

ICH E11A EWG Work Plan

January 28, 2022

Topic Adoption date: 17 October 2017

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Regulatory Chair: N/A

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2017</i>	<i>Concept Paper endorsed by Management Committee</i>
<i>Oct. 2017</i>	<i>Business Plan endorsed by Management Committee</i>
<i>Jun. 2018</i>	<i>Completed review of global literature on pediatric extrapolation</i>
<i>Jun. 2018</i>	<i>Completed review of pediatric extrapolation issues from E11(A) public comments</i>
<i>Nov. 2018</i>	<i>Completed draft Table of Contents Outline of Guideline</i>
<i>Jun. 2019</i>	<i>Completed Detailed Outline of Guideline</i>
<i>Nov. 2019</i>	<i>Began review of first draft of Guideline</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Feb. 2022</i>	<i>Step 1 Sign-off</i>
<i>Feb. 2022</i>	<i>Step 2a ICH Parties Consensus on Technical Document</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2020	Dec. 2021	<i>The EWG will continue to meet biweekly to edit the draft guidance and develop case examples for the proposed annex. The EWG also convened another virtual FTF meeting in place of the meeting scheduled in Vancouver.</i>	<i>The EWG completed work and sent document for review for Step 1 sign off to all EWG member organizations.</i>
Dec. 2021	Feb. 2022	<i>Review of document by EWG member organizations</i>	<i>Addressing comments from EWG organizations and plan for Step 1 sign off by early February and achieving Step 2a and b.</i>
Feb. 2022	Jun. 2022	<i>Develop initial training material case examples to be posted during public consultation period</i>	<i>Develop initial key examples that can be posted to the ICH website during the public consultation period to aid in the review of the guideline.</i>