ICH E21 EWG Work Plan
23 February 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: *Singapore, November 2025*

1 Key Milestones

1.1 Current Status of Key Milestones

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

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable

Jun. 2023	*E21 Guideline*
Jun. 2025	*Stakeholder Engagement Plan and associated Training Materials*

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Q1/Q2. 2026	*Implementation of Step 3 public consultation comments, stakeholder engagement, second Face-to-Face meeting to implement feedback from public consultation*
Jun. 2026	*2nd Face-to-Face meeting to implement Step 3 public consultation comments*
Nov. 2026	*3rd Face-to-Face meeting for line-by-line review*
Q1 2027	*Constituent review and feedback on the revised draft Guideline*
Jun. 2027	*4th Face-to-Face meeting to finalise constituent review input and brief review of draft training materials*
Nov. 2027	*5th Face-to-Face meeting for line-by-line review and step 4 sign off*
Q4 2027	*End of Step 3: Regulatory Consultation and Discussion* *Step 4 sign off*
Q1 2028	*Step 5: Implementation of an ICH Harmonised Guideline*

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
May. 2023	*Dec, 2024*	*Drafting of Technical Document*	*EWG will meet at least once a month via Microsoft (MS) Teams. Subgroups will meet more frequently to continue drafting chapters.*
Jul. 2023	*Mar, 2025*	*Start / continue engagement with expert representatives and EWG members during Guideline development to ensure that their perspectives on and experiences with clinical trials, specifically with GCP guidelines, are considered in developing ICH E21 guideline.*	*As needed and/or defined by topic leads*

Apr. 2025	*Dec, 2025*	*Planning for stakeholder engagement (e.g. workshops, training material)*	
Sep. 2025	*Oct, 2025*	*Compiling and categorizing public consultation comments ready for F2F discussion*	
Oct. 2025	*Jun, 2027*	*Implement public consultation comments, consult constituents on proposed revised Guideline, regional & global stakeholder engagement*	
Q3 2027		*Line-by-line review & finalization of the Technical Document*	