ICH Q2(R2)/Q14 EWG Work Plan
15 February 2019

**Topic Adoption date:** November 2018

**Rapporteur:** Dr. Yukio Hiyama - MHLW/PMDA, Japan

**Regulatory Chair:** Dr. David Keire - FDA, United States

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

1. Key milestones

1.a. Current status of key milestones

<table>
<thead>
<tr>
<th>Past completion date</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov. 2018</td>
<td>Concept Paper and Business Plan endorsements</td>
</tr>
</tbody>
</table>

1.b. Future anticipated key milestones

<table>
<thead>
<tr>
<th>Expected future completion date</th>
<th>Milestone</th>
</tr>
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<tbody>
<tr>
<td>June 2019</td>
<td>First draft</td>
</tr>
<tr>
<td>June 2020</td>
<td>Step 1 sign-off, Step2a/b endorsement</td>
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<tr>
<td>Q4 2020</td>
<td>Public consultation period</td>
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<tr>
<td>Q2 2021</td>
<td>Step 3 sign-off, Step 4 adoption by regulatory Members of the Assembly</td>
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2. Timeline for specific tasks

<table>
<thead>
<tr>
<th>Beginning date</th>
<th>End date</th>
<th>Task / Activity</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov. 2018</td>
<td>May 2019</td>
<td>10 EWG meetings via teleconference</td>
<td>Write structured texts for Q2(R2) and Q14. Identify key issues. This will be done mostly by the sub team communication.</td>
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<tr>
<td>Jan. 2019</td>
<td>May 2019</td>
<td>Communication with related ICH topics, i.e. Q12 and Q13</td>
<td>Make sure that Q2(R2)/Q14 is consistent with the ongoing related topics.</td>
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