

ICH S12 EWG Work Plan

January 24, 2022

Topic Adoption date: *May 2019*

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Regulatory Chair: *Ms. Mercedes Serabian - FDA, United States*

Last Face-to-Face Meeting: *Singapore, Singapore, Nov 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2019</i>	<i>Concept Paper and Business Plan endorsement</i>
<i>Nov. 2019</i>	<i>Initial outline of the Technical Document generated</i>
<i>May 2021</i>	<i>Step 1 Technical Document generated, and signed-off by the EWG experts</i>
<i>Jun. 2021</i>	<i>Technical Document endorsed by the Assembly as Step 2a, and endorsement by the Regulatory Members of the Assembly as Step 2b</i>
<i>Jun. 2021</i>	<i>Step 2 presentation slide set prepared by the EWG and submitted to the ICH Secretariat; Step 2b draft Guideline posted on the ICH website for public commenting.</i>
<i>Jan. 2022</i>	<i>All public comments received by respective region as well as ICH Secretariat were collected and compiled into a single list for consideration within the EWG.</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar. 2023</i>	<i>Step 3 Experts sign-off</i>
<i>May 2023</i>	<i>Step 4 Guideline adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2022	<i>Oct. 2022</i>	<i>Editing of the Step 3 experts draft Guideline.</i>	<i>Discussion of the received comments and deciding on the necessary edits via virtual meetings of the EWG.</i>
Nov. 2022		<i>Face to face meeting at the ICH Incheon meeting for editing and discussion of the Step 3 experts draft Guideline.</i>	<i>Discussion of remaining key issues and decisions to be made before completing a final draft of the Step 3 guideline.</i>
Nov. 2022		<i>Finalisation of the Step 3 experts draft Guideline.</i>	<i>After discussion and editing by the EWG via virtual meetings, the final draft of the Step 3 guideline will be circulated among the respective regulatory members of the EWG and the PWP. Comments from regulatory members and PWP are considered by the EWG and the Step 3 experts draft Guideline is modified, as applicable.</i>
Mar. 2023		<i>Regulatory sign-off of the Step 3 experts draft Guideline.</i>	<i>Regulatory EWG experts sign-off process on the final version of the Step 3 experts draft Guideline document. Submission to the ICH Secretariat.</i>
Apr. 2023	<i>May. 2023</i>	<i>Adoption by the Assembly as Step 4.</i>	<i>The submitted Step 3 document is adopted by Regulatory Members of the Assembly.</i>