18 October 2022

ICH Association

2023 Annual Work Plan

(1 January – 31 December 2023)

Version dated 18 October 2022

Approved by the Assembly on 15 November 2022

2023 Overview

In 2023 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.

2023 Work Plan

The following table summarises the key categories of work planned in 2023:

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 2023
	Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2023
	Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2023
	Approve the ICH Association 2023 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2023 Annual Work Plan	Assembly	November 2023

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Harmonisation	Progress current harmonisation activities on ICH topics ○ Annex I and II list the technical WGs expected to reach a key milestone in 2023 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 2023
	Assess new ICH topic proposals for harmonisation	Management Committee	March 2023
	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	June 2023
Operations			
	Implementation		
	Continue monitoring ICH Guideline Implementation by ICH Regulatory Members and confirm objectives and scope for a next survey on adequacy of implementation and adherence to the ICH Guidelines using an independent third party, to be initiated in Q4 2023 in preparation for the MC Elections in June 2024.	Management Committee ICH Secretariat	Q2-Q4 2023
	Training		
	Assist ICH WGs on high-priority guidelines to develop online training materials to be posted on the ICH website	Management Committee	Ongoing in 2023
	Continue working with ICH Training Associates towards the development of online training materials, including case studies for all ICH Guidelines, as well as tailored training for regulatory authorities	Management Committee Assembly	Ongoing in 2023
	Continue the ICH Regulatory Training Funding Process, with extension of eligibility in 2023 to ICH Observers representing or constituted by Regulators, namely Regional Harmonisation Initiatives (RHIs) and PIC/S.	Management Committee	Ongoing in 2023

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Maintain 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 2023
	ICH Meetings		
	Organise biannual ICH meetings and MC interim meeting using 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 2023 meetings in view of the COVID-19 pandemic	Management Committee	March/June/November 2023
	Identify dates and venues for June & November 2025 and June 2026 ICH Meetings	Management Committee	June/November 2023
	Membership and Observership		
	Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2023
	Take decisions on applications for ICH Membership and Observership applications	Assembly	June/November 2023
	Financial and Administrative Matters		
	Approve the ICH Association 2022 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	June 2023
	Approve the 2024 ICH and MedDRA Budgets, including the 2024 MedDRA MSSO Subscription fees and 2025 ICH Membership Fees	Assembly	November 2023
	Support the 5-year ICH and MedDRA budget projection for 2024-2027	Assembly	November 2023

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Support the audit of 2022 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By March/April 2023
	Approve the audited 2022 accounts of the Association	Assembly	June 2023
	Meet fiscal reporting requirements for ICH Association, including filing of 2022 tax return	Management Committee ICH Secretariat	Ongoing in 2023
	Continue registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2023
	Continue to develop/implement approaches to further enhance the efficiency of ICH operations	Management Committee ICH Secretariat	Ongoing in 2023
Procedures			
	Maintain as necessary the Rules of Procedure (RoP) for the Assembly	Assembly	Ongoing in 2023
	Maintain as necessary the RoP for the Management Committee	Management Committee	Ongoing in 2023
	Maintain as necessary the Standard Operating Procedures (SOP) for technical WGs	Management Committee	Ongoing in 2023
Communication			
	Consider outcome of pilot and approach for continued interactions between ICH and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on ICH Guideline work with relevance to both Regulatory assessor and Inspector disciplines.	Management Committee	Ongoing in 2023
	Coordinate with the ICMRA Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group in support of activities outlined in the recent ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper on PQ KMS Capability	Management Committee	Ongoing in 2023
	Continue to refine/implement approaches for patient stakeholder engagement in ICH	Management Committee	Ongoing in 2023

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	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 2023

Annex I

5 Technical WGs expected to reach *Step 4* or finalise deliverable in 2023

Topic Code	Type of WG	Topic Name	Anticipated Milestone
M11	EWG	Clinical electronic Structured Harmonised Protocol (CeSHarP)	*Step 4* is expected by October 2023
Q2(R2)/Q14	EWG	Analytical Procedure Development and Revision of Q2(R1) Analytical Validation	*Step 4* is expected by November 2023
Q5A(R2)	EWG	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	*Step 4* is expected by November 2023
Q9(R1)	EWG	Quality Risk Management	*Step 4* is expected by March 2023 and Training Materials by February 2023
S12	EWG	Nonclinical Biodistribution Considerations for Gene Therapy Products	*Step 4* is expected by January 2023

Annex II
5 Technical WGs expected to reach *Step 2a/b* in 2023

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E2D(R1)	EWG	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	*Step 2* is expected by May 2023
E20	EWG	Adaptive Clinical Trials	*Step 2* is expected by June 2023
M4Q(R2)	EWG	Revision of M4Q(R1) CTD on Quality Guidance	*Step 2* is expected by November 2023
M14	EWG	General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine	*Step 2* is expected by August 2023
Q3E	EWG	Impurities: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics	*Step 2* is expected by May 2023

Annex III
22 Other Technical WGs Expected to be Active in 2023*

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)
E6(R3)	EWG	Good Clinical Practice	*Step 4* expected by December 2024
E11A	EWG	Pediatric Extrapolation	*Step 4* expected by January 2024
E14/S7B	DG	Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential	N/A (Next steps to be determined)
E21	Informal WG	Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials	Informal Working Group to be established in 2022
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 (Ongoing Activity)
M8	M2 Sub-group	The Electronic Common Technical Document (eCTD)	N/A (Ongoing Activity)
M12	EWG	Drug Interaction Studies	*Step 4* expected by Q1 2024
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms	*Step 4* expected by May 2024 (M13A)
M15	EWG	General Principles for Model-Informed Drug Development	To be determined following completion of Concept Paper and Business Plan in 2022
Q1/Q5C	EWG	Targeted Revisions of the ICH Stability Guidelines Series	To be determined following completion of Concept Paper and Business Plan in 2022
Q3C(R9)	Maintenance EWG	Residual Solvents	N/A (Dormant state)
Q3D(R3)	Maintenance EWG	Maintenance of the Guideline for Elemental Impurities	N/A (Ongoing Activity)

Topic Code	Type of WG	Topic Name	Anticipated Milestones
Q12	IWG	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	N/A (Any further activity to be determined)
Q13	IWG	Continuous Manufacturing of Drug Substances and Drug Products	To be determined following completion of Concept Paper for the development of training materials
S1B(R1)	EWG	Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline	N/A (EWG tracking progress of implementation until Q2 2023)
S5(R4)	Maintenance EWG	Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals	N/A (Dormant State)
GDG	DG	Generic drug Discussion Group	N/A (Dormant state)
QDG	DG	Quality Discussion Group	N/A (Ongoing activity)

* Additional WGs may be established in 2023 if proposals for new topics are approved by the Assembly.