

ICH E22 EWG Work Plan

July 25, 2025

Topic Adoption date: *June 2023*

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Regulatory Chair: *Robyn Bent, FDA, United States*

Last Face-to-Face Meeting: *Madrid, Spain, 11-14 May 2025*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2024	<i>ICH MC endorsement of E22 Concept Paper and transition to E22 Expert Working Group</i>
May. 2025	<i>Stakeholder engagement plan</i>

1.b. Key Deliverables

MC Approval Date	Deliverable
Jun. 2024	<i>Training material: guideline implementation training material will be developed alongside the guideline.</i>
Jun. 2024	<i>Stakeholder engagement meeting</i>
Jun. 2024	<i>Final guideline</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>Aug. 2025</i>	<i>PWP consultation on Step 1 draft Technical Document; preparation of EWG Step 2 presentation</i>
<i>Nov. 2025</i>	<i>Step 1 sign-off</i>
<i>Dec. 2025</i>	<i>Step 2a/b endorsement</i>

May. 2026	<i>End of public consultation</i>
Sep. 2026	<i>PWP consultation on revised version of step 2b document; preparation of EWG step 4 presentation</i>
Oct. 2026	<i>Training material</i>
Dec. 2026	<i>Step 3 sign-off</i>
Dec. 2026	<i>Step 4 adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2025	Sep. 2025	<i>EWG review of PWP comments</i>	<i>EWG members review PWP comments and share comments with the rest of EWG members (in writing)</i>
Sep. 2025	Sep. 2025	<i>EWG monthly TC</i>	<i>PWP members are invited to join the EWG TC to discuss the draft Technical Document</i>
Feb. 2026	Feb. 2026	<i>Public stakeholder engagement meeting</i>	<i>EWG to present the draft guideline to stakeholders in TC.</i>
Dec. 2025	May. 2026	<i>Public consultation</i>	<i>Initial analysis of comments received</i>
Jun. 2026	Jun. 2026	<i>Review of comments received during the public consultation</i>	<i>EWG to review and discuss comments; revision of draft guideline</i>