

ICH M2 EWG Work Plan

20 July 2018

Topic Adoption date: 1994

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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
<i>Jun. 2018</i>	<i>The M2-identified Clinical electronic Structured Harmonized Protocol (CeSHarP) proposal was accepted as a new ICH topic.</i>
<i>Jun. 2018</i>	<i>The M2-identified Common Clinical Trial Submission (eCCTS) was finalized and presented to the MC and assembly. WSMI will submit it as an ICH new topic proposal.</i>
<i>Jun. 2018</i>	<i>Several new project opportunities were identified - the electronic Trial Master File was reviewed with the MC and Assembly</i>
<i>Jun. 2018</i>	<i>A new ESTR1 technical recommendation on electronic transfer of information on the Internet was finalized and will be published on the ICH website</i>
<i>May. 2018</i>	<i>Concept proposal for electronic Common Clinical Trial Submission (eCCTS) is finalized and delivered for MC review</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Oct. 2018</i>	<i>Finalize white paper on the potential of the HL7 FHIR standard for ICH initiatives</i>
<i>Dec. 2018</i>	<i>Implement ICH internal terminology list management process</i>

June 2019	<i>Finalize two recently identified project opportunities for MC and Assembly review</i>
Jun. 2019	<i>Assess ICH topics at Steps 1 and 3-4 for potential technical considerations and opportunities</i>

2. Timeline for specific tasks

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

Beginning date		Task / Activity	Details
<i>Project Opportunity Proposal</i>			
Jun. 2018	<i>Oct. 2018</i>	<i>Clarify party interest in eCCTS</i>	<i>Final consult with subject matter experts to confirm interest and concerns with eCCTS</i>
Sep. 2018	<i>Oct. 2018</i>	<i>Assess HL7 FHIR implications for ICH</i>	<i>Meet with HL7 leadership to discuss HL7 standards portfolio strategy and FHIR growth</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Develop opportunity proposals</i>	<i>Investigate identified project opportunity proposals for standardized quality data and use of FHIR.</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Evaluate new ICH topics for technical risks and opportunities – stage 1</i>	<i>Talk with topic experts in each EWG at Step 1 to explore potential technological risks or opportunities</i>
Jun. 2018	<i>Nov. 2018</i>	<i>Evaluate ICH topics for technical risks and opportunities – stage 2</i>	<i>Review Step 3-4 documents for technical risks and opportunities; Results are aggregated for discussion at next F2F meeting</i>
<i>ESTRI Recommendation</i>			
Jul. 2018	<i>Aug. 2018</i>	<i>Provide M2 web redesign support</i>	<i>Provide input to Secretariat on redesigning e-standards and ESTRI web pages presentation</i>
Apr. 2018	<i>Jul. 2018</i>	<i>Update M2 Glossary</i>	<i>Revise and publish updates to the M2 technical glossary</i>

Jun. 2018	<i>Sep. 2018</i>	<i>Update M2 web content</i>	<i>Review and revise M2 and ESTRI web content for usability and currency</i>
Supportive Activities			
Feb. 2018	<i>Aug. 2018</i>	<i>Finalize terminology list management process document</i>	<i>Incorporate final comments received into the terminology list maintenance process, including handling of any technical tools used</i>
Sep. 2018	<i>Nov. 2018</i>	<i>Implement SLU with E2B</i>	<i>Implement a jointly developed Service Level Understanding (SLU) with E2B for terminology list management.</i>
Aug. 2018	<i>Dec. 2018</i>	<i>Standard practice for technical artifacts used</i>	<i>Develop a standard practice for managing and maintaining technical artifacts used to support standards, such as EDQM controlled vocabulary extraction script for E2B(r3)</i>