21 October 2019

ICH Association

2020 Annual Work Plan

(1 January – 31 December 2020)

2020 Overview

In 2020 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.

2020 Work Plan

The following table summarises the key categories of work planned in 2020:

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 2020
	Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2020
	Continue ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines through surveying and results analysis	Management Committee	Ongoing in 2020
	Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2020
	Approve the ICH Association 2021 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2021 Annual Work Plan	Assembly	November 2020

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 2020 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 2020
	Assess new ICH topic proposals for harmonisation	Management Committee	March 2020
	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 2020
Operations			
	Implementation		
	Determine/consider needs for further surveying of Regulators and Industry on adequacy of implementation and adherence to the ICH Guidelines using an independent third party	Management Committee	Ongoing 2020
	Training		
	Continue work with ICH Recognised Training Programme Providers to promote their delivery of in-person training programmes on priority ICH Guidelines for regulators, industry and other stakeholders involved in drug development	Management Committee	Ongoing in 2020
	Assist ICH WGs on high-priority guidelines to develop online training materials to be posted on the ICH website	Management Committee	Ongoing in 2020
	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 2020
	ICH Meetings		

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Organise biannual ICH meetings using contracted Professional Conference Organiser as part of a sustainable, consistent and cost-efficient approach to ICH meeting organisation	Management Committee	May/November 2020
	Ensure continued PCO support for meetings beyond 2021.	Management Committee/ Assembly	By March 2020
	Identify dates for November 2022 and June 2023 ICH Meetings	Management Committee	By May 2020
	Identify venues for June and November 2022 ICH Meetings	Management Committee	By November 2020
	Membership and Observership		
	Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2020
	Take decisions on applications for ICH Membership and Observership applications	Assembly	May/November 2020
	Integrate any newly Elected Management Committee Representatives into the operations of the Management Committee	Management Committee	Ongoing in 2020
	Elections		
	Conduct a new election for the Management Committee Chair and Vice-Chair	Management Committee	November 2020
	Financial and administrative matters		
	Approve the ICH Association 2019 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	May 2020
	Approve the final 2021 ICH Budget	Assembly	November 2020
	Approve the provisional 2022 ICH budget including 2022 ICH Membership Fees	Assembly	November 2020

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Support the audit of 2019 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By March/April 2020
	Approve the audited 2019 accounts of the Association	Assembly	May 2020
	Meet fiscal reporting requirements for ICH Association, including filing of 2019 tax return	Management Committee ICH Secretariat	Ongoing in 2020
	Approve 2021 MedDRA Budget, including the 2021 Subscription fees	Assembly	November 2020
	Continue registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2020
Procedures	Maintain as necessary the Rules of Procedure (RoP) for the Assembly	Assembly	Ongoing in 2020
	Maintain as necessary the RoP for the Management Committee	Management Committee	Ongoing in 2020
	Maintain as necessary the Standard Operating Procedures (SOP) for technical WGs	Management Committee	Ongoing in 2020
	Organise a commemoration of ICH's 30th Anniversary in 2020, including hosting of an ICH event, and development of a video and publication	Assembly	Ongoing in 2020
	Develop and initiate a 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 2020

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Communication	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	Management Committee ICH Secretariat	Ongoing in 2020
	Increase the user-friendliness and functionalities of the ICH website with more accessible information on training	ICH Secretariat	Ongoing in 2020

Annex I

8 Technical WGs expected to reach *Step 4* or finalise deliverable in 2020

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E8(R1)	EWG	Revision of General Considerations for Clinical Trials	*Step 4* is expected by June 2020
E14/S7B	IWG	Clinical Evaluation of QT/QTc Interval Prolongation	*Step 4* is expected by June 2020
M7(R2)	Maintenance EWG	Addendum to Assessment and Control of DNA Reactive Impurities	*Steps 4* is expected by November 2020 (*Step 2* is expected by January 2019)
M10	EWG/IWG	Bioanalytical Method validation	*Step 4* is expected by November 2020
Q3C(R8)	Maintenance EWG	Residual Solvents	*Step 4* is expected by June 2020
Q3D(R2)	Maintenance EWG	Elemental Impurities	*Steps 4* is expected by November 2020 (*Step 2* is expected by January 2019)
S11	EWG	Guideline on Nonclinical Safety Testing - Paediatric Medicines	Training Materials are expected by June 2020
IGDG	DG	Informal Generic drug Discussion Group	Recommendations on areas for harmonisation of scientific and technical standards for generic drugs are expected by April 2020
IQDG	DG	Informal Quality Discussion Group	Assessment of ICH Quality and Multidisciplinary Guidelines is expected by November 2020

Annex II
5 Technical WGs expected to reach *Step 2a/b* in 2020

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E11A	EWG	Paediatric Extrapolation	*Step 2* is expected by November 2020
M11	EWG	CeSHarP	*Step 2* is expected by July 2020
Q2(R2)/Q14	EWG	Analytical Procedure Development and Revision of Q2 (R1)	*Step 2* is expected by May 2020
Q13	EWG	Continuous Manufacturing	*Step 2* is expected by June 2020
S1(R1)	EWG	Rodent Carcinogenicity Studies for Human Pharmaceuticals	*Step 2* is expected by May 2020

Annex III
19 Other Technical WGs Expected to be Active in 2020*

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)
E2D(R1)	Informal WG	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed
E6(R3)	Informal WG	Good Clinical Practice	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed
E19	EWG	Optimization of safety data collection	*Step 4* is expected by June 2021
E20	Informal WG	Adaptive Clinical Trials	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed
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	To be confirmed (dormant state)
M8	EWG/IWG	The Electronic Common Technical Document (eCTD)	N/A (Ongoing Activity)
M12	Informal WG	Drug Interaction Studies	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed
Q5A(R2)	Informal WG	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed

Topic Code	Type of WG	Topic Name	Anticipated Milestones
Q12	EWG	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	Expected timeline for development of training materials to be confirmed
S5(R3)	EWG	Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals	To be confirmed (expected to be in a dormant state in 2020)
S12	Informal WG	Biodistribution Studies for Gene Therapy Products	Concept Paper and Business Plan expected by November 2019 Next steps to be confirmed
PEpiDG	DG	Pharmacoepidemiology Discussion Group	Submission of an opportunity proposal by November 2021

* Additional WGs may be established in 2020 if proposals for new topics are approved by the Assembly.