

# ICH S5(R3) EWG Work Plan

## 23 January 2019

**Topic Adoption date:** April 2014

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**Regulatory Chair:** N/A

**Last Face-to-Face Meeting:** Charlotte, USA, November 2018

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
<b>Mar. 2015</b>	<i>Topic endorsed by the ICH Steering Committee.</i>
<b>Jul. 2017</b>	<i>Step 1 sign-off; Experts sign-off to confirm all Members agreement with the document.</i>
<b>Aug. 2017</b>	<i>Step 2a/b document sign-off; Plan for a <math>\leq 6</math>-month public review</i>
<b>Oct. 2017</b>	<i>Explanatory slides agreed by EWG members went online</i>
<b>March 2018</b>	<i>Public comment period closed</i>

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<b>Q1 2019</b>	<i>Revised document ready for internal stakeholder review.</i>
<b>Jun. 2019</b>	<i>Face to Face meeting to discuss comments from internal stakeholders and edit Step 2a/b document.</i>
<b>Nov. 2019</b>	<i>Step 3 experts sign-off / Step 4 adoption: Face-to-face meeting to finalize Step 3, sign-off and to request adoption at Step 4 of the ICH process.</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End Date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Sep. 2017</b>	<i>Nov. 2019</i>	<i>ICH S5(R3) EWG Teleconferences</i>	<i>Initiate review of the ICH Reference compounds currently in the list and those submitted through the public notification, as they become available, to double check data, ensure accessibility to source data and identify data gaps.  Formation of an ICH S5(R3) EWG subgroup to work on details.</i>
<b>Nov. 2018</b>	<i>December 2018</i>	<i>Revise Step 2a/b document</i>	<i>EWG agreed on reorganization and performed line by line editing of revised step 2a/b document.</i>
<b>January 2019</b>	<i>May 2019</i>	<i>Monthly ICH S5(R3) EWG and regional Teleconferences</i>	<i>Discuss progress of revisions and internal stakeholder comments.</i>
<b>November 2018</b>	<i>March 2019</i>	<i>Draft distributed to internal stakeholders</i>	<i>A revised draft of the Step 2a/b document will be provided to internal stakeholders for comment.</i>
<b>November 2018</b>	<i>March 2019</i>	<i>Concept paper for maintenance procedure submitted</i>	<i>EWG will provide the concept paper for the maintenance procedure of the annex to the MC.</i>