ICH E9(R1) EWG Work Plan
27 February 2019

Topic Adoption date: October 2014

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Last Face-to-Face Meeting: Charlotte, NC, USA, November 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/b* - Finalisation of the Technical Document (draft addendum), sign-off by Topic Leaders and adoption by Assembly Members and by Assembly Regulatory Members.
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
2019	*Step 3* - Discuss comments received during the public consultation period and consolidate the draft addendum.
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	**Sep. 2019**	Step 3 and Step 4	Finalise the addendum and any accompanying documents. Once all documents are finalised, engage the sign-off process. Step 3: Sign-off by topics leaders of Regulatory ICH Parties. Step 4: Adoption by ICH Assembly Regulatory Members. Plan for training and implementation activities, including the update of E9(R1) Step 2 slides.