

ICH Q2(R2)/Q14 EWG Work Plan

15 February 2019

Topic Adoption date: *November 2018*

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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

Past completion date	Milestone
<i>Nov. 2018</i>	<i>Concept Paper and Business Plan endorsements</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>June 2019</i>	<i>First draft</i>
<i>June 2020</i>	<i>Step 1 sign-off, Step2a/b endorsement</i>
<i>Q4 2020</i>	<i>Public consultation period</i>
<i>Q2 2021</i>	<i>Step 3 sign-off, Step 4 adoption by regulatory Members of the Assembly</i>

2. Timeline for specific tasks

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