

ICH E20 EWG Work Plan

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Topic Adoption Date: November 2018

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Last Face-to-Face Meeting Fukuoka, Japan, May 2024

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
Nov. 2019	<i>Concept Paper endorsement, Business Plan endorsement</i>
May 2020	<i>Operational issues team completed research and shared proposal on key issues to be potentially incorporated into the E20 guideline.</i>
Jul. 2020	<i>EWG endorsed Estimands team's proposal not to create a separate section on estimands but to discuss it as appropriate throughout the E20 guideline</i>
Nov. 2020	<i>Completed first draft of core sections of E20 guideline</i>
Mar. 2021	<i>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.</i>
Jun. 2021	<i>External data team shared research work and draft high-level recommendations with the EWG.</i>
Jul. 2022	<i>Bayesian team completed revised draft Bayesian Adaptive Design section</i>
Feb. 2023	<i>Writing team revised draft Bayesian Adaptive Design section and discussed it with the EWG</i>
Jun. 2023	<i>First full draft of E20 Technical Document completed for EWG discussion</i>
Oct. 2023	<i>Second full draft of E20 Technical Document completed for EWG discussion</i>

May 2024	<i>Third full draft of E20 Technical Document completed for EWG discussion</i>
Sep. 2024	<i>Draft of E20 Document disseminated for internal regulatory consultation</i>
Feb 2025	<i>Revisions of draft E20 document completed based on feedback from internal regulatory reviews and EWG discussions</i>
Jun. 2025	<i>Step 1 and Step 2a/b Sign-off of E20 draft Guideline</i>
Nov. 2025	<i>Completion of regional regulatory consultation period</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Nov. 2019	<i>ICH E20 Guideline and E20 related Training Material</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Aug. 2026	<i>Completion of review and discussion of regional consultation comments, revisions to guideline, and development of training materials</i>
Sep. 2026	<i>Step 3 PWP consultation of E20 guideline</i>
Oct. 2026	<i>Step 3 and Step 4 Sign-off of E20 guideline</i>

2. Timeline for Specific Tasks

Please provide in the table below **short-term high-level specific tasks for work to be done within the Working Group between now and the next ICH meeting (recommended 4 – 10 tasks).**

Beginning date	End date	Task / Activity	Details
Sep. 2025	Mar. 2026	<i>Discussion of approaches to review and address regional consultation comments</i>	<i>Develop and finalize plan to consolidate, organize, review, and discuss regional consultation comments</i>

<i>Dec. 2025</i>	<i>Aug. 2026</i>	<i>Review and discussion of regional consultation comments</i>	<i>Identify and align on revisions to guideline to address consultation comments and reach consensus</i>
<i>Dec. 2025</i>	<i>Aug. 2026</i>	<i>Development of training materials</i>	<i>Develop training materials to support implementation of Step 4 guideline</i>