22 November 2018

ICH Association

Multi-Annual Strategic Plan

The following table highlights the key areas of work foreseen for the ICH Association:

Category	Description
Strategy	• Continue review and planning of already identified strategic priorities and assess potential new areas of opportunity for the ICH Association with defining of priorities as part of multi-year strategic planning • Promote ICH Guideline implementation by Regulatory Members and encourage implementation of ICH Guidelines by other Drug Regulatory Authorities and Regional Harmonisation Initiatives supported by an established sustainable ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines • Continue implementation of a strategic approach to address ICH Guideline training needs • Continue multi-year budget planning to ensure sound financial management of the ICH Association's funds, including strategic use of surplus funds to further ICH's goals, whilst also ensuring the ongoing operational stability of the ICH Association
Harmonisation	• Progress harmonisation activities on all approved ICH topic proposals – Annex I provides a multi-year overview of harmonisation activities on current ICH topics • Assess / approve on a regular basis proposals for new ICH topics according to the agreed process in order to keep an ongoing stream of harmonisation activities based on the total number of concurrent technical Working Groups (WGs) which the Association can support at a given time
Communication	• Continue implementation of approved transparency policy with continued improvements as appropriate to ensure continuously enhanced communication with stakeholders

Category	Description
Procedures	• Maintain / update as necessary the Rules of Procedure (RoP) for the Assembly, the Management Committee, the MedDRA Management Committee and Standard Operating Procedures (SOPs) for the technical WGs to ensure the continued smooth operation of the ICH Association as it continues to grow and evolve
Operations	• Continue ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines through surveying and results analysis • 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 • Ensure availability on the ICH website of at least one introductory and one in-depth online training module on each priority Guideline, as well as the availability of other elementary overview online slide training presentations on other ICH Guidelines • Process / decide on applications for ICH Membership and Observership in an efficient manner • Organise annual audits of the Association's accounts • Ensure the meeting of fiscal reporting requirements for ICH Association • Continue implementation of sustainable, consistent and cost-efficient approach for the ICH Association's organisation of biannual ICH meetings • Register the ICH logo as a trademark in ICH Member and Observer countries/regions taking account of new Members and Observers joining ICH

ICH
harmonisation for better health

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Annex I: Multi-year overview of harmonisation activities on current ICH topics

Current ICH Topics		Activity type	Nov. 2018 - Dec. 2018	Amsterdam, the Netherlands	Singapore (TBC)	the Americas (TBD)	Europe (TBD)	Asia (TBD)	the Americas (TBD)	Europe (TBD)	Asia (TBD)
Workgroup code	Workgroup name			Jun-19	Nov-19	Jun-20	Nov-20	Jun-21	Nov-21	Jun-22	Nov-22
Standing Paediatric EWG	- Standing Paediatric	Ongoing activity									
E2B(R3) EWG/IWG	- Revision of Electronic Submission of ICSRs	Ongoing activity									
E8(R1) EWG	- General Consideration for Clinical Trials	Step process		Step 2 (February)		Step 4					
E9(R1) EWG	- Addendum to Defining Appropriate Estimand	Step process		Step 4							
E11A EWG	- Paediatric extrapolation	Step process					Step 2		Step 4		
E14/S7B IWG	- Clinical Evaluation of QT/QTc Interval Prolongation	Step process				Step 2		Step 4			
E17 IWG	- Multi-Regional Clinical Trials	Step process		Training Material							
E19 EWG	- Optimization of Safety data collection	Step process		Step 2 (March)			Step 4				
E20 informal WG *	- Adaptive Clinical Trials	Drafting of CP and BP									
M1 PtC WG	- MedDRA Points to Consider	Ongoing activity									
M2 EWG	- Electronic Standards for the Transfer of Regulatory Information	Ongoing activity									
M4Q(R1) IWG	- Addressing CTD-Q-Related Questions/Change Requests	Dormant									
M7(R2) Maintenance EWG/IWG	- Addendum to Assessment and Control of DNA Reactive Impurities	Step Maint.			Step 2		Step 4				
M8 EWG/IWG	- Electronic CTD	Ongoing activity									
M9 EWG	- Biopharmaceutic Classification System-basesd Biowaivers	Step process			Step 4						
M10 EWG	- Bioanalytical Method validation	Step process	Step 2 (December)				Step 4				
M11EWG	- CeSHarP	Step process				Step 2			Step 4		
M12 informal WG *	- Drug Interaction Studies	Drafting of CP and BP									
Q3C(R8) Maintenance EWG	- Residual Solvents	Step Maint.		Step 2 (March)		Step 4					
Q3D(R1)/(R2) Maintenance EWG	- Elemental Impurities *(R1: Revision to cadmium PDE / R2: Maintenance)*	Step Maint.		Step 4 (R1) (February)	Step 2 (R2)		Step 4 (R2)				
Q11 IWG	- Q&A on API Starting Materials	Step process	Narrated Training Material (December)								
Q12 EWG	- Considerations for Pharmaceutical Product Lifecycle Management	Step process			Step 4						
Q13 EWG	- Continuous Manufacturing	Step process				Step 2			Step 4		
Q2(R2)/Q14 EWG	- Analytical Procedure Development and Revision of Q2(R1	Step process				Step 2		Step 4			
S1(R1) EWG	- Rodent Carcinogenicity Studies for Human Pharmaceuticals	Step process				Step 2 (March)		Step 4			
S5(R3) EWG	- Revision on Detection of Toxicity to Reproduction for Med. Products	Step process			Step 4						
S11 EWG	- Guideline on Nonclinical Safety Testing - Paediatric Medicines	Step process			Step 4						

Light blue highlight = Work in progress
Dark blue highlight = Work completed
Blue highlight = Dormant
Grey = Deadlines to be confirmed
* Establishment of informal WG delayed