ICH E9(R1) EWG Work Plan
31 July 2018

Topic Adoption date: *October 2014*

Rapporteur: *Mr. Robert Hemmings (EC, Europe)*

Regulatory Chair: *Dr. Yuki Ando (MHLW/PMDA, Japan)*

Last Face-to-Face Meeting: *Kobe, Japan, June 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Oct. 2014	Concept Paper endorsement by the ICH Steering Committee.
2017	*Step 1 and Step 2a* - Finalisation of the Technical Document (draft addendum) and sign-off by all ICH Parties' members in the EWG and by the Assembly. *Step 2b* - draft addendum and sign-off by the ICH Regulatory Parties.
Aug. 2017	*Step 3* - Draft addendum published.
Apr. 2018	*Step 3* - Public comments received in all ICH regions.
Aug. 2018	Publication of *Step 2b* training material slide decks on the ICH website

1.b. Future anticipated key milestones

Expected future completion date	Milestone
2018-2019	*Step 3* - Discuss comments received during the public consultation period and consolidate the draft addendum.
2018-2019	Organise and participate to trainings and scientific meetings, within ICH parties and at international congresses.
2019	*Step 3 and Step 4* - Finalisation of the addendum and sign-off by topic leaders of the ICH Regulatory Parties and by the ICH Regulatory Parties.

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
Dec. 2017	**Early 2019**	Step 3	Organise or participate at meetings at a global or regional level to promote awareness and comments on the addendum. Discuss regional consultation comments and modify the addendum and accompanying documents, based on comments received. Outline plans for further progress towards finalisation.
Jan. 2018	**Early 2019**	In parallel with Step 3	Discuss methodological issues related with estimands and sensitivity analysis in clinical trials. Consider the relationship of ICH E9(R1) with other ICH documents.
Jun. 2019		Step 3 and Step 4	Finalise the addendum and accompanying documents. Organise an ICH training. Once all documents are finalised, engage the sign-off process. Step 3: Sign-off by topics leaders of Regulatory ICH Parties. Step 4: Sign-off by all ICH Regulatory Parties.