

ICH S13 EWG Work Plan

22 July 2026

Topic Adoption Date: *November 2024*

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Last Face-to-Face Meeting *Rio de Janeiro, Brazil, June 2026*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>June 2024</i>	Establishment of the S13 Working Group
<i>November 2024</i>	ICH MC endorsement of S13 Concept Paper
<i>June 2025</i>	High-level outline of guideline
<i>June 2026</i>	Draft Technical Document
<i>June - July 2026</i>	Constituent Review

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>November 2024</i>	Endorsement of S13 Concept Paper
<i>June 2025</i>	Endorsement of the technical document outline

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
<i>October 2026</i>	<i>PWP Review and draft Technical Document submitted to Secretariat for editorial review</i>
<i>November 2026</i>	<i>Develop Step 2 Presentation</i>

November 2026	<i>Step 1 and Step 2a/b sign-off submission of Final Technical Document and Step 2 Presentation at the ICH Assembly meeting</i>
Q2 2027	<i>Initiate review of comments from public consultation</i>
Q3 2027	<i>Revised draft guideline</i>
Q3 2027	<i>Constituent Review</i>
Q4 2027	<i>PWP Review and draft Guideline submitted to Secretariat for editorial review</i>
Q4 2027	<i>Develop Step 4 Presentation</i>
Q4 2027	<i>Step 3 and Step 4 sign-off email submission of Final draft Guideline Document and Step 4 Presentation</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
June 2026	November 2026	EWG teleconferences	Implementation of comments
July 2026	November 2026	Subgroup teleconferences	Discuss how to change respective guideline section considering the comments received
June 2026	November 2026	Finalize texts	Achieving adoption of “step 1 ready draft”