

ICH E11A EWG/IWG Work Plan

August 17, 2021

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>Nov. 2021</i>	<i>Step 1 Consensus Building, Drafting of Technical Document</i>
<i>Nov. 2021</i>	<i>Step 2 ICH Parties Consensus on Technical Document</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2018	Nov. 2019	<i>Continued work of EWG Subgroups: Disease Similarity Subgroup; Modeling and Simulation Subgroup; Statistics Subgroup</i>	<i>Subgroup work has largely been completed but the subgroups will continue to meet on an ad hoc basis as issues and the need arises</i>
Jun. 2019	Nov. 2019	<i>Drafting of guideline from detailed outline</i>	<i>Each subgroup will work on writing of initial first draft of the document</i>
Jan. 2020	May. 2020	<i>EWG met via conference call continue review and revisions of first draft</i>	<i>EWG met twice monthly to review and continue revisions of first draft</i>
May 2020	May 2020	<i>EWG met via conference call over 5 days continue review and revisions of first draft</i>	<i>EWG met for 5 days via conference call instead of the FTF meeting scheduled for Vancouver. Review of the entire draft was not completed due to inability to meet FTF.</i>
Jun. 2020	Nov. 2020	<i>In addition to regular TCs (every 2 weeks for the EWG, and weekly TCs for the Modeling and Simulation Subgroup), The EWG met on October 5-7 as well as on November 16-19, 2020</i>	<i>EWG has been working to complete revisions to first draft but is delayed due to inability to meet FTF. The EWG held an ad hoc meeting in October (3 days) and in November (4 days in lieu of the FTF meeting in Athens).</i>
Nov 2020	Nov 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</i>	<i>The EWG has voted to eliminate the pre-read step. Elimination of this step is intended to reach step 2a/2b in November 2021. However, the EWG noted that elimination of the pre-read</i>

		<i>another virtual FTF meeting in place of the meeting scheduled in Vancouver.</i>	<i>may lead to more comments and a delay in reaching step 4.</i>
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