M2 EWG engagement.
Oct. 2025	May. 2026	M2 AI Workgroup Charter	A charter for the already-established M2 AI Sub Workgroup to clearly identify its objectives and ensure its focus aligns with MC direction. The charter is

			<i>intended to ensure that the Sub Workgroup's activities fall within M2's current remit, specifically for gathering and evaluation of intelligence on technology and regulatory trends.</i> <i>In addition, the M2 AI Sub Workgroup will discuss opportunities for future collaboration and explore how the Sub Workgroup can effectively support the ICH AI Agenda with the Secretariat.</i>
Oct. 2025	May. 2026	<i>Proposal of Good Data Practice Landscape Analysis</i>	<i>The proposed landscape analysis will aim to gather currently established good regional data practices, identifying opportunities for harmonization to support updates to the M2 Concept Paper.</i>