

ICH Q3E EWG Work Plan
May 20, 2020

Topic Adoption date: *June 2019*

Rapporteur: *Dr. Kim Li – PhRMA*

Regulatory Chair: *Dr. Jason Rodriguez – FDA, United States*

Last Face-to-Face Meeting: *May 2020 (Virtual Meeting)*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2019</i>	<i>Topic was endorsed</i>
<i>Jul. 2020</i>	<i>Final Concept Paper and Business Plan endorsed</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2020</i>	<i>First EWG Meeting</i>
<i>June 2021</i>	<i>Second EWG Meeting</i>
<i>Nov. 2021</i>	<i>Third EWG Meeting</i>
<i>June 2022</i>	<i>Fourth EWG Meeting</i>
<i>Nov. 2022</i>	<i>Fifth EWG Meeting</i>
<i>Nov. 2022</i>	<i>Step 1 sign-off, Step 2a/b endorsed</i>
<i>Jan.- June 2023</i>	<i>Public Consultation Period</i>
<i>Nov. 2024</i>	<i>Step 4 adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>May. 2020</i>	<i>Jul. 2020</i>	<i>Develop and finalize Concept Paper, Business Plan and Work Plan</i>	<i>Identify key technical and regulatory elements and milestones to develop and finalize Concept Paper, Business Plan and Work Plan.</i>