

ICH Q13 EWG Work Plan

January 29, 2021

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>
April 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>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May 2021	<i>Virtual EWG Meeting to finalize the technical document and Step 1 sign-off</i>
Jun. 2021	<i>Step 2 a/b endorsement and initiation of public consultation</i>
Nov. 2022	<i>Step 3 sign-off and Step 4 adoption of final guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jan. 2021</i>	<i>May. 2021</i>	<i>Multiple EWG Meetings via Teleconference</i>	<i>Review feedback from internal consultations; revise draft text for the technical document based on feedback; discuss plans for next virtual EWG meeting</i>
<i>May. 2021</i>	<i>May. 2021</i>	<i>Virtual EWG Meeting</i>	<i>Finalize the technical document and achieve Step 1 sign-off</i>
<i>Jun. 2021</i>	<i>Jun. 2021</i>	<i>Step 2 a/b endorsement</i>	<i>Submit finalized document to the ICH Secretariat for Step 2 a/b endorsement</i>