

ICH E23 EWG Work Plan

03 June 2026

Topic Adoption Date: May 2025

Rapporteur/s: Patrice Verpillat, EC, Europe

Regulatory Chair: Andrew Raven, Health Canada, Canada

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

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
May, 2025	• Concept paper outline endorsement by ICH Assembly • Approval to form Expert Working Group (EWG) and Rapporteur/Regulatory Chair assigned
September, 2025	• Online Kick-off meeting of the EWG
November, 2025	• First Face-to-Face meeting of the EWG during ICH biannual meeting and start of the Technical Document drafting • Concept Paper endorsed by ICH Management Committee
June, 2026	• Second face-to-Face meeting of the EWG during the ICH biannual meeting • Agreement on the “Definitions” Section

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
May, 2025	Concept paper outline endorsed by ICH Assembly (one new ICH guideline to address 1) Common operational definitions of RWD and RWE; 2) Core list of metadata; and 3) General principles for assessment of RWD/RWE for regulatory purposes with a focus on effectiveness of medicines)

November, 2025	<i>Concept Paper endorsed by ICH Management Committee</i>
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1.3 Future Anticipated Milestones

Expected future completion date	Milestone
June, 2026 – January, 2027	<i>Work and finalisation of “General Principles” Section and then “Metadata” Section</i>
February, 2027	<i>Finalisation of “Introduction” Section and Glossary/References</i>
March, 2027	<i>Final version of Draft technical document submitted to internal parties for review</i>
March, 2027 – May, 2027	<i>Internal party review of the draft technical document</i>
May/June 2027	<i>Initiate review of comments from internal party review (face-to-face meeting)</i>
September, 2027	<i>Step 1 (Technical Document), Step 2a (Final Technical Document), and Step 2b (Draft Guideline) sign-off email submission and Step 2 (Informational Presentation)</i>
September, 2027 – February, 2028	<i>Public consultation period</i>
March 2028	<i>Initiate review of comments from public consultation</i>
March, 2028 – February, 2029	<i>Revised draft guideline including in-person review of comments (face to face meetings in 2028)</i>
March, 2029	<i>Step 3 (Draft Guideline) and Step 4 (ICH Harmonised Guideline) sign-off email submission and Step 4 (Training Presentation)</i>
November, 2029	<i>Finalise Training Material</i>

2 Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
June, 2026	<i>November, 2026</i>	<i>Drafting of Technical Document: “General Principles” and “Metadata” Sections</i>	<i>The composition of the Drafting Group has been adjusted to include alternates from regulatory and industry</i>

			<i>representatives, thereby expanding the pool of contributors.</i> <i>The Drafting Group will continue to develop the technical document content under the guidance of the full EWG which will then review, revise, and comment on the draft content.</i>
November, 2026	<i>December, 2026</i>	<i>EWG consultation on “General Principles” and “Metadata” Sections</i>	• <i>Review of “General Principles” and “Metadata” Sections by EWG;</i> • <i>Meetings with EWG to address comments</i>