ICH M4Q(R2) EWG Work Plan
July 25, 2025

Topic Adoption date: *May 2020*

Rapporteur: *Dr. Lawrence Yu, FDA, United States*

Regulatory Chair: *Dr. Hugo Hamel, Health Canada, Canada*

Last Face-to-Face Meeting: *Madrid, Spain 2025*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
May 2020	*ICH endorsed the FDA M4Q(R2) Proposal*
Apr. 2021	*ICH endorsed the FDA M4Q(R2) outline of Concept Paper*
Aug. 2021	*ICH formed M4Q(R2) Informal Working Group (IWG)*
Nov. 2021	*ICH endorsed the M4Q(R2) IWG Concept Paper and Business Plan*
Nov. 2021	*ICH formed M4Q(R2) Expert Working Group (EWG) and approved Dr. Lawrence Yu as Rapporteur*
May 2022	*ICH approved Mr. Antonius Johannes (Ton) van der Stappen as Regulatory Chair*
May 2022	*EWG agreed on high level conceptional thinking of M4Q(R2)*
Nov. 2022	*EWG agreed on definition of Overall Control Strategy, Roles and Objectives of M2 and M3, and ToC of Module 3*
Mar. 2023	*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)*
Nov. 2023	*EWG agreed on the design of Module 2 using mock examples*
Mar. 2024	*EWG developed the first consensus draft of M4Q(R2) guideline*
Apr. 2024	*Plenary Working Party (PWP) and Stakeholder Consultation (Informal)* *ICH approved Dr. Hugo Hamel as Regulatory Chair replacing Mr. Antonius Johannes (Ton) van der Stappen*

Jun. 2024	*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*
Nov. 2024	*EWG discussed and reached agreement on the second draft of M4Q(R2) guideline*
Dec. 2024	*Plenary Working Party (PWP) and Stakeholder Consultation (Formal)*
May 2025	*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.*

1.b. Key Deliverables

MC Approval Date	Deliverable
Nov. 2021	*M4Q(R2) Concept Paper and Business plan*
Nov. 2021	*Developing M4Q (R2) Training Material*
Nov. 2021	*Developing M4Q (R2) Guideline*

1.c. Future anticipated key milestones

Expected future completion date	Milestone
Jan. 2026	*Complete Public Consultation period*
Nov. 2026	*Review and resolve public comments*
Jun. 2027	*Step 3 Sign-off and Step 4 Adoption of Final Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jun. 2025	***Jan. 2026***	*Public Consultation period and development of training materials initiated by the EWG*	*As part of the initial development of training materials, mapping M4Q(R1) structure versus M4Q(R2), and mock application(s) to be provided as examples to stakeholders*

Feb. 2026	*Mar. 2026*	*Collect and triage comments from Public Consultation*	*Collect comments from Public Consultation and triage them to be addressed by subworking groups/members of the EWG*
Mar. 2026	*Mar. 2026*	*Face to face meeting*	*Discuss major comments at interim meeting*
Apr. 2026	*Jun. 2026*	*Biweekly 2 h EWG meetings via teleconference + weekly subWGs meetings as needed*	*Discuss and address public comments*
Jun. 2026	*Jun. 2026*	*Face to face meeting*	*Agree on the revisions/way forward relating to major comments at the ICH meeting in Rio de Janeiro, Brazil*