

ICH Q13 EWG Work Plan *January 04, 2022*

Topic Adoption date: *November 2018*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2018	<i>Concept Paper and Business Plan Endorsement</i>
Nov. 2018	<i>Initiation of consensus building</i>
May. 2019	<i>Outline for technical document developed</i>
Jun. 2019	<i>Face-to-Face Meeting in support of consensus building, outline finalization, and technical document drafting</i>
Nov. 2019	<i>Face-to-Face Meeting in support of development of the technical document</i>
Apr. 2020	<i>Completed draft distributed to individual organizations for feedback</i>
May 2020	<i>Virtual Meeting in support of revisions of the technical document</i>
Nov. 2020	<i>Virtual Meeting to continue revisions of the technical document and plan training materials</i>
Mar. 2021	<i>Virtual Interim Meeting to continue revisions of the technical document</i>
May 2021	<i>Virtual Meeting to finalize the technical document and Step 1 sign-off</i>
Jul. 2021	<i>Step 2 a/b endorsement and initiation of public consultation</i>
Oct. 2021	<i>Virtual Meeting to discuss training materials development</i>
Nov. 2021	<i>Virtual Meeting to discuss training materials development; formed subgroup to develop training materials on introduction to ICH Q13</i>
Dec. 2021	<i>Virtual meeting with subgroup to discuss development of introduction to training materials</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2022	<i>Public comments due</i>
May 2022	<i>Face-to-Face Meeting to review and resolve public comments</i>
Nov. 2022	<i>Face-to-Face Meeting for Step 3 sign-off and Step 4 adoption of final guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2021	Nov. 2021	<i>Multiple EWG Meetings via Teleconference</i>	<i>Discuss training material topics and reach consensus on the topics. Plan for next virtual EWG meeting</i>
Nov. 2021	Nov. 2021	<i>Virtual EWG Meetings</i>	<i>Discuss training materials development; formed subgroup to develop introduction to training materials</i>
Nov. 2021	Feb. 2022	<i>Multiple subgroup meetings via teleconference</i>	<i>Develop and finalize introduction to training materials. Gather public comments</i>
Mar. 2022	May 2022	<i>Multiple EWG Meetings via Teleconference</i>	<i>Review and address public comments ahead of next ICH meeting</i>