

ICH M11 EWG Work Plan

October 13, 2020

Topic Adoption date: *November 2018*

Rapporteur: *Ms. Vivian Combs - PhRMA*

Regulatory Chair: *Dr. 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>Guideline, Template, Basis of Requirements, Technical Description*</i>	<i>Full Technical Specification for Electronic Exchange*</i>
<i>May. 2021</i>	<i>Step 1 Sign-off</i>	
<i>Sep. 2021</i>	<i>Step 2a / 2b endorsement</i>	
<i>Nov. 2021</i>		<i>Step 1 Sign-off</i>
<i>Feb. 2022</i>		<i>Step 2a/2b endorsement</i>
<i>Jun. 2022</i>	<i>End of Public Consultation Period</i>	
<i>Dec. 2022</i>		<i>End of Public Consultation Period</i>
<i>May. 2023</i>	<i>Step 3 Signoff of Technical Document (ALL deliverables)</i> <i>Step 4 Adoption of Technical Document (ALL deliverables)</i>	
	*Note: <i>Delivery of the Guideline and Template are being decoupled from the Technical Specification. Two important precursors to the full Technical</i>	

	<p><i>Specification WILL be delivered with the Guideline and Template so that public comments can be collected (left column above). Technical Specification can follow relatively quickly. Like the approach taken with ICH E2B, a second public comment cycle focused on the Technical Specification will be needed (right column above).</i></p> <p><i>Despite the delays reflected in the timeline due to pandemic disruptions that have occurred, additional risk is ongoing. Certainty in the timeline will increase with</i></p> <ul style="list-style-type: none"> • <i>the EWG’s ability to maintain focus through year-end, and</i> • <i>ability of ICH Parties to mobilize reviewers and complete timely reviews in the Jan-Feb 2021 review window.</i>
--	---

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Oct. 2020	<i>Dec 2020</i>	<i>Front-to-back review and revision</i>	<i>EWG members to complete a front-to-back review and revision of the template and Basis of Requirements to ensure consistency throughout</i>
Jan. 2021	<i>Feb 2020</i>	<i>Party review of draft template and technical documents</i>	<i>ICH Parties to review draft template and Basis of Requirements/ Technical Description</i>
Mar. 2021	<i>May 2021</i>	<i>Resolve comments from party review</i>	<i>Disposition comments from party review and revise accordingly</i>
Mar 2020	<i>May 2021</i>	<i>Update tech documents</i>	<i>Update the Basis of Requirements and Technical Description synchronously with revisions to template</i>
Oct. 2020	<i>May 2021</i>	<i>Coordinate with other ICH Working Groups</i>	<p><i>Maintain established contact (E6, E20, etc.) with ICH EWGs as previously agreed.</i></p> <p><i>Establish contact with additional EWGs/IWGs per Coordination Strategy and as needs emerge.</i></p>