

# ICH E22 EWG Work Plan

## February 14, 2025

**Topic Adoption date:** June 2023

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**Regulatory Chair:** Dr. Robyn Bent, FDA, United States

**Last Face-to-Face Meeting:** Montreal, Canada, November 2024

### 1. Key milestones

#### 1.a. Current status of key milestones

Past completion date	Milestone
<i>Feb. 2024</i>	<i>Establishment of the E22 informal Working Group</i>
<i>Jun. 2024</i>	<i>ICH MC endorsement of E22 Concept Paper and transition to E22 Expert Working Group</i>

#### 1.b. Key Deliverables

MC commencement of work approval date	Deliverable
<i>Jun. 2024</i>	<i>Stakeholder Engagement Plan: A dedicated plan will be developed to ensure timely engagement with stakeholders outside regulatory and industry organisations (e.g. the patient community) around key milestones.</i>
<i>Jun. 2024</i>	<i>Training material: guideline implementation training material will be developed alongside the guideline</i>
<i>Jun. 2024</i>	<i>Final guideline</i>

#### 1.c. Future anticipated key milestones

Expected future completion date	Milestone
<i>May. 2025</i>	<i>Stakeholder engagement Plan</i>
<i>Sep. 2025</i>	<i>Stakeholder consultation</i>
<i>Sep. 2025</i>	<i>PWP consultation on Step 1 draft Technical Document; preparation of EWG Step 2 presentation</i>

<b>Dec. 2025</b>	<i>Step 1 sign-off</i>
<b>Dec. 2025</b>	<i>Step 2a/b endorsement</i>
<b>Apr. 2026</b>	<i>Public consultation</i>
<b>Oct. 2026</b>	<i>Training material</i>
<b>Sep. 2026</b>	<i>PWP consultation on revised version of Step 3 document; preparation of EWG Step 4 presentation</i>
<b>Dec. 2026</b>	<i>Step 3 sign-off</i>
<b>Dec. 2026</b>	<i>Step 4 adoption</i>

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b>Feb. 2025</b>	<i>Feb. 2025</i>	<i>EWG teleconference</i>	<i>EWG agreement on Draft Technical Document (v5) ahead of internal consultations</i>
<b>Feb. 2025</b>	<i>Apr. 2025</i>	<i>Internal consultations on draft Technical Document</i>	<i>EWG members to consult with respective ICH parties as appropriate on pre-final draft before Step 1 consensus</i>
<b>Mar. 2025</b>	<i>May. 2025</i>	<i>Development of Stakeholder Engagement Plan</i>	<i>A dedicated plan will be developed to ensure timely engagement with stakeholders outside regulatory and industry organisations (e.g. the patient community) around key milestones.</i>