

ICH E6(R3) EWG Work Plan

July 26, 2021

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	<i>Concept Paper and Business Plan Endorsement by the Management Committee</i>
Nov. 2019	<i>Expert Working Group Established</i>
Mar. 2020	<i>Approval of Stakeholder Engagement Proposal</i>
Dec. 2020	<i>Caucus Review of Draft R3 Introduction and Principles</i>
Jan-Mar. 2021	<i>Applied and consolidated input from the Caucus Review to the principles</i>
Apr. 2021	<i>Draft R3 Principles – Published on ICH Website</i>
May. 2021	<i>Organize and Conduct two E6 Spring Public Web Conference.</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jul. 2022	<i>Update Concept Paper for Annex 2</i>
Aug. 2022	<i>Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document</i>
Sep. 2022	<i>Step 1 Sign-off of Technical Document (Principles and Annex 1)</i>
Sep. 2022	<i>Seek MC endorsement/approval of updated Concept Paper for Annex 2</i>
Oct. 2022	<i>Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)</i>

Oct. 2022	<i>Step 3 Begin Public Consultation (Principles and Annex 1)</i>
Jan - Feb. 2023	<i>Based on the approved concept paper for Annex 2, outline of the content will be developed and will seek ICH MC approval if appropriate</i>
Mar. 2023	<i>Begin draft for Annex 2</i>
Apr. 2023	<i>Step 3 End of Public Consultation (Principles and Annex 1)</i>
Jul. 2023	<i>PWP Consultation Period prior to Step 3 Sign-off of Technical Document</i>
Aug. 2023	<i>Step 3 Sign-off of Technical Document (Principles and Annex 1)</i>
Aug. 2023	<i>Step 4 Adoption of Technical Document (Principles and Annex 1)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2021		<i>Teleconference every 2 weeks</i>	<i>Small EWG group will work on drafting Annex 1</i>
Jan. 2021		<i>Teleconference every 1 to 2 weeks</i>	<i>Three drafting teams are working on drafting Annex 1. The three teams are focused on data management, responsibilities, and monitoring</i>
Jan. 2021		<i>Teleconference every 2 to 4 weeks</i>	<i>EWG will review and discuss on the work of the small group for Annex 1</i>
Aug. 2020		<i>Approximately once a month</i>	<i>Continue engagement with stakeholder representatives and EWG 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)</i>
Feb. 2021	Nov. 2021	<i>Meet PWP E6(R3) PWP Group</i>	<i>Schedule meeting with the PWP group to discuss the current work and progress of E6 EWG</i>