

# ICH E11A EWG Work Plan

## 31 January 2019

**Topic Adoption date:** 17 October 2017

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**Regulatory Chair:** N/A

**Last Face-to-Face Meeting:** Charlotte, NC, USA, November 2018

### 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>

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2020</i>	<i>Step 1 Consensus Building, Drafting of Technical Document</i>
<i>Nov. 2020</i>	<i>Step 2a and 2b Endorsement of Draft Guideline by Assembly Members and Assembly Regulatory Members</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Jun. 2018</b>	<i>Ongoing</i>	<i>Creation and Continued work 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>
<b>Jun. 2018</b>	<i>ongoing</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. The EWG is continuing to use these key terms in the development of each subsection</i>
<b>Nov. 2018</b>	<i>Jan. 2019</i>	<i>Identification of EWG Subgroup Subject Matter Experts (SMEs)</i>	<i>Each Subgroup lead will review list of SMEs nominated by E11A member groups and vote on a list of SMEs to serve as proposed by subgroup leads. This work was completed in January 2019.</i>
<b>Nov. 2018</b>	<i>ongoing</i>	<i>Refinement and initial drafting of E11A guideline</i>	<i>Each subgroup will meet via conference call to begin work to refine the table of contents outline and begin drafting of specific sections of the guideline</i>
<b>Nov. 2018</b>	<i>Ongoing</i>	<i>Review progress of document drafting</i>	<i>E11A will meet via montly conference call to review ongoing work of each subgroup.</i>
<b>May 2019</b>	<i>Jun. 2019</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>