

ICH E6(R3) EWG Work Plan

7 July 2026

Topic Adoption Date: *June 2019*

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Regulatory Chair, E6(R3): *Mr. Peter Twomey, EC, Europe*

Regulatory Chair, Annex 2 Sub-group: *Dr. Catherine Cohet, EC, Europe*

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

1 Key Milestones

1.1 Current Status of Key Milestones

- List key **past milestones** in the table for context.
- Key Milestones Include:
 - Concept Paper endorsement,
 - Completion of PWP Consultation (if applicable)
 - ICH *Step sign-off (Guidelines, Q&As, Implementation Packages)*
 - Completion of *Step 3* Public Consultation,
 - *Step 2* and *Step 4* Presentations
 - Stakeholder Engagement Activities
 - Training materials developed.
- **Choose only the most relevant achievements.**

Completion date	Milestone – Annex 2
Oct. 2024	<i>Step 1 Sign-off of Technical Document</i>
Nov. 2024	<i>Step 2a/2b Endorsement of Technical Document</i>
Nov. 2024	<i>Developed Step 2 Presentation</i>
Nov. 2024	<i>Step 3 Begin Public Consultation</i>
Mar. 2025	<i>Step 3 End of Public Consultation and begin review of public comments</i>
Jul. 2025	<i>Completed review of public comments for Final Consensus Version</i>
Dec. 2025	<i>Review by the ICH E6(R3) EWG</i>
Jan. 2026	<i>Caucus review</i>
Jan. 2026	<i>PWP Consultation Period prior to Step 3 Sign-off</i>

May 2026	<i>Step 3 Sign-off</i>
June 2026	<i>Developed Step 4 Presentation</i>
June 2026	<i>Step 4 Sign-off</i>

Completion date	Milestone - E6(R3) Training Modules
Oct. 2025	<i>Module 1 (Introduction and Foundational Concepts)</i>
Jan. 2026	<i>Module 4 (Informed Consent)</i>

1.2 ICH MC Key Deliverables

- The table records **all deliverables** that the ICH MC has approved for development, either:
 - those listed in the **Concept Paper**, or
 - additional deliverables **approved later** by the MC.
- “**Approval Date**” = the date the MC **approved starting work** on that deliverable (either the **Concept Paper approval date** or a **later time point based on MC approval**).

MC Approval Date	Deliverable
April 2023	<i>Development of Annex 2</i>
November 2019	<i>Training Materials</i>

1.3 Future Anticipated Milestones

Please provide in the table below the **main deliverable(s) to be achieved in the next year(s)**:

Dates or expected timeline (e.g. Q1 2026 etc.) should be provided for:

- PWP engagement (if applicable) ahead of Step 1 and Step 3 Sign off
- Step 1 sign-off and Step 2a/b endorsement and delivery of the Step 2 Presentation
- Step 3 sign-off and Step 4 adoption and delivery of the Step 4 Presentation
- Any other relevant high-level deliverables (finalised documents, public consultation period, special actions to advance the topic through ICH, e.g. stakeholder engagement or training, etc.)

Expected future completion date	Milestone - E6(R3) Training Modules
December 2026	<i>Complete development of E6 Training materials:</i> <i>Module 2 (Responsibilities and Oversight) – November/December 2026</i> <i>Module 3 (Data Governance) – August 2026</i> <i>Module 5 (Essential Records) – August 2026</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 biannual meeting** (recommended 4 – 10 tasks).*

Beginning date	End date	Task / Activity	Details
Jan. 2025	<i>December 2026</i>	<i>E6(R3) EWG Small Training Group meeting every 1 or 2 days a week</i>	<i>Develop and review E6 training materials with MRCT</i>