

# ICH E2B(R3) EWG/IWG Work Plan

## 20 July 2018

**Topic Adoption date:** *July 2013*

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**Last Face-to-Face Meeting:** *Kobe, Japan, June 2018*

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
<b>May. 2018</b>	<i>Publish the updated IG package including the User Guide for Use of EDQM Terminologies for Dosage Forms and Routes of Administration (version 1.06)</i>
<b>Jun. 2018</b>	<i>Step 4 sign-off of the revised E2B(R3) Q&amp;A document</i> <i>Endorsement of the common template of core data elements and business rules</i> <i>Finalize 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>

#### 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<b>Jul. 2018</b>	<i>Publish the updated IG package including the common template of core data elements and business rules (version 1.07) and the revised Q&amp;A document</i>
<b>Oct. 2018</b>	<i>Make a decision about the RoA term mapping between E2B(R2) and EDQM</i>
<b>Nov. 2018</b>	<i>Finalize a service level understanding (SLU) with M2 regarding the SOP to extract and post the EDQM DF and RoA terminology lists for E2B(R3) use</i>
<b>Nov. 2018</b>	<i>Update IG package as needed</i>
<b>Nov. 2018</b>	<i>Process and update Q&amp;As as needed</i>

<b>Dec. 2018</b>	<i>Plan for developing training materials for E2B(R3) adopters</i>
<b>Mar. 2019</b>	<i>Publish the DF and RoA code lists</i>
<b>Apr. 2019</b>	<i>Develop business requirement for EDQM Application Programming Interface (API) for use of E2B(R3)</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Jun. 2018</b>	<i>Jul. 2018</i>	<i>Publish the updated IG package and the revised Q&amp;A document</i>	<ul style="list-style-type: none"> <li>➤ <i>Create updated IG package</i></li> <li>➤ <i>Prepare the contents to be uploaded</i></li> <li>➤ <i>Update ESTRi E2B(R3) web page</i></li> </ul>
<b>Jul. 2018</b>	<i>Oct. 2018</i>	<i>RoA term mapping between E2B(R2) and EDQM</i>	<ul style="list-style-type: none"> <li>➤ <i>Assess the proposal from EDQM regarding the three E2B(R2) terms (Intrameningeal, Intrasynovial, Intrathoracic) by regional experts</i></li> <li>➤ <i>Make a decision on the three terms</i></li> </ul>
<b>Jul. 2018</b>	<i>Nov. 2018</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"> <li>➤ <i>Ask M2 to draft the SLU</i></li> <li>➤ <i>Review the draft SLU and provide feedback to M2</i></li> <li>➤ <i>Finalize the SLU with M2</i></li> </ul>
<b>Jul. 2018</b>	<i>Nov. 2018</i>	<i>Update IG package as needed</i>	<ul style="list-style-type: none"> <li>➤ <i>Revise documents included in the IG package</i></li> <li>➤ <i>Update the IG package if applicable</i></li> </ul>
<b>Jul. 2018</b>	<i>Nov. 2018</i>	<i>Process and update Q&amp;As as needed</i>	<ul style="list-style-type: none"> <li>➤ <i>Monitor and discuss any comments received by the ICH mail box or within the regions</i></li> <li>➤ <i>Add Q&amp;As to the document if applicable</i></li> </ul>
<b>Jul. 2018</b>	<i>Dec. 2018</i>	<i>Plan for developing training materials for E2B(R3) adopters</i>	<ul style="list-style-type: none"> <li>➤ <i>Discuss training materials based on early E2B(R3) implementers' experiences</i></li> <li>➤ <i>Identify contents to be provided</i></li> </ul>

			<p><i>to new E2B(R3) adopters</i></p> <ul style="list-style-type: none"> <li>➤ <i>Draft the plan for developing training materials</i></li> </ul>
<b><i>Jul. 2018</i></b>	<i>Apr. 2019</i>	<i>Develop business requirement for EDQM API for use of E2B(R3)</i>	<ul style="list-style-type: none"> <li>➤ <i>Evaluate the functions of EDQM API</i></li> <li>➤ <i>Consider requirements for dynamic refresh of EDQM DF and RoA term list by each party</i></li> <li>➤ <i>Gather requirements from all parties for dynamic refresh of EDQM DF and RoA term lists</i></li> </ul>