ICH E6(R3) EWG Work Plan

January 02, 2023

Topic Adoption date: *June 2019*

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

Regulatory Chair: *Mr. Peter Twomey, EC, Europe*

Last Face-to-Face Meeting: *Incheon, Republic of Korea, November 2022*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2019	*Concept Paper and Business Plan Endorsement by the Management Committee*
Nov. 2019	*Expert Working Group Established*
Mar. 2020	*Approval of Stakeholder Engagement Proposal*
Dec. 2020	*Caucus Review of Draft R3 Introduction and Principles*
Jan-Mar. 2021	*Applied and consolidated input from the Caucus Review to the principles*
Apr. 2021	*Draft R3 Principles – Published on ICH Website*
May. 2021	*Organize and conducted two E6 Spring Public Web Conference*
Jul. 2022	*Caucus Review of full Draft E6(R3) Annex 1*
Aug. 2022	*Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Dec. 2022 – Feb. 2023	• *Complete review of caucus comments* • *Complete overall document review*
Jan. 2023	*Annex 2 Concept Paper Updated*

Feb. 2023	*Seek MC endorsement/approval of updated Concept Paper for Annex 2*
Mar. 2023	• *Complete consistency review and reference check* • *Complete editorial review* • *EWG to review and agree on draft consensus version* • *Complete 2-week deal breaking review*
Mar. 2023	*Interim Meeting – Geneva, Switzerland (March 27 – 30, 2023)* • *Resolve key issues/blockers* • *Finalize draft consensus version*
Apr. 2023 – May. 2023	*Step 1 Sign-off of Technical Document (Principles and Annex 1)*
Apr. 2023 – May. 2023	*Start outlining the content of Annex 2*
May. 2023 – Jun. 2023	*Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)*
May. 2023 – Jun. 2023	*Step 3 Begin Public Consultation (Principles and Annex 1)*
Jun. 2023 – Jul. 2023	*Begin/continue drafting for Annex 2*
Nov. 2023 – Dec. 2023	*Step 3 End of Public Consultation (Principles and Annex 1)*
Apr. 2024 – May. 2024	*PWP Consultation Period prior to Step 3 Sign-off of Draft Guideline*
May. 2024 – Jun. 2024	*Step 3 Sign-off of Draft Guideline (Principles and Annex 1)*
Jun. 2024 – Jul. 2024	*Step 4 Adoption of Draft Guideline (Principles and Annex 1)*

2.Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Aug. 2020		*Approximately once a month*	*Continue engagement with stakeholder representatives and EWG members during guideline development to ensure that stakeholders' perspectives on and experiences with clinical trials, specifically with GCP guidelines, are considered in developing ICH-E6(R3)*
Sep. 2022		*Teleconference every 1 or 2 days a week*	*Begin review/discussion of caucus' comments for each of the sections.*
Nov. 2022		*Small WG Meeting every 1 or 2 days a week*	*Small group of EWG members convene to provide draft language based on caucus comments*

Mar. 2023	***Mar. 2023***	*Interim (hybrid) meeting*	*A 4-day interim (hybrid) E6(R3) meeting scheduled for March 27 – 30, 2023 in Geneva, Switzerland to resolve key issues/blockers and finalise draft consensus version of ICH E6(R3) for Step 1 sign-off and public consultation.*