

ICH Q3E EWG Work Plan

July 17, 2023

Topic Adoption date: June 2019

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

Last Face-to-Face 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>
<i>Jun. 2023</i>	<i>ICH funding approved for Threshold Project and 1-year extension from vendor contract approval</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jul. 2023</i>	<i>Vendor contract approval and initiate Threshold Project Part 2 (PDE generation and EWG peer review).</i>
<i>Sep. 2023</i>	<i>EWG meeting</i> <ul style="list-style-type: none"> • <i>Threshold Project progress review and Part 3 (Data integration and analysis).</i>
<i>Oct. 2023</i>	<i>F2F meeting in Prague</i> <ul style="list-style-type: none"> • <i>Threshold Project</i> <ul style="list-style-type: none"> ○ <i>Part 2 (EWG peer review of key PDEs)</i> ○ <i>Part 3 (Data integration and analysis).</i> • <i>Further develop consensus on Safety section.</i>
<i>Jun. 2024</i>	<i>Reach consensus on draft Technical Document</i>
<i>Aug. 2024</i>	<i>Begin PWP consultation</i>
<i>Oct. 2024</i>	<i>Step 1 and 2a/b Sign-off and endorsement</i>
<i>May 2025</i>	<i>End of Public Consultation period</i>
<i>Aug. 2026</i>	<i>Begin PWP consultation</i>
<i>Oct. 2026</i>	<i>Step 3 and 4 Sign-off and adoption of final Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2023	<i>Mar. 2024</i>	<i>Finalization of chemistry/quality sections</i>	<i>Reach consensus on final sections of chemistry/quality sections</i>
Jun. 2023	<i>Mar. 2024</i>	<u>Threshold Project</u> <ul style="list-style-type: none"> • Approval of contracts and MOU • Initiate external and internal activities pertaining to Part 2 • Ongoing peer reviews and EWG adoption of PDEs drafted by external and internal resources 	<ul style="list-style-type: none"> • Critical reviews of PDEs generated by external and internal resources • Real time distribution analysis with peer reviewed PDEs • Determine/plan for statistical analysis of the PDE distribution as appropriate
Apr. 2024	<i>Jul. 2024</i>	<u>Technical Document</u> <ul style="list-style-type: none"> • Integrate learning from Threshold Project into the safety assessment strategy • Align all aspects of the integrated draft guideline • Format draft guideline per ICH template 	<ul style="list-style-type: none"> • Conclude on QT values based on threshold project data • Develop content that harmonizes the issues raised in the Concept Paper • EWG reaches consensus and prepares for any potential PWP concerns
Aug. 2024	<i>Sep. 2024</i>	<i>PWP consultation</i>	<ul style="list-style-type: none"> • Address PWP comments
Oct. 2024	<i>Nov. 2024</i>	<i>Step 1 and 2 a/b sign-off and endorsement</i>	