

ICH E2B(R3) EWG Work Plan

10th July 2026

Topic Adoption Date: July 2013

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Regulatory Chair Name of Regulatory Chair, Member

Last Face-to-Face Meeting Prague, Czech, October 2023

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
Jun., 2021	<i>Published the information paper regarding ISO IDMP use in E2B(R3) messages</i>
Dec., 2021	<i>Finalised the revision of Appendix I (B) Backwards and Forwards Compatibility Recommendations</i>
Jan., 2023	<i>Updated the Q&As</i>
Jan., 2023	<i>Completed the voice over presentation of Training Material Module I</i>
Jun., 2025	<i>Published the Training Module II</i>
Jul., 2025	<i>Revised the Implementation Guide including Appendix I (G) Technical Information and Q&As</i>
Dec., 2025	<i>Completed the Information Paper Regarding Alignment with ICH E2D(R1) Guideline</i>
Jan., 2026	<i>Updated the ICH E2B code list 8</i> <i>Completed the Training Material Module III</i>
Feb., 2026	<i>Published the Training Material Module III</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Nov., 2012	<i>Step 4 E2B(R3) Implementation Package including Implementation Guide, BFC document, Reference Instances, Example Instances, Code Lists, Technical information and Xpath</i>
Jul., 2013	<i>Approved IWG Concept Paper</i>
Nov., 2014	<i>Step 4 E2B(R3) Q&As</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Feb., 2027	<i>Review and update the Implementation Guide (Minor Revision) and the ICH E2B(R3) code-lists</i> <i>Develop additional Q&As in response to the ICH E2B(R3) code list updates</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Jun., 2019	N/A	<i>Process and update Q&As as needed</i>	➤ Monitor and discuss any comments submitted to the ICH mailbox and/or from E2B experts ➤ Add new Q&As to the document if applicable
Feb., 2026	Feb., 2027	<i>Review and update the Implementation Guide and the ICH E2B(R3) code-lists</i>	➤ Review and update the Implementation Guide and the existing ICH E2B(R3) code-lists where necessary for coded structured data