

ICH Q3E EWG Work Plan

December 16, 2021

Topic Adoption date: *June 2019*

Rapporteur: *Dr. Kim Li, PhRMA*

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

Last Face-to-Face Meeting: *None; all meetings have been virtual*

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>
<i>Oct. 2020</i>	<i>First EWG Meeting (virtual)</i>
<i>Nov. 2020</i>	<i>Second EWG Meeting (virtual)</i>
<i>Feb. 2021</i>	<i>Third EWG Meeting (virtual)</i>
<i>Jun. 2021</i>	<i>Fourth EWG Meeting (virtual)</i>
<i>Sep. 2021</i>	<i>Fifth EWG Meeting (virtual)</i>
<i>Dec. 2021</i>	<i>Sixth EWG Meeting (virtual)</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Feb. 2022 – May 2025</i>	<i>Quarterly EWG Meetings (virtual or face-to-face)</i>
<i>May 2023</i>	<i>Step 1 Sign-off, Step 2a/b endorsed</i>
<i>Jun. – Nov. 2023</i>	<i>Public consultation period</i>
<i>May 2025</i>	<i>Step 3 sign-off and Step 4 Adoption of final guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2022	Oct. 2022	<i>Continue with content development for Technical Document</i>	<i>Develop content that harmonizes the issues raised in the Concept Paper</i>
Nov. 2022	Feb. 2023	<i>Reach consensus on Technical Document (Step 1)</i>	<i>EWG reaches consensus prior to PWP consultation</i>
Mar. 2023	Apr. 2023	<i>PWP consultation</i>	
Apr. 2023	May 2023	<i>Step 1 sign-off, Step 2 a/b endorsed</i>	