

ICH M2 EWG Work Plan 27 March 2017

Topic Adopted: 1994

Last Face-to-Face Meeting: Jacksonville, FL, USA – December 2015

Anticipated Milestones

Completion Date	Deliverable
20 April 2017	<p>ICH Project Opportunities Proposals</p> <p>An assessment will be made of potential opportunities with significant relevance to ICH and how these might impact existing guidance and/or specifications and the current or future work of ICH. Based on this assessment, 1-2 potential (non-consensus) technological project proposals will be developed and provided for MC review and discussion.</p>
20 May 2017	<p>Evaluation of existing ICH topics for technical opportunities</p> <p>Existing ICH topics will be assessed for technical opportunities.</p> <ol style="list-style-type: none"> 1) Within each party, M2 members will talk with their topic experts around Step 1 to understand the topic and to explore potential technological issues or opportunities. 2) M2 will review EWG guidelines at Step 3 or 4 when the EWG has more fully established its thinking on the topic. M2 will identify and discuss technological opportunities or concerns with the EWGs. <p>Where technological risks or opportunities are identified for a topic, M2 will request joint meetings with the EWG to share and discuss the risk or opportunity.</p>
20 May 2017	<p>Finalized Information Paper on Redaction</p> <p>M2 identified a set of requirements for redaction and evaluated usability of electronic formats and tools within the ICH regions. The findings will be provided in this paper. This paper will be analogous to the MedDRA Points to Consider document. The document will not identify a new standard. Instead, the document will present the capabilities and constraints when redacting specific ICH recommended submission file standards such as PDF and JPEG. This document will be published on the ESTRI website where recommended submission file standards are published. It is intended to support the redaction requirements that each region has.</p>
20 May 2017	<p>Finalized PDF Specification update</p> <p>Current PDF recommendation is only on the use of specific PDF versions and agreed restrictions, but each regulator maintains separate PDF specification. M2 will investigate further harmonization of requirements and revise PDF recommendation.</p>

20 May 2017	<p>Defined Maintenance Process for External Terminologies</p> <p>A process (operating model) will be defined for handling terminology change requests and appeals to external maintenance organizations (ex: EDQM, Regenstrief).</p>
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Timelines

(note – periodic administrative activities such as SDO liaison activities are not included)

<i>Date</i>	<i>Task / Activity</i>	<i>Details</i>
ICH Project Opportunities Proposals		
15 Mar 2017	Consider potential project opportunities	<ul style="list-style-type: none"> ➤ Discuss individual party observations and proposals. Proposals may or may not be connected with an existing EWG’s work. ➤ Identify 1-2 opportunities to elaborate.
20 April 2017	Develop 1-2 proposals for MC	<ul style="list-style-type: none"> ➤ Develop (non-consensus) technological project opportunity proposals. ➤ Provide proposals to MC for review.
Montreal meeting	Present proposals to MC	<ul style="list-style-type: none"> ➤ 1-2 project opportunity proposals are presented to the MC or a MC subgroup for discussion.
Evaluation of existing ICH topics for technical opportunities		
20 Apr 2017	Evaluate new ICH topics for technical risks and opportunities – stage 1	<ul style="list-style-type: none"> ➤ M2 members in each party will talk with their topic experts in each EWG at around Step 1 to understand the topic better and to explore potential technological risks or opportunities.
30 April 2017	Discuss and confirm potential technological risks and opportunities	<ul style="list-style-type: none"> ➤ Results of discussions will be shared across M2. ➤ Potential technological risks, opportunities and questions identified by multiple parties will be documented with next steps and shared with the EWG
15 May 2017	Evaluate mature ICH topics for technical risks and opportunities – stage 2	<ul style="list-style-type: none"> ➤ All parties review Step 3-4 documents for technological risks and opportunities. This will be accomplished through M2 subgroups to support concurrent evaluations. Review results are aggregated for discussion and development of opportunity proposals.
Montreal meeting	Joint meetings with select EWGs, Develop outcome reports Present outcomes to MC	<ul style="list-style-type: none"> ➤ Where technological risks or opportunities are identified for a topic, M2 will request joint meetings with the EWG to share and discuss the risk or opportunity. ➤ Outcomes and next actions will be documented ➤ Outcomes will be presented to MC (presentation may be in paper only if no immediate actions or opportunities are identified)

Finalized Information Paper on Redaction		
20 May 2017	Finalize Information Paper on Redaction	<ul style="list-style-type: none"> ➤ All parties agree on paper scope. ➤ Final draft Information Paper on Redaction is distributed for review/agreement. ➤ This will be analogous to the MedDRA Points to Consider document. The document will not identify a new standard. Instead, the document will present the capabilities and constraints when redacting specific ICH recommended submission file standards such as PDF and JPEG. This document will be published on the ESTRI website where recommended submission file standards are published. It is intended to support the redaction requirements that all regions have.
Montreal meeting	Sign-off at Montreal meeting	
Finalized PDF Specification update		
20 Apr 2017	Update M2 PDF specification for possible ESTRI recommendation revision	<ul style="list-style-type: none"> ➤ Review existing regional PDF requirements, identify common requirements, reconcile differences & discrepancies where possible. ➤ Update M2 PDF specification based on review outcomes
Montreal meeting	Sign off and publish PDF updated recommendations	
Defined maintenance process for external terminologies		
30 April 2017	Define change request process for externally maintained vocabularies	<ul style="list-style-type: none"> ➤ Evaluate the request and concerns from E2B about change request process for EDQM Draft change request process; confirm actions and timeframes with EDQM
Montreal meeting	Joint meeting with E2B to explain and implement process; M2 Maintenance document revised	
SDO project survey		
20 Apr 2017	Draft M8 SDO project survey report	<ul style="list-style-type: none"> ➤ Draft a report on the survey results ➤ Discuss initially with M8 Rapporteur and Regulatory Chair
20 May 2017	Finalize report of M8 SDO Project survey results	<ul style="list-style-type: none"> ➤ A report of M8 SDO project survey results is finalized and confirmed by M8 ➤ Submit to the MC for information