

ICH Q1 EWG Work Plan

July 11, 2025

Topic Adoption date: *June 2022*

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Regulatory Chair: *Ms. Ana Cerúlia Moraes do Carmo, ANVISA, Brazil*

Last Face-to-Face Meeting: *Montreal, Canada, November 2024*

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>
<i>Mar. 2025</i>	<i>Step 1 sign-off by EWG</i>
<i>Apr. 2025</i>	<i>Step 2a/b endorsement by ICH Assembly and Regulatory Members of the ICH Assembly</i>

1.b. Key Deliverables

MC commencement of work approval date	Deliverable
<i>Nov. 2022</i>	<i>Q1 Guideline</i>
<i>Nov. 2022</i>	<i>Q1 Training Materials</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>Sep. 2025</i>	<i>End of Public Consultation Period</i>
<i>Aug. 2026</i>	<i>Plenary Working Party engagement ahead of Step 3 sign-off</i>

Nov. 2026	<i>Step 3 sign-off/ Step 4 adoption and delivery of the Step 4 Presentation</i>
Mar. 2027	<i>Delivery of training material</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2025	<i>Oct. 2025</i>	<i>Training Material</i>	<i>Align upon and start preparation of core training materials.</i>
Jun. 2025	<i>Dec. 2026</i>	<i>Training Material</i>	<i>Align upon and complete core training materials and case studies.</i>
Jun. 2025	<i>Sep. 2025</i>	<i>Public consultation</i>	<i>Ongoing receipt of public comments, triage and discussion of public comments. Discuss need for training or revisions to address comments</i>
Jul. 2025	<i>Oct. 2025</i>	<i>Revision based on Public Consultation</i>	<i>Begin resolving critical comments and reach EWG consensus on comments that warrant further Q1 revisions.</i>
Jul. 2025	<i>Apr. 2026</i>	<i>Revision based on Public Consultation</i>	<i>Resolve all comments and reach EWG consensus on comments that warrant further Q1 revisions.</i>