

ICH M11 EWG Work Plan

February 01, 2019

Topic Adoption date: *November 2018*

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Last Face-to-Face Meeting: *Charlotte, NC, USA, November 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2018</i>	<i>Concept Paper Outline endorsed at Kobe meeting</i>
<i>Sep. 2018</i>	<i>Establishment of Informal Working Group</i>
<i>Nov. 2018</i>	<i>Endorsement of Final Concept Paper, Business Plan, and Work Plan</i>
<i>Nov. 2018</i>	<i>Establishment of formal Expert Working Group (EWG)</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2020</i>	<i>Step 1 Sign-off of Technical Document (guideline, template, technical specification)</i>
<i>Jul. 2020</i>	<i>Step 2a / 2b endorsement of Technical Document</i>
<i>Jul. 2021</i>	<i>Step 3 End of Public Consultation Period</i>
<i>Nov. 2021</i>	<i>Step 3 Signoff of Technical Document</i>
<i>Nov. 2021</i>	<i>Step 4 Adoption of Technical Document</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Feb. 2019	<i>Mar. 2019</i>	<i>Refine Table of Contents of the template</i>	<i>Review and refine draft TOC as proposed by working subgroup</i>
Feb. 2019	<i>May. 2019</i>	<i>Define Strategy for Development of Technical Specification</i>	<i>Consult informally with representatives from the M2 EWG to define goals, explore options, and team approach to development of a technical specification</i>
Feb. 2019	<i>Mar 2019</i>	<i>Define Strategy for Coordination with other EWG's</i>	<i>Complete assessment of areas/points of overlap with other ICH EWGs and determine contact expert names, type and timing of connection needed, and team members responsible for this informal connectivity.</i>
Mar. 2019	<i>Apr. 2019</i>	<i>Establish Content Development Strategy</i>	<i>Prioritize sections for content development; identify relevant reference or source materials by section; assign preparation of first drafts by section among team volunteers; establish timeline for content development and review</i>
Mar 2019	<i>May 2019</i>	<i>Make contact with other EWGs as defined in Coordination Strategy</i>	<i>Establish contact with other EWGs, as appropriate, to ensure alignment; confirm whether subsequent or periodic check-ins are necessary and discuss appropriate timing</i>
Apr. 2019	<i>May. 2019</i>	<i>Preliminary Content Development- draft template content</i>	<i>Preparation of draft template content; conventions and guiding principles will be captured as they are developed</i>