

ICH M4Q(R2) EWG Work Plan

18 February 2026

Topic Adoption Date: May 2020

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Regulatory Chair Dr. Hugo Hamel, Health Canada, Canada

Last Face-to-Face Meeting Madrid, Spain 2025

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>

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>
May, 2025	<i>Step 1 and Step 2a Sign-off of the draft Technical Document</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Mar, 2026	<i>Complete Public Consultation period</i>
Nov, 2026	<i>Review and resolve public comments</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
Feb, 2026	<i>Mar, 2026</i>	<i>Collect and triage comments from Public Consultation</i>	<i>Collect comments from Public Consultation and triage them to be addressed by subworking groups/members of the EWG</i>
Mar, 2026	<i>Mar, 2026</i>	<i>Face to face meeting</i>	<i>Discuss major comments at interim meeting</i>

<i>Apr, 2026</i>	<i>Jun, 2026</i>	<i>Biweekly 2 h EWG meetings via teleconference + weekly subWGs meetings as needed</i>	<i>Discuss and address public comments</i>
<i>Jun, 2026</i>	<i>Jun, 2026</i>	<i>Face to face meeting</i>	<i>Agree on the revisions/way forward relating to major comments at the ICH meeting in Rio de Janeiro, Brazil</i>