

ICH Q1/Q5C EWG Work Plan

July 20, 2023

Topic Adoption date: *June 2022*

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Last Face-to-Face Meeting: *Vancouver, Canada, June 2023*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2022</i>	<i>Concept paper endorsement</i>
<i>Nov. 2022</i>	<i>Business plan endorsement</i>
<i>Nov. 2022</i>	<i>Establishment of EWG</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Dec. 2024</i>	<i>Step 1 and 2a/b Sign-off of Q1/Q5C draft Technical Document</i>
<i>Dec. 2025</i>	<i>Step 3 and 4 Sign-off and Adoption of the Q1/Q5C Guideline</i> <i>Completion of Training Materials</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jun. 2023</i>	<i>Jul. 2023</i>	<i>Define workstreams for next 6 months</i>	<i>Identify/align on workstreams/subteams for next unit of work, which includes addressing comments received, completing content authoring, aligning terminology with other ICH guidelines and incorporating examples</i>

<i>Jul. 2023</i>	<i>Oct. 2023</i>	<i>Comment resolution</i>	<i>Complete comment resolution for early draft</i>
<i>Jul. 2023</i>	<i>Oct. 2023</i>	<i>Section Drafting</i>	<i>Complete drafting additional sections (e.g. bracketing/matrixing section)</i>
<i>Oct. 2023</i>	<i>Nov. 2023</i>	<i>Comprehensive EWG review</i>	<i>Complete EWG comprehensive review of content, identify any remaining gaps, define actions to Step 1 Draft</i>
<i>Oct. 2023</i>	<i>Dec. 2023</i>	<i>Alignment with other ICH content</i>	<i>Alignment with active EWGs and guidelines on common and complementary content</i>
<i>Oct. 2023</i>	<i>Jan. 2024</i>	<i>Glossary and terminology</i>	<i>Complete glossary and harmonisation of terminology with other ICH documents</i>
<i>Oct. 2023</i>	<i>Feb. 2024</i>	<i>Complete examples</i>	<i>Incorporation of examples into Step 1</i>
<i>Mar. 2024</i>	<i>May. 2024</i>	<i>Collect constituency feedback</i>	<i>Issue Step 1 DRAFT for constituency review (2-month review planned after draft is shared)</i>