

ICH M7 Sub-Group Work Plan

March 05, 2025

Topic Adoption date: *June 2024*

Rapporteur: *Dr. Krista Dobo, PhRMA*

Regulatory Chair: *Dr. Alisa Vespa, Health Canada, Canada*

Last Face-to-Face Meeting: *Not applicable*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2024</i>	<i>Concept Paper Outline endorsed by the Assembly on 4 June 2024</i>
<i>Dec. 2024</i>	<i>Mutual Understanding Presentation Series: October – December 2024</i>

1.b. Key Deliverables

Approval Date	Deliverable
<i>Jun. 2024</i>	<i>M7 Sub-Group Concept Paper to be submitted to ICH Management Committee for endorsement</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar. 2025</i>	<i>Final Concept Paper</i>
<i>Jun. 2028</i>	<i>Step 1 Consensus reached on draft Technical Documents</i>
<i>Aug. 2028</i>	<i>Step 2a/2b - Confirmation of Technical Document by Assembly and Adoption of draft guideline by Regulatory Members</i>
<i>Dec. 2029</i>	<i>Step 3 Public consultation and address comments</i>
<i>Mar. 2030</i>	<i>Step 4 Finalize Guidance</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
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<i>Jan. 2025</i>	<i>Mar. 2025</i>	<i>Develop/finalize concept paper</i>	<i>EWG will meet 2X/month to develop and finalize the concept paper</i>
<i>Mar. 2025</i>	<i>May. 2025</i>	<i>Build consensus on addendum topics to prioritize at F2F meeting in Madrid.</i>	<i>Based on Final Concept Paper (anticipated to be agreed and approved by end March)</i>