Dated 30 October 2025

ICH ASSEMBLY SINGAPORE MEETING

AGENDA

Tuesday 18 November and Wednesday 19 November 2025

Singapore

Opening of the ICH Assembly Meeting

Welcoming remarks from the ICH Assembly Chair Ms. Lenita Lindström (EC, Europe), and ICH Assembly Vice-Chair Dr. Gabriela Zenhäusern (Swissmedic, Switzerland).

- The Assembly is invited to note the Member Representatives and Observer Delegates appointed to the Assembly.

Adoption of the Agenda

- The Assembly is invited to **adopt** the agenda for the ICH Assembly meeting.

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1. Membership and Observership

The ICH Secretariat will inform the Assembly of any Membership and/or Observership application(s) processed by the ICH Management Committee (MC) since the Assembly Meeting in May 2025.

The Applicants for ICH Membership and/or Observership will be invited to provide a brief introduction and present their interest in joining ICH.

- The Assembly is invited to share its views and take a **decision** regarding any applications for ICH Membership and/or Observership recommended by the ICH MC;
- The Assembly is invited to note the first call organised by the ICH Secretariat with ICH Regulatory Observers in September 2025, and the planning for regular calls to be organised every six months.

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2. Financial Matters

The ICH Finance and Procurement Director will provide an update on ongoing activities of the ICH Finance Committee, which includes representation from the ICH MC and MedDRA SC, including presentation of 2026 ICH Association Budget, and 5-Year Budget Plan for 2026-2030.

In addition, the Assembly will be updated on the progress of modernisation of the ICH Secretariat operations since the last meeting, as a strategic imperative for ICH.

- The Assembly is invited to share its views on the update and provide any input requested.

- The Assembly is invited to take a **decision** to approve the 2026 ICH Association Budget, including the 2027 ICH Membership fees and 2026 MedDRA subscription fees.
- The Assembly is invited to take a **decision** to support the 5-Year Budget Plan for 2026-2030.

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3. Update on MedDRA

The MedDRA Steering Committee (SC) Vice-Chair will provide an update on current MedDRA activities.

- The Assembly is invited to share its views on the report;
- Pursuant to ICH MC's recommendation, the Assembly is invited to take a **decision** on the MedDRA Service Agreement, currently in force until 31 December 2027.

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4. General Operational Matters

ICH Operational Efficiency

The Efficiency Group leads will provide an update on current activities related to further enhancing the efficiency of ICH WG operations.

- The Assembly is invited share its views.

ICH Secretariat Report

The ICH Secretariat will provide a brief update to the Assembly on ICH general operational matters, including on current participation of ICH Members and Observers.

- The Assembly is invited to share its views on the report.

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5. Annual Work Plan and Multi-Annual Strategic Plan of the Association

The ICH MC will present to the Assembly the 2026 Work Plan and Multi-Annual Strategic Plan of the Association.

- The Assembly is invited to take a **decision** to approve the 2026 Work Plan and Multi-Annual Strategic Plan of the Association.

The MedDRA SC Vice-Chair will present to the Assembly the 2026 MedDRA SC Work Plan.

- The Assembly is invited to take a **decision** to approve the 2026 MedDRA SC Work Plan.

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6. New Topics & Strategic Discussions

2026 New Topics Process

The Leads of the ICH MC New Topics Subcommittee will provide an update on the new topics activities.

- The Assembly is invited to note that the 2026 New Topics process will be paused for 1 year per the MC decision taken in Madrid, Spain May 2025;
- The Assembly is invited to note no topics for urgent need of harmonisation were received in advance of the Singapore November 2025 meeting;
- The Assembly is invited to note that the ICH MC will consider the formal New Topic process for the 2027 cycle at the June 2026 MC meeting in Rio de Janeiro, Brazil.

7. Implementation of ICH Guidelines

General

- The Assembly is invited to note that information on the implementation status of ICH Guidelines by ICH Regulatory Members is made available on the ICH website and updated at least twice a year.

8. Training

General

Training Leads will update the Assembly on the training activities, including: considerations on a more strategic approach to developing training materials; and support provided to ICH Working Groups (WGs) developing training materials.

- The Assembly is invited to share its views on the update.

ICH Training Associates

The Secretariat will update the Assembly on the status of work regarding ICH Training Associates, to address in a strategic manner the training needs of ICH Members and Observers.

- The Assembly is invited to share its views on the update.

ICH Funding of Regulatory Training

The ICH Secretariat will update the Assembly on: the rolling process for expressions of interest from ICH Regulatory Members and Observers for training funding in 2026; and the status of trainings previously approved by the ICH Management Committee as part of process for ICH Funding of Regulatory Training.

- The Assembly is invited to share its views on the update.

9. ICH Collaboration with PIC/S

The ICH MC Chair will inform the Assembly on the status of collaboration between ICH and PIC/S, further to the establishment of a Memorandum of Understanding with PIC/S in 2023, including the use of the training funding provided by ICH to PIC/S in 2024 and plans for funding in future years.

- The Assembly is invited to share its views on the report.

10. Communication

ICH Association 10th Anniversary

- The Assembly is invited to take note of the planning underway for the ICH Association's 10th Anniversary celebration and related activities.

ICH Regional Public Meetings

- The Assembly is invited to note that Members are invited to inform the ICH Secretariat on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Singapore, for publication on the ICH website.

11. ICH Technology Task Force

The ICH MC Chair will provide the Assembly with an update on the remit of the ICH Technology Task Force (TF) which was created based on the work of the initial ICH Pharmaceutical Quality Knowledge Management System (PQKM) TF, with an objective to discuss a development of a secure platform capable of supporting document and data sharing as well as regulatory discussions and collaboration—to address emerging technology harmonisation challenges.

- The Assembly is invited to share its views on the report.

12. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) will be invited to provide an update on the status of activities related to the Q4B maintenance.

13. ICH Award

The ICH MC Chair will present the nominations for the second ICH Award for *Outstanding Contribution to ICH Harmonisation for Better Health* received by the closing of nominations on 1 June 2025, which aims to recognise individual ICH experts for their sustained leadership and outstanding contributions to ICH work.

- The Assembly is invited to take a **decision** on 2025 awardees, who will join the session virtually.

14. Election of ICH Assembly Chair and Vice Chair

The ICH Secretariat will inform the Assembly of the nominations received for the positions of Chair and Vice-Chair. Elections will be conducted in accordance with the established procedures, after which the Secretariat will announce the results of the elections for the ICH Assembly Chair and Vice-Chair.

- The Assembly is invited to note the results of the elections and the appointment of the ICH Assembly Chair and Vice Chair for a two-year term from the end of the meeting;
- In addition, the Assembly will be informed of the newly appointed ICH MC Chair and Vice-Chair.

15. WGs Meeting in Singapore

The Assembly will receive reports from the WGs and be invited to take any decisions.

15.1. E14/S7B IWG: Questions & Answers: the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Rapporteur: Dr. Leishman –PhRMA; Regulatory Chair: Dr. Johannesen –FDA, United States)

The E14/S7B IWG was re-established in March 2024.

The Rapporteur will report on the meeting of the E14/S7B IWG, including progress made on second-stage Q&As and E14/S7B IWG training materials.

- The Assembly is invited to share its views on the report.

Step 3 and 4 for the second-stage Q&As and accompanying training materials are expected by May 2026.

The E14/S7B IWG will provide a recommendation to the MC for the disbandment of the E14/S7B IWG following the completion of deliverables.

15.2. E21 EWG: Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials (Rapporteur: Dr Corinne de Vries – EC, Europe; Regulatory Chair: Dr. Sahin – FDA, United States)

Steps 1 and 2a/b for the E21 draft Guideline were reached in May 2025.

The E21 Stakeholder Engagement Plan was approved by the MC in June 2025.

Step 3 public consultation for the E21 draft Guideline concluded in October 2025, and any comments received were shared with the E21 EWG.

The Rapporteur will report on the meeting of the E21 EWG, including progress made on the review of the E21 draft Guideline public consultation comments.

- The Assembly is invited to share its views on the report.

Steps 3 and 4 for the E21 final Guideline is expected by Q4 2027- Q1 2028.

15.3. E23 EWG: Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a focus on Effectiveness of Medicines (Rapporteur: Dr. Verpillat – EC, Europe; Regulatory Chair: Mr. Raven – Health Canada, Canada)

The E23 EWG was established in August 2025.

The E23 EWG completed the E23 EWG Concept Paper in October 2025 and submitted for MC endorsement.

The Rapporteur will report on the meeting of the E23 EWG, including progress made on the development of the Concept Paper.

- The Assembly is invited to share its views on the report.

15.4. M7 Sub-Group: Risk Assessment and Control of Nitrosamine Impurities (Rapporteur: Dr. Dobo – PhRMA; Regulatory Chair: Dr. Vespa – Health Canada, Canada)

The M7 Sub-Group was established in August 2024.

The M7 Sub-Group Concept Paper was endorsed in May 2025 including the development of training material.

The Rapporteur will report on the meeting of the M7 Sub-Group, including progress made on the development of the M7 Sub-Group Addendum.

- The Assembly is invited to share its views on the report.

Steps 1 and 2a/b for the M7 Sub-Group Addendum are expected by August 2028.

Steps 3 and 4 for the M7 Sub-Group Addendum are expected by March 2030.

15.5. M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Dr. Pei – FDA, United States; Regulatory Chair: Dr. Manent– EC, Europe)

Steps 1 and 2a/b for the draft Guideline, Template, and Technical Specification were reached in September 2022.

Steps 1 and 2a/b for the updated Technical Specification were reached in February 2025 and entered a second round of Step 3 public consultation which closed in July 2025.

The Rapporteur will report on the meeting of the M11 EWG, including progress made on the M11 final Guideline, Template, and Technical Specification.

- If *Step 3* sign-off of the M11 Final Guideline, Template, and Technical Specification is reached by the Regulatory Topic Leaders of the M11 EWG, the Regulatory Members of the Assembly are invited to take a **decision** to adopt the M11 Final Guideline, Template, and Technical Specification under *Step 4*.
- The Assembly is invited to share its views on the report.

The M11 EWG continues the development of M11 Training Materials expected to be completed by May 2026.

The M11 EWG will collaborate with the M2 EWG and HL7 towards the development of the ICH Technical Implementation Guide for Fast Healthcare Interoperability Resources (FHIR) standard.

15.6. M13 EWG: Bioequivalence for Immediate-Release Solid Oral Dosage Forms (Rapporteur: Dr. Zhang – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)

Steps 3 and 4 for the ICH M13A final Guideline and M13A Q&A were reached in July 2024.

Steps 1 and 2a/b for the ICH M13B draft Guideline were reached in March 2025.

Step 3 Public consultation for the M13B draft Guideline concluded in September 2025, and any comments received were shared with the M13 EWG.

The Rapporteur will report on the meeting of the M13 EWG, including progress on the review of the M13B draft Guideline public consultation comments and the M13C Technical Document.

- The Assembly is invited to share its views on the report.

Steps 3 and 4 for the M13B final Guideline are expected by June-July 2026.

Steps 1 and 2a/b for the M13C draft Guideline are expected by June-July 2027.

Steps 3 and 4 for the M13C final Guideline are expected by October-November 2028.

15.7. M15 EWG: General Principles for Model-Informed Drug Development (Rapporteur: Dr. Karlsson – EC, Europe; Regulatory Chair: Dr. Zhu – FDA, United States)

Steps 1 and 2a/b for the ICH M15 draft Guideline were reached in November 2024.

The M15 draft Guideline was shared with the M15 EWG PWP in October 2025 ahead of Step 3 Sign-off.

The Rapporteur will report on the meeting of the M15 EWG, including progress made on the M15 final Guideline and proposed M15 EWG training materials.

- The Assembly is invited to share its views on the report.

Steps 3 and 4 for the M15 Guideline are expected by the end of 2025.

The M15 EWG will develop training materials following the completion of the M15 Guideline expected to be completed within 12 months after finalization of the M15 Guideline.

15.8. M18 EWG: Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar (Rapporteur: Dr. Yim – FDA, United States; Regulatory Chair: Mr. Tavares-Neto – ANVISA, Brazil)

The M18 EWG was established in July 2025

The Rapporteur will report on the meeting of the M18 EWG, including progress made on the development of the Concept Paper.

- The Assembly is invited to share its views on the report.

15.9. Q1 EWG: Stability Testing of Drug Substances and Drug Products (Rapporteur: Dr. Rao – FDA, United States; Regulatory Chair: Ms. Cerulia Moraes do Carmo – ANVISA, Brazil)

The Q1 EWG was established in November 2022.

Steps 1 and 2a/b for the ICH Q1 draft Guideline were reached in April 2025.

Step 3 Public consultation for the ICH Q1 draft Guideline concluded in September 2025, and any comments received were shared with the Q1 EWG.

The Rapporteur will report on the meeting of the Q1 EWG, including progress made on the review of the Q1 draft Guideline public consultation comments and training material.

- The Assembly is invited to share its views on the report.

The revised Q1 draft Guideline is expected to be shared with the Q1 EWG PWP by August 2026 ahead of Step 3 Sign-off.

Steps 3 and 4 for the Q1 final Guideline are expected to be reached by November 2026.

The Q1 training materials are expected to be completed by March 2027.

15.10. Q6(R1) EWG: Revision of Specification Guidelines (Co-Rapporteurs: Ms. Silveira Andreoli – ANVISA, Brazil / Dr. Dirat – PhRMA; Regulatory Chair: Dr. Levis– FDA, United States)

The Q6(R1) EWG was established in June 2024.

The Rapporteur will report on the meeting of the Q6(R1) EWG, including progress made on the draft Guideline.

- The Assembly is invited to share its views on the report.

Steps 1 and 2a/b for the Q6(R1) draft Guideline are expected by November 2026.

Steps 3 and 4 for the Q6(R1) final Guideline are expected to be reached by June 2028.

15.11. Q9(R1) Training Group: Training on Quality Risk Management (Rapporteur: Dr. O'Donnell – EC, Europe; Regulatory Chair: Mr. Viehmann – FDA, United States)

The Q9(R1) Training Group was formed as a pilot to revise of the Q9 Briefing Pack in June 2024 (revised pack to consist of 18 Presentations).

The Rapporteur will report on the meeting of the Q9(R1) Training Group, including progress made on the development of the Q9(R1) Training Group remaining training material.

- The Assembly is invited to share its views on the report.

The Q9(R1) Briefing Pack consisting of 18 presentations is expected to be finalised by the end of 2025.

The Q9(R1) is expected to be disbanded following the completion of the training materials.

15.12. S13 EWG: Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics (Rapporteur: Dr. Brendler-Schwaab – EC, Europe; Regulatory Chair: Dr. Hirabayashi – MHLW/PMDA, Japan)

The S13 EWG was established June 2024 and Concept Paper endorsed by the ICH MC in November 2024.

The Rapporteur will report on the meeting of the S13 EWG, including progress made on final draft for topics that will be covered in the draft Guideline.

- The Assembly is invited to share its views on the report.

Steps 1 and Step 2a/b of the S13 draft Guideline are expected by October 2026.

Steps 3 and 4 of the S13 final Guideline are expected by November 2027.

16. WGs not Meeting in Singapore

The Assembly will note the written status reports and the work plans of the groups not meeting in Singapore.

The Coordinators will raise any items requiring discussion by the Assembly.

16.1. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports (Rapporteur: Dr. Yamaguchi– MHLW/PMDA, Japan)

The E2B(R3) EWG/IWG completed the voice-over presentation of Training Module I in January 2023.

The E2B(R3) EWG/IWG completed the revised Implementation Guide, including Appendix I(G) Technical Information and Q&As and finalized Training Module II in July 2025. The completed deliverables were published in July 2025.

The E2B(R3)/E2D(R1) Information Paper, update to code 8 list, as well as the Training Module III, are expected to be completed by the end of 2025 and published on the ICH website.

16.2. E2D(R1) EWG: Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports (Rapporteur: Ms. Van Haren – EC, Europe; Regulatory Chair: Dr. Ball – FDA, United States)

Steps 3 and 4 of the E2D(R1) final Guideline were reached by September 2025.

The E2D(R1) EWG continues to develop E2D(R1) Training Materials.

The E2D(R1) Training Materials and E2B(R3)/E2D(R1) Information Paper are expected to be finalized by the end of 2025 and published on the ICH website.

The E2D(R1) EWG is expected to be disbanded following the completion of the training materials.

16.3. E6(R3) EWG & Annex 2 Sub-group: Good Clinical Practice (Rapporteur: Dr. Ayalew – FDA, United States; Regulatory Chair for E6(R3): Mr. Twomey – EC, Europe; Regulatory Chair for Annex 2: Dr. Cohet)

Steps 1 and 2a/b for the E6(R3) Annex 2 were reached by November 2024.

Steps 3 and 4 for the E6(R3) Principles and Annex 1 were reached in January 2025.

The E6(R3) Annex 2 was shared with the E6(R3) PWP by August 2025 ahead of Step 3 Sign-off.

The E6(R3) Module 1 training materials, developed in collaboration with the ICH Training Associate, were completed and published on the ICH website in September 2025.

The E6(R3) EWG continues to develop the E6(R3) Annex 2.

Steps 3 and 4 for the E6(R3) Annex 2 is expected by December 2025.

Following Step 4 sign-off the E6(R3) Annex 2 will be integrated into the E6(R3) Guideline.

The E6(R3) EWG continues the development of E6(R3) Training Materials with the ICH Training Associate support, with Modules 2–5 remaining under development expected to be completed by Q3-Q4 2025.

16.4. E11A EWG: Paediatric Extrapolation (Rapporteur: Dr. Yao – FDA, United States)

Steps 3 and 4 for the E11A final Guideline were reached in August 2024.

The E11A EWG continues work to finalize the E11A Training Materials.

The E11A EWG Training Materials are expected to be finalized by the end of 2025.

The E11A EWG is expected to be disbanded following the completion of the training materials.

16.5. E20 EWG: Adaptive Designs for Clinical Trials (Rapporteur: Dr. Levin – FDA, United States; Regulatory Chair: Dr. Roes – EC, Europe)

The E20 EWG was established in November 2019.

Steps 1 and 2a/b for the E20 draft Guideline were reached in June 2025.

The *Step 3* Public Consultation for the E20 draft Guideline is ongoing and will close in November 2025.

The revised E20 draft Guideline is expected to be shared with the E20 EWG PWP by September 2026 ahead of Step 3 Sign-off.

Steps 3 and 4 for the E20 final Guideline is expected by October 2026.

16.6. E22 EWG: General Considerations for Patient Preference Studies (Rapporteur: Dr. Pignatti – EC, Europe; Regulatory Chair: Ms. Bent – FDA, United States)

The E22 EWG was established in June 2024.

The E22 EWG Stakeholder Engagement Plan was approved in May 2025.

The draft E22 Technical Document was shared with the E22 EWG PWP by September 2025.

- The Members of the Assembly are invited to take a **decision** to endorse the E22 EWG Final Technical Document under *Step 2a/b.*

A Stakeholder Engagement Meeting is planned for February 2026.

The E22 draft Guideline is expected to be shared with the E22 PWP by September 2026 ahead of Step 3 Sign-off.

The E22 EWG Training Materials are expected to be completed by October 2026.

Steps 3 and 4 for the E22 final Guideline are expected by December 2026.

16.7. M1 PtC EWG: MedDRA Points to Consider (Rapporteur: Mr. Menke – EFPIA; Regulatory Chair: Dr. Doi – FDA, United States)

The M1 PtC WG completed the update of the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents having released language versions in English, Japanese, Chinese, Korean, Russian and Spanish, which was published on the MedDRA Website in March 2025.

The M1 PtC WG continues to work on updating the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents in English, Japanese, Chinese, Korean, Russian, and Spanish. The next release will include Brazilian Portuguese and French with the expected release in March 2026.

The M1 PtC WG continues to work on updating the Companion Document v4.0 which will include further guidance on terms related to manufacturing and quality system issues relevant to large molecules, biologics, vaccines, and drug delivery devices, as well as amendments to existing sections, expected for publication in May 2026.

16.8. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) (Co-Rapporteurs: Mr. Chen– FDA, United States / Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Dr. Jaermann – Swissmedic, Switzerland)

In May 2024, the Assembly endorsed the M2 JSON Recommendation for publication on the ICH website. The M2 EWG remain as the contact point for CDISC and CIOMS activities.

The M2 EWG AI Proof of Concept (focused on Managing Public Comments Using AI Tools) was put forward to the ICH MC in June 2025.

The M2 EWG continues its collaboration with the M11 EWG for the identification of a suitable file format for ICH M11 code lists and a joint review of the M11 Technical Implementation Guide. The M2 EWG have initiated activities with M4Q(R2) to discuss harmonisation needs regarding Structured Data Exchange, review of ICH Concept Papers for opportunities in harmonisation of data exchange and engage with other ICH WGs to identify support opportunities. The M2 EWG continue to develop the revised Streamlined SDO Engagement Process.

The M2 EWG will Explore Good Data Practices and Good AI Practices, surveying existing guidance and regulations from regulatory authorities and industry to provide recommendations to the ICH MC and update the remit of work in the M2 EWG Concept Paper.

16.9. M4Q(R2) EWG: Revision of M4Q(R1) CTD on Quality guidance (Rapporteur: Dr. Yu – FDA, United States; Regulatory Chair: Dr. Hamel – Health Canada, Canada)

The M4Q(R2) EWG reached Step 1 and Step 2a/b of the draft Guideline in May 2025.

The M4Q(R2) EWG continues their work on collection of public consultation comments and developing Training Materials.

Step 3 public consultation for the M4Q(R2) draft Guideline is expected to conclude in January 2026, and any comments received will be shared with the M4Q(R2) EWG.

Steps 3 and 4 of the M4Q(R2) final Guideline are expected in June 2027.

The M4Q(R2) Mock Dossier Examples were completed and are expected to be published on the ICH Website by the end of 2025.

16.10. M7(R3) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

Steps 3 and 4 for the M7(R2) final Guideline and Addendum were reached in April 2023 and published along with the M7(R2) Q&As which reached Step 4 in May 2022.

No proposals for revisions have been received at this time and therefore the M7(R3) Maintenance EWG remains in a dormant state.

16.11. M8 IWG/EWG: The Electronic Common Technical Document (eCTD) (Co-Rapporteurs: Mr. McCormick – FDA, United States and Ms. Puusaari – EC, Europe; Regulatory Chair: Mr Saito - MHLW/PMDA, Japan)

Steps 3 and 4 of the eCTD v.3.2.2 Q&A Document v.1.33; eCTD V3.2.2 Valid Values v6.0; eCTD v4.0 Implementation Guide v1.6 and eCTD v4.0 Controlled Vocabulary Package v1.0 were reached in May 2024.

The M8 EWG continues engagement with eCTD v4.0 vendors to discuss the implementation of eCTD v4.0 and the development of eCTD 4.0 Implementation Guide Package v1.7 and eCTD 4.0 Q&A v1.10.

Steps 3 and 4 for the eCTD v4.0 Implementation Guide Package v1.7 and eCTD 4.0 Q&A v1.10 are expected to be reached by the end of 2025.

The M8 EWG continues eCTD 4.0 evolution activities with joint collaboration with the M2 and M4Q(R2) EWG and develop recommendations for eCTD v4.0 updates to the controlled vocabulary and implementation guide to align with new requirements. The recommendations will be focused on three identified key areas: Vendor Engagement, Standardisation of Content and Shared Content Environments.

16.12. M14 EWG: General Principles on Plan, Design, Analysis and Reporting of Non-Interventional Studies that Utilize Real-World Data for Safety Assessment of Medicines (Rapporteur: Dr. Moeny – FDA, United States; Regulatory Chair: Dr. Kajiyama – MHLW/PMDA, Japan)

Steps 1 and 2a/b for the M14 draft Guideline were reached in May 2024.

Step 3 public consultation concluded in October 2024, and any comments received were shared with the M14 EWG.

Steps 3 and 4 for the M14 final Guideline were reached in August 2025.

The M14 EWG will be disbanded following the completion of the M14 Guideline.

16.13. M16 EWG: Structured Product Quality Submissions (SPQS) Guideline (Rapporteur: TBD; Regulatory Chair: TBD)

The M16 EWG Concept Paper Outline was endorsed by the ICH Assembly in October 2025.

The M16 EWG 6-week call for nominations is currently ongoing, and the M16 EWG will be established following the ICH Meeting in Singapore.

16.14. Q3C(R10) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. Froetschl – EC, Europe)

The Q3C(R10) Concept Paper for Revising PDEs for Dimethylformamide (DMF), Dichloromethane (DCM) and Ethylene glycol (EtG) and the restructuring of support document was endorsed by the ICH MC in January 2025.

The Q3C(R10) Maintenance EWG continues work on the PDE revisions for DMF, DCM and EtG and the restructured support document.

Steps 1 and 2a/b are expected to be reached by Q1 2026.

Steps 3 and 4 are expected to be reached by December 2026.

16.15. Q3E EWG: Guideline for Extractables and Leachables (Acting Rapporteur: Dr. Parris – PhRMA ; Regulatory Chair: TBD)

The Q3E EWG was established in July 2020.

Steps 1 and 2a/b for the Q3E draft Guideline were reached in August 2025.

The *Step 3* Public Consultation period for stakeholder comments for the Q3E draft Guideline is ongoing and will close in 2026. The Q3E EWG continue the development of example case studies illustrating Extractable & Leachable study conduct, assessment and control for selected therapeutic modalities.

Steps 3 and 4 for the Q3E final Guideline and completion of the Q3E Training Materials are expected by July 2027.

16.16. Q5E Annex EWG: Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process (Rapporteur: TBD; Regulatory Chair: TBD)

The ICH Assembly endorsed the topic in May 2025.

The 6-week call for nominations of experts is expected to follow the completion of CGTDG Activities.

16.17. S1B(R1) IWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. Goodwin – FDA, United States; Regulatory Chair: Dr. Siezen – EC, Europe)

The S1B(R1) transitioned to an IWG in March 2024, with a work mandate of 3 years.

The S1B(R1) IWG continues work, monitoring the implementation of the S1B(R1) Guideline and identification of recommendations such as developing best practices for submission and review of WOE documents, training materials and proposal of a Q&A document to be put forward to the ICH MC for consideration.

16.18. Cell and Gene Therapies Discussion Group (CGTDG) (Rapporteur: Dr. Francissen – BIO; Regulatory Chair: Dr. Eacho – FDA, United States)

The CGTDG was established in September 2023.

The CGTDG completed the Final Recommendation Paper summarizing a strategic roadmap and high-level principles for MC review.

The CGTDG is expected to be disbanded following completion of work.

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17. Organisation of Next Meetings

The ICH Secretariat will provide an update to the Assembly on the organisation of next ICH meetings.

The Assembly is invited to note the organisation of next ICH meetings:

- 30 May - 3 June 2026 in Rio de Janeiro, Brazil
- 14 - 18 November 2026 in Prague, Czech Republic
- 12 - 16 June 2027 in Seoul, Republic of Korea
- 13 – 17 November 2027 in Americas (location to be confirmed)

Any Other Business

- The Assembly is invited to raise any other business for discussion.

Press Release

The Assembly will be informed on the development and publication of the ICH Press Release for the meeting.