

ICH M11 EWG/IWG Work Plan

November 15, 2018

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>Sept. 2018</i>	<i>Establishment of Informal Working Group</i>
<i>Nov 2018</i>	<i>Presentation of Final Concept Paper, Business Plan, and Work Plan for endorsement; formalization of Expert Working Group</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2020</i>	<i>Step 1 Technical Document (Guideline, template, technical specification) sign-off Possible Step 2a/2b endorsement</i>
<i>July 2020</i>	<i>Step 2a/2b endorsement</i>
<i>July 2021</i>	<i>Public comment period ends (4-6 months preparation, 6 months comment period)</i>
<i>Nov 2021</i>	<i>Step 3 Signoff (6 months for adjudication by EWG) Possible Step 4 adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2018	<i>May. 2019</i>	<i>Working group teleconferences and internal consultation</i>	<i>Working Group will meet every other week via tele/web conference to develop draft guideline, template table of contents, strategy for content development, first draft content, and strategy for coordination with other WGs.</i>
Jun. 2019	<i>Jun. 2019</i>	<i>F2F meeting to continue progress on WG deliverables and consult with other ICH WG representatives</i>	<i>Align within M11 working group on table of contents, consult F2F with other ICH working groups, and refine first draft content, explore options related to technical specification.</i>
Jun. 2019	<i>Nov. 2019</i>	<i>Working group teleconferences and internal consultation</i>	<i>Working Group will meet every other week via tele/web conference to refine draft guideline, progress on content development, and develop the technical specification.</i>
Nov. 2019	<i>Nov. 2019</i>	<i>F2F meeting to continue progress on WG deliverables</i>	<i>Finalize guideline, template, and technical specification for sharing internally with ICH stakeholders</i> <i>Consult as needed with other ICH working groups</i>
Nov. 2019	<i>Jun. 2020</i>	<i>Working group teleconferences and internal consultation</i>	<i>Working Group will meet every other week via tele/web conference to refine draft guideline and respond to feedback from ICH stakeholders.</i>
Jun. 2020	<i>Jun. 2020</i>	<i>F2F meeting to finalize Technical Document for Step 1 Sign-off; possible Step 2a/2b endorsement</i>	<i>Finalize Technical Document (guideline, template, technical specification); present for Step 1 signoff</i> <i>Possible Step 2a/2b endorsement</i>