ICH Association

Multi-Annual Strategic Plan

Version dated 30 October 2025

Approved by the Assembly on 18 November 2025

The following table highlights the key areas of work foreseen for the ICH Association:

Category	Description
Strategy	• Continue review and planning of already identified strategic priorities and assess potential new areas of opportunity for the ICH Association • Promote ICH Guidelines implementation by Regulatory Members and Observers, and encourage implementation of ICH Guidelines by other Drug Regulatory Authorities and Regional Harmonisation Initiatives. Consider improvements to the established sustainable ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines • Continue implementation of a strategic approach to address ICH Guideline training needs • Continue multi-year budget planning to ensure sound financial management of the ICH Association's funds, whilst also ensuring the ongoing operational stability of the ICH Association • Continue activities related to the modernisation of the ICH Secretariat, including developing the Secretariat's technology platform and streamlining the procedures.
Harmonisation	• Progress harmonisation activities on all approved ICH topic proposals – Annex I provides a multi-year overview of harmonisation activities on current ICH topics • Assess / approve on a regular basis proposals for new ICH topics according to the agreed process in order to keep an ongoing stream of harmonisation activities based on the total number of concurrent technical Working Groups (WGs) which the Association can support at a given time
Communication	• Continue implementation of approved transparency policy with continued improvements as appropriate to ensure continuously enhanced communication with stakeholders

Category	Description
Procedures	• Maintain / update as necessary the Rules of Procedure (RoP) for the Assembly, the Management Committee, the MedDRA Steering Committee and Standard Operating Procedure (SOPs) of the ICH WGs to ensure the continued smooth operation of the ICH Association as it continues to grow and evolve
Operations	• Continue ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines through surveying and results analysis • Continue developing the ICH training strategy in line with the approach of creating online training materials for all ICH Guidelines and offering tailored training. • Process / decide on applications for ICH Membership and Observership according to the ICH Articles of Association (AoA) • Organise annual audits of the Association's accounts and ensure the meeting of fiscal reporting requirements for ICH Association • Continue implementation of sustainable, consistent and cost-efficient approach for the ICH Association's organisation of biannual ICH meetings • Register the ICH logo as a trademark in ICH Member and Observer countries/regions taking account of new Members and Observers joining ICH

ICH
harmonisation for better health

Multi-Year Overview of Harmonisation Activities
30 October 2025

Work in progress
Work completed
No ongoing activity
Deadlines to be confirmed
*WGs with Plenary Working Parties

	WG	2025	2026	2027	2028
Delayed Start WGs	**M17 EWG (Adopted May 2023)**			**To be established after M13C reaches *Step 2***	
Incoming EWGs	**E24 EWG (incoming)**	***To be Established***			
	M16 EWG (incoming)	***To be Established***			
	Q5E Annex (incoming)	***To be Established***			
Active WGs	**E2D(R1) EWG***	***Step 4*** (Sep) E2B(R3)/E2D(R1) Information Paper (Oct) E2D(R1) Training Material (Oct)			
	E6(R3) EWG and Annex 2*		E6(R3) Training Material (Q1)		
		Annex 2 *Step 4* (Dec)			
	E14/S7B IWG		***Step 4*** Q&A (May) Second Stage Q&A Training Material (May)		
	E20 EWG*	***Step 2*** (Jun)	***Step 4*** (October)		

	E21 EWG	***Step 2*** (May) Stakeholder Engagement Plan (Jun)			***Step 4*** (Q1)
	E22 EWG*	***Step 2*** (Dec) Stakeholder Engagement Plan (May)	***Step 4*** (Dec) E22 Training Materials (Oct)		
	E23 EWG				
	M4Q(R2) EWG*	***Step 2*** (May)		***Step 4*** (Jun)	
	M7 Sub-Group				***Step 2*** (Aug)
	M11 EWG	***Step 4*** GL, Template & Tech Spec (Nov)	M11 Training Materials (May)		
			M13B Step 4 (Jul)		
	M13 EWG			***M13C Step 2*** (Jun)	***M13C Step 4*** (Nov)
	M14 EWG	***Step 4*** *(Sep)*			
	M15 EWG*	***Step 4*** (Dec)	M15 Training Material		
	M18 EWG*				
	Q1 EWG*		***Step 4*** (Nov)	Q1 Training Materials (Mar)	
	Q3E EWG*	***Step 2*** (Aug)		***Step 4*** (Jul) Q3E Training Material (Jul)	
	Q6(R1) EWG		***Step 2*** (Nov)		***Step 4*** (Jun)
	S13 EWG*		***Step 2*** (Oct)	***Step 4*** (Nov)	

Standing WGs	**E2B(R3) EWG/IWG**	***Step 4*** Imp. Guide and Q&As, Tr. Module II (Jul) E2B/E2D(R1) Information Paper, updated code 8 list (Oct) Tr. Module III (Nov)			
	M1 PtC WG		MedDRA Term Selection: PtC (Mar) Companion Document V4.0 (May)		
	M2 EWG	AI Proof of Concept (Jun) SDO Engagement Process (Jul)			
	M7(R3) Maint. EWG				
	M8 EWG/IWG	***Step 4*** *eCTD 4.0 Q&A v1.10 (Dec)* ***Step 4*** *eCTD v4.0 Imp Guide v1.7 (Dec)*			
	Q3C(R10) Maint. EWG		***Step 2*** *(Q1)* ***Step 4*** (Dec)		
Training/ DG	**E11A EWG**	E11A Training Materials (Dec)			
	Q9(R1) TG	Revised Q9 Briefing Pack (Dec)			
	CGTDG	Recommendation Paper and Holistic Roadmap (Oct)			
Dormant/Low activity	**S1B(R1) IWG**		Reccommendation to ICH MC for training, Q&A document, or other initiatives (May)		

ICH WG Title List

1. M17 EWG - Bioequivalence for Modified-Release Products
2. E24 EWG - Natural History Studies and Registry Data to Advance Rare Disease Drug Development
3. M16 EWG - Structured Product Quality Submissions
4. Q5E Annex EWG - Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process
5. E2D(R1) EWG- Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports
6. E6(R3) EWG and Annex 2- Good Clinical Practice
7. E14/S7B IWG- Questions & Answers: the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
8. E20 EWG- Adaptive Designs for Clinical Trials
9. E21 EWG- Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials
10. E22 EWG - General Considerations for Patient Preference Studies
11. E23 EWG - Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a focus on Effectiveness of Medicines
12. M4Q(R2) EWG - Revision of M4Q(R1) CTD on Quality guidance
13. M7 Sub-Group- Risk Assessment and Control of Nitrosamine Impurities
14. M11 EWG- Clinical electronic Structured Harmonized Protocol (CeSHarP)
15. M13 EWG- Bioequivalence for Immediate-Release Solid Oral Dosage Forms
16. M14 EWG- General Principles on Plan, Design, Analysis and Reporting of Non-Interventional Studies that Utilize Real-World Data for Safety Assessment of Medicines
17. M15 EWG- General Principles for Model-Informed Drug Development
18. M18 EWG- Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar
19. Q1 EWG- Stability Testing of Drug Substances and Drug Products
20. Q3E EWG - Guideline for Extractables and Leachables
21. Q6(R1) EWG - Revision of Specification Guidelines
22. S13 EWG- Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics
23. E2B(R3) EWG/IWG - Revision of the Electronic Submission of Individual Case Safety Reports
24. M1 PtC WG - MedDRA Points to Consider
25. M2 EWG - Electronic Standards for the Transfer of Regulatory Information (ESTRI)
26. M7(R3) Maint. EWG - Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
27. M8 EWG/IWG - The Electronic Common Technical Document (eCTD)
28. Q3C(R10) Maint. EWG - Maintenance of the Guideline for Residual Solvents
29. E11A EWG - Paediatric Extrapolation
30. Q9(R1) TG - Training on Quality Risk Management
31. CGTDG - Cell and Gene Therapies Discussion Group
32. S1B(R1) IWG - Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline