ICH E20 EWG Work Plan

January 28, 2022

Topic Adoption date: *November 2018*

Rapporteur: *Dr. John Zhong, PhRMA*

Regulatory Chair: *Dr. Greg Levin, FDA, United States*

Last Face-to-Face Meeting: *Singapore, November 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2019	*Concept Paper endorsement, Business Plan endorsement*
May 2020	*Operational issues team completed research and shared proposal on key issues to be potentially incorporated into the E20 guideline.*
Jul. 2020	*EWG endorsed Estimands team's proposal not to create a separate section on estimands but to discuss it as appropriate throughout the E20 guideline*
Nov. 2020	*Completed first draft of core sections of E20 guideline*
Mar. 2021	*Simulation team discussed with the EWG an outline of discussion points on the scope for the use of simulations in adaptive clinical trials and key considerations for planning simulations to assess operating characteristics relevant to adaptive designs.*
Jun. 2021	*External data team shared research work and draft high-level recommendations with the EWG.*
Nov. 2021	*Bayesian team completed and discussed the draft Bayesian Adaptive Design section with the writing team*
Dec. 2021	*Held weekly virtual meetings to discuss industry experiences and regulatory perspectives on DMCs/Adaptation Committees in adaptive clinical trials*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May. 2022	*Either face-to-face meeting or additional virtual meetings (if in-person meeting is cancelled) to discuss completed sections of E20 guideline*
Nov. 2022	*Final draft of E20 guideline with EWG consensus*
Dec. 2022	*ICH Member internal consultation on technical document*
Mar. 2023	*PWP consultation on technical document*
May. 2023	*Step 1: Technical document signed off by topics leaders*
Jun. 2023	*Step2a and Step 2b: Draft E20 guideline endorsed*
Sep. 2023	• *Step 3: Regulatory Consultation and Discussion* • *Develop training materials*
Aug. 2024	*PWP consultation on draft E20 guideline*
Oct. 2024	*Step 3: Regulatory Experts sign off*
Dec. 2024	• *Step 4: Finalize training materials* • *Step 4: Finalization of E20 guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2022	***May. 2022***	*Drafting remaining sections of the E20 guideline*	*The writing team will continue to draft remaining sections and meet monthly to discuss and revise. Completed paragraphs and sections will be sent to the EWG for review before full EWG meetings.*
Jan. 2020	***May. 2022***	*Writing team monthly review and discussion*	*The core writing team will continue to meet monthly to review and discuss the preliminary draft section(s) before sharing with the EWG.*

Jan. 2020	***May. 2022***	*EWG monthly review and discussion*	*The EWG will meet monthly to review and discuss the work completed, identify and discuss gaps and issues, and determine whether to start additional sub-team activities.*
Jan. 2022	***May. 2022***	*Bayesian design in adaptive clinical trials*	*The Bayesian team will review the final draft of Bayesian Adaptive Design section with the writing team and the EWG.*
May. 2022	***May. 2022***	*Face-to-face meeting (Athens, Greece) or additional virtual meetings if F2F meeting is cancelled*	*Discuss draft E20 guideline, identify gaps, and agree on future strategy*