ICH E9(R1) EWG Work Plan
September 2017

Topic Adopted: October 2014
Face-to-Face Meeting: Montreal, Canada - May-June 2017

1. Anticipated Milestones

<table>
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<tr>
<th>Completion Date</th>
<th>Deliverable</th>
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| 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. |
| 2017            | *Step 3 phase* Publish draft addendum. |
| 2018 - 2019     | *Step 3 phase* Discuss comments received during the public consultation period and consolidate the draft addendum. |
| 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. Timelines

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<tr>
<th>Date</th>
<th>Task / Activity</th>
<th>Details</th>
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| June up to November 2017  | *Step 1, Step 2a* and *Step 2b* | ➢ Finalise the *Step 1* Technical Document.  
➢ Finalise training material that will help users to understand the draft addendum and implement its principles.  
➢ Further communication strategies to be discussed and implemented at a regional level.  
➢ *Step 1*: Sign-off by all ICH Parties’ members of the EWG (June 2017).  
➢ *Step 2a*: Sign-off by the Assembly (July 2017).  
➢ *Step 2b*: ICH Regulatory parties adapt the *Step 1* Technical Document into a draft addendum which is then signed by the ICH Regulatory Parties (July 2017).  
➢ Publish the draft addendum in each region under the *Step 3* procedure guidelines for a six-month public consultation period, beginning in Q3 2017 and ending in Q2 2018.  
➢ Continue the review of other ICH guidelines or proposals.  
➢ Produce a short video/animation to explain the principles developed in the addendum to a broader audience, and have it reviewed by ICH parties. |
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<tr>
<th>Step 3 phase</th>
<th>Step 3 and Step 4</th>
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| Discuss the need to meet at the ICH meeting in November in Geneva.  
Organise full group EWG teleconferences frequently to ensure progress. | 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. |
| December 2017 to early 2019 | ICH Meeting June 2019 |
| 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. |