

ICH E23 EWG Work Plan

12 February 2026

Topic Adoption Date: May 2025

Rapporteur/s: Dr. Patrice Verpillat, EC, Europe

Regulatory Chair: Mr. Andrew Raven, Health Canada, Canada

Last Face-to-Face Meeting: Singapore, November 2025

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
Sep, 2025	• Online Kick-off meeting of the EWG
Nov, 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

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)
Nov, 2025	Concept Paper endorsed by ICH Management Committee

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
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May, 2026	<i>Internal organisations review of pre-final draft “RWD/RWE definitions” Section</i>
Jun, 2026	<i>Draft technical document Table of Content for all sections; Final version of “RWD/RWE definitions” Section</i>
Sep, 2026	<i>Internal organisations review of pre-final draft “General assessment principles” Section</i>
Nov, 2026	<i>Final version of “General assessment principles” Section Internal organisations review of pre-final draft “Metadata” Section</i>
Feb, 2027	<i>Final version of “Metadata” Section</i>
Mar, 2027	<i>Draft technical document circulated for internal party review</i>
Sep, 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>
Sep, 2027 – Feb, 2028	<i>Step 3 public consultation period</i>
Mar, 2028	<i>Initiate review of comments from Step 3 public consultation</i>
Mar, 2028 – Feb, 2029	<i>Step 3 revised draft Guideline</i>
Mar, 2029	<i>Step 3 (Draft Guideline) and Step 4 (ICH Harmonised Guideline) sign-off email submission and Step 4 (Training Presentation)</i>
Nov, 2029	<i>Finalise Training Material</i>

2 Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Jan, 2026	<i>Jan, 2026</i>	<i>Creation of a small Drafting Group within the EWG</i>	<i>The Drafting Group will develop the technical document content under the guidance of the full EWG which will then review, revise, and comment on the draft content</i>
Feb, 2026	<i>Mar, 2026</i>	<i>Drafting of Technical Document sections</i>	<i>Development by the Drafting Group of the Section of the Technical Document on “RWD/RWE definitions”</i>
Mar, 2026	<i>Apr, 2026</i>	<i>EWG consultation on “RWD/RWE definitions” Section</i>	<i>Draft “RWD/RWE definitions” Section available for review by EWG;</i> <i>Meetings with EWG to address comments and</i>

			<i>finalise the “RWD/RWE definitions” Section before internal organisations review</i>
May, 2026	<i>May, 2026</i>	<i>Internal organisations review and start of discussion on “General Principles” Section</i>	• <i>Internal organisations review of pre-final draft “RWD/RWE definitions” Section;</i> • <i>Discussion with EWG on “General Principles” Section</i>
May, 2026	<i>Jun, 2026</i>	<i>Finalisation of Technical Document Section on “RWD/RWE definitions” based on comments from internal organisations review</i>	<i>Face to face EWG meeting in Rio de Janeiro, Brazil:</i> • <i>Consideration of comments from internal organisations review and finalisation of “RWD/RWE definitions” Section;</i> • <i>Agreement on Tables of Content (TOC) for “General principles” Section (and “core list of metadata” Section if possible);</i> • <i>Start drafting “General Principles” Section</i>