

ICH E6(R3) EWG Work Plan

July 03, 2023

Topic Adoption date: *June 2019*

Rapporteur: *Dr. Khair ElZarrad, FDA, United States*

Regulatory Chair: *Mr. Peter Twomey, EC, Europe & Mr. Andrew Thomson, EC, Europe*

Last Face-to-Face Meeting: *Vancouver, Canada, June 2023*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2019	<i>Concept Paper and Business Plan Endorsement by the Management Committee</i>
Nov. 2019	<i>Expert Working Group Established</i>
Mar. 2020	<i>Approval of Stakeholder Engagement Proposal</i>
Dec. 2020	<i>Caucus Review of Draft R3 Introduction and Principles</i>
Jan.-Mar. 2021	<i>Applied and consolidated input from the Caucus Review to the principles</i>
Apr. 2021	<i>Draft R3 Principles – Published on ICH Website</i>
May. 2021	<i>Organize and conducted two E6 Spring Public Web Conference</i>
Jul. 2022	<i>Caucus Review of full Draft E6(R3) Annex 1</i>
Aug. 2022	<i>Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document</i>
Mar. 2023	<i>Completed review of caucus comments and document review</i>
Mar. 2023	<i>Developed updated Concept Paper for Annex 2</i>
Apr. 2023	<i>MC endorsement/approval of updated Concept Paper for Annex 2</i>
Apr. 2023	<i>EWG agreed on Draft Consensus Version (Principles and Annex 1)</i>
May. 2023	<i>Step 1 Sign-off of Technical Document (Principles and Annex 1) Complete</i>
May. 2023	<i>Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)</i>
May. 2023	<i>Began Step 3 Public Consultation (Principles and Annex 1)</i>
Jun. 2023	<i>Began drafting Annex 2</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Nov. 2023	<i>Step 3 End of Public Consultation (Principles and Annex 1)</i>
Nov. 2023	<i>Begin review of public comments for Principles and Annex 1</i>
Nov. 2023	<i>Complete initial draft – Consensus Version of Annex 2</i>
Dec. 2023	<i>Annex 2 Caucus Review</i>
Q1 2024	<i>Interim Meeting to Incorporate Public Comments for Final Version (Principles and Annex 1)</i>
Feb. 2024	<i>Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document (Annex 2)</i>
Mar. 2024	<i>Complete Annex 2 caucus review comments with final consensus version for Annex 2</i>
Mar. 2024	<i>Step 1 Sign-off of Technical Document (Annex 2)</i>
Apr. 2024	<i>Step 2a/2b Sign-off and Endorsement of Technical Document (Annex 2)</i>
Apr. 2024	<i>Step 3 Begin Public Consultation (Annex 2)</i>
Jul. 2024 – Aug. 2024	<i>PWP Consultation Period prior to Step 3 Sign-off of Technical Document (Principles and Annex 1)</i>
Sep. 2024	<i>Step 3 Sign-off of Technical Document (Principles and Annex 1)</i>
Oct. 2024	<i>Step 4 Adoption of Technical Document (Principles and Annex 1)</i>
Sep. 2024	<i>PWP Consultation Period prior to Step 3 Sign-off of Technical Document (Annex 2)</i>
Oct. 2024	<i>Step 3 End of Public Consultation (Annex 2)</i>
Dec. 2024	<i>Step 3 Sign-off of Technical Document (Annex 2)</i>
Q1 2025	<i>Step 4 Adoption of Technical Document (Annex 2)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
May. 2023		<i>Annex 2 Sub-Group Meeting every other week</i>	<i>Draft Annex 2</i>
May. 2023		<i>Annex 2 small group 1 and 2 Meeting every other week</i>	<i>Small group 1 and 2 working on drafting specific sections of Annex 2</i>

<i>Jul. 2023</i>	<i>Nov. 2023</i>	<i>Teleconference every month for E6(R3) EWG</i>	<i>Provide updates for Annex 2</i>
<i>Jul. 2023</i>	<i>Nov. 2023</i>	<i>Teleconference every 2 weeks for E6(R3) EWG</i>	<i>Sub-Group to begin working on E6(R3) training materials</i>
<i>Nov. 2023</i>		<i>E6(R3) EWG meeting every 1 or 2 days a week</i>	<i>Review public comments for draft E6(R3) document (Principles and Annex 1)</i>