

ICH E2B(R3) EWG/IWG/Subgroup Work Plan

15 March 2017

Topic Adopted: July 2013

Last Face-to-Face Meeting: Osaka, Japan – November 2016

1. Anticipated Milestones

Completion Date	Deliverable
March 2017	Finalise plans for cross-regional pilot
June 2017	Finalise annex to the IG for use of UCUM terms with E2B(R3)
June 2017	Finalise annex to the IG for use of EDQM terms with E2B(R3)
June 2017	Update BFC document

2. Timelines

Date	Task / Activity	Details
November 2016 to March 2017	Review and finalise plans for cross-regional pilot	<ul style="list-style-type: none"> ➤ Discuss procedure, role, outcome and timeline of cross-regional pilot ➤ Update the plan and finalise
March 2017 to May 2017	Conduct cross-regional pilot	<ul style="list-style-type: none"> ➤ Create ICSR messages using regional tools ➤ Exchange ICSR messages among the regions ➤ Apply regional data validation and share ACK message
May to June 2017	Analyse results from the pilot	<ul style="list-style-type: none"> ➤ Analyse results from the pilot ➤ Address issues (if applicable)
November 2016 to June 2017	Draft annex to the IG on use of EDQM	<ul style="list-style-type: none"> ➤ Draft and review the annex on use of EDQM ➤ Confirm EDQM with maintenance process (versioning, translation, format, etc) ➤ Discuss ICH change request process with M2 ➤ Review mapping between E2B codes and EDQM terms for route of administration
November 2016 to June 2017	Submission of requests to EDQM	<ul style="list-style-type: none"> ➤ Identify the terms to be requested to EDQM for R2-R3 conversion purpose ➤ Develop definitions for the terms
April 2017 to June 2017	Draft annex to the IG on use of UCUM	<ul style="list-style-type: none"> ➤ Draft and review the annex on use of UCUM ➤ Update E2B constrained code lists for R2-R3 conversion
April 2017	Address discrepancies in the BFC document	<ul style="list-style-type: none"> ➤ Address discrepancies in R2-R3 conversion rules ➤ Update the BFC document
November 2016 to June 2017	Q&A	<ul style="list-style-type: none"> ➤ Monitor and discuss any comments received by the ICH mail box or within the regions. ➤ Add Q&As to the document if applicable.
January 2017 to February 2017	Test E2B web page	<ul style="list-style-type: none"> ➤ E2B IWG asked ICH secretariat to update E2B web page with new layout. ➤ After the web page is updated, E2B IWG test if the web page works correctly.
November 2016 to June 2017	Discuss holistic maintenance process with M2	<ul style="list-style-type: none"> ➤ Input M2 to develop ICH change request process for SDOs ➤ Provide E2B business requirements to M2 so that M2 can develop a detailed process for maintenance
November 2016 to June 2017	Monitor IDMP developments	<ul style="list-style-type: none"> ➤ Monitor ISO IDMP activities which may impact on E2B