ICH E20 EWG Work Plan
March 11, 2024

Topic Adoption date: *November 2018*

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

Last Face-to-Face Meeting: *Prague, Czech Republic, October 2023*

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.*
Jul. 2022	*Bayesian team completed revised draft Bayesian Adaptive Design section*
Feb. 2023	*Writing team revised draft Bayesian Adaptive Design section and discussed it with the EWG*
Jun. 2023	*First full draft of E20 Technical Document completed for EWG discussion*
Oct. 2023	*Second full draft of E20 Technical Document completed for EWG discussion*
Oct. 2023	*Face-to-face meeting to discuss draft E20 Technical Document*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2024	*Face-to-face meeting in Fukuoka, Japan*
Sep. 2024	*Final draft of E20 Technical Document with E20 EWG consensus*
Oct. 2024	*Step 1 PWP consultation of E20 draft Technical Document*
Nov. 2024	• *Steps 1 and 2a/b Sign-off of E20 draft Technical Document by E20 EWG Topic Leaders and ICH Assembly Regulatory Members* • *Finalize Step 2 Informational Presentation*
Dec. 2024 – Mar. 2025	• *Step 3: Public Regulatory Consultation* • *Progress on development of Step 4 introductory presentation*
Apr. 2025 – Feb 2026	• *Incorporate comments and revise document* • *Develop training materials*
Feb. 2026	*Step 3 PWP consultation of draft E20 draft Guideline*
Apr. 2026	• *Steps 3 and 4 Sign-off of E20 draft Guideline by E20 EWG Topic Leaders and ICH Assembly Regulatory Members* • *Finalize Step 4 Introductory Presentation*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2023	***May. 2024***	*Writing team*	*Writing team will incorporate comments and revise to create an updated full draft*
Nov. 2023	***May. 2024***	*Biweekly full working group meetings, including robust discussion of the Bayesian section after completion of the principles and examples sections*	*WG to review the revision and provide comments and suggestion to address their comments* *Discuss the revisions* *Address comments to Bayesian and Simulation subsections*
May. 2024	***Jun. 2024***	*Face-to-face meeting (Fukuoka)*	*Discuss and reach consensus on any residual concerns about revised draft and consensus on most challenging special topics (e.g., Bayesian section)*