

ICH Association
2026 Annual Work Plan
 (1 January – 31 December 2026)
Version dated 3 October 2025
Approved by the Assembly on 18 November 2025

2026 Overview

In 2026 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.

2026 Work Plan

The following table summarises the key categories of work planned in 2026:

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 2026
	 Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2026
	 Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2026

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	 Approve the ICH Association 2026 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2026 Annual Work Plan	Assembly	November 2026
Harmonisation	 Continue activities related to the modernisation of the ICH Secretariat which had been initiated in 2024, including developing the Secretariat's technology platform and streamlining the procedures	Management Committee ICH Secretariat	Ongoing in 2026
	 Assess ICH Technology Task Force (previously PQKM) recommendations regarding a secure platform capable of supporting document and data sharing — to address emerging technology harmonisation challenges by Q2 2026	Assembly Management Committee	March - June 2026
Harmonisation	 Progress current harmonisation activities on ICH topics - Annex I and II list the technical WGs expected to reach a key milestone in 2026 by either reaching <i>Step 2a/b</i>, <i>Step 4</i> 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 2026
	 Continue to explore the enhancement of operational efficiency of ICH and its WGs, including work on a portfolio management process, the use of technical writers, and explore potential enhancement of the Plenary Working Party Process	Management Committee ICH Secretariat	Ongoing in 2026
Operations			
	Implementation		
	 Continue monitoring ICH Guideline Implementation by ICH Regulatory Members, by establishing the multi-annual strategy for ICH Guidelines Implementation	Management Committee ICH Secretariat	Ongoing in 2026

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 2026
	 Implement a new training strategy focused on enabling Working Groups to develop interactive training materials, e.g., by using AI tools	Management Committee ICH Secretariat	Ongoing in 2026
	 Conduct the ICH Regulatory Training Funding Process on a rolling basis	Management Committee	Ongoing in 2026
	 Continue evaluating ICH-funded Regulatory Trainings and work on establishing a process for evaluating online ICH trainings	Management Committee ICH Secretariat	Ongoing in 2026
	 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 2026
	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 2026
	 Identify the venue for May/June 2028 ICH Biannual Meeting	Management Committee	May 2026
	 Identify the venue for 2027 ICH Interim Meeting		July/August 2026
	 Identify the venue and dates for October/November/December 2028 ICH Biannual Meeting		November 2026
	Membership and Observership		

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	✧ Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2026
	✧ Take decisions on applications for ICH Membership and Observership applications	Assembly	June/November 2026
	✧ Continue pro-active and regular engagement with ICH Regulatory Observers	ICH Secretariat	Ongoing in 2026
	Financial and Administrative Matters		
	✧ Support the audit of 2025 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By March/April 2026
	✧ Approve the audited 2025 accounts of the Association	Assembly	June 2026
	✧ Approve the ICH Association 2025 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	June 2026
	✧ Approve the 2027 ICH and MedDRA Budgets, including the 2027 MedDRA MSSO Subscription fees and 2028 ICH Membership Fees	Assembly	November 2026
	✧ Support the 5-year ICH and MedDRA budget projection for 2027-2031	Assembly	November 2026
	✧ Meet fiscal reporting requirements for ICH Association, including filing of 2025 tax return	Management Committee ICH Secretariat	Ongoing in 2026
	✧ Implement approach and process for the funding of Regulatory Observers' travel to ICH meetings	Management Committee ICH Secretariat	Ongoing in 2026
	✧ Continue to develop/implement approaches to further enhance the efficiency of ICH operations	Management Committee ICH Secretariat	Ongoing in 2026

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	 Continue registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2026
Procedures	 Maintain and enhance the Rules of Procedure (RoP) for the Assembly, with a view to improving the operational efficiency of ICH and its Working Groups	Assembly	Ongoing in 2026
	 Maintain and enhance the Rules of Procedure (RoP) for the Management Committee, with a view to improving the operational efficiency of ICH and its Working Groups	Management Committee	Ongoing in 2026
	 Reorganise and revise the Standard Operating Procedures (SOP) for ICH WGs, dividing SOP into separate documents for a specific audience	Management Committee	Ongoing in 2026
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 2026
	 Continue to refine/implement approaches for patient stakeholder engagement in ICH	Management Committee	Ongoing in 2026
	 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 2026
	 Develop and implement a communication strategy to enhance visibility of ICH activities and support effective internal communication within the ICH Community	ICH Secretariat	Ongoing in 2026

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	 Continue implementation of the ICH Anniversary Campaign as an opportunity to highlight ICH's achievements and strengthen stakeholder engagement	ICH Secretariat	By November 2026

Annex I

9 Technical WGs expected to reach *Step 4* or finalise deliverables in 2026

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E6(R3)	EWG	Good Clinical Practice	Training materials expected Q1 2026
E14/S7B	IWG	Questions and Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential	<i>Step 4</i> is expected by May 2026 Q&A Training Material May 2026
E20	EWG	Adaptive Designs for Clinical Trials	<i>Step 4</i> is expected by October 2026
E22	EWG	General Considerations for Patient Preference Studies	E22 Training Materials is expected by October 2026 <i>Step 4</i> is expected by December 2026
M1	PtC WG	MedDRA Points to Consider	MedDRA Term Selection: PtC is expected by March 2026 Companion Document V4.0 is expected by May 2026
M11	EWG	CeSHarP	Training materials expected by May 2026
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms -Additional Strengths Biowaiver	<i>Step 4</i> is expected by July 2026
Q1	EWG	Stability Testing of Drug Substances and Drug Products	<i>Step 4</i> is expected by November 2026
Q3C(R10)	EWG	Maintenance of the Guideline for Residual Solvents	<i>Step 4</i> is expected by December 2026

Annex II
2 Technical WGs expected to reach *Step 2a/b* in 2026

Topic Code	Type of WG	Topic Name	Anticipated Milestone
Q6(R1)	EWG	Revision of the Specification Guidelines	<i>Step 2</i> is expected by November 2026
S13	EWG	Non-clinical Safety Evaluation of Oligonucleotide-based Therapeutics	<i>Step 2</i> is expected by October 2026

Annex III

17 Other Technical WGs Expected to be Active in 2026

Topic Code	Type of EWG	Topic Name	Anticipated Milestones
E2B(R3)	EWG/IWG	Revision of the Electronic Submission of Individual Case Safety Reports	<i>N/A (Ongoing Activity)</i>
E21	EWG	Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials	<i>Steps 4 is expected by Q1 2028.</i>
E23	EWG	Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a focus on Effectiveness of Medicines	<i>Timeline TBC</i>
E24	EWG	Natural History Studies and Registry Data to Advance Rare Disease Drug Development	<i>Timeline TBC</i>
M1	PtC WG	MedDRA Points to Consider	<i>Ongoing Activity (reoccurring MedDRA Term Selection: PtC deliverable)</i>
M2	EWG	Electronic Standards for the Transfer of Regulatory Information (ESTRI)	<i>N/A (Ongoing Activity)</i>
M4Q(R2)	EWG	Revision of M4Q(R1) CTD on Quality guidance	<i>Steps 4 is expected by June 2027</i>
M7(R3)	Maint. EWG/IWG	Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	<i>N/A (No Ongoing Activity)</i>
M7 Sub-Group	EWG	Risk Assessment and Control of Nitrosamine Impurities	<i>Step 2 is expected by August 2028</i>
M8	EWG/IWG	The Electronic Common Technical Document (eCTD)	<i>N/A (Ongoing Activity)</i>
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms	<i>Step 2 is expected by July 2027</i>
M15	EWG	General Principles for Model-Informed Drug Development	<i>Training Material (Timeline TBD)</i>
M16	EWG	Structured Product Quality Submissions (SPQS) Guideline	<i>Timeline TBC</i>

M18	EWG	Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilars	<i>Timeline TBC</i>
Q3C(R10)	Maint. EWG	Maintenance of the Guideline for Residual Solvents	<i>N/A (Ongoing Activity)</i>
Q3E	EWG	Guideline for Extractables and Leachables	<i>Step 4 is expected by July 2027 Q3E Training Materials are expected by July 2027.</i>
Q5E Annex	EWG	Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process	<i>Timeline TBC</i>
S1B(R1)	IWG	Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline	<i>N/A (Ongoing Activity)</i>