6 October 2020

ICH Association

2021 Annual Work Plan

(1 January – 31 December 2021)

2021 Overview

In 2021 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.

2021 Work Plan

The following table summarises the key categories of work planned in 2021:

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Strategy	Continue refinement and implementation of a strategic approach to address ICH Guideline training needs	Management Committee	Ongoing in 2021
	Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2021
	Continue ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines through surveying and results analysis	Management Committee	Ongoing in 2021
	Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2021
	Approve the ICH Association 2022 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2022 Annual Work Plan	Assembly	November 2021

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 2021 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 2021
	Assess new ICH topic proposals for harmonisation	Management Committee	March 2021
	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 2021
Operations			
	Implementation		
	Present the results from the Phase 2b Survey to the Assembly including results from the surveying of all Regulatory Members in view of MC Elections, as well as results from surveying of Regulatory Observers which may support potential future interest in ICH membership	Management Committee	May/June 2021
	Review the outcomes of Phase 2b of the project and consider objectives for further surveying of Regulators and Industry on adequacy of implementation and adherence to the ICH Guidelines using an independent third party	Management Committee	By the end of 2021
	Training		
	Continue work with Providers of ICH Recognised Training Programme to promote their delivery of training programmes on priority ICH Guidelines for regulators, industry and other stakeholders involved in drug development	Management Committee	Ongoing in 2021
	Assist ICH WGs on high-priority guidelines to develop online training materials to be posted on the ICH website	Management Committee	Ongoing in 2021

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Work with ICH Training Associates on the development of online training materials, including case studies for prioritised Tier 1 and Tier 2 ICH Guidelines	Management Committee/ Assembly	Ongoing in 2021
	Continue development of ICH website Training Library to provide user-friendly access to materials developed by Training Associates, Training Providers and ICH WGs, as well as links to training materials translated to other languages by ICH Members	Management Committee / ICH Secretariat	Ongoing in 2021
	ICH Meetings		
	Organise biannual ICH meetings 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 2021 meetings in view of the COVID-19 pandemic	Management Committee	May-June/November 2021
	Ensure continued PCO support for meetings beyond 2023 by finalising the call for tenders started in 2020 and approving the signature of a new contract	Management Committee	By March 2021
	Identify dates for November 2023 and June 2024 ICH Meetings	Management Committee	By May 2021 and November 2021
	Identify venues for June and November 2023 ICH Meetings	Management Committee	By November 2021
	Membership and Observership		
	Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2021
	Take decisions on applications for ICH Membership and Observership applications	Assembly	June/November 2021

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Integrate any newly Elected Management Committee Representatives into the operations of the Management Committee	Management Committee	From June 2021
	Elections		
	Conduct a new election for Elected Management Committee Representatives	Assembly	June 2021
	Conduct a new election for the Management Committee Chair and Vice-Chair	Management Committee	November 2021
	Conduct a new election for the Assembly Chair and Vice-Chair	Assembly	November 2021
	Financial and administrative matters		
	Approve the ICH Association 2020 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	June 2021
	Approve the draft provisional 2023 ICH budget	Assembly	June 2021
	Approve the final 2022 ICH and MedDRA Budgets, including the 2022 MedDRA MSSO Subscription fees	Assembly	November 2021
	Approve the final provisional 2023 ICH budget including 2023 ICH Membership Fees	Assembly	November 2021
	Support the audit of 2020 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By March/April 2021
	Approve the audited 2020 accounts of the Association	Assembly	June 2021
	Meet fiscal reporting requirements for ICH Association, including filing of 2020 tax return	Management Committee ICH Secretariat	Ongoing in 2021

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Establish a sustainable funding model for the ICH Association following recommendations from the ICH Finance Committee	Management Committee Assembly	May/June 2021
	Continue registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2021
Procedures	Maintain as necessary the Rules of Procedure (RoP) for the Assembly	Assembly	Ongoing in 2021
	Maintain as necessary the RoP for the Management Committee	Management Committee	Ongoing in 2021
	Maintain as necessary the Standard Operating Procedures (SOP) for technical WGs	Management Committee	Ongoing in 2021
Communication			
	Organise a commemorative event for ICH's 30th Anniversary which occurred in 2020, but commemoration of which was delayed due to the COVID-19 pandemic	Assembly	To be confirmed
	Issue a stand-alone ICH publication to commemorate the ICH's 30th Anniversary	Assembly	2021
	Monitor the progress of the pilot process regarding 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 2021
	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 2021

Annex I

9 Technical WGs expected to reach *Step 4* or finalise deliverable in 2021

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E8(R1)	EWG	Revision of General Considerations for Clinical Trials	*Step 4* is expected by February 2021
E14/S7B	IWG	Clinical Evaluation of QT/QTc Interval Prolongation	*Step 4* is expected by June 2021
M7(R2)	Maintenance EWG	Addendum to Assessment and Control of DNA Reactive Impurities	*Step 4* on the Q&A is expected by April 2021 *Step 4* on the Guideline is expected by November 2021
M10	EWG/IWG	Bioanalytical Method validation	*Step 4* on the Guideline and finalisation of training materials are expected by November 2021
Q3D(R2)	Maintenance EWG	Elemental Impurities	*Steps 4* is expected by July 2020
Q12	IWG	Considerations for Pharmaceutical Product Lifecycle Management	Finalisation of training materials is expected by June 2021
GDG	DG	Generic drug Discussion Group	Recommendations on areas for harmonisation of scientific and technical standards for generic drugs are expected by April 2020
QDG	DG	Quality Discussion Group	Assessment of ICH Quality and Multidisciplinary Guidelines is expected by November 2020
PEpiDG	DG	Pharmacoepidemiology Discussion Group	Finalisation of the opportunity proposal on general principles on study plan expected by June 2021.

Annex II
8 Technical WGs expected to reach *Step 2a/b* in 2021

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 November 2021
E11A	EWG	Paediatric Extrapolation	*Step 2* is expected by June 2021
M11	EWG	CeSHarP	*Step 2* is expected by September 2021
M12	EWG	Drug Interaction Studies	*Step 2* is expected by November 2021
Q2(R2)/Q14	EWG	Analytical Procedure Development and Revision of Q2 (R1)	*Step 2* is expected by May 2021
Q5A(R2)	EWG	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	*Step 2* is expected by November 2021
Q13	EWG	Continuous Manufacturing	*Step 2* is expected by May 2021
S12	EWG	Biodistribution Studies for Gene Therapy Products	*Step 2* is expected by May 2021

Annex III
15 Other Technical WGs Expected to be Active in 2021*

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 2* is expected by January 2022
E19	EWG	Optimization of safety data collection	*Step 4* is expected by November 2022
E20	EWG	Adaptive Clinical Trials	Step 2 is expected by June 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)
M4Q(R1)	IWG	Addressing CTD-Q-Related Questions	N/A (dormant state)
M8	EWG/IWG	The Electronic Common Technical Document (eCTD)	N/A (Ongoing Activity)
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms	*Step 2* is expected by June 2022
Q3C(R8)	Maintenance EWG	Residual Solvents	Next timeline to be determined following completion of *Step 4* in December 2020
Q3E	EWG	Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics	*Step 2* is expected in November 2022
Q9(R1)	Informal WG	Quality Risk Management	To be determined following completion of Concept Paper and Business Plan (expected by November 2020)
S1(R1)	EWG	Rodent Carcinogenicity Studies for Human Pharmaceuticals	*Step 4* is expected by May 2022
S5(R4)	Maintenance EWG	Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals	To be confirmed (expected to be in a dormant state until March 2021)

* Additional WGs may be established in 2021 if proposals for new topics are approved by the Assembly.