

ICH E19 EWG Work Plan

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Topic Adoption date: *September 2016*

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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
<i>Jul. 2017</i>	<i>Final concept paper endorsed by ICH Management Committee</i>
<i>Apr. 2019</i>	<i>Finalise the technical document and Step 1 Experts sign-off</i>
<i>Apr. 2019</i>	<i>Step 2a/b Endorsement of the Draft Guideline</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Feb. 2022</i>	<i>Finalise Step 3 for signoff by Regulatory Topic Leaders</i>
<i>Mar. 2022</i>	<i>Step 4 Adoption of the Final Guideline by Regulatory Members of the Assembly</i>
<i>Mar. 2022</i>	<i>Step 5 Implementation by ICH Regulators</i>

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
<i>Jan. 2021</i>	<i>Jul. 2021</i>	<i>Biweekly TCons</i>	<i>Revise technical document to address public comments</i>

<i>Aug. 2021</i>	<i>Sep. 2021</i>	<i>Regional technical document review</i>	<i>Each organization with take the revised technical document to their region for final review</i>
<i>Oct. 2021</i>	<i>Nov. 2021</i>	<i>Biweekly Tcon(s)</i>	<i>Tcon(s) to address regional issues in revised technical document</i>
<i>Dec. 2021</i>	<i>Feb. 2022</i>	<i>Finalise Step 3</i>	<i>Finalise Step 3 - sign-off by Regulatory Topic Leaders</i>
<i>Feb. 2022</i>	<i>Mar. 2022</i>	<i>Tcon(s)</i>	<i>Tcon(s) to address issues in revised technical document</i>
<i>Mar. 2022</i>	<i>Apr. 2022</i>	<i>Finalise Step 4</i>	<i>Finalise Step 4 Adoption of the Final Guideline by Regulatory Members of the Assembly</i>
<i>Mar. 2022</i>	<i>Apr. 2022</i>	<i>Step 5 Implementation</i>	<i>Guideline implementation by ICH Regulators</i>