

ICH M4Q(R2) EWG Work Plan

10 July 2026

Topic Adoption Date: May 2020

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Regulatory Chair Dr. Hugo Hamel, Health Canada, Canada

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

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
May, 2020	<i>M4Q(R2) Proposal endorsement</i>
Apr, 2021	<i>M4Q(R2) outline of Concept Paper endorsement</i>
Aug, 2021	<i>M4Q(R2) Informal Working Group (IWG) established</i>
Nov, 2021	<i>M4Q(R2) IWG Concept Paper and Business Plan Endorsement</i>
Nov, 2021	<i>M4Q(R2) Expert Working Group (EWG) establishment</i>
May, 2022	<i>ICH approved Mr. Antonius Johannes (Ton) van der Stappen as Regulatory Chair</i>
May, 2022	<i>EWG agreed on high level conceptional thinking of M4Q(R2)</i>
Nov, 2022	<i>EWG agreed on definition of Overall Control Strategy, Roles and Objectives of M2 and M3, and ToC of Module 3</i>
Mar, 2023	<i>EWG agreed on the design of Module 3 and developed a detailed plan to deliver outlines of Quality Module 2 and Module 3 of M4Q(R2)</i>
Nov, 2023	<i>EWG agreed on the design of Module 2 using mock examples</i>
Mar, 2024	<i>EWG developed the first consensus draft of M4Q(R2) guideline</i>
Apr, 2024	<i>Plenary Working Party (PWP) and Stakeholder Consultation (Informal)</i> <i>ICH approved Dr. Hugo Hamel as Regulatory Chair replacing Mr. Antonius Johannes (Ton) van der Stappen</i>
Jun, 2024	<i>EWG agreed on the revised (working) definition of Core Quality Information (CQI) and the revised (working) wording in Development Summary and Justifications (DSJ) and in Module 3 sections of the technical document</i>

Nov, 2024	<i>EWG discussed and reached agreement on the second draft of M4Q(R2) guideline</i>
Dec, 2024	<i>Plenary Working Party (PWP) and Stakeholder Consultation (Formal)</i>
May, 2025	<i>Step 1 Experts Sign-off of the draft Technical Document Step 2a ICH Assembly endorsed the draft Technical Document and agreed to proceed to the next stage of regulatory consultation. Draft Technical Document available for Public Consultation.</i>
Nov, 2025	<i>M4Q(R2) Mock example was published on ICH website.</i>
Dec, 2025	<i>Mapping of M4Q(R1) to M4Q(R2) was published on ICH website.</i>
Mar, 2026	<i>Public Consultation period was completed and over 2500 comments were received.</i>
Jun, 2026	<i>EWG discussed and generally agreed on proposed revisions to sections 2.3.1, 2.3.2, 2.3.3, 2.3.5 and 2.3.6 of the draft Common Technical Document</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
Nov, 2021	<i>ICH endorsed the M4Q(R2) IWG Concept Paper and Business Plan</i>
Nov, 2025	<i>M4Q(R2) Mock Example</i>
Jan, 2026	<i>R1 to R2 Mapping</i>
Apr, 2026	<i>M4Q(R2) Q&A</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Nov, 2026	<i>Review and resolve public comments</i>
Mar, 2027	<i>PWP Engagement ahead of Step 3 Sign-off</i>
Jun, 2027	<i>Step 3 Sign-off and Step 4 Adoption of Final Guideline</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
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<i>Jun, 2026</i>	<i>Aug, 2026</i>	<i>Email communication</i>	<i>Complete review of sections 2.3.1, 2.3.2, 2.3.3, 2.3.5, 2.3.6 and share them with M16 EWG</i>
<i>Jun, 2026</i>	<i>Nov, 2026</i>	<i>Biweekly 2 h EWG meetings via teleconference + weekly subWGs meetings as needed</i>	<i>Discuss and address public comments received for sections 2.3.4, 3.2 and Glossary</i>
<i>Nov, 2026</i>	<i>Dec, 2026</i>	<i>Face-to-face meeting</i>	<i>Complete guideline revisions and discuss Q&A, and Implementation WG proposal at the ICH meeting in Prague, Czech Republic</i>