

ICH E9(R1) EWG Work Plan 17 February 2017

Topic Adopted: October 2014

Face-to-Face Meeting: Osaka, Japan – November 2016

1. Anticipated Milestones

Completion Date	Deliverable
2017	<i>Step 1 and Step 2a</i> Finalisation of the Technical Document (draft Addendum) and sign-off by all ICH Parties' members in the EWG and by the Assembly. <i>Step 2b</i> Draft Addendum and sign-off by the ICH Regulatory Parties.
2017	<i>Step 3 phase</i> Publish draft Addendum.
2018 - 2019	<i>Step 3 phase</i> Discuss comments received during the public consultation period and consolidate the Draft Addendum.
2018 - 2019	<i>Step 3 and Step 4</i> Finalisation of the Addendum and sign-off by topic leaders of the ICH Regulatory Parties and by the ICH Regulatory Parties.

2. Timelines

Date	Task / Activity	Details
December 2016 to May 2017	Progress towards <i>Step 1</i> and <i>Step 2a</i>	<ul style="list-style-type: none"> ➤ Follow actions to be undertaken until the ICH meeting in May 2017, and that will contribute to the finalisation of the <i>Step 1</i> Technical Document (draft Addendum) ➤ Update the <i>Step 1</i> Technical Document based on Osaka discussions and comments received from members. ➤ After another round of comments and update within the EWG, share the document for comments within each region, with statisticians and non-statisticians. ➤ Review alignment of the original ICH E9 with the <i>Step 1</i> Technical Document. ➤ Draft training material, i.e. document(s) to support communication and steer comments during the public consultation. ➤ Discuss the need to meet in May/June at the ICH

		<p>meeting in Canada. The draft Addendum Document should be near final before the meeting.</p> <ul style="list-style-type: none"> ➤ Full group EWG teleconferences will be facilitated by the Rapporteur monthly (or biweekly if needed) to ensure progress. ➤ Additional meetings of EWG subteams may be organised to progress the drafting of the Addendum, training material and other relevant topics.
ICH Meeting May/June up to November 2017	<i>Step 1, Step 2a and Step 2b</i>	<ul style="list-style-type: none"> ➤ Finalise the <i>Step 1</i> Technical Document. ➤ Finalise annotations or changes in the original ICH E9, if any. ➤ Develop training material that will help users to understand the draft Addendum and implement its principles. Communication activities to support the consultation period will be agreed with the Assembly. ➤ Once these three documents are finalised, engage the sign-off process. ➤ <i>Step 1</i>: Sign-off by all ICH Parties' members of the EWG. ➤ <i>Step 2a</i>: Sign-off by the Assembly. ➤ <i>Step 2b</i>: ICH Regulatory parties adapt the <i>Step 1</i> Technical Document into a draft Addendum which is then signed by the ICH Regulatory Parties. ➤ Identify whether themes and aspects would be more relevant in a 'technical' appendix or scientific publication. ➤ Continue the review of other ICH 'E' guidelines.
November 2017 to November 2018 (or later)	<i>Step 3 phase</i>	<ul style="list-style-type: none"> ➤ Deliverables set for this period will depend on the duration of the public consultation in each region and may be delayed. ➤ Publish the draft Addendum in each region under the <i>Step 3</i> procedure guidelines. The duration of public consultation, either 6 or 12 months, is subject to approval by each of the ICH Regulatory Parties. ➤ Organise meetings at a global or regional level to promote awareness and comments on the Addendum. ➤ Discuss regional consultation comments and

		modification of the Addendum and accompanying documents, based on comments received. Outline plans for further progress towards finalisation.
ICH Meeting November 2018 (or later)	<i>Step 3 and Step 4</i>	<ul style="list-style-type: none"> ➤ Deliverables set for this period will depend on the duration of the public consultation in each region and may be delayed. ➤ Finalisation of the Addendum. ➤ Finalise the training package that will accompany the Addendum. ➤ Organise an ICH training. ➤ Once all documents are finalised, engage the sign-off process. ➤ <i>Step 3</i>: Sign-off by topics leaders of Regulatory ICH Parties. ➤ <i>Step 4</i>: Sign-off by all ICH Regulatory Parties.