

ICH S11 EWG Work Plan

01 February 2019

Topic Adoption date: 10 November 2014

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2018</i>	<i>EWG agreement on Step 1 document</i>
<i>Sep. 2018</i>	<i>Endorsement by the Members/Regulatory Members of the ICH Assembly under Step 2a/b and release for public consultation</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar-Jun 2019</i>	<i>Monthly TCs to review and discuss comments</i>
<i>Jun. 2019</i>	<i>Face-to-face meeting to discuss comments and revise document</i>
<i>Jun-Nov. 2019</i>	<i>Monthly TCs to prepare final document</i>
<i>Nov. 2019</i>	<i>Face-to-face meeting to finalize Step 4 Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Mar. 2019	<i>Apr. 2019</i>	<i>Collation and sharing of submitted comments</i>	<i>Collate and organize comments. Remove redundant comments. Share comments electronically.</i>
Mar. 2019	<i>Jun. 2019</i>	<i>Review comments. Begin editing document.</i>	<i>Detailed review of all comments. Teleconferences to discuss comments, prioritization of comments and possible edits. Prepare for June 2019 meeting.</i>