

ICH E2B(R3) EWG/IWG Work Plan

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Topic Adoption date: July 2013

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jul. 2020</i>	<i>Complete the revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms</i>
<i>Dec. 2020</i>	<i>Completed the Training Material Module II</i>
<i>Jun. 2021</i>	<i>Published the information paper regarding ISO IDMP use in E2B(R3) messages</i>
<i>Dec. 2021</i>	<i>Finalised the revision of Appendix I (B) Backwards and Forwards Compatibility Recommendations</i>
<i>Jan. 2023</i>	<i>Updated the Q&A</i>
<i>Jan. 2023</i>	<i>Complete the voice over presentation of Training Material Module I</i>
<i>Nov. 2023</i>	<i>Finalised the revision of Implementation Guide including Appendix I (G) Technical Information and Q&As</i> <i>Finalised the revision of Training Material Module II</i>

1.b. Key Deliverables

Approval Date	Deliverable
<i>Nov. 2012</i>	<i>Step 4 E2B(R3) Implementation Package including Implementation Guideline, BFC document, Reference Instances, Example Instances, Code Lists, Technical information and Xpath</i>
<i>Nov. 2014</i>	<i>E2B(R3) Q&As Step 4</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
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Mar. 2025	<p><i>Publish the revised Implementation Guide including Appendix I(G) Technical Information and Q&As</i></p> <p><i>Publish the Training Material Module I and II</i></p> <p><i>Finalise the contents of Training Material Module III</i></p> <p><i>Publish the Training Material Module III</i></p>
Jul. 2025	<p><i>Update code list 8 and other documents, and develop Information Paper according to E2D(R1) request</i></p>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2019	<i>Nov. 2025</i>	<i>Process and update Q&As as needed</i>	<ul style="list-style-type: none"> ➤ <i>Monitor and discuss any comments submitted to the ICH mail box and/or from E2B experts</i> ➤ <i>Add new Q&As to the document if applicable</i>
Jun. 2019	<i>Mar. 2025</i>	<i>Finalise contents of the Training Material Module III</i>	<ul style="list-style-type: none"> ➤ <i>Create contents by each subsection: Regulatory section, Industry section and Technical section</i> ➤ <i>Finalise the subsections</i>
Dec. 2020	<i>Mar. 2025</i>	<i>Revise Appendix I (G) Technical Information</i>	<ul style="list-style-type: none"> ➤ <i>Correct the language regarding “Total Dosage” expression</i> ➤ <i>Xpath for “Total Dosage” is going to be corrected</i>
Jul. 2023	<i>Mar. 2025</i>	<i>Integrate some Q&As into the Implementation Guide and revise the Q&A document</i>	<ul style="list-style-type: none"> ➤ <i>To improve the readability of the IG, some descriptions of Q&As is integrated into the IG</i> ➤ <i>Revise the Q&A document appropriately</i>
Jul. 2023	<i>Jul. 2025</i>	<i>Discuss ICSR updates and consider how to work on new issues with M2 EWG</i>	<ul style="list-style-type: none"> ➤ <i>ISO TC215 WG6 has decided to revise ISO/HL7 27953, ICSR standard, to add a part 3 for logical model</i> ➤ <i>E2B(R3) EWG and M2 EWG will discuss ICSR updates and consider how to work on new issues</i>

Oct. 2023	<i>May. 2025</i>	<i>Update code list 8 and other documents, and develop Information paper according to E2D(R1) request</i>	➤ <i>To decide timing of updating documents, monitor E2D(R1) EWG's progress revise of its guideline</i>
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