

ICH E2B(R3) EWG/IWG Work Plan

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1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2017	<i>Endorsement of User Guide for Use of EDQM Terminologies for Dosage Forms and Routes of Administration ICH E2B code list #9 and E14 updated</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Feb. 2018	<i>Publish the updated IG package</i>
May. 2018	<i>Finalize common business rules and data elements template</i>
May. 2018	<i>Test and finalise the standard operation procedure (SOP) to extract and post the EDQM Dose Forms (DF) and Routes of Administration (RoA) terminology lists for E2B(R3) use</i>
May. 2018	<i>Develop the mapping table for RoA between E2B(R2) and EDQM terms</i>
May. 2018	<i>Evaluate and develop business requirement for dynamic refresh of EDQM DF and RoA lists</i>
May. 2018	<i>Process and update Q&As</i>
May. 2018	<i>Update BFC document and element mapping spreadsheet</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Dec. 2017	<i>Feb. 2018</i>	<i>Publish the updated IG package</i>	<ul style="list-style-type: none"> ➤ <i>Create updated IG package</i> ➤ <i>Update ESTRi E2B(R3) web page</i>
Dec. 2017	<i>May. 2018</i>	<i>Finalize common business rules and data elements template</i>	<ul style="list-style-type: none"> ➤ <i>Add the ICH core data elements and their business rules to the template capturing regional business rules and data elements</i>
Dec. 2017	<i>May. 2018</i>	<i>Test and finalise the standard operation procedure to extract and post the EDQM DF and RoA terminology lists for E2B(R3) use</i>	<ul style="list-style-type: none"> ➤ <i>Revise the preliminary draft of the SOP</i> ➤ <i>Test the SOP</i> ➤ <i>Finalize the document of SOP reflecting the E2B/M2 agreement</i>
Jan. 2018	<i>May. 2018</i>	<i>Develop the mapping table for RoA between E2B(R2) and EDQM terms</i>	<ul style="list-style-type: none"> ➤ <i>Reflect the result of the E2B request to EDQM to include E2B legacy RoA terms</i>
Dec. 2017	<i>May. 2018</i>	<i>Evaluate and develop business requirement for dynamic refresh of EDQM DF and RoA lists</i>	<ul style="list-style-type: none"> ➤ <i>Evaluate the functions of EDQM Application Programming Interface (API)</i> ➤ <i>Consider 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>
Dec. 2017	<i>May. 2018</i>	<i>Process and update Q&As</i>	<ul style="list-style-type: none"> ➤ <i>Monitor and discuss any comments received by the ICH mail box or within the regions</i> ➤ <i>Add Q&As to the document if applicable</i>
Dec. 2017	<i>May. 2018</i>	<i>Update BFC document and element mapping spreadsheet</i>	<ul style="list-style-type: none"> ➤ <i>Address discrepancies in R2-R3 conversion rules</i> ➤ <i>Update the BFC document and element mapping spreadsheet</i>

			<i>to reflect the adoption of EDQM DF and RoA terms</i>
Dec. 2017	<i>May. 2018</i>	<i>Monitor regional IDMP implementations</i>	<ul style="list-style-type: none"> ➤ <i>Monitor regional plans and activities for ISO IDMP implementation</i> ➤ <i>Assess the need for further user guidance on use of IDMP in E2B(R3) messages</i>