

ICH E11A EWG/IWG Work Plan

31 July 2018

Topic Adoption date: *17 October 2017*

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Regulatory Chair: *TBD*

Last Face-to-Face Meeting: *Kobe, Japan, June 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2017</i>	Concept Paper endorsed by Management Committee
<i>Oct. 2017</i>	Business Plan endorsed by Management Committee
<i>Jun. 2018</i>	Completed review of global literature on pediatric extrapolation
<i>Jun. 2018</i>	Completed review of pediatric extrapolation issues from E11(R1) public comments

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2020</i>	<i>Step 1</i> sign-off on the Technical Document
<i>Nov. 2020</i>	<i>Step 2a/b</i> Endorsement of the draft Guideline

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2018	<i>Ongoing</i>	<i>Creation of EWG Subgroups</i>	<i>Three subgroups were created to lead specific topics within the ICH guideline: Disease Similarity Subgroup; Modeling and Simulation Subgroup; Statistics Subgroup</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Develop key items for inclusion in the guideline using concept paper as basis</i>	<i>The EWG agreed that the concept paper should be used as the basis for the guideline. Therefore, the EWG is using the concept paper as the framework for the purposes of beginning the outline for the guideline. This work was initiated in Kobe and will be reviewed at the next FTF meeting.</i>
Nov. 2017	<i>Nov. 2018</i>	<i>Incorporation of key terminology into each of the three topic areas within the guideline</i>	<i>Each subgroup will review the key terminology to decide which items should be included in their specific topic.</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Development of scope of work for each subgroup</i>	<i>Each subgroup will meet via conference call to review the scope of work, the process for review and drafting of an outline for each section.</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Preparation of presentations for face to face meeting</i>	<i>Each subgroup will provide an update and presentation on work accomplished to date</i>