

ICH Q2(R2)/Q14 EWG Work Plan

February 10, 2021

Topic Adoption date: *November 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>
<i>January 2021</i>	<i>Drafts of Q2(R2) and Q14 for 2nd intra party consultation</i>
<i>December 2021</i>	<i>Step 1 drafts completed</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>February 2022</i>	<i>Step 1 sign-off of Q2(R2) and Q14</i>
<i>February 2022</i>	<i>Step 2a/b endorsement</i>
<i>March 2022</i>	<i>Start Public Consultation</i>
<i>May 2023</i>	<i>Step 4 adoption, Initiation of Implementation Working Group for Q2 and Q14</i>

2. Timeline for specific tasks

Beginning Date	End Date	Task/Activity	Details
<i>February 2022</i>	<i>March 2022</i>	<i>Web meetings</i>	<i>Step2 Presentation Slides preparation. Initiate training discussion including possible IWG formation.</i>
<i>March 2022</i>	<i>August 2022</i>	<i>Regional public comment period</i>	<i>Some regions would host public meetings to explain the step2 drafts.</i>
<i>May and/or September 2022</i>	<i>May and/or September 2022</i>	<i>Virtual EWG(s)</i>	<i>To be determined.</i>
<i>November 2022</i>	<i>November 2022</i>	<i>Face to Face EWG</i>	<i>Review public comments and decide revision directions.</i>