ICH Association

2025 Annual Work Plan

(1 January – 31 December 2025)

Version dated 27 September 2024

Approved by the Assembly on 5 November 2024

2025 Overview

In 2025 the ICH Association will continue its harmonisation activities, progressing work on the development, maintenance and implementation of ICH Guidelines on Quality, Safety, Efficacy and Multidisciplinary topics, as well as definition of strategic priorities and identification of new topics for harmonisation.

2025 Work Plan

The following table summarises the key categories of work planned in 2025:

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Strategy	Continue to implement enhanced strategic approach to address ICH Guideline training needs with a view to benefiting more broadly, and in an expedited manner, ICH Members and Observers	Management Committee	Ongoing in 2025
	Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2025
	Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2025
	Approve the ICH Association 2025 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2025 Annual Work Plan	Assembly	November 2025

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Continue activities related to the modernisation of the ICH Secretariat which had been initiated in 2024, including developing the Secretariat's technology platform, streamlining the procedures, and optimising the structure and organisation of the Secretariat	Management Committee ICH Secretariat	Ongoing in 2025
	Assess ICH Pharmaceutical Quality Knowledge Management (PQKM) Technology Platform Task Force (TF) recommendations to determine the foundation for establishing and governing a secure, standardised collaborative technology platform further to a Request for Information (RFI) released in Q4 2024.	Assembly Management Committee	March - May 2025
Harmonisation			
	Progress current harmonisation activities on ICH topics ○ Annex I and II list the technical WGs expected to reach a key milestone in 2025 by either reaching *Step 2a/b*, *Step 4* or finalising a deliverable ○ Annex III lists all other active WGs at the time of writing of this work plan	Assembly Management Committee	Ongoing in 2025
	Assess new ICH topic proposals for harmonisation and provide recommendations to the ICH Assembly	Management Committee	March 2025
	Approve new ICH topic proposals for harmonisation consistent with the availability of staff with the requisite scientific and technical expertise, with a view to establishing new technical WGs	Assembly	May 2025
	Continue to explore the enhancement of operational efficiency of ICH and its WGs, through initiatives such as the use of technical writers, and explore potential enhancement of the Plenary Working Party Process	Management Committee ICH Secretariat	Ongoing in 2025
Operations			
	Implementation		
	Continue monitoring ICH Guideline Implementation by ICH Regulatory Members	Management Committee ICH Secretariat	Ongoing in 2025

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Training		
	Assist ICH WGs on high-priority guidelines to develop online training materials to be posted on the ICH website	Management Committee	Ongoing in 2025
	Continue working with ICH Training Associates towards the development of online training materials, including case studies for identified ICH Guidelines, with considerations to contract new Training Associates for additional training development informed by the 2023 ICH Survey on training needs and 2024 ICH Implementation Survey	Management Committee Assembly	Ongoing in 2025
	Conduct the ICH Regulatory Training Funding Process on a rolling basis	Management Committee	Ongoing in 2025
	Continue evaluating ICH-funded Regulatory Trainings and work on establishing a process for evaluating online ICH trainings, mainly developed by ICH Training Associates.	Management Committee ICH Secretariat	Ongoing in 2025
	Maintain/improve the Training Library available on the ICH website providing user-friendly access to materials developed by Training Associates, Training Providers and ICH WGs	Management Committee ICH Secretariat	Ongoing in 2025
	ICH Meetings		
	Organise biannual ICH meetings, as well as interim MC and WG meetings using a contracted Professional Conference Organiser (PCO) as part of a sustainable, consistent and cost-efficient approach to ICH meeting organisation, and consider any adjustment to be made to the format of future meetings	Management Committee ICH Secretariat	March/May/November 2025
	Identify the venue for May/June 2027 ICH Biannual Meeting Identify the venue for 2026 ICH Interim Meeting Identify the venue and dates for October/November/December 2027 ICH Biannual Meeting	Management Committee	May 2025 July/August 2025 November 2025

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Membership and Observership		
	Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2025
	Take decisions on applications for ICH Membership and Observership applications	Assembly	May/November 2025
	Elections		
	Conduct a new election for the Management Committee Chair and Vice-Chair	Management Committee	November 2025
	Conduct a new election for the Assembly Chair and Vice-Chair	Assembly	November 2025
	Financial and Administrative Matters		
	Support the audit of 2024 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By March/April 2025
	Approve the audited 2024 accounts of the Association	Assembly	May 2025
	Approve the auditor to audit the 2026 and 2027 annual financial statements of the ICH Association.	Assembly	May 2025
	Approve the ICH Association 2024 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	May 2025
	Approve the 2026 ICH and MedDRA Budgets, including the 2026 MedDRA MSSO Subscription fees and 2027 ICH Membership Fees	Assembly	November 2025
	Support the 5-year ICH and MedDRA budget projection for 2026-2030	Assembly	November 2025
	Meet fiscal reporting requirements for ICH Association, including filing of 2024 tax return	Management Committee ICH Secretariat	Ongoing in 2025
	Implement approach and process for the funding of Regulatory Observers' travel to ICH meetings	Management Committee ICH Secretariat	Ongoing in 2025

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Continue to develop/implement approaches to further enhance the efficiency of ICH operations	Management Committee ICH Secretariat	Ongoing in 2025
	Continue registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2025
Procedures			
	Maintain as necessary the Rules of Procedure (RoP) for the Assembly	Assembly	Ongoing in 2025
	Maintain as necessary the RoP for the Management Committee	Management Committee	Ongoing in 2025
	Reorganise and revise the Standard Operating Procedures (SOP) for ICH WGs, dividing SOP into separate documents for a specific audience	Management Committee	Ongoing in 2025
Communication			
	Continue interactions between ICH and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on training on ICH Guidelines with relevance to both Regulatory assessor and Inspector disciplines in line with the framework provided by the Memorandum of Understanding (MOU) between ICH and PIC/S	Management Committee	Ongoing in 2025
	Coordinate with the ICMRA Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group in support of activities outlined in the ICMRA-ICH-PIC/S-IPRP Work Plan	Management Committee	Ongoing in 2025
	Continue to refine/implement approaches for patient stakeholder engagement in ICH	Management Committee	Ongoing in 2025
	Continue to implement the approved transparency policy for ICH, with continued publication of ICH Assembly/Management Committee meeting reports/minutes, Working Group (WG) expert names, governing body representative/delegate biographies, and information on ICH funding	ICH Secretariat	Ongoing in 2025

Annex I

10 Technical WGs expected to reach *Step 4* or finalise deliverables in 2025

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E2D(R1)	EWG	Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports	*Step 4* expected by May 2025
E6(R3)	EWG	Good Clinical Practice	*Step 4* (Annex 2) expected by June 2025
E11A	EWG	Paediatric Extrapolation	Training materials expected by August 2025
E14/S7B	IWG	Questions and Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential	*Step 4* expected by November 2025
M11	EWG	CeSHarP	*Step 4* expected by November 2025
M14	EWG	General Principles on Plan, Design and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines	*Step 4* and training materials expected by June 2025
M15	EWG	General Principles for Model-Informed Drug Development	*Step 4* expected by Q4 of 2025
Q2(R2)/Q14	IWG	Training on Validation of Analytical Procedures and Analytical Procedure Development	Training materials expected by March 2025
CGT	DG	Cell and Gene Therapies Discussion Group	Recommendation Paper expected by October 2025
Q9(R1)	Training Group	Training on Quality Risk Management	Training Materials (Briefing Pack) expected by June 2026

Annex II
7 Technical WGs expected to reach *Step 2a/b* in 2025

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E21	EWG	Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials	*Step 2* is expected by Q2 2025
E22	EWG	General Considerations for Patient Preference Studies	*Step 2* is expected by December 2025
M4Q(R2)	EWG	Revision of M4Q(R1) CTD on Quality Guidance	*Step 2* is expected by June 2025
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms	*Step 2* M13B is expected by January 2025
Q1/Q5C	EWG	Targeted Revisions of the ICH Stability Guidelines Series	*Step 2* is expected by January 2025
Q3C(R10)	Maint. EWG	Maintenance of the Guideline for Residual Solvents	*Step 2* expected by September 2025
Q3E	EWG	Impurities: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics	*Step 2* is expected by June 2025

Annex III
15 Other Technical WGs Expected to be Active in 2025*

Topic Code	Type of WG	Topic Name	Anticipated Milestones
Standing Paediatric	EWG	Standing Paediatric EWG	N/A (Ongoing activity)
E2B(R3)	EWG/IWG	Revision of Electronic Submission of ICSRs	N/A (Ongoing activity)
E20	EWG	Adaptive Clinical Trials	*Step 2* expected by April 2026
M1	PtC WG	MedDRA Points to Consider	N/A (Ongoing activity)
M2	EWG	Electronic Standards for the Transfer of Regulatory Information (ESTRI)	N/A (Ongoing activity)
M7(R3)	Maintenance EWG/IWG	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	N/A (No ongoing activity)
M7 Sub-Group	EWG	Risk Assessment and Control of Nitrosamine Impurities	N/A (Timeline TBC)
M8	EWG/IWG	The Electronic Common Technical Document (eCTD)	N/A (Ongoing activity)
Q3D(R3)	Maintenance EWG	Maintenance of the Guideline for Elemental Impurities	N/A (No ongoing activity)
Q6(R1)	EWG	Revision of Specifications Guidelines	*Step 2* expected by June 2026
Q12	IWG	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	N/A (No ongoing activity)
S1B(R1)	IWG	Testing for Carcinogenicity of Pharmaceuticals	N/A (Ongoing activity)
S5(R4)	Maintenance EWG	Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals	N/A (No ongoing activity)
S13	EWG	Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics	N/A (Timeline TBC)
QDG	DG	Quality Discussion Group	N/A (Timeline TBC)

* Additional WGs may be established in 2025 if proposals for new topics are approved by the Assembly, and a WG with delayed start on the topic: Structured Product Quality Submissions (once M4Q(R2) EWG reaches *Step 2*).