

ICH M2 EWG Work Plan

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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
June 2018	<i>The M2-identified Clinical electronic Structured Harmonized Protocol (CeSHarP) proposal was accepted as a new ICH topic.</i>
June 2018	<i>The M2-identified Common Clinical Trial Submission (eCCTS) was finalized and presented to the MC and assembly. WSMI submitted it as an ICH new topic proposal</i>
Nov. 2018	<i>Met with HL7 leadership to discuss HL7 standards portfolio strategy and FHIR growth to understand implications to ICH adopted standards. Reviewed material from HL7 CTO regarding FHIR and FHIR uptake.</i>
Dec. 2018	<i>Implement ICH internal terminology list management process</i>
Dec. 2018	<i>TMF/eTMF opportunity proposal was submitted by JPMA</i>
Dec. 2018	<i>Defined and confirmed Liaison approach with ISO TC215 WG6</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
March 2019	<i>Joint meeting with M8 to discuss implications HL7 FHIR and potential paths forward for eCTD.</i>
April-May 2019	<i>Revised draft white paper on the potential impacts and benefits of the HL7 FHIR standard for ICH initiatives</i>
June 2019	<i>Face to Face working meeting with HL7 CTO on plan for ICH-adopted HL7 V3 messages potential transition to FHIR, as well as considerations for new work</i>
June 2019	<i>Present considerations to MC regarding new standards and potential future transition of existing ICH adopted HL7 v3 standards to HL7 FHIR standard.</i>
June 2019	<i>Identify project opportunity for MC and Assembly review</i>

2. Timeline for specific tasks

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

Beginning date	End date	Task / Activity	Details
<i>Project Opportunity Proposal</i>			
Oct 2018	May 2019	Assess HL7 FHIR implications for ICH	Based on knowledge gained to date from face to face interactions with HL7, available material and experiences, refine white paper on the potential impacts and benefits of HL7 FHIR for ICH implications, and draft considerations for existing and future ICH exchange standards.
Oct 2018	June 2019	Validate FHIR assumptions and recommendations	Work with HL7 CTO to validate assumptions made in the white paper, refine considerations and potential migration strategy, and address more specific questions regarding any transition.
Apr. 2018	Jun. 2019	Develop opportunity proposals	Develop a project opportunity proposal on standardized quality data for internal discussion and presentation of the concept to the MC.
May 2019	May 2019	Evaluate new ICH topics for technical risks and opportunities – stage 1	Talk with topic experts in each EWG at Step 1 to explore potential technological risks or opportunities
May 2019	June 2019	Evaluate ICH topics for technical risks and opportunities – stage 2	Review Step 3-4 documents for technical risks and opportunities; aggregate and discuss at next F2F meeting; discuss findings with EWG Rapporteurs
May 2019	June 2019	Execute working relation and discuss technical specification development with the CeSHarP EWG	Discuss working arrangements and plan for the development of a technical specification with the CeSHarP EWG

ESTRI Recommendation			
Jan 2019	<i>June 2019</i>	<i>Update M2 web content</i>	<i>Review, revise and organize M2 and ESTRI web content for usability and currency</i>
Supportive Activities			
Sep. 2018	<i>Jun. 2019</i>	<i>Implement SLU with E2B</i>	<i>Confirm jointly developed Service Level Understanding (SLU) with E2B for terminology list management. Discussion with E2B Co-Rapporteurs</i>
Aug. 2018		<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) Deferred until EMA transition is completed</i>