

ICH E2B(R3) EWG/IWG Work Plan

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Rapporteur: Dr. Takashi Misu - MHLW/PMDA, Japan

Regulatory Chair: Mr. Ta-Jen Chen – FDA, United States

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1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2018</i>	<i>Step 4 sign-off of the revised E2B(R3) Q&A document Endorsement of the common template of core data elements and business rules</i>
<i>Sep. 2018</i>	<i>Published the updated IG package (ver. 1.07) and the updated Q&A document (ver. 2.2)</i>
<i>Dec. 2018</i>	<i>Made a decision about the Route of Administration (RoA) terminology mapping between the ICH E2B code list and EDQM standard terms</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2019</i>	<i>Finalize a service level understanding (SLU) with M2 regarding the SOP to extract and post the EDQM dose form (DF) and RoA terminology lists for E2B(R3) use</i>
<i>Jun. 2019</i>	<i>Plan the publication of extracted EDQM DF and RoA terminologies as ICH code lists</i>
<i>Jun. 2019</i>	<i>Complete the RoA term mapping table between the ICH E2B code list and EDQM standard terms</i>
<i>Jun. 2019</i>	<i>Update IG package: revise the Appendix I(B) Backwards and Forwards Compatibility (BFC) Recommendations and the Appendix I(G) Technical Information for EDQM terminology use in E2B(R3) messages</i>
<i>Jun. 2019</i>	<i>Process and update Q&As as needed</i>

Jun. 2019	<i>Develop first draft training materials for E2B(R3) adopters</i>
Jun. 2019	<i>Develop business requirement for EDQM Application Programming Interface (API) for use of E2B(R3)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2018	<i>Jun. 2019</i>	<i>Finalize a SLU with M2 regarding the SOP to extract and post the EDQM DF and RoA terminology lists for E2B(R3) use</i>	<ul style="list-style-type: none"> ➤ <i>Review the draft SLU developed by M2 and provide feedback to M2</i> ➤ <i>Finalize the SLU with M2</i>
Jul. 2018	<i>Jun. 2019</i>	<i>Plan the publication of extracted EDQM DF and RoA terminologies as ICH code lists</i>	<ul style="list-style-type: none"> ➤ <i>Consult with M2 about technical issues of the publication</i> ➤ <i>Make a plan of the publication of the DF and RoA terminologies as ICH code lists</i>
Dec. 2018	<i>Jun. 2019</i>	<i>RoA term mapping between the ICH code list and EDQM standard terms</i>	<ul style="list-style-type: none"> ➤ <i>Develop a mapping table based on the E2B decision regarding the five EDQM proposals</i>
Dec. 2018	<i>Jun. 2019</i>	<i>Developing first draft training materials for E2B(R3) adopters</i>	<ul style="list-style-type: none"> ➤ <i>Draft the plan for developing training materials</i> ➤ <i>Consider contents depending on the target of training materials</i> ➤ <i>Develop first draft of the training materials</i>
Dec. 2018	<i>Jun. 2019</i>	<i>Update IG package: revise the Appendix I(B) Backwards and Forwards Compatibility Recommendations and the Appendix I(G) Technical Information for EDQM terminology use in E2B(R3) messages</i>	<ul style="list-style-type: none"> ➤ <i>Revise the BFC recommendation and the Technical Information</i> ➤ <i>Update the IG package</i>

Dec. 2018	<i>Jul. 2019</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>
Dec. 2018	<i>Jun. 2019</i>	<i>Develop business requirement for EDQM API for use of E2B(R3)</i>	<ul style="list-style-type: none"> ➤ <i>Evaluate the functions of EDQM API</i> ➤ <i>Consider business requirements for dynamic refresh of EDQM DF and RoA term list by each party</i> ➤ <i>Gather requirements from all parties for dynamic refresh of EDQM DF and RoA term lists</i>