

ICH E21 EWG Work Plan

22 July 2026

Topic Adoption Date: *March 2022*

Rapporteur/s: *Dr Corinne de Vries, EC, Europe*

Regulatory Chair *Dr. Leyla Sahin, FDA, United States*

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

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
Mar, 2022	<i>Recommendation of the Topic to ICH General Assembly</i>
May, 2022	<i>Concept paper outline endorsed by ICH Assembly</i>
Oct, 2022	<i>Approval to form Informal Working Group (IWG)</i>
Jan, 2023	<i>Informal Working Group held first meeting</i>
Apr, 2023	<i>Final Concept Paper submitted</i>
Jun, 2023	<i>Approval of Final Concept Paper & started drafting Technical Document Approval to form Expert Working Group (EWG) Regulatory Chair assigned to E21 EWG</i>
Jun 2023-Jun, 2024	<i>Three Face-to-Face meetings to work on the Technical Document</i>
Oct, 2024	<i>Constituent review and feedback on the Technical Document</i>
Nov, 2024	<i>Face-to-Face meeting to discuss and implement feedback from the constituent review</i>
Mar, 2025	<i>Interim Face-to Face meeting to finalize the document for step 1 sign off</i>
Jun, 2025	<i>Steps 1 and 2a/b for the draft Guideline</i>
Nov, 2025	<i>1st Face-to-Face meeting to implement public consultation comments</i>
June, 2026	<i>2nd Face-to-Face meeting to implement public consultation comments</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>June, 2023</i>	<i>E21 Guideline concept paper</i>
<i>June, 2025</i>	<i>Draft E21 for public consultation</i> <i>Stakeholder Engagement Plan and associated Training Materials</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
<i>Q1 2027</i>	<i>Interim meeting</i> <i>3rd Face-to-Face meeting for line-by-line review in preparation for constituent consultation in Q1 2027</i>
<i>Q1, 2027</i>	<i>Constituent review and feedback on the revised draft Guideline</i>
<i>June, 2027</i>	<i>4th Face-to-Face meeting to finalise constituent review input and brief review of draft training materials</i>
<i>Nov, 2027</i>	<i>5th Face-to-Face meeting for line-by-line review and step 4 sign off</i>
<i>Q4, 2027</i>	<i>End of Step 3: Regulatory Consultation and Discussion</i> <i>Step 4 sign off</i>
<i>Q1, 2028</i>	<i>Step 5: Implementation of an ICH Harmonised Guideline</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
<i>June - July, 2026</i>	<i>August, 2026</i>	<i>All minor comments divided between subgroups to be implemented.</i>	<i>Redraft section 4. Implement all minor comments and expert feedback on appendix 2. Development planning of training materials.</i>

August, 2026	September, 2026	Text review & commenting rounds	<i>Review, comment & respond to comments following implementation of the minor comments.</i>
September – October 2026	Early November, 2026	<i>teleconference, review & edit, stakeholder engagement.</i>	<i>Finalise text ready for line-by-line review at interim meeting. Further develop training materials. Stakeholder engagement: EU workshop, Saudi FDA webinar, Bioethics conference Asia</i>