

ICH M12 EWG Work Plan

January 28, 2022

Topic Adoption date: *July 2019*

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Last Face-to-Face Meeting: *November 2021*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2018	<i>Concept Paper Outline was endorsed at the Charlotte Meeting</i>
Jun. 2019	<i>Establishment of Informal Working Group</i>
Nov. 2019	<i>Endorsement of Final Concept Paper and Business Plan</i>
Nov. 2019	<i>Establishment of formal Expert Working Group</i>
May 2020	<i>Consensus reached on the table of content</i>
Nov. 2020	<i>Alignment reached on the scope of several topics; continued discussion on the scope of outstanding topics; initiated drafting.</i>
May 2021	<i>Alignment reached on the final language of the draft guideline (applies to a number of the completed sections); continued discussion on the scope of outstanding topics.</i>
Nov. 2021	<i>Draft guideline completed and submitted for 6 weeks-long internal consultation period. Prioritized comments are now being addressed to ensure step 1 sign-off</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2022	<i>Share technical guideline document with PWP experts</i>
Apr. 2022	<i>Finalize technical document and Step 1 Experts sign-off</i>

May. 2022	<i>Step 2a/2b Endorsement of the draft guideline</i>
Jan. 2024	<i>Share draft guideline document with PWP experts</i>
Q1 2024	<i>Step 3 Sign-off and Step 4 Adoption of the final guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2022	<i>Mar. 2022</i>	<i>Address key scientific concepts from internal consultation period</i>	<p><i>Drafting team and M12 members identifies comments that require discussion and need addressing prior to step 1 sign off</i></p> <p><i>Drafting team reviews and address the prioritized comments</i></p> <p><i>M12 hold focused sessions to discuss/ resolve outstanding comments for step 1 sign off.</i></p>
Mar. 2022	<i>Apr. 2022</i>	<i>PWP experts' consultation</i>	<i>M12 to share EWG consensus technical document with PWP experts for a one-month consultation</i>
Apr. 2022	<i>May 2022</i>	<i>Review and address feedback from PWP experts</i>	<i>M12 will hold focused sessions to address comments from PWP, and finalize technical document</i>
May 2022	<i>May 2022</i>	<i>Step 1 sign off</i>	<i>EWG reach consensus and sign the step 1 experts sign off sheet</i>