12 January 2026

FINAL MINUTES
ICH ASSEMBLY SINGAPORE MEETING
18-19 NOVEMBER 2025

Please find hereafter the final minutes of the Assembly Meeting held in Singapore on 18-19 November 2025.

List of Assembly Participants

ICH Assembly Member Representatives:

Ms. Andrea Ricchiuti	ANMAT, Argentina
Mr. Raphael Sanches Pereira	ANVISA, Brazil
Ms. Bianca Zimon	ANVISA, Brazil
Dr. Wassim Nashabeh	BIO
Dr. Derek Scholes	BIO
Mr. Christian Garnica*	COFEPRIS, Mexico
Dr. Georgios Balkamos	EC, Europe
Ms. Lenita Lindström *(Assembly Chair)*	EC, Europe
Dr. Bruno Sepodes	EC, Europe
Dr. Asmaa Fouad	EDA, Egypt
Mr. Stefan Herdinius	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin	FDA, United States
Dr. Manuel Osorio	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Dr. Elana Cherry	Health Canada, Canada
Mr. Jeffrey Skene	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Dorothy Toh	HSA, Singapore
Dr. Nicholas Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Ms. Nagham Alhourani	JFDA, Jordan
Dr. Wesal Salem Alhaqaish	JFDA, Jordan
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Ms. Hyun Ah Oh*	MFDS, Republic of Korea
Dr. Su Jin Kong	MFDS, Republic of Korea
Mr. Daisuke Koga	MHLW/PMDA, Japan
Mr. Takayuki Okubo	MHLW/PMDA, Japan
Mr. Julian Beach	MHRA, UK
Mr. Steve Hoare*	MHRA, UK
Prof. Mojisola Adeyeye	NAFDAC, Nigeria
Dr. Gongtao Lan	NMPA, China
Dr. Zhimin Yang	NMPA, China
Dr. Michelle Rohrer	PhRMA
Ms. Janet Vessotskie	PhRMA
Ms. Silverani Padayachee	SAHPRA, South Africa
Dr. Adel Alharf	SFDA, Saudi Arabia
Dr. Abdullah Alhatareshah	SFDA, Saudi Arabia
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Dr. Gabriela Zenhäusern *(Assembly Vice-Chair)*	Swissmedic, Switzerland
Ms. Mei-Chen Huang	TFDA, Chinese Taipei
Mr. Muhammed Emin Çelik	TITCK, Türkiye

* Replacement for Singapore meeting only

Mr. Ömer Hakan Şimşek	TITCK, Türkiye

ICH Management Committee Member Representatives:

Dr. Milton Bonelli	EC, Europe
Dr. Shinichi Okudaira	MHLW/PMDA, Japan

ICH MedDRA Steering Committee:

Dr. Craig Simon	Health Canada, Canada

ICH Assembly Technical Coordinators:

Dr. Kevin Cunningham	EC, Europe
Dr. Marijo Kambere**	FDA, United States
Dr. Takashi Misu	MHLW/PMDA, Japan

ICH Assembly Coordinators:

Ms. Balbiana Verazez Sampaio Oliveira	ANVISA, Brazil
Mr. Neil Ichiro Laruan	BIO
Dr. Georgios Balkamos	EC, Europe
Dr. Sondos Moshtohry	EDA, Egypt
Dr. Jyothsna Krishnan	EFPIA
Ms. Brooke DalSanto	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Ms. Shu Yi Ong	HSA, Singapore
Ms. Lidija Samardzic	IFPMA
Dr. Shinichiro Hirose	IGBA
Ms. Mariko Kato	JPMA
Ms. Mirinea Kim	MFDS, Republic of Korea
Mr. Fumiya Tamura	MHLW/PMDA, Japan
Ms. Nannan Li	NMPA, China
Ms. Amanda Roache	PhRMA
Mr. Nawaf Almotairi	SFDA, Saudi Arabia
Ms. Sarah Koechlin	Swissmedic, Switzerland
Ms. Wei-Fang Liang	TFDA, Chinese Taipei
Ms. Özlem Toprak Ikidag	TITCK, Türkiye
Dr. Luther Gwaza	WHO

ICH Assembly Standing Observer Delegates:

Ms. Ginny Beakes-Read	IFPMA
Ms. Flavia Firmino	IFPMA
Mr. Hiiti Sillo	WHO

** Virtual attendance

ICH Assembly Observer Delegates:

Prof. Nassima Ammi*	ANPP, Algeria
Dr. Heesung Kim*	APEC
Ms. Luisa Paulo	APIC
Ms. Worasuda Yoongthong	ASEAN
Dr. Celeste Aurora Sanchez Gonzalez	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Mr. Alisher Temirov	CPPS, Uzbekistan
Mr. Darwin Yacer Marcelo Feliz[1]	DIGEMAPS, Dominican Republic
Ms. Cory Montera Suyo	DIGEMID, Peru
Mr. Chang Kun Cho*	DINAVISA, Paraguay
Dr. Mariem Kadri	DPM, Tunisia
Mr. Felchism Apolnary Oisso	EAC
Dr. Petra Doerr	EDQM
Dr. Charles Preston*	Gates Foundation
Mr. Khalid Al Sudais	GHC
Ms. Ade Irma Haryani*	Indonesian FDA, Indonesia
Ms. Janeen Skutnik-Wilkinson	IPEC
Dr. Donia AlBastaki	MOH, Kuwait
Ms. Suhailah Abu Bakar*	NPRA, Malaysia
Dr. Robin Rojas-Cortés*	PANDRH
Dr. Lionel Viornery*	PIC/S
Ms. Jesusa Joyce M. Cirunay**[1]	Philippine FDA, Philippines
Mr. Yee-Fai Raphael Yeung*	PPBHK, Hong-Kong, China
Ms. Anastasia Nikitina**	Roszdravnadzor, Russia
Dr. Lilit Ghazaryan**	SCDMTE, Armenia
Ms. Pilar Hernández	SRS, El Salvador
Dr. Michael Harding*	TGA, Australia
Dr. Athiporn Doomkaew	Thai FDA, Thailand
Dr. Kevin Moore	USP

ICH Additional Participants:

Mr. Mark Abdoo	FDA, United States
Dr. Robyn Bent	FDA, United States
Dr. Yoshiyuki Hattori	JPMA
Ms. Reiko Manabe	MHLW/PMDA, Japan
Ms. Akanksha Kaushal	PhRMA
Dr. Chih-Kang Chiang	TFDA, Chinese Taipei
Ms. Mesil Aksoy	TITCK, Türkiye

* Replacement for Singapore meeting only
** Virtual attendance
[1] At the Assembly meeting under Agenda item 1, DIGEMAPS, Dominican Republic and Philippine FDA, Philippines were welcomed as new ICH Observers

ICH Secretariat:

Ms. Géraldine Lissalde-Bonnet	ICH Secretariat Secretary General
Ms. Miray Aizouki	
Ms. Lucie Archambeau	
Mr. Sivashen Cunden	
Ms. Magda Dubert	
Ms. Nikoleta Luludi	
Mr. Francis Panlilio	

TABLE OF CONTENT

ICH ASSEMBLY FINAL MINUTES

Assembly Chair: Ms. Lenita Lindström, EC, Europe

Assembly Vice-Chair: Dr. Gabriela Zenhäusern, Swissmedic Switzerland

Opening of the ICH Assembly Meeting

The ICH Assembly Meeting, held on 18 and 19 November in Singapore was chaired by Ms. Lenita Lindström (Chair – EC, Europe) and Dr. Gabriela Zenhäusern (Vice-Chair – Swissmedic, Switzerland).

The Assembly noted the Member Representatives and Observer Delegates participating in the Assembly meeting.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. Membership and Observership

The ICH Secretariat presented to the Assembly an overview of the applications for Membership and Observership processed by the ICH MC since the last ICH Assembly meeting in May 2025 and shared the ICH MC's recommendations on these applications in view of the eligibility criteria.

The applicants were invited to give a short presentation in support of their applications.

Assembly Decisions/Actions:

- The Assembly approved the following applications for Membership under Article 11.1 of the ICH Articles of Association:
  - NAFDAC, Nigeria;
  - SAHPRA, South Africa;
- The Assembly approved the following applications for Observership under Article 17.1(a) of the ICH Articles of Association:
  - DIGEMAPS, Dominican Republic;
  - Philippine FDA, Philippines.

2. Financial Matters

The Assembly was updated by ICH Finance and Procurement Director, on the work of the Finance Committee (FC), which included a report-out from the FC meeting held in Singapore on 15 November. Based on preparatory work of the zero-based 2026 Budget and the Plan 2026-2030 and the discussions within the FC, the update of the scenarios agreed in Madrid were presented to the Assembly.

Assembly Decisions/Actions:

- The Assembly approved the increase of the Strategic Reserve to remain in line with the ICH Sustainable Funding Model;
- The Assembly approved the financial contribution to PIC/S for 2025. Further financial support to PIC/S for 2026 and 2027 will be subject to MC and Assembly approval in respective years;

- The Assembly noted that the ICH membership fees for 2027 and the MedDRA subscription fee for 2026 remain unchanged;
- The Assembly was informed about planned optimisation of Secretariat costs following the review of contractual commitments, revised training strategies, and updated assumptions;
- The Assembly approved the 2026 Budget and the 2026–2030 Plan. Overall, the 2026 ICH Association Budget and the 2026–2030 Plan support a sound and balanced financial position for the organization.

ICH Modernisation

The Assembly was updated by ICH Finance and Procurement Director on recent activities related to the IT modernisation of the ICH Secretariat, initiated in 2024, leveraging on the use of modern IT tools and solutions for improved process efficiency, data security and cost optimisation.

Assembly Decision/Action:

- The Assembly noted the recent migration of the Secretariat data and emails to the cloud, use of website analytics and AI enhanced translation tools. The Assembly also took note of the plans to upgrade the global ICH platform and the ICH website redesign.

3. Update on MedDRA

The MedDRA Steering Committee (SC) Vice-Chair, acting as MedDRA SC Chair, reported to the Assembly on MedDRA activities following the MedDRA SC meeting held in Singapore on 16 and 17 November 2025. The Assembly was informed of the election of the MedDRA SC Chairs: Dr. Ana Cochino (EC, Europe), as MedDRA SC Chair and Ms. Charlotte James (MHRA, UK), as MedDRA SC Vice-Chair. The Assembly noted that MedDRA is used by over 9,000 organisations in 143 countries and available in 27 languages.

The Assembly also acknowledged the continuing efforts by the MedDRA SC to support the needs of MedDRA users, including: translation development for additional languages of the European Economic Area (EEA) in collaboration with EC, Europe and individual EU Member State Regulatory Authorities, as well as translation development for Uzbek in collaboration with CPPS, Uzbekistan; numerous MedDRA training opportunities, available to MedDRA users as part of their MedDRA subscription package, including the key launch of the MedDRA Learning Management System (LMS) in early 2025, offering structured, on-demand video courses tailored to varying levels of expertise; the continued work on targeted mappings with other terminologies such as SNOMED CT, ICD-10/11, and the International Medical Device Regulators Forum (IMDRF); the production of 110 Standardised MedDRA Queries (SMQ)sand the ongoing IT activities, including potential future use of Artificial Intelligence (AI), and the close partnership with the Uppsala Monitoring Centre.

The Assembly also noted the detection of a new trademark application in the European Union as well as the proposed response by ICH. In order to allow sufficient time to finalise the business continuity assessment which aims at ensuring continuous provision of services to the MedDRA subscribers in case of any unexpected disruptions, the SC considered it advisable to extend the contract with the current Service Provider.

Assembly Decision/Action:

- Pursuant to ICH MC's recommendation, the Assembly approved the extension of the current MedDRA Service Agreement for an additional two years.

4. General Operational Matters

ICH Operational Efficiency

ICH WG Sustainability and Pipeline Management

The ICH Efficiency Team Members presented the results and recommendations coming out of the ICH MC WG Pipeline and Sustainability Survey run between the Madrid meeting and Singapore meeting. The survey results in general captured concerns on the current WG overall timelines and the need for measures to address delays. Based on the survey results, high-level recommendations were endorsed by the ICH MC for development to improve the efficiency of guideline development.

Furthermore, key WG template documents for the ICH Concept Paper, ICH WG Work Plan Template and ICH Assembly/Management Committee Slide-based Report were revised to include sections for clarification of Guideline scope, identification of risks, key milestones and mechanisms for MC communication. The MC-approved revised templates will be in use from 2026 onward.

Assembly Decisions/Actions:

- The Assembly noted the results of the ICH WG Sustainability and Pipeline Management Survey and the high-level recommendations which will be further developed by the ICH Efficiency Team;
- The Assembly noted that the recommendations are focused on the upstream development process of the ICH Guidelines.

ICH Secretariat Report

The ICH Secretariat informed the Assembly on general operational matters and the current level of participation of ICH Members and Observers in the ICH Assembly and WGs.

Assembly Decision/Action:

- The Assembly noted as of the start of the meeting, the participation in 28 ongoing Working Groups and 2 Subgroups of 681 experts from amongst the 23 ICH Members and 41 ICH Observers.

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

The Assembly was updated by the ICH Secretariat on the 2026 Work Plan and Multi-Annual Strategic Plan of the ICH Association and by the MedDRA SC Vice-Chair on the 2026 MedDRA SC Work Plan.

Assembly Decisions/Actions:

- The Assembly approved the 2026 ICH Work Plan and Multi-Annual Strategic Plan of the Association, which will be published on the ICH website;
- The Assembly approved the 2026 MedDRA SC Work Plan, which will be published on the ICH website.

6. New Topics & Strategic Discussions

ICH New Topics Process

The Assembly was informed by the ICH MC New Topic Subcommittee Co-Leads about the status of the 2026 New Topic Process.

Assembly Decisions/Actions:

- The Assembly noted the ongoing pause for the 2026 New Topic process due to current large number of active and delayed working groups, as well as constraints in regulatory capacity;

- The Assembly noted that no urgent harmonisation needs from ICH Members/Observers were communicated to the ICH New Topic Co-Leads in advance of the Singapore November 2025 meeting;
- The Assembly noted that the formal New Topic Cycle for 2027 will be discussed for recommencement, including its format and scope, at the June 2026 meeting in Rio de Janeiro.

ICH Reflection Paper Process

The New Topic Subcommittee Co-Leads provided an update to the Assembly on ongoing discussions related to the Reflection Papers (RP) process and the development of an overall Strategic Plan. In addition, the Co-Leads presented the minor changes to the Reflection Paper process including its formal decoupling from the New Topic Process. The updates included a working definition of RPs to be incorporated into the revised SOPs to support consistency across future RP development, as well as developing a high-level Reflection Paper template and evaluation forms to gather feedback from MC and Assembly Members to improve the quality and utility of future RPs.

Assembly Decisions/Actions:

- The Assembly noted that yearly New Topic proposals not taken up should not be pivoted to Reflection Papers, unless under exceptional and justified/ICH agreed circumstances;
- The Assembly noted a working definition for Reflection Papers to be embedded in ICH SOP and procedural documents "*ICH Reflection Papers are intended to articulate ideas for potential future harmonisation work, lay out an area where harmonisation work is needed **AND** make proposals for a series of future topics for harmonisation";*
- The Assembly noted the plan to develop a high-level Reflection Paper Template as well as a Reflection Paper Evaluation Form to support consistency and structured feedback.

7. Implementation of ICH Guidelines

Implementation by ICH Regulatory Members

Assembly Decision/Action:

- The Assembly noted 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. In addition, the MC noted that an implementation survey will be launched again in 2026 to monitor progress on implementation, identify training needs and support MC Elections in 2027.

8. Training

General

The Training Co-Leads provided an update to the Assembly on recent ICH Training activities, including:

- Progress on developing the new training vision and strategy, aimed at supporting timely, globally harmonised implementation of ICH Guidelines. The strategy focuses on a lean, sustainable model, leveraging modern technology and AI tools to streamline development of training materials;

- Introduction of the optimised mission and vision: "Achieve timely global harmonised implementation of ICH Guidelines" and ensure that high-quality scientific and regulatory training is timely available and accessible to all stakeholders;
- Support provided to ICH Working Groups in creating training materials, with plans to enable earlier development during the guideline lifecycle;
- Exploration of modern tools and approaches, including phased introduction of AI-assisted solutions, to improve efficiency and sustainability of training delivery.

Assembly Decision/Action:

➢ The Assembly noted the proposed strategic direction for training, including phased implementation and technology integration, and noted that a separate plan will be developed for training on older ICH guidelines where no or very limited training materials are available.

ICH Training Associates

The Secretariat updated the Assembly on the status of work regarding ICH Training Associates (i.e. outside contractors), aimed at addressing training needs of ICH Members and Observers in a more strategic manner.

Assembly Decisions/Actions:

➢ The Assembly noted the update on ICH training activities, including that most training on the ICH Q3 Series, Q5 Series, E6(R3), E8(R1), Q8–12 Guidelines is expected to be completed by the Q1 of 2026;

➢ The Assembly noted that, in line with the new training strategy and financial considerations, certain projects initially foreseen to be carried out by Training Associates have been discontinued.

ICH Funding of Regulatory Training

The Secretariat provided an update on the status of requests approved under the 2025 ICH Funding for Regulatory Training, as part of the rolling call for applications from ICH Regulatory Members and Observers, as well as on the 2026 process.

Assembly Decisions/Actions:

➢ The Assembly noted that the funding process operates on a rolling basis, with applications reviewed at three decision points each year. The next decision time point will be at the Interim MC Meeting in March 2026***;***

  ➢ The Assembly noted two complete applications received at the third decision time point. Specifically, the Assembly noted that funding was approved for:

    - SFDA, Saudi Arabia's training programme on ICH Guidelines E14, E15, E16, E18, M13A, and Q12; and
    - CPPS, Uzbekistan's training on applying ICH-harmonised approaches to strengthen the integrity, safety and quality of clinical trials and bioequivalence studies (lCH Guidelines E5(R1), E6(R3), E8(R1), E17, E19, and M13A);

➢ The Assembly noted training requests received for 2026. It also noted that the postponed training, originally scheduled for 2024 and moved to 2025, has now been completed.

9. ICH Collaboration with PIC/S

The ICH MC Chair and PIC/S Representative provided an update on the ongoing collaboration between ICH and PIC/S, following the Memorandum of Understanding established 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 update highlighted:

- The purpose of the collaboration is to support harmonised implementation of ICH Quality Guidelines, specifically Q7, Q9, Q10, Q12, and Q13, by developing training tailored for inspectors through the PIC/S Pharmaceutical Inspectorate Academy (PIA);
- PIC/S emphasised the usefulness of continued support from ICH to ensure inspectors are trained on both existing and new ICH Guidelines, which is critical for common understanding by assessors and inspectors and for enforcement.

Assembly Decisions/Actions:

- The Assembly noted the update from the ICH MC Chair and PIC/S Representative on the collaboration between ICH and PIC/S; including on the progress on training modules covering key ICH Quality Guidelines (such as Q7, Q9, Q10, Q12, and Q13);
- The Assembly noted increased engagement with the PIA platform and encouraged Members and Observers to make use of the training resources available.

10. Communication

Assembly Decision/Action:

- The Assembly noted the launch of the ICH anniversary campaign, beginning with the creation of an official LinkedIn page, and the following objectives of the campaign:
    - Publicly mark 35 years since ICH's founding and 10 years as an Association;
    - Share ICH activities and achievements with key stakeholders and new audiences;
    - Develop new communications tools for outreach and information, including a video, plain-language explainers, and additional materials.

11. ICH Technology Task Force

The MC Chair provided an update on the work of the recently established ICH Technology Task Force (TF), which was created based on the work of the initial ICH Pharmaceutical Quality Knowledge Management (PQKM) TF. The Technology TF is being tasked to deliver an analysis of the capabilities of a secure platform needed to support document and data sharing as well as regulatory discussions and collaboration—to address emerging technology harmonisation and implementation challenges by focusing on specific use cases. This platform will future-proof ICH operations and ensure consistent application of guidelines across regions.

As per the Remit, the Technology TF will analyse platform capabilities based on use cases, identifying technical, IT, and security requirements, legal considerations, and estimated costs. Once established, the platform may also enable regulatory collaborative assessment, work-sharing, and reliance activities that are conducted and governed outside of ICH.

The Assembly was informed that the platform governance and operational oversight are out of scope of the remit of the Task Force. In addition, the proposed solution should be already commercially available

with minimal customisation, enabling secure collaboration and compliance with legal and security requirements.

Assembly Decisions/Actions:

- The Assembly noted the update and that sample use cases, if endorsed, could be further developed into detailed requirements for platform capabilities;
- The Assembly noted that as a next steps, the TF will refine use cases and analyse platform capabilities to fully support ICH mission readiness and harmonisation goals. The TF will develop a Report on the document-sharing process, technical, legal and security requirements implied by the use cases, anticipated value to the ICH community and estimated costs, with expected recommendations to be delivered in March 2026.

12. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) reported to the Assembly on the challenges encountered during the pilot phase for updating the Q4B Annexes. The PDG had originally proposed a phased approach to revising the annexes in alignment with PDG texts; however, the pilot demonstrated that the current process is no longer sustainable due to the expansion of ICH membership and the increasing number of pharmacopoeias involved.

Further discussion is planned where PDG will make a proposal a more feasible approach of demonstrating implementation of the Q4B Annexes how to operationalise this approach going forward.

Assembly Decisions/Actions:

- The Assembly noted the update from the PDG on the outcomes of the pilot phase and the challenges identified with the current process for updating the Q4B Annexes;
- The Assembly noted that further discussions are planned on a modified approach to reviewing the Q4B annexes and demonstrating implementation;
- The Assembly acknowledged the significant resource implications for both pharmacopoeias and Regulators under the existing process and supported exploring more pragmatic and sustainable approaches going forward;
- The Assembly suggested to consider the importance of ensuring that new Regulatory Members understand Q4B process and PDG operations and supported exploring mechanisms to facilitate orientation or further exchange with existing and new Members.

13. ICH Award

The ICH Secretariat presented 5 nominations recommended by the ICH MC as meeting the eligibility criteria for the 2025 ICH Award for *Outstanding Contribution to ICH Harmonisation for Better Health*. The award serves to recognise those experts who have made significant and sustained contributions through their leadership roles in developing ICH Guidelines.

Assembly Decisions/Actions:

- The Assembly awarded the 5 recommended nominees with the 2025 *Award for Outstanding Contribution to ICH Harmonisation for Better Health*, with all awardees joining the sessions virtually:
    - Dr. Johannes Blümel (EC, Europe)

- Dr. Yukio Hiyama (MHLW/PMDA, Japan)
- Dr. Masayuki Mishima (JPMA)
- Dr. Lutz Mueller (EFPIA)
- Dr. Joel Welch (FDA, United States)

➢ The Assembly noted that the names of the awardees will be published on the ICH website.

14. Election of ICH Assembly Chair and Vice Chair

Assembly Decision/Action:

➢ The Assembly elected Dr. Gabriela Zenhäusern (Swissmedic, Switzerland) as ICH Assembly Chair and Mr. Jeffrey Skene (Health Canada, Canada) as ICH Assembly Vice Chair and noted that they would serve for a two-year mandate.

15. WGs Meeting in Singapore

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 Rapporteur and Regulatory Chair reported on status and progress made during the Singapore meeting. The E14/S7B IWG is currently working on the development of a set of Q&As to align the scope of ICH E14 and S7B while addressing novel alternative methodologies for QTc assessment. In addition, the IWG is developing a decision framework regarding what tests and assays are necessary for QTc and proarrhythmic assessment again considering the novel modalities noting that E14 and S7B largely address small molecules. In Singapore the E14/S7B IWG collaborated with the S13 EWG, to address and have feedback on the oligonucleotide therapeutics modalities and adjust and finalize the 4 Q&As.

Assembly Decisions/Actions:

➢ The Assembly noted the E14/S7B IWG is expected to complete all deliverables and submit the 4 Q&As for *Step 4* adoption by May-June 2026 and finalize the decision framework;

➢ The Assembly noted that the E14/S7B IWG are creating the Q&As with the flexibility for industry product development and efforts such as reducing reliance on individual animal studies and cost-efficiency.

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)

The E21 EWG Rapporteur and Regulatory Chair reported on progress made during the Singapore meeting, including the group's review of public consultation comments on the *Step 2b* draft Guideline. The E21 EWG discussed several major topics requiring clarification in the next draft, including the use of diversity, equity and inclusion language; planning for the inclusion of pregnant and breastfeeding individuals early in the product development plan; non-clinical considerations; ethics-related revisions; updates to breastfeeding and lactation study guidance; and the use of Physiologically based pharmacokinetic (PBPK) modelling, including non-clinical aspects. Further discussions addressed how

and whether to reference Real World Evidence (RWE) in the E21 Guideline, differentiation of pregnancy trimesters, the duration and nature of neonatal and infant follow-up, treatment considerations for foetal benefit, and statistical aspects.

Assembly Decisions/Actions:

- The Assembly noted the update on progress made by the E21 EWG, including ongoing review of public consultation comments;
- The Assembly suggested that the E21 EWG further develop its stakeholder engagement and training strategy, including identifying priority stakeholder groups and aligning training materials with expected implementation challenges;
- The Assembly noted the E21 EWG's planned engagement with E23 on RWE aspects and with M15 on PBPK modelling and acknowledged the need for pregnancy-specific PBPK expertise;
- The Assembly noted that finalization of training materials and *Step 3* and *Step 4* Sign-off are planned for November 2027.
- The Assembly noted the E21 EWG's request to meet for 4-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

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 Rapporteur and Regulatory Chair reported on progress made during the Singapore meeting. The final Concept Paper was endorsed by the ICH MC (12 November 2025). The E23 EWG began planning development of the Technical Document, and discussed the proposed structure and initial text. Subgroups were created to draft the first two sections on the introduction and definitions, including Real World Data (RWD)/RWE definitions, data types and collection methods, and contexts of use.

Assembly Decisions/Actions:

- The Assembly suggested continued alignment with M14, noting the need to consider how definitions used in M14 relate to the definitions being developed under E23;
- The Assembly suggested the E23 EWG to work efficiently by using small drafting groups to prepare text between plenary calls and by bringing subgroup proposals back to the full EWG for review;
- The Assembly discussed coordination with E21 EWG and advised that E23 EWG prioritize development of its own guideline, limit interactions with the E21 EWG to targeted exchanges that do not delay either group, or consider using a small sounding-board approach rather than deeper integration at this stage;
- The Assembly noted that the E23 EWG will not request to meet in Rio de Janeiro; however, the group was advised to reconsider this, as the first 12 months will be critical for progressing the Technical Document and a face-to-face meeting may be integral to maintaining momentum.

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 Rapporteur and Regulatory Chair reported on status and progress made during the Singapore meeting. Nitrosamines are captured in the cohort of concern in the M7(R2) Guideline, there is very limited guidance regarding nitrosamine impurities. The addendum to the M7(R2) Guideline will specifically address the safety assessment and control of nitrosamine impurities, including specific compound monographs for cases where there is sufficient data to establish a compound specific limit. To complete the work within the agreed 4-year timeframe the M7 Sub-group established 4 internal sub-teams:

- Team 1 is focused on quality attributes of the guideline.
- Team 2 is focused on the Ames test, and the use of weight of evidence approaches for helping support the safety assessment.
- Team 3 is focused on the carcinogenic potency categorization approach, establishing a framework for acceptable intakes based on a structure of the nitrosamines and monograph generation.
- Team 4 is responsible for developing a framework for applying less than lifetime adjustments to acceptable intakes in addition to looking at the use of *in vivo* mutation data to support quantitative assessment.

Assembly Decisions/Actions:

- The Assembly noted the M7 Sub-Group will reach *Steps 1 and 2a/b* Sign-off by June-August 2028;
- The Assembly noted *Steps 3* and *4* Sign-off are anticipated in March 2030;
- The Assembly noted the M7 Sub-Group's request to meet for 4-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026 noting that M7 Sub-Group will not be discussing quality topics in June of 2026. It is anticipated that the work on quality topics will begin between June and December of 2026.

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

The M11 Rapporteur and Regulatory Chair reported on status and progress made during the Singapore meeting. The M11 has developed 3 deliverables – a high level M11 Guideline, which provides background on why a harmonised clinical protocol template is needed, and describes design principles on how the template and technical specification were developed, a M11 Template which includes identification of headers, common text, instructions, data fields and terminologies for the protocol and a M11 technical specification which serves as a technical representation of the M11 protocol template to support the exchange of protocol information. The M11 EWG completed all preparation for planned training modules for M11 EWG and collaborated with M2 EWG on the development of FHIR (HL7 Fast Healthcare Interoperability Resources) Technical Implementation Guide (TIG) which is to be posted on the ICH website under ESTRI recommendation in May 2026. Furthermore, the M11 EWG discussed the maintenance of the controlled terminology and options for change control process with the M2 EWG and plan to discuss future stakeholder engagement to support implementation of M11 and the supporting documents.

Assembly Decisions/Actions:

- The Regulatory Members of the Assembly adopted the M11 Guideline, M11 Template and the M11 technical specification under ICH *Step 4* which now enters *Step 5* implementation;

- The Assembly noted the M11 EWG are expected to complete work on the FHIR TIG and M11 Training Materials in May 2026;
- The Assembly noted the M11 EWG will consider the need for stakeholder engagement to promote the use of the M11 template, as well as to inform stakeholders, including ethics committees, on how to implement the digital protocol and use the controlled terminology, to ensure consistency and organization of the information that is currently provided in the template;
- The Assembly requested the M11 EWG will propose a suitable mechanism for maintenance of the controlled terminology to the ICH MC.

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

The M13 EWG Rapporteur and Regulatory Chair updated the Assembly on the development of guidelines M13A, M13B, and M13C. M13A which covers the general principles of the BE study design of the data analysis to support the outcomes assessment for oral, immediate, solid dosage points has reached *Step 5*, M13B covers the additional strength biowaiver and has recently concluded *Step 3* public consultation with 670 comments received and M13C which covers Data analysis and BE for narrow therapeutic index, highly variable drugs and other complex BE study designs is in *Step 1* as the M13 EWG continue to develop the M13C technical document. During the meeting the M13 EWG discussed the remaining comments from public consultation and the potential need for possible M13B Q&A or M13B training material (addressing regional-relevant implementation).

Assembly Decisions/Actions:

- The Assembly noted the Work Plan for the M13 EWG, noting that the final M13B Guideline is expected to reach *Steps 3* and *4* in June 2026;
- The Assembly noted the Work Plan for the M13 EWG, noting that the M13C Technical Document is expected to reach *Steps 1* and *2a/b* in June 2027, dependent on finalisation of M13B;
- The Assembly noted M13 EWG requests MC approval to develop the M13B Q&A document to be developed in parallel with finalising M13B Guideline;
- The Assembly noted M13 EWG's consideration to develop the M13B training materials, noting specific comments received might be best addressed in Training Material not in the Q&A;
- The Assembly noted the M13 EWG request to meet for 5-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

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

The M15 EWG Rapporteur and Regulatory Chair reported on progress made during the Singapore meeting. The main focus of the face-to-face discussions was achieving a *Step 3* sign-off-ready version of the Guideline, following review of regulatory party feedback on the revised draft. The M15 EWG also initiated planning for the development of training materials, including a general training module on the Guideline and case-based examples to be delivered over a one-year period, in line with the MC's previously endorsed 12-month extension for training material development.

Assembly Decisions/Actions:

- The Assembly noted the update on progress made by the M15 EWG, including completion of a *Step 3* sign-off-ready version of the guideline and initiation of the *Step 3* sign-off process;

- The Assembly noted the *Step 3* and *Step 4* Sign-offs are planned for December 2025.
- The Assembly noted the M15 EWG's plans for developing training materials, including a general training module and case-based examples;
- The Assembly proposed that the M15 EWG take into account the Points to Consider Document that will be produced by Q9(R1) to feed into creating their training material and training strategy;
- The Assembly requested that the M15 EWG should review the MIDD roadmap to determine which topics could be addressed with case studies as part of the training materials and topics that may need a traditional ICH deliverable (Annex, Q&A, Guideline etc.).

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

The M18 EWG Rapporteur and Regulatory Chair reported on status of work and the progress made during the Singapore meeting. M18 is a new ICH Guideline which will focus on Comparative Efficacy Studies (CES) that are conducted by default in biosimilar development, but CES are expensive, take multiple years, and place a resource burden on development. Given modern analytical technology and negligible differences in efficacy, CES are increasingly viewed as no longer scientifically necessary. Following the submission of the Concept Paper to the MC, the M18 EWG further discussed the work strategy for guideline development and began productive discussions on M18 Guideline content and organization.

Assembly Decisions/Actions:

- The Assembly noted the M18 Concept Paper has been submitted to the MC for approval at the Singapore meeting;
- The Assembly noted a detailed Work Plan will be submitted following the MC approval of the Concept Paper;
- The Assembly noted the M18 EWG request to meet for 4-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

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 Rapporteur and Regulatory Chair reported on status of work and the progress made during the Singapore meeting. The Q1 EWG are revising and consolidating the ICH Stability Guideline Series Q1A-F and Q5C to streamline the Guideline series into a single Guideline focused on core stability principles promoting a harmonised interpretation by addressing potential gaps and areas of ambiguity while addressing additional technical issues. Following *Step 3* public consultation which closed in August 2025, 3447 comments were received and prior to the meeting in Singapore triaged into by priority with 608 comments considered as "Major" related to conceptual aspects of the Q1 draft Guideline, 2138 comments as "Standard" mainly related clarification or value consistency between draft Guideline sections and 701 comments as "Minor" regarding editorial and syntax issues of the Q1 draft Guideline. During the public consultation period the Q1 EWG begun developing the training material regarding how each of the modules be structured and the content per module. During the meeting the Q1 EWG progressed on comment resolution. Alignment was reached on 4 key topics:

- Naturally occurring substances regulated as drug products, radiopharmaceuticals, combination products;
- Terminology and scope of drug device combination products, radiopharmaceuticals with the Q6(R1) EWG;
- Clarifications on retesting for biological drug substance;
- Data expectations for production/primary batches for biologics.

Assembly Decisions/Actions:

- The Assembly noted the Q1 EWG plan to submit the revised draft Q1 Guideline to the Q1 PWP and internal clearance in August 2026;
- The Assembly noted the Q1 draft Guideline on track to reach *Steps 3* and *4* Sign-off in November 2026;
- The Assembly noted the Q1 training materials are expected to be completed in June 2027 - 1 month later than previously expected due to the volume of comments received;

  The Assembly noted the Q1 EWG request to meet at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

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 Co-Rapporteurs and Regulatory Chair reported on progress made during the Singapore meeting. The EWG identified no critical issues following its draft review and focused on addressing comments and improving the content. The overall structure of the document was refined, including restructuring of the biologics and chemicals sections to improve readability and flow. The group aligned on incorporating product-specific concepts and ensuring consistent terminology across the draft. Progress was also made on enhanced and traditional approaches, including consistent use of batch data, defining starting points for specification development, selecting relevant attributes, describing batches used to set acceptance criteria, and agreeing on Real Time Release Testing (RTRT) content. Additional discussions advanced biologics-specific topics on Critical Quality Attributes (CQAs), terminology, desired/target product, and annexes for vaccines and Advanced Therapy Medicinal Products (ATMPs) and chemicals-specific topics. The Q6(R1) EWG also interacted with the S13 EWG on oligonucleotide impurity considerations and with the Q1 EWG on drug–device combination terminology, pharmacopeial stability requirements, and scope-related topics such as the inclusion of herbal or naturally occurring substances regulated as drugs in the ICH Q1 guideline.

Assembly Decisions/Actions:

- The Assembly noted that the ICH MC approved an extension of the *Step 1* sign-off deadline from June 2026 to November 2026;
- The Assembly noted the *Step 3* and *Step 4* Sign-off are planned for June 2028;
- The Assembly noted the Q6(R1) EWG's request to meet for 5-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

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 (TG) Rapporteur and Regulatory Chair provided a report to the Assembly on the status of work and on progress made during the Singapore meeting. The Q9(R1) TG was convened in 2024 as a pilot working group operating with a smaller expert number. The Q9(R1) TG were tasked with updating the old training materials in the published Q9 Briefing Pack and reviewing training material developed by the ICH Training Associate. Regarding the progress made during the meeting, the Q9(R1) TG completed work on 21 of 24 presentations prior to meeting, the Q9(R1) TG progressed on work of the final 3 presentations and review of ICH Training Associate material with the expectation that all work will be completed and submitted to the ICH Secretariat for publication by the end of December 2025, following which the Q9(R1) TG will be disbanded. However, dependent on need the experts may be in position to review ICH Training Associate material after disbandment if needed.

Assembly Decisions/Actions:

- The Assembly noted the Q9(R1) TG is expected to complete activities on the Q9 briefing pack in December 2025 and provide written feedback to the MC as to inform formation of future TGs;
- The Assembly noted that an identified gap for training materials developed by WGs is organization in terms of access sequencing by stakeholders which should be addressed to aid implementation;
- The Q9(R1) TG also identified that while the older materials provided a roadmap for updating that ultimately, a full redraft of the materials should be considered by other TGs noting only 20% of the old materials was actually utilized in view of the Q9(R1) Guideline;
- The Assembly requested the Q9(R1) TG consider how best to handle the life cycle management of the materials and include any thoughts in their points to consider before the close out of the Q9(R1) TG.

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 Rapporteur and Regulatory Chair updated the Assembly on progress made during the Singapore S13 EWG meeting. Key discussions included Oligonucleotides-Based Therapeutics (ONT)-dedicated topics developed by subgroups, ONT-related QTc/cardiac safety aspects in a joint session with the E14/S7B IWG, and initial consideration of ONT-related impurities in a short exchange with the Q6 EWG. The EWG held several dedicated work sessions to review draft texts on defining "well-characterized" ONTs, refining the Scope section, and comparing sub-chronic versus chronic safety data to inform species number and selection for well-characterized ONTs in chronic studies. Further discussions addressed testing strategies for surrogates, general toxicity, carcinogenicity, reproductive toxicity, and impurities.

Assembly Decisions/Actions:

- The Assembly suggested to consider options for sharing of potentially confidential carcinogenicity, reproductive toxicity, and impurity data for oligonucleotides within the EWG.
- The Assembly noted the Work Plan and expected future key milestones, with the most immediate being the PWP Consultation expected in July 2026, followed by the *Step 1* and *Step 2a/2b* sign-off planned for October 2026;
- The Assembly noted the *Step 3* and *Step 4* Sign-off are planned for November 2027.

- The Assembly noted the S13 EWG's request to meet for 5-days at the next ICH face-to-face meeting in Rio de Janeiro in June 2026.

16. WGs not Meeting in Singapore

Section 16 provides written reports on the status of work for WGs not meeting at the Biannual meeting and any decision the Assembly may have taken on the EWG deliverables which are listed below:

- The Members of the Assembly and Regulatory Members of the Assembly endorsed the E22 (Item 16.6) Final Technical Document under *Step 2a/b.*

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) 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 and 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.

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.

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

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)

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 are 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 E22 EWG is creating a video for public consultation engagement to be shared with the MC for approval.

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.

Assembly Decisions/Actions:

- The Members of the Assembly endorsed the E22 EWG Final Technical Document under *Step 2a* and the Regulatory Members of the Assembly endorsed the Final Technical Document at *Step 2b.*

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)

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 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)

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 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 and mandated work.

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) 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)

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 call for nominations of experts is expected following the ICH Meeting in Singapore.

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

The CGTDG will be disbanded noting completion of work mandated.

15. Organisation of Next Meetings

The Assembly was updated by the ICH Secretariat on the organisation of next ICH biannual meetings.

Assembly Decision/Action:

- The Assembly noted the dates and locations of the next ICH meetings as per the below:
    - 30 May - 3 June 2026 in Rio de Janeiro, Brazil
    - 14 – 18 November 2026 in Prague, Czech Republic
    - 12 - 16 June 2027 in Seoul, South Korea
    - 13 – 17 November 2027 in Americas (location to be confirmed)

16. Press Release

Assembly Decision/Action:

- The Assembly noted the development of a Press Release to be issued shortly after the close of the meeting in line with the usual process, with the aim being to publish on the ICH website within a week of the end of the meeting.