

# ICH S7B / E14 IWG Work Plan

## 15 November 2018

**Topic Adoption date:** 15 November 2018

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

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
<b>Dec. 2015</b>	<i>Finalized E14 Q&amp;A regarding concentration-QTc analysis as an alternative analysis endpoint for QTc evaluation.</i>
<b>Dec. 2017</b>	<i>Publication of a white paper article to describe in more detail the steps involved in appropriate concentration-QTc analysis. (<a href="https://doi.org/10.1007/s10928-017-9558-5">https://doi.org/10.1007/s10928-017-9558-5</a>)</i>
<b>June 2018</b>	<i>A recommendation (a concept paper proposed through FDA) to ICH Assembly to reconstitute a WG at this time for the ICH E14 / S7B topic for clarification of the ICH S7B guideline through Q&amp;As.</i>
<b>Aug. 2018</b>	<i>Revised concept paper for submission to the MC.</i>
<b>Nov. 2018</b>	<i>E14/S7B Discussion Group (DG) met in person and revised the concept paper to develop Q&amp;As to both ICH S7B and E14. The concept paper describes a two-stage approach where Q&amp;As will be written for both S7B and E14 in each stage. The concept paper was endorsed by the ICH Assembly and an Implementation Working Group (IWG) was formed.</i>

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

Expected future completion date	Milestone
<b>June 2020</b>	<i>Finalize first stage Q&amp;As for ICH S7B and E14</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Nov. 2018</b>	<i>Nov. 2018</i>	<i>Create Concept Paper for MC and Assembly</i>	<i>Create Concept Paper regarding updating ICH E14 and S7B with Q&amp;As. Develop work plan.</i>
<b>Nov. 2018</b>	<i>Nov. 2018</i>	<i>Finalize Concept Paper and work plan for IWG</i>	<i>Finalize a detailed plan on the timelines to write the proposed Q&amp;As for S7B and E14.</i>
<b>Dec. 2018</b>	<i>June 2019</i>	<i>Scope first stage Q&amp;As for S7B and E14 and develop draft text</i>	<i>In regular teleconferences discuss scope and detail of potential Q&amp;As for ICH S7B and E14.</i>
<b>June 2019</b>	<i>June 2019</i>	<i>Meet face-to-face at ICH Meeting</i>	<i>Discuss the potential Q&amp;As on best practices for ICH S7B assays, and criteria for robust proarrhythmia prediction model. Discuss the potential Q&amp;As for E14 in clinical implementation scenarios.</i>
<b>June 2019</b>	<i>June 2020</i>	<i>Finalize first stage Q&amp;As for S7B and E14</i>	<i>In regular teleconferences draft the Q&amp;A text in preparation for the face-to-face meeting and Q&amp;A finalization.</i>
<b>June 2020</b>	<i>June 2020</i>	<i>Meet face-to-face at ICH Meeting</i>	<i>Finalize first stage Q&amp;As.</i>
<b>Jan. 2019</b>	<i>June 2020</i>	<i>Discuss potential second stage Q&amp;As for S7B and E14 and generate any data needed</i>	<i>In regular teleconferences discuss the potential second stage Q&amp;As focusing on data needs and gaps. In face-to-face meetings discuss data needs and timelines. A detailed timeline to finalize Q&amp;As will be developed.</i>