

ICH Q1/Q5C EWG Work Plan

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Topic Adoption date: *June 2022*

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Last Face-to-Face Meeting: *Prague, Czech Republic, November 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</i>
<i>Dec. 2025</i>	<ul style="list-style-type: none"> • <i>Step 3 Sign-off and Step 4 Adoption</i> • <i>Completion of Training Materials</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Nov. 2023</i>	<i>Mar. 2024</i>	<i>Complete Draft for Constituency Review</i>	<i>Drive EWG consensus on draft sections, incorporate EWG feedback and create compilation of draft document</i>
<i>Apr. 2024</i>	<i>Jun. 2024</i>	<i>Constituency commenting period</i>	<i>Collect/compile constituency support team feedback on compiled Draft Q1 document</i>

Apr. 2024	<i>Jun. 2024</i>	<i>Develop examples and training content</i>	<i>Continue to collect and develop examples for inclusion with guideline and for training</i>
Jun. 2024	<i>Sep. 2024</i>	<i>Comment resolution and example inclusion</i>	<i>Address comments from constituency review. Alignment on examples to include and format</i>
Oct. 2024	<i>Dec. 2024</i>	<i>Address any final gaps for consensus</i>	<i>Discussions to align on final Step 1 consensus document</i>
Oct. 2024	<i>Dec. 2024</i>	<i>ICH EWG Alignment on Step 1</i>	<i>Alignment with EWG and ICH guidelines on common and complementary content. Completion of Step 1</i>