ICH E2D (R1) EWG Work Plan
October 12, 2023

Topic Adoption date: *November 2019*

Rapporteur: *Ms. Vicki Edwards, EFPIA*

Regulatory Chair: *Dr. Robert Ball, FDA, United States*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2019	*Topic endorsed by ICH Assembly*
Sep. 2019	*ICH approval to form Informal Working Group*
Nov. 2019	*Endorsement of formal EWG by ICH Management Committee*
Nov. 2019	*Concept Paper Endorsement by ICH Management Committee*
Nov. 2019	*Business Plan Endorsement by ICH Management Committee*
Jul. 2023	*Plenary Working Party (PWP) Consultation*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jan. 2024	*Step 1 Experts sign off*
Feb. 2024	*Step 2a Endorsement by Members of the Assembly/Step 2b Endorsement by Regulatory Members of the Assembly. Release for public consultation*
Jul.2024	*Step 3 Regulatory Consultation and Discussion*
Jan. 2025	*Plenary Working Party (PWP) Consultation*
Apr. 2025	*Step 3 Regulatory Experts sign off*
May. 2025	*Step 4 Adoption of ICH Harmonized Guideline by Regulatory Members of the Assembly*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Dec. 2022	***Dec. 2023***	*EWG will meet weekly via tele/web conferences*	*Weekly EWG meetings extended, and biweekly meetings added as needed to meet timelines*
01 Aug. 2023	***31 Dec 2023***	*EWG final amendments to guideline*	*Final amendments made to guideline based on PWP and stakeholder comments*
01 Jan. 2024	***15 Jan. 2024***	*EWG consensus on final guideline*	1. *EWG reaches consensus on the final revised guideline (this will become the Step 1 Technical Document)* 2. *Prepare supplementary documentation to support Step 2 public consultation.*
16 Jan. 2024	***31 Jan. 2024***	*Step 1 Sign-Off by Topic Leaders of EWG*	*ICH Secretariat to organize Step 1 Experts Sign-Off by the Topic Leaders of the EWG*
01 Feb. 2024	***29 Feb. 2024***	*Step 2a Endorsement by Members of the Assembly/Step 2b Endorsement by Regulatory Members of the Assembly.*	
01 Mar. 2024	***30 July 2024***	*Step 3 Regulatory Consultation and Discussion*	*Released for Public consultation (5 months)*
01 Aug. 2024	***31 Dec. 2024***	*EWG Comment Review and Final Amendments to Guideline*	*Review and adjudicate all comments from public consultation. Prepare final amendments to guideline based on public comments.*
01 Jan. 2025	***31 Jan. 2025***	*Plenary Working Party (PWP) Consultation (1 month)*	*Revised guideline sent to PWP for consultation*

01 Feb. 2025	***31 Mar. 2025***	*EWG Final Review and Internal Stakeholder Sign-off. (2 months)*	*Final amendments made to guideline. EWG reaches consensus on the final revised guideline. Prepares guideline for Step 3 Regulatory Experts sign off.*
01 Apr. 2025	***30 Apr. 2025***	*Step 3 Regulatory Experts sign off (1 month)*	
01 May 2025	***31 May 2025***	*Step 4 Adoption of ICH Harmonized Guideline by Regulatory Members of the Assembly (1 month)*	