

ICH S5(R3) EWG Work Plan

30 July 2018

Topic Adoption date: April 2014

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Regulatory Chair: -

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

1. Key milestones

1.a. Current status of key milestones

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

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2018</i>	<i>Face to Face meeting to discuss and edit the revised step 2a/b document</i>
<i>Jun. 2019</i>	<i>Face to Face meeting to continue discussing and edit step 2a/b document</i>
<i>Nov. 2019</i>	<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

Beginning date	End date	Task / Activity	Details
Sep. 2017	<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>
Jun. 2018	<i>Oct. 2018</i>	<i>Revise step 2a/b document</i>	<i>Individuals / groups will work to revise the step 2a/b document per the work packages developed during the F2F meeting</i>
Aug. 2018	<i>Oct. 2018</i>	<i>Monthly ICH S5(R3) EWG and regional Teleconferences</i>	<i>Discuss progress of revisions and any obstacles faced in addressing public comments Development of a justification for the application of a regular maintenance procedure and drafting procedural elements to be included in the ICH SOP for MC approval</i>
Nov. 2018	<i>December 2018</i>	<i>Revise step 2a/b document</i>	<i>EWG will further revise step 2a/b document and have a draft available for internal stakeholder review by EOY 2018.</i>