

# ICH M13 EWG Work Plan

## *October 30, 2020*

**Topic Adoption date:** November 2019

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**Regulatory Chair:** *Dr. Jan Welink* - EC, Europe

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

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
November 2019	Endorsement of Concept Paper Outline
February 2020	Establishment of Informal Working Group
July 2020	Endorsement of Final Concept Paper and Business Plan
July 2020	Establishment of Formal Expert Working Group (EWG)

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
October 2020	Finalize the EWG work plan
October 2020	Reach consensus on the table of contents and draft outline for the first guideline that includes Tier 1 topics in the concept paper
November 2020	Virtual meetings (in lieu of the Face-to-Face Meetings) in support of consensus building and technical document drafting
May 2021	Face-to-Face or virtual meetings in support of development of the technical document
November 2021	Face-to-Face or virtual meetings in support of development of the technical document
April 2022	Finalize draft technical document of the first guideline in the series (M13A) and Step 1 topic leads sign-off
June 2022	Face-to Face or virtual meeting to finalize the technical document if needed and move to Step 2a/2b ICH endorsement of the first draft

	guideline in the series (M13A), and initiate public consultation
<b>July 2022</b>	Initiate work for second guideline in the series or annex (Tier 2 topic)
<b>January 2023</b>	Step 3 End of Public Consultation Period
<b>November 2023</b>	Step 4 Adoption of the final guideline of M13A
<b>July 2024</b>	Initiate work for third guideline in the series or annex (Tier 3 topics)

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Sep. 2020</b>	<b>Oct. 2020</b>	<ol style="list-style-type: none"> <li>1. Draft and finalize the work plan</li> <li>2. Draft and finalize the table of contents and draft outline of the first guideline, e.g., M13A, that includes Tier 1 topics in the concept paper</li> <li>3. Form writing groups to initiate work on various sections of the guideline with a focus on topics that are relatively aligned</li> </ol>	<ul style="list-style-type: none"> <li>• Discuss the draft work plan and finalize.</li> <li>• Discuss the table of contents and draft outline for the first guideline that includes Tier 1 topics</li> <li>• Writing groups to               <ol style="list-style-type: none"> <li>a. draft language for parts that are relatively aligned</li> <li>b. identify areas that need more work</li> <li>c. identify scope and content for most controversial areas</li> </ol> </li> </ul>
<b>Nov. 2020</b>	<b>Nov. 2020</b>	<ol style="list-style-type: none"> <li>1. Hold virtual meetings (in lieu of Face-to-Face (FTF) meetings)</li> </ol>	<ul style="list-style-type: none"> <li>• Review and revise parts of sections drafted by the writing groups that are relatively aligned</li> <li>• Agree on the topics that need more time to work on</li> <li>• Form new subgroups to start to work on controversial topic areas that need more time to work on</li> </ul>

<b>Dec. 2020</b>	<b>Apr. 2021</b>	<ol style="list-style-type: none"> <li>1. Subgroups to work on controversial topic areas; Multiple subgroup meetings via teleconferences</li> <li>2. Hold monthly EWG teleconferences to check on the status and provide input on aligning topics that are controversial</li> </ol>	<ul style="list-style-type: none"> <li>• Subgroups to work on drafting and aligning the most controversial topic areas</li> <li>• Writing groups continue to polish the sections that are aligned</li> <li>• Monitor progress and draft proposal to update the work plan as needed prior to May FTF meeting</li> </ul>
<b>May 2021</b>	<b>May 2021</b>	<ol style="list-style-type: none"> <li>1. Hold FTF meeting or virtual meeting</li> </ol>	<ul style="list-style-type: none"> <li>• EWG discussion on the controversial topics and determine path forward</li> <li>• Update the work plan and timeline as needed</li> <li>• Submit updated workplan for ICH endorsement</li> </ul>
<b>Jun. 2021</b>	<b>Sept./Oct. 2021</b>	<ol style="list-style-type: none"> <li>1. Hold monthly EWG teleconferences to check on the status and provide input on aligning topics that are controversial</li> <li>2. Subgroups work continues; Multiple subgroup meetings via teleconferences</li> </ol>	<ul style="list-style-type: none"> <li>• Continue to work on parts related to controversial topics and the whole draft first guideline</li> <li>• Monitor progress and draft proposal to update the work plan as needed prior to Nov FTF meeting</li> </ul>
<b>Nov. 2021</b>	<b>Nov. 2021</b>	<ol style="list-style-type: none"> <li>1. Hold FTF or virtual meeting</li> </ol>	<ul style="list-style-type: none"> <li>• Continue to work on the technical documents for consensus building</li> <li>• Submit updated workplan for ICH endorsement</li> </ul>
<b>Dec 2021</b>	<b>April 2022</b>	<ol style="list-style-type: none"> <li>1. Hold monthly EWG teleconferences to check on the status and provide input on aligning topics</li> <li>2. Subgroups work continues; Multiple subgroup meetings</li> </ol>	<ul style="list-style-type: none"> <li>• Finalize the technical document of the first guideline</li> <li>• Obtain member consensus</li> <li>• Topic leads sign off (Step 1)</li> <li>• Submit the draft guideline document for ICH endorsement at their May/June 2022 meeting</li> </ul>

		via teleconferences Subgroups work continues; Multiple subgroup meetings via teleconferences	
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