

ICH M13 EWG Work Plan

January 28, 2022

Topic Adoption date: *November 2019*

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Last Face-to-Face Meeting: *N/A*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
November 2019	<i>Endorsement of Concept Paper Outline</i>
February 2020	<i>Establishment of Informal Working Group</i>
July 2020	<i>Endorsement of Final Concept Paper and Business Plan</i>
July 2020	<i>Establishment of Formal Expert Working Group (EWG)</i>
October 2020	<i>Finalised the EWG work plan and reached consensus on the table of contents and outline for the first guideline that includes Tier 1 topics in the concept paper</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May 2022	<i>Possible Face-to-Face Meetings in support of resolving differences and working towards harmonisation for the first draft guideline in the series with Tier 1 topics (M13A)</i>
November 2022	<i>Possible Face-to-Face Meetings in support of finalising the draft technical document of the first guideline in the series with Tier 1 topics (M13A) and Step 1 topic leads sign-off</i>
December 2022	<i>Step 2a/2b ICH endorsement of the first draft guideline in the series (M13A), and initiate public consultation</i>
January 2023	<i>Initiate work for the second guideline in the series (M13B) or annex (Tier 2 topic)</i>

July 2023	<i>Step 3 End of Public Consultation Period for the first draft guideline in the series (M13A) (Tier 1 topics)</i>
May 2024	<i>Step 4 Adoption of the final guideline of M13A</i>
July 2024	<i>Initiate work for the third guideline in the series (M13C) or annex (Tier 3 topics)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2022	May. 2022	<ol style="list-style-type: none"> 1. <i>Hold multiple EWG teleconferences every month</i> 2. <i>Possible Face-to-Face Meetings in May if feasible</i> 	<ul style="list-style-type: none"> • <i>Continue to resolve differences and work towards harmonisation for the draft guideline with Tier 1 topics</i> • <i>Wrap up the whole draft guideline with Tier 1 topics</i> • <i>Edit and finalise the draft technical document (guideline) prior to member group internal clearance</i>
Jun. 2022	Aug. 2022	<ol style="list-style-type: none"> 1. <i>Hold EWG teleconferences as needed</i> 	<ul style="list-style-type: none"> • <i>Member group internal clearance</i>
Sep. 2022	Oct. 2022	<ol style="list-style-type: none"> 1. <i>Hold multiple EWG teleconferences every month as needed</i> 	<ul style="list-style-type: none"> • <i>Review and discuss comments received</i>
Nov. 2022	Nov. 2022	<ol style="list-style-type: none"> 1. <i>Possible Face-to-Face Meetings</i> 	<ul style="list-style-type: none"> • <i>Address comments, resolve differences, and finalise the draft technical document of the first guideline in the series with Tier 1 topics (M13A)</i> • <i>Step 1 topic leads sign-off</i>
Dec. 2022	Dec. 2022	<ol style="list-style-type: none"> 1. <i>Hold multiple EWG teleconferences every month as needed</i> 	<ul style="list-style-type: none"> • <i>Step 2a/2b ICH endorsement of the first draft guideline in the series (M13A)</i> • <i>Initiate public consultation</i>