






ICH Association
2019 Annual Work Plan
(1 January – 31 December 2019)

 **2019 Overview**

In 2019 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.

 **2019 Work Plan**



The following table summarises the key categories of work planned in 2019:

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 2019
	 Update Strategic Priorities for the coming years through the progression of Strategic discussions including consideration of Reflection Papers	Management Committee	Ongoing in 2019
	 Continue work to establish a sustainable ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines	Management Committee	Ongoing in 2019
	 Update multi-year budget planning to ensure strategic use of ICH Association funds	Management Committee	Ongoing in 2019
	 Approve the ICH Association 2020 Annual Work Plan and Multi-Annual Strategic Plan, as well as MedDRA 2020 Annual Work Plan	Assembly	November 2019

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Harmonisation	<ul style="list-style-type: none"> ✧ Progress current harmonisation activities on ICH topics <ul style="list-style-type: none"> ○ Annex I and II list the technical WGs expected to reach a key milestone in 2019 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 2019
	<ul style="list-style-type: none"> ✧ Assess new ICH topic proposals for harmonisation 	Management Committee	March/April 2019
	<ul style="list-style-type: none"> ✧ Approve new ICH topic proposals for harmonization consistent with the availability of staff with the requisite scientific and technical expertise, with a view to establishing new technical WGs 	Assembly	June 2019
Operations	Implementation		
	<ul style="list-style-type: none"> ✧ Conduct a survey for Regulators and Industry on adequacy of implementation and adherence to the ICH Guidelines using an independent third party 	Management Committee	By March 2019
	<ul style="list-style-type: none"> ✧ Present the results from the Phase 2a Survey to the Assembly 	Management Committee	June 2019
	<ul style="list-style-type: none"> ✧ Review the outcomes of Phase 2a of the project and discuss opportunities for Phase 2b study 	Management Committee	By the end of 2019
	Training		
	<ul style="list-style-type: none"> ✧ Continue work with trusted training 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 2019
	<ul style="list-style-type: none"> ✧ Continue work with trusted training providers to develop at least one in-depth online training material on each priority Guideline within 3 years 	Management Committee	Ongoing in 2019

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
Operations	Ensure ICH WG development of standardized informational materials on draft ICH Guidelines after <i>Step 2</i> and online slide training presentations on Final ICH Guidelines after <i>Step 4</i>	Management Committee	Ongoing in 2019
	Assist ICH WGs on high-priority guidelines to develop online training materials to be posted on the ICH website	Management Committee	Ongoing in 2019
	ICH Meetings		
	Organise first biannual ICH meetings using contracted Professional Conference Organiser as part of implementation of a sustainable, consistent and cost-efficient approach to ICH meeting organisation	Management Committee	June/November 2019
	Identify dates for June and November 2021 ICH Meetings	Management Committee	By June 2019
	Identify venues for June and November 2021 ICH Meetings	Management Committee	By November 2019
	Membership and Observership		
	Process applications received for ICH Membership and Observership and develop recommendations for the Assembly	Management Committee	Ongoing in 2019
	Take decisions on applications for ICH Membership and Observership applications	Assembly	June/November 2019
	Integrate newly Elected Management Committee Representatives into the operations of the Management Committee	Management Committee	Ongoing in 2019
	Elections		
	Conduct a new election for the Management Committee Chair and Vice-Chair	Management Committee	November 2019
	Conduct a new election for the Assembly Chair and Vice-Chair	Assembly	November 2019

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	Financial and administrative matters		
Operations	Approve the ICH Association 2018 Annual Report, including MedDRA activities, and provide discharge to the Management Committee, MedDRA Management Committee and ICH Secretariat	Assembly	June 2019
	Approve the final 2020 ICH Budget	Assembly	November 2019
	Support the audit of 2018 financial statements of ICH Association for reporting to the Assembly	Management Committee ICH Secretariat	By April/May 2019
	Approve the audited 2018 accounts of the Association	Assembly	June 2019
	Meet fiscal reporting requirements for ICH Association, including filing of 2018 tax return	Management Committee ICH Secretariat	Ongoing in 2019
	Approve 2020 MedDRA Budget, including the 2020 Subscription fees	Assembly	November 2019
	Complete initial registration of the ICH logo as a trademark in current ICH Member and Observer countries/regions	ICH Secretariat	Ongoing in 2019
Procedures	Maintain as necessary the Rules of Procedure (RoP) for the Assembly	Assembly	Ongoing in 2019
	Maintain as necessary the RoP for the Management Committee	Management Committee	Ongoing in 2019
	Maintain as necessary the Standard Operating Procedures (SOP) for technical WGs	Management Committee	Ongoing in 2019
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 2019

Category	Description	ICH Body/Bodies Responsible	Anticipated Timelines
	 Organise an ICH public stakeholder meeting following the closure of the public consultation phase for the Revision of the ICH E8 Guideline General Considerations for Clinical Trials, as per the GCP renovation plan	Management Committee	Q3/Q4 2019
	 Increase the user-friendliness and functionalities of the ICH website with more accessible information on training and implementation	ICH Secretariat	Ongoing in 2019

Annex I

7 Technical WGs expected to reach *Step 4* or finalise deliverable in 2019

Topic Code	Type of WG	Topic Name	Anticipated Milestone
E9(R1)	EWG	Addendum to Defining Appropriate Estimand for a Clinical Trial/Sensitivity Analyses	<i>Step 4</i> is expected by June 2019
E17	IWG	Multi-Regional Clinical Trials	<i>Training Materials</i> are expected by March 2019
M9	EWG	Biopharmaceutic Classification System-based Biowaivers	<i>Step 4</i> is expected by November 2019
Q3D(R1)	Maintenance EWG	Elemental Impurities	<i>Step 4</i> is expected by March 2019
Q12	EWG	Considerations for Pharmaceutical Product Lifecycle Management	<i>Step 4</i> is expected by November 2019
S5(R3)	EWG	Revision on Detection of Toxicity to Reproduction for Med. Products	<i>Step 4</i> is expected by November 2019
S11	EWG	Guideline on Nonclinical Safety Testing - Paediatric Medicines	<i>Step 4</i> is expected by November 2019

Annex II
6 Technical WGs expected to reach *Step 2a/b* in 2019

Topic Code	Type of WG	Topic Name	Anticipated Milestones
E8(R1)	EWG	Revision of General Considerations for Clinical Trials	<i>Step 2</i> is expected by February 2019
E19	EWG	Optimization of Safety data collection	<i>Step 2</i> is expected by March 2019
M7(R2)	Maintenance EWG	Addendum to Assessment and Control of DNA Reactive Impurities	<i>Step 2</i> is expected by November 2019
Q3C(R8)	Maintenance EWG	Residual Solvents	<i>Step 2</i> is expected by March 2019
Q3D(R2)	Maintenance EWG	Elemental Impurities	<i>Step 2</i> is expected by November 2019
S1 (R1)	EWG	Rodent Carcinogenicity Studies for Human Pharmaceuticals	<i>Step 2</i> is expected by November 2019

Annex III
15 Other Technical WGs Expected to be Active in 2019*

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)
E11A	EWG	Paediatric Extrapolation	<i>Step 2</i> is expected by November 2020
E14/S7B	IWG	Clinical Evaluation of QT/QTc Interval Prolongation	<i>Step 2</i> is expected by June 2020
E19	EWG	Optimization of safety data collection	<i>Step 4</i> is expected by November 2020
E20	To be established	Adaptive Clinical Trials	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	eCTD	N/A (Ongoing Activity)
M10	EWG/IWG	Bioanalytical Method validation	<i>Step 4</i> is expected by November 2020
M11	Informal WG	CeSHarP	<i>Step 2</i> is expected by June 2020
M12	To be established	Drug Interaction Studies	To be confirmed
Q13	Informal WG	Continuous Manufacturing	<i>Step 2</i> is expected by June 2020
Q2(R2)/Q14	Informal WG	Analytical Procedure Development and Revision of Q2 (R1)	<i>Step 2</i> is expected by June 2020

* Additional WGs may be established in 2019 if proposals for new topics are approved by the Assembly.