

ICH E20 EWG Work Plan

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Topic Adoption Date: November 2018

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Last Face-to-Face Meeting Amsterdam, Netherlands, March 2026

1 Key Milestones

1.1 Current Status of Key Milestones

- List key **past milestones** in the table for context.
- Key Milestones Include:
 - Concept Paper endorsement,
 - Completion of PWP Consultation (if applicable)
 - ICH *Step* sign-off (*Guidelines, Q&As, Implementation Packages*)
 - Completion of *Step 3* Public Consultation,
 - *Step 2* and *Step 4* Presentations
 - Stakeholder Engagement Activities
 - Training materials developed.
- **Choose only the most relevant achievements.**

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

- The table records **all deliverables** that the ICH MC has approved for development, either:
 - those listed in the **Concept Paper**, or
 - additional deliverables **approved later** by the MC.
- “**Approval Date**” = the date the MC **approved starting work** on that deliverable (either the **Concept Paper approval date** or a **later time point based on MC approval**).

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

1.3 Future Anticipated Milestones

Please provide in the table below the **main deliverable(s) to be achieved in the next year(s)**:

Dates or expected timeline (e.g. Q1 2026 etc.) should be provided for:

- PWP engagement (if applicable) ahead of Step 1 and Step 3 Sign off
- Step 1 sign-off and Step 2a/b endorsement and delivery of the Step 2 Presentation
- Step 3 sign-off and Step 4 adoption and delivery of the Step 4 Presentation

- Any other relevant high-level deliverables (finalised documents, public consultation period, special actions to advance the topic through ICH, e.g. stakeholder engagement or training, etc.)

Expected future completion date	Milestone
Dec. 2026	<i>Completion of review and discussion of regional consultation comments, revisions to Guideline, and development of training materials</i>
Jan. 2027	<i>Step 3 PWP consultation of E20 Guideline</i>
Feb. 2027	<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
Dec. 2025	Dec. 2026	<i>Review and discussion of constituent review comments</i>	<i>Identify and align on revisions to Guideline to address consultation comments and reach consensus</i>
Dec. 2025	Sep. 2026	<i>Complete full revised draft to address public comments</i>	<i>Discussion of public comments and revisions has been proceeding by section/topic; a complete revised draft for EWG review is expected by September</i>
Dec. 2025	Feb. 2027	<i>Development of training materials</i>	<i>Develop training materials to support implementation of Final Guideline</i>