

ICH Q2(R2)/Q14 EWG Work Plan

April 30, 2020

Topic Adoption date: *June 2018*

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

Last Face-to-Face Meeting: *Singapore, November 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>November 2018</i>	<i>Concept Paper and Business Plan endorsements</i>
<i>June 2019</i>	<i>Structured texts for Q2(R2) and Q14</i>
<i>November 2019</i>	<i>Coordinated drafts of Q2(R2) and Q14</i>
<i>April 2020</i>	<i>Drafts of Q2(R2) and Q14 for intra party consultation</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>June 2020</i>	<i>Drafts of Q2(R2) and Q14 with feedback from intra party consultation</i>
<i>November 2020</i>	<i>Step 1 sign-off, Step2a/b endorsement</i>
<i>January-June 2021</i>	<i>Public Consultation Period</i>
<i>November 2021</i>	<i>Step 4 adoption</i>

2. Timeline for specific tasks

Beginning Date	End Date	Task/Activity	Details
<i>May 2020</i>	<i>May 2020</i>	<i>A series of virtual EWG meetings during the Vancouver week.</i>	<i>Review of the feedback. Editing based on the feedback of intra party review.</i>
<i>May 2020</i>	<i>June 2020</i>	<i>A series of Web meetings.</i>	<i>Complete pre step 2 drafts of Q2/Q14.</i>
<i>September 2020</i>	<i>October 2020</i>	<i>A series of Web meetings.</i>	<i>Further review of the pre step 2 drafts.</i>