ICH M2 EWG Work Plan
January 28, 2022

Topic Adoption date: *1994*

Rapporteur: *Ms. Mary Ann Slack - FDA, United States & Dr. Mihoko Okada - MHLW/PMDA, Japan (Co-Rapporteurs)*

Regulatory Chair: *Dr. Stephan Jaermann - Swissmedic, Switzerland*

Last Face-to-Face Meeting: *Amsterdam, the Netherlands (June 2019)*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2021	*MC presentation on Streamlined Standards Development Process submitted to the Secretariat.*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2022	*Report on the dedicated sessions on the potential to innovate regulatory process through technology*
Jun. 2022	*Assessment of a potential next step or project opportunity*
Jun. 2022	*If needed, revised recommendations to streamline ICH standards development process*

2. Timeline for specific tasks

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

Beginning date	End date	Task / Activity	Details
ESTRI Recommendation			
Dec. 2021	*Jun. 2022*	2D Bar code	Develop recommendation for 2D barcodes usage in submissions.
Project Opportunity Proposal			
(recurring activity)		*Evaluate new ICH topics concept papers for understanding – stage 1*	*Talk with topic experts in each EWG at Step 1 to explore potential technological risks or opportunities*
(recurring activity)		*Evaluate ICH topics at step 3 or 4 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*
Dec. 2021	*Jun. 2022*	*Ensure that the ICH topics evaluation is clear to EWGs*	*Work with Secretariat to ensure that the ICH topics evaluation is clear in ICH step procedure*
Supportive Activities			
Oct. 2021	*Jun. 2022*	*Develop report on the dedicated sessions on the potential to innovate regulatory process through technology*	*Summarize the multiple dedicated sessions on the potential innovations to electronic exchange, data sharing and computation that could innovate the regulatory process*
Dec. 2021	*Jun. 2022*	*If needed, revise recommendations to streamline ICH standards development process based on ICH MC input.*	*Review and Revise recommendations to streamline ICH standards development process based on the paper study and ICH MC input*
Jul. 2020	*Continuous*	*M11-M2 subgroup continues to refine the Technical Description*	*M11 and M2 subgroup continue to refine the Technical Description version 1 for Clinical electronic*

		version 1 (phase 1 derivable)	*Structured Harmonized Protocol (CeSHarP) based on M11 work progresses.*
Jan. 2020	*Continuous*	*Monitor FHIR development and maturity progress that is relevant to ICH*	*Monitor FHIR development and maturity progress that is relevant for ICH purposes with updates to the MC as significant progress occurs.*