

# ICH Q2(R2)Q14 EWG Work Plan

## September 15, 2020

**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

<b>Past completion date</b>	<b>Milestone</b>
<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>May 2020</i>	<i>Review key issues from the intra party consultation (Virtual EWG)</i>

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

<b>Expected future completion date</b>	<b>Milestone</b>
<i>November 2020</i>	<i>Drafts of Q2(R2) and Q14 ready for a second round of intra party consultation</i>
<i>February 2021</i>	<i>A second round of intra party consultation completed</i>
<i>March 2021</i>	<i>Review key issues from the intra party consultation by an interim EWG meeting</i>
<i>May 2021</i>	<i>Step 1 sign-off, Step 2a/b endorsement</i>

<i>June 2021 - January 2022</i>	<i>Public Consultation Period</i>
<i>May 2022</i>	<i>Step 4 adoption</i>

## 2. Timeline for specific tasks

<b>Beginning Date</b>	<b>End Date</b>	<b>Task/Activity</b>	<b>Details</b>
<i>June 2020</i>	<i>October 2020</i>	<i>A series of Web meetings.</i>	<i>Editing based on the feed back of intra party review.</i>