

ICH M2 EWG Work Plan

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Topic Adoption date: *October 1994*

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Regulatory Chair: *Dr. Stephan Jaermann, Swissmedic, Switzerland*

Last Face-to-Face Meeting: *Berlin, Germany, June 2023 (Interim Meeting)*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2024</i>	<i>Finalized JSON ESTRI Recommendations Document with assembly approval</i>
<i>Jun. 2024</i>	<i>Drafted recommendation for harmonisation of terms in ICH guidelines</i>
<i>Jul. 2024</i>	<i>ICH-CDISC MoU approved by assembly, signed by both parties</i>
<i>Jul. 2024</i>	<i>Finalized draft for ICH-CIOMS agreement for CIOMS to share the excel source file of the CIOM Glossary of ICH Terminology</i>
<i>Jul. 2024</i>	<i>Designated new M2 liaison with HL7</i>

1.b. Key Deliverables

Approval Date	Deliverable
<i>Jun. 2023</i>	<i>AI Proof of Concept</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>Sept. 2024 (TBD)</i>	<i>M2 review of M11 Tech Spec & template</i>
<i>Oct. 2024</i>	<i>Finalize ICH – CIOMS agreement for use of CIOMS Glossary of Terminologies source file</i>
<i>Nov. 2024</i>	<i>Revise/refine streamlined standards development process document</i>
<i>Nov. 2024</i>	<i>ICH ESTRI webpage review and revision</i>
<i>Nov. 2024</i>	<i>Draft collaborative framework between M2 and M4Q</i>
<i>Dec. 2024</i>	<i>ICH Technical Specification template review and revision</i>

2025 - TBD	<i>Emerging Technology assessment</i>
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2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Recurring</i>	<i>Recurring</i>	<i>Evaluate ICH topics at step 3 or 4 for technical risks and opportunities – stage 2</i>	<i>Review Step 3-4 documents for technical risks and opportunities; discuss findings with EWG Rapporteurs.</i>
<i>Jan. 2025</i>	<i>Oct. 2024</i>	<i>ICH CIOMS Glossary of Terminology Collaborative Agreement</i>	<i>Establish a collaboration agreement between ICH and CIOMS for ICH use of CIOMS Glossary of Terminologies source file</i>
<i>May. 2024</i>	<i>Nov. 2024</i>	<i>Develop a collaborative framework between M2 and M4Q</i>	<i>Define M2's scope and establish a framework and process to support M4Q terminology harmonisation needs.</i>
<i>Jun. 2023</i>	<i>Oct. 2024</i>	<i>AI Proof of Concept</i>	<i>Assess capability of AI tool available at FDA, and explore the potential to be made available for ICH use.</i>
<i>Jan. 2020</i>	<i>Recurring</i>	<i>Monitor FHIR development and maturity progress</i>	<i>Monitor FHIR development and maturity progress that is relevant for ICH purposes with updates to the MC as significant progress occurs.</i>
<i>Sep. 2024</i>	<i>Sep. 2024</i>	<i>M2 review of M11 tech spec & template</i>	<i>Concurrent with regional review, M2 will conduct its review of M11 Technical Specification & template</i>
<i>Sep. 2024</i>	<i>Oct. 2024</i>	<i>Evaluation of deliverables for revision during Nov F2F meeting</i>	<i>Conduct review of deliverables that are scheduled for revision during the Nov F2F meeting, with the goal of enhancing meeting efficiency by identifying areas of focus</i>