

ICH M11 EWG Work Plan

February 24, 2022

Topic Adoption date: *November 2018*

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Regulatory Chair: *Ron Fitzmartin, FDA, United States*

Last Face-to-Face Meeting: *Singapore, November 2019*

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. 2022</i>	<i>Step 1 Sign-off</i>
<i>Jul. 2022</i>	<i>Step 2a / 2b endorsement</i>
<i>Feb. 2023</i>	<i>End of Public Consultation Period</i>
<i>Jul. 2023</i>	<i>Step 3 Signoff of Draft Guideline, Template and Technical Specification Step 4 Adoption of the ICH Harmonised Guideline, Template and Technical Specification</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2021	<i>Dec. 2021</i>	<i>Review and prepare final draft version of the Guideline and Template</i>	<i>EWG members to complete a front-to-back review and revision of the template and guideline to ensure consensus with final content; conduct document checks for consistency and editing/formatting</i>
Dec. 2021	<i>Jan. 2022</i>	<i>Consultation with ICH E6</i>	<i>Review by ICH E6 EWG, as requested by E6, to ensure alignment, followed by adjudication and revisions to deliverables per E6 feedback.</i>
Jan. 2022	<i>Apr. 2022</i>	<i>Prepare final draft Technical Specification</i>	<i>Update the Technical Specification to reflect revisions to template</i>
Apr. 2022	<i>Jun. 2022</i>	<i>Pre-clearance legal review</i>	<i>Pre-clearance legal review prior to Step 1 as required by one party</i>
Jun. 2022	<i>Jun. 2022</i>	<i>EWG Step 1 Sign-off</i>	<i>Guideline, Template and Technical Specification are signed off by EWG Topic Leads</i>
Jul. 2022	<i>Jul. 2022</i>	<i>Step 1 Documents are submitted for endorsement under Step 2a/2b</i>	<i>Step 2a / 2b endorsement of Step 1 documents by the Assembly and released for Public Consultation Period</i>
Jul. 2022	<i>Feb. 2023</i>	<i>End of Regional Public Consultation Period</i>	<i>Regional consultation is completed; discussion of regional comments is initiated</i>