ICH E6(R3) EWG Work Plan
September 09, 2020

Topic Adoption date: *June 2019*

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Regulatory Chair: *Dr. Fergus Sweeney* – EC, Europe

Last Face-to-Face Meeting: *Singapore, November 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2019	*Concept Paper and Business Plan Endorsement by the Management Committee*
Nov. 2019	*Expert Working Group Established*
Mar. 2020	*Approval Engagement Proposal*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Oct. 2021	*Update Concept Paper for Annex 2*
Dec. 2021	*Step 1 Sign-off of Technical Document (Principles and Objectives/Annex 1)*
Dec. 2021	*Seek MC endorsement/approval of updated Concept Paper for Annex 2*
Jan. 2022	*Step 2a/2b Endorsement of Technical Document (Principles and Objectives/Annex 1)*
Jun 2022	*Begin draft for Annex 2*
Jul. 2022	*Step 3 End of Public Consultation (Principles and Objectives/Annex 1)*
Nov. 2022	*Step 3 Sign-off of Technical Document (Principles and Objectives/Annex 1)*
Nov. 2022	*Step 4 Adoption of Technical Document (Principles and Objectives/Annex 1)*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2019	*Feb. 2020*	*Teleconference every 2 weeks*	*Develop Engagement Proposal* *Submit Engagement Proposal to MC for Approval*
Jan. 2020	*Sep. 2020*	*Teleconference every 2 weeks*	*Continue to Develop the Principles and Objectives for E6(R3)*
Oct. 2020	*Nov. 2020*	*Teleconference every 2 weeks*	*Outline the framework for Annex 1* *Begin drafting language for Annex 1*
Aug. 2020	*Nov. 2020*	*Approximately once a month*	*Begin engagement with stakeholder representatives and EMG members during guideline development to ensure that stakeholders' perspectives on and experiences with clinical trials, specifically with GCP guidelines, are considered in developing ICH-E6(R3)*
Nov. 2020	*Nov. 2020*	*Athens Virtual Meeting*	*Review the Principles and Objectives for E6(R3) and continue to develop the framework for Annex 1*