

ICH M2 EWG Work Plan

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Topic Adoption date: 1994

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Last Face-to-Face Meeting: Geneva, Switzerland - November 2017

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2017	<i>Pre-concept paper for Clinical electronic Structured Harmonized Protocol (CeSHarP) was proposed to the MC. (The new topic was proposed to ICH by PhRMA in Dec. 2017)</i>
Nov. 2017	<i>M2 was directed to further develop a pre-concept paper (concept proposal) for electronic Common Clinical Trial Submission (eCCTS) by the MC.</i>
Nov. 2017	<i>Terminology list management process was discussed with E2B(R3) EWG/IWG and M8 EWG/IWG and reached conceptual agreement on key points.</i>
Jan. 2018	<i>Project opportunities with technical components were proposed and discussed within M2 EWG.</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
May. 2018	<i>Concept proposal for electronic Common Clinical Trial Submission (eCCTS) is finalized and delivered for MC review</i>
May. 2018	<i>Project opportunity proposals (non-consensus) including e-Trial Master File metadata harmonization (eTMF) are delivered for MC review</i>

May. 2018	Aggregate assessment results of existing ICH topics for technical opportunities
May. 2018	Revised ESTRI recommendation on secure information exchange over the Internet is drafted
May. 2018	Revise the terminology list management process and establish Service Level Agreement (SLA) between M2 EWG and E2B(R3) EWG/IWG for terminology list maintenance

2. Timeline for specific tasks

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

Beginning date		Task / Activity	Details
Project Opportunity Proposal			
Feb. 2018	Mar. 2018	Benefit and risk analysis of eCCTS	Consult with SMEs (subject matter experts) to perform benefit and risk analysis of electronic Common Clinical Trial Submission (eCCTS).
Mar. 2018	May. 2018	Deliver concept proposal for eCCTS	Concept proposal for eCCTS is provided to the MC before the Kobe meeting.
Feb. 2018	Apr. 2018	Discuss potential opportunity proposals	Potential project opportunities are discussed for further development
Apr. 2018	May. 2018	Develop opportunity proposals for the MC review	Develop and deliver (non-consensus) project opportunity proposals including eTMF for MC review.
Feb. 2018	May. 2018	Evaluate new ICH topics for technical risks and opportunities – stage 1	Talk with topic experts in each EWG at around Step 1 to explore potential technological risks or opportunities.
Feb. 2018	May. 2018	Evaluate mature ICH topics for technical risks and opportunities – stage 2	Review Step 3-4 documents for technical risks and opportunities; Results are aggregated for discussion in Kobe.

ESTRI Recommendation			
Feb. 2018	<i>Apr. 2018</i>	<i>Draft revised ESTRI recommendation</i>	<i>Develop draft revision of ESTRI recommendation on secure information exchange over the Internet based on regulator input.</i>
Apr. 2018	<i>May. 2018</i>	<i>Near final revised ESTRI Recommendation</i>	<i>Reach consensus on revised recommendation for M2 sign off and MC/Assembly endorsement.</i>
Supportive Activities			
Feb. 2018	<i>Apr. 2018</i>	<i>Revise the terminology list management process document</i>	<i>Revise the terminology list management process document to clarify roles and responsibilities and align with ICH process.</i>
Mar. 2018	<i>May. 2018</i>	<i>Jointly develop SLA with E2B(R3) EWG/IWG</i>	<i>Jointly develop draft Service Level Agreement (SLA) with E2B(R3) EWG/IWG for terminology list management.</i>