

ICH E22 EWG Work Plan

13 February 2026

Topic Adoption Date: *June 2023*

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Regulatory Chair: *Dr. Laura Lee Johnson, FDA, United States*

Last Face-to-Face Meeting *Madrid, Spain, May 2025*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Jun, 2024</i>	<i>ICH MC endorsement of E22 Concept Paper</i>
<i>May, 2025</i>	<i>ICH MC endorsed Stakeholder engagement plan</i>
<i>Aug, 2025</i>	<i>Completion of PWP review</i>
<i>Nov, 2025</i>	<i>Completion of Step 1 and Step 2a/b Sign-off</i>
<i>Dec, 2025</i>	<i>Publication of Step 2 presentation and training materials</i>
<i>Feb, 2026</i>	<i>Publication of E22 explanatory video</i>
<i>Feb, 2026</i>	<i>Stakeholder engagement webinar</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>Jun, 2024</i>	<i>Develop E22 Guideline</i>
<i>Jun, 2024</i>	<i>Develop E22 Training materials</i>
<i>Jun, 2024</i>	<i>Develop plan for E22 Stakeholder engagement meeting</i>
<i>Oct, 2025</i>	<i>Develop E22 public consultation video</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
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Apr-May, 2026	<i>End of Step 3 public consultation</i>
Sep, 2026	<i>PWP consultation on revised version of Step 3 draft Guideline; preparation of EWG Step 4 presentation</i>
Nov, 2026	<i>Training material completed</i>
Nov, 2026	<i>ICH Pilot on AI supported development of basic and advanced training module</i>
Dec, 2026	<i>Step 3 sign-off; Step 4 adoption of final Guideline</i>

2. Timeline for Specific Tasks

Please provide in the table below short-term high-level specific tasks for work to be done within the Working Group between now and the next ICH meeting (recommended 4 – 10 tasks).

Beginning date	End date	Task / Activity	Details
Feb, 2026	<i>May, 2026</i>	<i>Monthly teleconferences</i>	<i>Planning of face-to-face meeting in May-June in Rio de Janeiro, Brazil</i>
Feb, 2026	<i>May, 2026</i>	<i>Refinement of existing training material</i>	<i>Exploring the possibility of complementing existing training material through AI tool</i>
Dec, 2025	<i>May, 2026</i>	<i>Receiving and translating public comments</i>	<i>Regional authorities and ICH planned public consultation period</i>
Apr, 2026	<i>May, 2026</i>	<i>Collating comments</i>	<i>Combine all comments together</i>
May, 2026	<i>May, 2026</i>	<i>Teleconference, review</i>	<i>EWG organizes and discusses comments</i>