

ICH M4Q(R2) EWG Work Plan

March 11, 2024

Topic Adoption date: *May 2020*

Topic Starting Date: *September 2021*

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

Regulatory Chair: *Mr. Antonius (Ton) Johannes van der Stappen, EC, Europe*

Last Face-to-Face Meeting: *Prague Meeting, October-November 2023*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
May 2020	<i>ICH endorsed the FDA M4Q(R2) Proposal</i>
Apr. 2021	<i>ICH endorsed the FDA M4Q(R2) outline of Concept Paper</i>
Aug. 2021	<i>ICH formed M4Q(R2) Informal Working Group (IWG)</i>
Nov. 2021	<i>ICH endorsed the M4Q(R2) Expert Working Group (EWG) Concept Paper and Business Plan</i>
Nov. 2021	<i>ICH formed M4Q(R2) EWG and approved Dr. Lawrence Yu as Rapporteur</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 conceptual 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>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2024	<i>Consensus EWG first draft of technical document</i>
Apr. 2024	<i>Plenary Working Party (PWP) and Stakeholder Consultation</i>
Jun. 2024	<i>ICH meeting in Fukuoka, Japan to address the comments received</i>

Nov. 2024	<i>ICH meeting in Montreal, Canada Step 1 Expert sign off</i>
Nov. 2024	<i>Step 2a Endorsement by Members of the Assembly Step 2b Endorsement by Regulatory Members of the Assembly Release for public consultation</i>
2025	<i>Public workshops on introduction of M4Q(R2) Step 2 in Asia, EU, and America</i>
Nov. 2025	<i>Review and resolve public comments</i>
Jun. 2026	<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
Mar. 2023	<i>Jan. 2024</i>	<i>Biweekly 2 h EWG meetings via teleconference + weekly SubWG meetings as needed</i>	<i>Discuss and draft each section of M4Q(R2) and reach consensus of technical document</i>
Feb 2024	<i>Mar 2024</i>	<i>Every other day 3 h EWG meetings via teleconference</i>	<i>Compile and circulate the draft technical document to the EWG for comments and discussion. Review and edit to reach consensus</i>
Mar. 2024	<i>Apr. 2024</i>	<i>PWP and Constituents Informal Consultation</i>	<i>Share draft guidance with PWP and constituents for review and comments</i>
Jun. 2024	<i>Jun. 2024</i>	<i>Face to face meeting</i>	<i>Discuss and address comments at the ICH meeting in Fukuoka, Japan</i>
Jul. 2024	<i>Aug, 2024</i>	<i>PWP and Constituents Formal Consultation</i>	<i>Consultation period prior to Step 1 sign off</i>
Sep. 2024	<i>Oct. 2024</i>	<i>Biweekly 2 h EWG meetings via teleconference + weekly</i>	<i>Discuss and address comments</i>

		<i>SubWG meetings as needed</i>	
Oct. 2024	<i>Oct. 2024</i>	<i>Face to face meeting</i>	<i>Finalize and sign off by the topic leaders of the EWG, and ICH Assembly at the Montreal, Canada meeting</i>