

ICH E11A EWG Work Plan

10 July 2026

Topic Adoption Date: 17 October 2017

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Last Face-to-Face Meeting: Lisbon, Portugal, March 2024

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Oct, 2017</i>	<i>Concept Paper endorsement</i>
<i>Dec, 2021</i>	<i>Step 1 Sign-off of draft Guideline</i>
<i>Apr, 2022</i>	<i>Step 2a/b Sign-off of draft Guideline</i>
<i>Nov, 2022</i>	<i>Completion of Step 3 public consultation period</i>
<i>Mar, 2024</i>	<i>Completion of review of Step 3 public comments</i>
<i>Aug, 2024</i>	<i>Step 3 signoff of final Guideline</i> <i>Step 4 adoption of final Guideline</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>Aug, 2024</i>	<i>Development of training materials</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
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Aug, 2026	<i>Finalised training materials</i>
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2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
April 2026	May 2026	Complete draft case examples	IWG members have been assigned to complete each of the case examples
May 2026	August 2026	Review case examples	IWG will review these case examples for consensus prior to final completion
August 2026	August 2026	Finalize	Submit to Secretariat for posting