

ICH E6(R3) EWG Work Plan

July 18, 2022

Topic Adoption date: *June 2019*

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Regulatory Chair: *Prof. Spiros Vamvakas, EC, Europe*

Last Face-to-Face Meeting: *Athens, Greece, May 2022*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2019</i>	<i>Concept Paper and Business Plan Endorsement by the Management Committee</i>
<i>Nov. 2019</i>	<i>Expert Working Group Established</i>
<i>Mar. 2020</i>	<i>Approval of Stakeholder Engagement Proposal</i>
<i>Dec. 2020</i>	<i>Caucus Review of Draft R3 Introduction and Principles</i>
<i>Jan-Mar. 2021</i>	<i>Applied and consolidated input from the Caucus Review to the principles</i>
<i>Apr. 2021</i>	<i>Draft R3 Principles – Published on ICH Website</i>
<i>May. 2021</i>	<i>Organize and conducted two E6 Spring Public Web Conference</i>
<i>Jun. 2022</i>	<i>Caucus Review of full Draft E6(R3) Annex 1</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Sep. 2022</i>	<i>Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document</i>
<i>Nov. 2022</i>	<i>Step 1 Sign-off of Technical Document (Principles and Annex 1)</i>
<i>Nov. 2022</i>	<i>Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)</i>
<i>Dec. 2022 – Jan. 2023</i>	<i>Step 3 Begin Public Consultation (Principles and Annex 1)</i>

Dec. 2022 – Jan. 2023	<i>Update Concept Paper for Annex 2</i>
Dec. 2022 – Jan. 2023	<i>Seek MC endorsement/approval of updated Concept Paper for Annex 2</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>
Jun. 2023 – Jul. 2023	<i>Step 3 End of Public Consultation (Principles and Annex 1)</i>
Jul. 2023 – Aug. 2023	<i>PWP Consultation Period prior to Step 3 Sign-off of Technical Document</i>
Oct. 2023 – Nov. 2023	<i>Step 3 Sign-off of Technical Document (Principles and Annex 1)</i>
Dec. 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
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>
Jan. 2022	Jun. 2022	<i>Teleconference every 1 or 2 days a week</i>	<i>EWG working on drafting ICH E6(R3)/Annex 1. A consensus version of the draft document was finalized by the EWG on 6/30/2022.</i>
Jul. 2022	Aug. 2022	<i>Caucus/Agency Review</i>	<i>EWG began caucus review of draft ICH E6(R3) with each individual agency.</i>
Aug. 2022	Sep. 2022	<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>

Sep. 2022		<i>Teleconference every 1 or 2 days a week</i>	<p><i>Begin review/discussion of caucus' comments for each of the sections.</i></p> <p><i>A 4-day interim E6 meeting scheduled for September 26th to September 29th in Amsterdam to continue review of caucus comments and finalize draft version of ICH E6(R3) for Step-1 sign-off and public consultation.</i></p>
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