

# ICH E6(R3) EWG Work Plan

## January 03, 2022

**Topic Adoption date:** *June 2019*

**Rapporteur:** *Dr. Khair ElZarrad – FDA, United States*

**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
<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 Conduct two E6 Spring Public Web Conference</i>

#### 1.b. Future anticipated key milestones

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

<b>Oct. 2022</b>	<i>Step 3 Begin Public Consultation (Principles and Annex 1)</i>
<b>Jan - Feb. 2023</b>	<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>
<b>Mar. 2023</b>	<i>Begin draft for Annex 2</i>
<b>Apr. 2023</b>	<i>Step 3 End of Public Consultation (Principles and Annex 1)</i>
<b>Jul. 2023</b>	<i>PWP Consultation Period prior to Step 3 Sign-off of Technical Document</i>
<b>Aug. 2023</b>	<i>Step 3 Sign-off of Technical Document (Principles and Annex 1)</i>
<b>Aug. 2023</b>	<i>Step 4 Adoption of Technical Document (Principles and Annex 1)</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Aug. 2020</b>		<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>
<b>Jan. 2022</b>		<i>Teleconference every week</i>	<i>EWG working on drafting Annex 1</i>
<b>Apr. 2022</b>	<i>May. 2022</i>	<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>