

ICH M8 EWG/IWG Work Plan

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Topic Adoption Date: November 2011

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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
Dec. 2015	<i>Revised Concept Paper endorsement</i>
June 2021	<i>Step 4 Specification for Submission Formats for CTD v1.3</i>
May 2024	<i>Step 4 eCTD v3.2.2 Valid Values 6.0</i>
May 2024	<i>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.33</i>
March 2025	<i>eCTD v4.0 Vendor Group Q&A v1.0</i>
January 2026	<i>eCTD v4.0 Implementation Vendor Group</i>
June 2026	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.10</i>
June 2026	<i>Step 3 sign-off eCTD v4.0 Q&A v1.10</i>

June 2026	Step 3 sign-off eCTD v4.0 Controlled Vocabulary Package v1.0.3
June 2026	Step 3 sign-off eCTD v4.0 Implementation Guide Package v1.7.
August 2026	Step 4 Adoption eCTD v4.0 Q&A v1.10
August 2026	Step 4 Adoption eCTD v4.0 Controlled Vocabulary Package v1.0.3
August 2026	Step 4 Adoption eCTD v4.0 Implementation Guide Package v1.7.

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
December 2015	Ongoing maintenance and update of the Step 4 eCTD v4 Questions and Answers and Specification Change Request Document
December 2015	Ongoing maintenance and update of the Step 4 eCTD v4 Implementation Guide Package (incorporating changes from eCTD Q&A)
December 2015	Ongoing maintenance and update of the Step 4 eCTD v4 Controlled Vocabulary Package (incorporating changes from eCTD Q&A)
December 2015	Ongoing maintenance and update of the Step 4 eCTD v3 Questions and Answers and Specification Change Request Document (if Change Requests are received)
December 2015	Ongoing maintenance and update of the Step 4 eCTD v4 Questions and Answers and Specification Change Request Document (if Change Requests are received)

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
October 2026	<i>Step 4 eCTD v3 Questions and Answers and Specification Change Request Document v1.34 (if Change Requests are received)</i>
October 2026	<i>Step 4 eCTD v4 Questions and Answers and Specification Change Request Document v1.04 (if Change Requests are received)</i>
October 2026	<i>Step 4 eCTD v4 Implementation Guide Package v1.8 (if necessary)</i>
October 2026	<i>Step 4 eCTD v4 Controlled Vocabulary Package v1.2 (if necessary)</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 biannual meeting (recommended 4 – 10 tasks).

Beginning date	End date	Task / Activity	Details
January 2026	<i>TBD</i>	<i>Prepare Q&A Updates.</i>	<i>Discuss v3.2 and v.40 Change Requests, and update and agree to the Q&A's.</i>
January 2026	<i>TBD</i>	<i>Prepare IG Updates.</i>	<i>Update eCTD v4.0 IG as necessary.</i>
January 2026	<i>TBD</i>	<i>Prepare CV Updates.</i>	<i>Update eCTD v4.0 CV as necessary.</i>
June 2023	<i>TBD</i>	<i>Develop plan to support and implement M4Q R2 business requirements.</i>	<i>M4Q(R2) continues to meet with M2/M8 subgroup to review the CTD changes to M4Q content in Modules 2 and 3. This joint workgroup is tasked to discuss the technical aspects and implications of the proposed changes, and to determine an approach to support M4Q changes in eCTD v4.0.</i>
July 2024	<i>TBD</i>	<i>eCTD v4.0 Vendor Group</i>	<i>Quarterly meetings with industry to discuss the implementation of eCTD v4.0.</i>

<i>June 2023</i>	<i>TBD</i>	<i>eCTD v4.0 Evolution</i>	<i>Subgroup focused on adapting the v4.0 standard to align with new requirements from ICH WG's and evolving regulatory needs (e.g., Content Standardisation, Shared Environments).</i>
<i>January 2026</i>	<i>TBD</i>	<i>Working Group Meetings</i>	<i>Biweekly full working group meetings as needed.</i>