ICH E6(R3) EWG Work Plan
April 27, 2020

Topic Adoption date: *June 2019*

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Regulatory Chair: *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	*Engagement Proposal approved by the Management Committee*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Dec. 2021	*Step 1 Sign-off of Technical Document (Principles and Objectives/Annex 1)*
Dec. 2021	*Update Concept Paper for Annex 2*
Jan. 2022	*Step 2a/2b Endorsement of Technical Document (Principles and Objectives/Annex 1)*
May. 2022	*Seek MC endorsement/approval of updated Concept Paper for Annex 2*
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*
Feb. 2020	*Jun. 2020*	*Teleconference every 2 weeks*	*Written first draft of Introduction and Scope for E6(R3)*
Jan. 2020	*Apr. 2020*	*Teleconference every 2 weeks*	*Development of the list of Principles and Objectives for E6(R3)*
Apr. 2020	*June. 2020*	*Teleconference every week*	*Continue Principles development for E6(R3)*
May. 2020	*May. 2020*	*Vancouver Web-based meeting*	*Continue to Develop the Principles for E6(R3) and outline the framework for Annex 1*
July. 2020	*Nov. 2020*	*Teleconference every 2 weeks*	*Continue to Develop the Principles for E6(R3) and Annex 1*
Nov. 2020	*Nov. 2020*	*Athens ICH Meeting*	*Continue to Develop Annex 1 and outline framework for Annex 2*