

ICH E22 EWG Work Plan

22 July 2026

Topic Adoption Date: *June 2023*

Rapporteur/s: *Dr. Francesco Pignatti, EC, Europe*

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

Last Face-to-Face Meeting: *Rio de Janeiro, Brazil, May-June 2026*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>June 2024</i>	<i>ICH MC endorsement of E22 Concept Paper and transition to E22 Expert Working Group</i>
<i>May 2025</i>	<i>Stakeholder engagement plan</i>
<i>August 2025</i>	<i>Completion of PWP review</i>
<i>November 2025</i>	<i>Completion of Step 1 and Step 2a/b Sign-off</i>
<i>December 2025</i>	<i>Completion and publication of Step 2 presentation</i>
<i>December 2025</i>	<i>Completion and publication of training materials</i>
<i>February 2026</i>	<i>Publication of E22 explanatory video</i>
<i>February 2026</i>	<i>Stakeholder engagement webinar</i>
<i>April 2026</i>	<i>Completion of Step 3 Public Consultation</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>June 2024</i>	<i>E22 Guideline</i>
<i>June 2024</i>	<i>Training materials</i>
<i>May 2025</i>	<i>Stakeholder engagement plan</i>
<i>October 2025</i>	<i>Public consultation video</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
September 2026	<i>PWP consultation on revised version of Step 2b document and draft Guideline submitted to Secretariat for editorial review</i>
November 2026	<i>Develop Step 4 Presentation</i>
November 2026	<i>Finalise Training Material</i>
November 2026	<i>Finalise AI-supported basic and advanced Training Modules</i>
December 2026	<i>Step 3 and Step 4 sign-off email submission of Final draft Guideline Document and Step 4 Presentation</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
July 2026	<i>August 2026</i>	<i>EWG consensus on Step 3 Draft Guideline</i>	
August 2026	<i>November 2026</i>	<i>Finalise Training Materials and Modules</i>	<i>Includes AI-supported basic and advanced Training Modules</i>
September 2026	<i>September 2026</i>	<i>PWP consultation</i>	<i>Ahead of Step 3 sign-off, the PWP are provided 1 month to review and comment on the Step 3 Draft Guideline.</i>
October 2026	<i>October 2026</i>	<i>Incorporate PWP input</i>	
November 2026	<i>December 2026</i>	<i>Step 3 sign-off by Regulatory Topic Leaders</i>	