10 December 2024

FINAL MINUTES
ICH ASSEMBLY MONTREAL MEETING
5-6 NOVEMBER 2024

Please find hereafter the final minutes of the Assembly Meeting held in Montreal, Canada on 5-6 November 2024.

List of Assembly Participants

Chair: Ms. Lenita Lindström

Vice-Chair: Dr. Gabriela Zenhäusern

ICH Assembly Member Representatives:

Ms. Andrea Ricchiuti	ANMAT, Argentina
Mr. Nélio Cezar De Aquino	ANVISA, Brazil
Ms. Bianca Zimon	ANVISA, Brazil
Dr. Wassim Nashabeh	BIO
Dr. Derek Scholes	BIO
Ms. Miriam Jackeline Loera Rosales	COFEPRIS, Mexico
Dr. Georgios Balkamos	EC, Europe
Dr. Bruno Sepodes	EC, Europe
Ms. Asmaa Fouad	EDA, Egypt
Mr. Raun Kupiec	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Michelle Limoli	FDA, United States
Dr. Theresa Mullin	FDA, United States
Dr. Léo Bouthillier	Health Canada, Canada
Mr. Jeffrey Skene	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Ms. Enas Hijjih*	JFDA, Jordan
Dr. Manabu Yanagisawa	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Su Jin Kong	MFDS, Republic of Korea
Ms. Hyunah Oh*	MFDS, Republic of Korea
Mr. Daisuke Koga	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Ms. Lisa Fraser*	MHRA, UK
Ms. Charlotte James*	MHRA, UK
Mr. Siyuan Zhou	NMPA, China
Dr. Michelle Rohrer	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Adel Alharf	SFDA, Saudi Arabia
Dr. Abdullah Hamad Al Hatareshah	SFDA, Saudi Arabia
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Ms. Mei-Chen Huang	TFDA, Chinese Taipei
Ms. Elif Inci Ergonul	TITCK, Türkiye
Ms. Fikriye Handan Öztunca	TITCK, Türkiye

ICH Management Committee Member Representatives:

Mr. Andrew Kish	FDA, United States
Dr. Shinichi Okudaira	MHLW/PMDA, Japan

* Replacement for Montreal meeting only

ICH MedDRA Management 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
Ms. Mara Hatziri Ramirez Sanchez*	COFEPRIS, Mexico
Dr. Georgios Balkamos	EC, Europe
Dr. Sondos Moshtohry**	EDA, Egypt
Dr. Jyothsna Krishnan	EFPIA
Ms. Jill Adleberg	FDA, United States
Mr. Ulfur Jonsson**	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Ms. Lidija Samardzic	IFPMA
Dr. Shinichiro Hirose	IGBA
Ms. Mariko Kato	JPMA
Ms. Mi Ri Nea Kim	MFDS, Republic of Korea
Ms. Yasuko Inokuma	MHLW/PMDA, Japan
Dr. Yu Bai	NMPA, China
Ms. Amanda Roache	PhRMA
Mr. Nawaf Almutairi*	SFDA, Saudi Arabia
Ms. Sarah Koechlin	Swissmedic, Switzerland
Ms. Yi Ju Lin	TFDA, Chinese Taipei
Ms. Elif Inci Ergonul	TITCK, Türkiye
Ms. Marion Laumonier	WHO

ICH Assembly Standing Observer Delegates:

Ms. Flavia Firmino	IFPMA
Ms. Angelika Joos	IFPMA
Dr. Samvel Azatyan	WHO

* Replacement for Montreal meeting only
** Virtual attendance

ICH Assembly Observer Delegates:

Dr. Ouatfa Benayad Cherif* **[4]	ANPP, Algeria
Ms. Reiko Manabe*	APEC
Ms. Worasuda Yoongthong	ASEAN
Dr. Celest Sánchez González**	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Ms. Rachel Shimonovitz**	CPED, Israel
Mr. Alisher Temirov[1]	CPPS, Uzbekistan
Dr. Cory Montero Suyo[1]	DIGEMID, Peru
Prof. Abderrazek Hedhili**	DPM, Tunisia
Dr. Petra Doerr	EDQM
Ms. Janeen Skutnik-Wilkinson	IPEC
Prof. Christianah Mojisola Adeyeye	NAFDAC, Nigeria
Ms. Suhaila Abu Bakar*	NPRA, Malaysia
Mr. Edgard Robin Rojas-Cortés	PANDRH
Ms. Fabienne Bochaton* **	PIC/S
Mr. Frank Ling-Fung Chan	PPBHK, Hong-Kong, China
Ms. Anastasia Nikitina**	Roszdravnadzor, Russia
Ms. Silverani Padayachee	SAHPRA, South Africa
Dr. Tharnkamol Chanprapaph*[1]	Thai FDA, Thailand
Dr. Kevin Moore	USP

ICH Additional Participants:

Dr. Milton Bonelli	EC, Europe
Ms. Miyako Okayama	JPMA
Ms. Nannan Li	NMPA, China
Ms. Akanksha Kaushal	PhRMA

Invited Participants:

Ms. Pamela Aung-Thin	Health Canada, Canada

ICH Secretariat:

Ms. Lucie Archambeau
Mr. Sivashen Cunden
Ms. Nikoleta Luludi
Ms. Anca-Elena Matei
Mr. Francis Panlilio

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* Replacement for Montreal meeting only
** Virtual attendance
[1] At the Assembly meeting under Agenda item 1, CPPS, Uzbekistan, DIGEMID, Peru and Thai FDA, Thailand were welcomed as new ICH Observers

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 5 and 6 November in Montreal, Canada was chaired by Ms. Lenita Lindström (Chair – EC, Europe) and Dr. Gabriela Zenhäusern (Vice-Chair – Swissmedic, Switzerland).

Ms. Pamela Aung-Thin (Assistant Deputy Minister, Health Products and Food Branch, Health Canada, Canada) delivered opening remarks at the beginning of the meeting.

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 Observership processed by the ICH MC since the last ICH Assembly meeting in June 2024 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 to introduce their organisation.

Assembly Decision/Action:

- The Assembly approved the following applications for Observership under Article 17.1(a) of the ICH Articles of Association:
  - CPPS, Uzbekistan;
  - DIGEMID, Peru;
  - Thai FDA, Thailand.

2. Procedural Matters

The Assembly Chair and the ICH Secretariat presented to the Assembly amendments proposed for its approval to the ICH Articles of Association and the Assembly Rules of Procedure (RoP), and updates approved by the ICH MC to the ICH MC RoP, related to the: (1) Proposal for adding a new article on confidentiality of information with related revision to the Assembly and MC RoPs accordingly; (2) Clarification on the meeting participation criterion towards Membership / MC Election application; and (3) Clarification of the term "implemented" in Annex 1: Definitions of terms in the context of the implementation of ICH Guidelines.

Assembly Decisions/Actions:

- The Assembly noted the proposed changes to the ICH Articles of Association v.5.0 and approved the ICH Articles of Association v.6.0, which will be published on the ICH website;

- The Assembly noted the proposed changes to the ICH Assembly Rules of Procedure (RoP) v.14.0, and approved the ICH Assembly Rules of Procedure v.15.0, which will be published on the ICH website;
- The Assembly noted the changes to the ICH MC RoP v14.0 and that the MC approved the ICH MC RoP v.15.0 at its meeting in Montreal, which will be published on the ICH website.

3. Update on MedDRA

The MedDRA MC Chair reported to the Assembly on MedDRA activities further to the MedDRA MC meeting held in Montreal on 3 and 4 November 2024. The Assembly was informed that MedDRA is now used by over 7,800 organisations in 139 countries. The Assembly noted the continuing efforts by the MedDRA MC to ensure support of the needs of MedDRA users, including: ongoing translation development for new languages of the European Economic Area (EEA) in collaboration with EC, Europe and individual Member State Regulatory Authorities with the recent releases of Croatian, Lithuanian and Icelandic, making MedDRA available in 24 languages; numerous MedDRA training opportunities, available to MedDRA users as part of their MedDRA subscription package; the continuation of 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 SMQs (Standardised MedDRA Queries); and the ongoing IT activities including potential future use of Artificial Intelligence (AI) / Machine Learning (ML).

The Assembly received updates on the status of work on the MedDRA Business Continuity Assessment in the face of various scenarios to ensure the high level of functionality which MedDRA users have come to expect.

Additionally, the Assembly was updated on the 2025 budget and subscription fees, as well as the 2025 MedDRA MC Work Plan (see items #4 and #5 below).

The following updates have also been provided: (1) Dr. Craig Simon (Health Canada, Canada) has been elected to serve as MedDRA MC Vice-Chair for a two-year term; (2) Dr. Barbee Whitaker (FDA, United States) has been appointed by the MedDRA MC to serve as Finance Committee Co-Chair for a two-year term (see item #4 below); (3) the MedDRA MC approved the ICH Secretariat staff, Ms. Nikoleta Luludi and Ms. Lucie Archambeau as ICH Signatories for MedDRA activities.

Finally, the Assembly was updated on the proposed changes related to the transformation of the MedDRA MC, including: (1) the reporting structure; (2) the renaming of the MedDRA MC to MedDRA "Steering Committee"; (3) the expansion of the membership of the MedDRA MC, with the necessity to set up membership criteria.

Assembly Decisions/Actions:

- The Assembly noted the decisions taken by the MedDRA MC during its meeting on 3 and 4 November 2024;
- The Assembly took note of the proposed changes regarding the transformation of the MedDRA MC, with the understanding that Assembly approval would be sought in writing after the Montreal Meeting;
- The Assembly approved the revised ICH/IMDRF Memorandum of Understanding (MoU), expanding the scope of the IMDRF-MedDRA mapping by removing the specific references to Annex E with the view that IMDRF and ICH would determine, on a case-by-case basis, which annexes will be mapped and maintained under the MoU.

4. Financial Matters

The ICH Finance Committee (FC) Chair updated the Assembly on the ongoing activities of the ICH FC, including: the re-appointment of the FC Chair & Co-Chairs; the future outlook of key priorities; the asset preservation update; the change on the process of the Regulatory Training Funding and the expected underspending on the 2024 budget due to delay on several projects.

Finally, the Assembly was informed that the new contract with the current Professional Conference Organiser (PCO) has been finalised in July/August 2024 for the meeting organisation from October/November 2026 to May/June 2029.

Assembly Decisions/Actions:

- The Assembly approved the 2025 ICH Association Budget with the inclusion of the fund placement result into the income section;
- The Assembly approved the 2026 ICH Membership Fees which are kept at the same level as for 2025;
- The Assembly approved the 2025 MedDRA subscription fees which are unchanged from 2024;
- The Assembly noted the 5-year budget projection with the inclusion of the fund placement result into the income section; the Modernisation Activities of the Secretariat and adjustments for training and Working Groups support activities.
- The Assembly noted the proposed change of process of the Regulatory Training Funding, moving from one call per year for expressions of interest to a rolling call to promote the submission of more complete applications to be implemented from 2025 (see also item #8);

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

The Assembly was updated by the ICH Secretariat on the 2025 Work Plan and Multi-Annual Strategic Plan of the ICH Association and by the MedDRA MC Chair (under agenda item #3) on the 2025 MedDRA MC Work Plan.

Assembly Decisions/Actions:

- The Assembly approved the 2025 ICH Work Plan and Multi-Annual Strategic Plan of the Association, which will be published on the ICH website;
- The Assembly approved the 2025 MedDRA MC Work Plan, which will be published on the ICH website.

6. New Topics & Strategic Discussions

The Co-Leads of the New Topics Subcommittee provided the ICH Assembly a reminder that the 2025 New Topic Proposal process will run as a standard process, with a criterion to limit 3 proposals per nominating party and a requirement of at least 2 parties (including the proposing party) to co-sponsor the proposal at the time of submission as per the decision taken in Fukuoka, Japan in June 2024. ICH Members presented their initial informal New Topics proposals under consideration for submission and seeking sponsorship circulated to the ICH Assembly as part of the ICH Assembly Document Package.

Assembly Actions/Decisions:

- The Assembly noted that the New Topics submission deadline is on 22 November 2024 after which the New Topic Subcommittee will assess the New Topics with recommendations to be put forward to the Assembly for endorsement during the Madrid, Spain meeting in May 2025;

- The Assembly noted brief overviews of new topic proposals under consideration for submission in 2025, which were circulated to the ICH Assembly to explore the initial interest and identify co-sponsoring parties;
- The Assembly noted the approved new topics with delayed start dates:
    - Structured Product Quality Submissions – to start work when M4Q(R2) reaches *Step 2*, foreseen for June 2025;
    - Bioequivalence for Modified-Release Products – to start work when M13C reaches *Step 2*.

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.

8. Training

General

The Lead of the Training Subcommittee of the ICH MC provided an update to the Assembly on recent ICH Training activities, including:

- ICH WG training materials, including: ICH M13A and ICH E11A *Step 4* presentations; updated Q8/Q9/Q10 training materials developed by Q9(R1) Implementation Working Group recently published on the ICH website; ICH Q13 WG materials under development with FDA, United States Studios thanks to a grant it has provided for the development of ICH training materials to be finalised shortly, as well as the development of an ICH E19 video module by FDA, United States with its Studios to be completed by Q4 2024;
- Progress made by ICH's Training Associates to develop online training materials on the ICH Q3 series, ICH Q5 series, ICH E6(R3), ICH E8(R1), ICH E2, ICH E17 and ICH Q8-12 Guidelines;
- Progress of the pilot process for the Training Associate to engage with relevant EWGs early in the Guideline development process (e.g., at *Step 2*) initiated in November 2023 between ICH E6(R3) EWG and a Training Associate contracted to develop training materials on ICH E6(R3), with discussions with the Training Associate initiated with ICH M11 EWG for training development.

Assembly Decisions/Actions:

- The Assembly noted the update and the ICH Training activities;
- The Assembly noted consideration was also being given to developing more advanced, interactive training materials to better align with the audience's needs with an enhancement of the ICH website's capabilities to be explored to allow hosting more advanced training programmes;
- The Assembly noted that further discussions are needed to confirm a more strategic approach to developing training materials, considering collaboration with Training Associates as a strategic partnership; and to allow cross-talk among EWGs/IWGs on approaches and experiences with training development.

ICH Funding of Regulatory Training

The ICH Secretariat provided an update on the status of requests approved for the 2024 ICH Funding of Regulatory training, as well as applications postponed from previous years, and the planning of the 2025 Call for Expression of Interest for the ICH Regulatory Training Funding.

Assembly Decisions/Actions:

- The Assembly noted the revised process for the ICH Regulatory Training Funding which was approved by the MC, moving from one call per year for expressions of interest to a rolling call to promote the submission of more complete applications to be implemented from 2025. The Assembly noted that candidates can submit applications at any time. The ICH Secretariat will then verify the eligibility of the submitted applications and share the applications with the ICH MC for a decision to be taken at three key intervals each year, with the deadline for applications for each interval to be clearly communicated to the ICH Assembly by the ICH Secretariat;

- The Assembly noted that funding will be made available on the basis of only one invoice to the ICH Secretariat to be issued in either CHF or USD only, by the Member or Observer (or recipient/training provider if different);

- The Assembly noted the launch of the rolling Call of Expression of interest on 2 December 2024, with a first decision to be taken by the MC at the MC Interim meeting in March 2025;

- The Assembly noted the addition of an optional time point for after the October/November Biannual Meetings for decision to be taken electronically, should the volume of applications and remaining funds warrant it.

9. ICH PQKM Task Force

The ICH Assembly was updated by the ICH MC Chair on the progress of work of the Pharmaceutical Quality Knowledge Management (PQKM) Task Force (TF) since its creation in March 2024 to begin exploring what it would take to establish and govern a secure, standardised technology platform to both enable the PQKM vision and make it scalable to other collaborative regulatory use cases. This included an update on work in three main focus areas: Governance & Operations, Policy & Regulation and Journey Map; and work on finalizing key decisions and components for the Request for Information (RFI) with an objective to enable the TF to gather market information and refine assumptions to support final TF's recommendations.

Assembly Action/Decision:

- The Assembly noted the work progress of the ICH PQKM Task Force, and that the RFI will be released in early-December 2024 for a 1-month Market Consultation, with further update to be provided to the Assembly at the May 2025 meeting in Madrid.

10. Communication

General

The ICH Assembly Chair informed the Assembly on planning of two sessions on ICH at the DIA Europe meeting in Basel to be organised by EC, Europe, Swissmedic, Switzerland and EFPIA

In addition, the ICH Assembly Chair and WHO Delegate provided an update from the recent 19th International Conference of Drugs Regulatory Authorities (ICDRA) meeting which took place from 14 to 18 October 2024 in New Delhi, India first time since 6 years, with a session on global harmonisation activities, where the ICH MC Vice-Chair was amongst the speakers.

The Assembly was also informed that the ICH has been awarded by DIA Europe the 2025 DIA Regional Inspire Award for Outstanding Contribution to Global Health for its significant and innovative contribution to advancing global health, with ICH Assembly and MC Chairs invited to attend the Award Ceremony taking place in March 2025 in Basel.

Assembly Decision/Action:

- The Assembly noted un update.

ICH Regional Public Meetings

The Assembly shared information on ICH Regional Public Meetings in their respective regions prior to and following the ICH meeting in Montreal in November 2024, including meetings organised by: FDA, United States and Health Canada, Canada; and JPMA.

Assembly Decision/Action:

- The Assembly noted that ICH Regional Public Meetings taking place prior to/following the ICH meeting in Montreal should be communicated to the Secretariat and will be published on the ICH website.

11. General Operational Matters

ICH Modernisation

The Assembly was updated on the ICH Secretariat modernisation activities which had been initiated in 2024 with a view to reducing administrative burden and workload challenges for the Secretariat and better positioning ICH for the future. The Assembly noted that the modernisation efforts included: developing the Secretariat's technology platform, with an IT consultant being engaged to advise on this towards developing a strategic plan; optimising the structure and organisation of the Secretariat; and streamlining the procedures.

Assembly Actions/Decisions:

- The Assembly noted that further to the holistic assessment of the current ICH Secretariat IT platform performed by an IT Consultant in May/June 2024, multiple (off-the-shelf) IT solutions were recommended for implementation, with a step-wise implementation approach proposed for deployment of various tools to be supported by the IT Consultant and the Secretariat;
- The Assembly noted that the MC provided its support for the Executive Sponsor Group to proceed with recruiting a new ICH Secretariat Executive Director, with recruitment facilitated by an executive recruiting firm with extensive experience with international non-profit organisations in Switzerland and an HR Consultant that ICH has contracted to assist in the modernization efforts.

ICH Operational Efficiency

The Efficiency Co-Lead provided the Assembly an update, on behalf of the ICH Efficiency Group, on activities towards streamlining the Working Group Standard Operating Procedures (SOP) which has grown due to numerous revisions and become difficult to manage, reducing its practicality and effectiveness for its intended purpose. The Efficiency Group will rewrite and unpackage the SOP to reflect in-use processes relevant and remain concise to WGs removing processes relevant to the ICH MC/Coordinators and ICH Secretariat. The Efficiency Group will develop 3 documents: the Operational Guide for ICH Working Groups, the ICH Secretariat Handbook and the Coordinators Handbook. The Efficiency Group has progressed work on a high-level draft of the Operational Guide for ICH Working Groups which will retain specific annexes relevant WG operations with many other annexes to be reallocated or removed as needed. The Efficiency Group will also begin the development of the Coordinators Handbook, for which feedback from the Coordinators would be sought at a scheduled

meeting, and a mechanism for update would be determined. The development of all 3 documents is expected to be completed within a 2-year period.

Assembly Actions/Decisions:

- The Assembly noted the progress of work towards the development of the 3 documents;
- The Assembly noted that selected Annexes currently in the SOP v13.0 will published on the ICH website or relevant SharePoint site as standalone documents, and specific Annexes considered obsolete will be removed;
- The Assembly noted the next steps towards developing the suite of documents with the support of a Technical Writer to support the development within a 2-year period approved by the ICH MC.

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 33 ongoing active WGs of 787 experts from amongst the 23 ICH Members and 35 ICH Observers.

12. Q4B Maintenance

The Pharmacopoeial Discussion Group (PDG) updated the Assembly on the status of maintenance of Q4B Annexes, with a proposal to implement a stepwise approach to bring Annexes up to date, including the first phase comprising revision of Annex 6, 7 and 8 to be finalised by the end of 2025, with a final timeline for pharmacopoeias to transmit data on these Annexes by 31 December 2024. The PDG also presented next steps, with Annexes to be included in each phase to be shared in future meetings and deadlines for further annexes to be announced by the PDG in due time.

Assembly Actions/Decisions:

- The Assembly noted PDG update, and that the current Q4B Q&As and slide deck on ICH homepage will be updated by PDG following recent confirmation by the ICH MC;
- The Assembly noted a recommendation to go through ICH Secretariat for requests for data from the PDG;
- The Assembly noted that in view of the revision of the Standard Operating Procedures (SOPs) for Working Groups (WGs), the Annex 5: Q4B Maintenance Procedure will be published directly on the ICH website as a separate document;
- The Assembly noted that new ICH Regulatory Members may need to establish different timelines for Q4B implementation, and therefore PDG would reach out to them to initiate the implementation process.

13. WGs Meeting in Montreal

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

The E6(R3) Rapporteur and Regulatory Chair reported progress to the Assembly on the E6(R3) Principles and Annex 1 and Annex 2 activities. Before the Montreal meeting, the E6(R3) EWG completed the review of 6000 public comments and focused showstopper comments for Principles and Annex 1. Based on the comments received, the E6(R3) EWG identified key themes and met with Harvard MRCT to determine the initial structure for E6(R3) training materials. The Principles and Annex 1 draft Guideline was shared with the E6(R3) PWP and will shortly be finalized to proceed to the final stages of the ICH formal process. Regarding E6(R3) Annex 2, the E6(R3) Annex 2 Subgroup completed caucus review, incorporated showstopper inputs and was approved by all Topic leaders at *Step 1* of the ICH process.

During the Montreal meeting, the Training Subgroup of the E6(R3) EWG closely engaged with a Training Associate contracted to develop E6(R3) training materials, and established a comprehensive structure of 7 training modules and outlined use cases, with initial modules to be delivered by mid-2025. After the publication of the training material, the E6(R3) EWG will assess stakeholder engagement and the impact of the training material on the ICH website. In addition, during the meeting, E6(R3) presented a proposal for a targeted update approach to the E6(R3) Guideline for ICH MC consideration.

Assembly Actions/Decisions:

- The Assembly noted that the Topic Leaders of the E6(R3) Annex 2 Subgroup have signed off at *Step 1* for the E6(R3) Annex 2 Technical Document, further to which ICH Assembly Members and Regulatory Members of the Assembly endorsed the draft E6(R3) Annex 2 Guideline under *Step 2a/b*;
- The Assembly noted the E6(R3) Annex 2 draft Guideline now enters into *Step 3* for public consultation;
- The Assembly noted the E6(R3) Work Plan, noting the E6(R3) Principles and Annex 1 draft Guideline is expected to reach *Steps 3* and *4* in December 2024;
- The Assembly noted the E6(R3) Work Plan, noting the E6(R3) Annex 2 draft Guideline is expected to reach *Steps 3* and *4* in June 2025;
- The Assembly noted the E6(R3) EWG has requested a 5-day for the E6(R3) Training Subgroup meeting in Madrid, Spain in May 2025;
- The Assembly noted the need for further MC discussion with Training Leads regarding the tracking of the completion of training modules;
- The Assembly noted the proposal for a targeted update approach to the E6(R3) guideline, which will be considered and approved by the ICH MC.

13.2. 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)

The E2D(R1) Rapporteur and Regulatory Chair reported progress to the Assembly on the E2D(R1) after the closure of public consultation, which closed in July 2024; 450 comments were received and prioritised into local regional requirements, terms and definitions used in the draft Guideline and comments on digital platforms. Before arriving at the Montreal meeting 70% of comments were reviewed, and EWG resolved 50% of comments. Major issues were clarified during the meeting, such as the ambiguous text on spontaneous versus solicited reporting, text on patient sex and gender, and text for secondary use of data for non-interventional studies. Based on the comments received, the E2D(R1) EWG have determined the need to develop practical case training materials. Furthermore, E2D(R1) EWG also determined that there would be further need to support the development of the E2B(R3) EWG/IWG explanatory note for additional values to already existing data element to be applied for cases from 'Patient Support Programmes', 'Market Research

Programs', 'Organized Data Collection Systems on digital platforms' with the consideration for supporting the 3rd biological sex category as per ISO standard 5218.

Assembly Actions/Decisions:

- The Assembly noted the E2D(R1) Work Plan, noting the draft Guideline is expected to reach *Step 3* and *4* in May 2025 with PWP consultation planned for March 2025;
- The Assembly noted that the E2D(R1) Training Material will be slide-based examples based on digital datasets to provide practical use-cases to support the implementation of the guideline and will be completed shortly after reaching *Step 4*.

13.3. E21 EWG: Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials (Rapporteur: Dr. Bischof – EFPIA; Regulatory Chair: Dr. Sahin – FDA, United States)

The E21 Rapporteur and Regulatory Chair reported to the Assembly on the progress of the E21 EWG meeting since the Fukuoka, Japan meeting. The E21 EWG continues to work on the draft Technical Document. After an internal constituent review of an initial draft, 900 comments were received, of which no show-toppers were identified. During the meeting, the E21 EWG addressed significant comments categorised into 3 topics. Firstly, regarding the scope of the guideline related to the benefit-risk of the E21 guideline development strategy, the inflection points when an appropriate level of data is available, which the E21 EWG determined will need to be examined on a case-by-case basis. Secondly, major comments regarding the type, timing, potential flexibility and stage of developmental and reproductive toxicology (DART) studies were received, which require further discussion and the identification of gaps in ICH M3 and S5(R4). Finally, comments were received regarding lactation/breastfeeding studies defining the appropriateness and infant exposure. Based on the significance of comments received on the pre-clinical section and DART studies, consultation with non-clinical experts would be beneficial to ensure adding an appropriate level of information in the technical document for benefit-risk assessment prior to inclusion of pregnant/breastfeeding individuals in clinical trials.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan for the E21 EWG, noting the draft Technical Document is expected to reach *Steps 1* and *2 a/b* in Q1-Q2 2025;
- The Assembly noted the E21 EWG has requested an interim meeting in parallel to the ICH MC meeting in Budapest, Hungary;
- The Assembly noted the E21 EWG will contact the Secretariat regarding an ad-hoc toxicity expert to join the E21 EWG;
- The Assembly noted that the E21 EWG will put forward a stakeholder engagement plan that will be shared with the ICH MC for approval.

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

The E22 Rapporteur and Regulatory Chair reported progress to the Assembly on the first E22 EWG face-to-face meeting after its establishment in June 2024. The E22 guideline aims to optimise patient preference information as input to pharmaceutical product development and to inform benefit-risk assessment. During the meeting, the E22 EWG reached a consensus on the structure and important topics for inclusion within the guideline. The E22 guideline is expected to remain at a high level, including guiding principles. Due to the nature of the E22 Guideline, the E22 EWG has begun planning the development of training materials and a stakeholder engagement plan.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan for the E22 EWG, noting the draft Technical Document is expected to reach *Steps 1* and *2 a/b* in December 2025;
- The Assembly noted the E22 EWG has requested to meet for 4-days in Madrid, Spain, in May 2025;
- The Assembly noted that the E22 EWG will put forward a stakeholder engagement plan to be shared with the ICH MC for approval in Q3-Q4 2025;
- The Assembly noted the E22 strongly recommends the development of training material to support the implementation of the guideline.

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

The M2 Co-Rapporteurs and Regulatory Chair reported progress to the Assembly on the M2 EWG meeting. The M2 EWG provided updates towards the project opportunities, Standard Developing Organization (SDO) relationship management and technical consultive support to the M11 EWG, M4Q(R2) EWG and M8 EWG/IWG. The M2 EWG discussed the uptake of regional initiatives related to artificial intelligence (AI) as a project opportunity. The M2 EWG will further assess these regional best practices and AI use cases for their applicability and value to regulatory data exchange as a next step to be integrated into the AI Proof of Concept. Instances and feedback of AI-assisted processing for comments used by WGs will also be used to assess a suitable AI tool for the AI proof of concept.

Regarding the SDO engagement, the M2 EWG continues its collaboration with Health Level Seven (HL7), The Clinical Data Interchange Standards Consortium (CDISC), and the International Organization for Standardization (ISO) to ensure the interoperability of standardization initiatives. Concerning the SDO engagement and M11 EWG activities, the M2 EWG plans to update and support the National Cancer Institute Enterprise NCI/CDISC processes, collaborate with CDISC to initiate terminology maintenance process for M11 EWG terms and definitions and provide technical support to the M11 EWG for the creation of the final ICH technical implementation guide (TIG) in partnership with HL7 Vulcan. Furthermore, the M2 EWG will propose a streamlined SDO engagement process to the ICH MC by June 2025, which will consider the resources required from the ICH.

The M2 EWG has also begun the development of a proposal for ICH terminology harmonization due to the variations of terminology definitions across ICH guidelines that present a challenge. As more ICH Guidelines are developed, these definition variations may lead to inconsistent usage and misinterpretation. As the next step, the M2 EWG will present a targeted approach to the ICH MC to harmonize ICH terminology for further discussion.

Assembly Actions/Decisions:

- The Assembly noted the M2 EWG will complete the AI proof of Concept in April 2025;
- The Assembly noted the M2 EWG will collaborate with the NCI to identify a file format for the ICH Code list download in June 2025;
- The Assembly noted the first draft of the streamlined SDO engagement process is expected in June 2025;
- The Assembly approved the entering into collaboration with The Council for International Organizations of Medical Sciences (CIOMS) to share an electronic source document of ICH glossary definitions with ICH Members and Observers with the M2 EWG as the point of contact for the ICH;

- The Assembly recommended that the M2 EWG assess the value of ICH terminology harmonization. If considered valuable, to develop a step-by-step pilot strategy for proposal and focus on the terms from legacy guidelines, which would have a considerable impact on other ICH guidelines.

13.6. 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) Rapporteur and Regulatory Chair reported to the Assembly on the progress of the M4Q(R2) EWG meeting. Before the meeting, the M4Q(R2) EWG addressed all 1580 comments received from internal consultation of the first M4Q(R2) draft technical document and resolved all major comments. Based on the comments, the M4Q(R2) EWG revised the M4Q(R2) design to include new sections, the "Overall Development and Overall Control Strategy" and "Post-Approval Change Summary and Justification" to take into consideration the burden to regulators and the industry. During the Montreal meeting, the M4Q(R2) EWG worked to align the revised draft M4Q(R2) technical document to prepare constituents' formal consultation in December 2024-January 2025. Further to the M4Q(R2) EWG discussion, based on comments received, the M4Q(R2) EWG has determined the need for clear direction implementation and the need to establish an M4Q(R2) IWG following *Step 4*.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan for the M4Q(R2) EWG, noting the draft Technical Document is expected to reach *Steps 1* and *2 a/b* in May 2025 and be shared with the PWP in January 2025;
- The Assembly noted the M4Q(R2) EWG has requested a 5-day meeting in Madrid, Spain in May 2025;
- The Assembly noted the M4Q(R2) EWG recommendation to establish an M4Q(R2) IWG to be discussed with the ICH MC;
- The Assembly noted the M4Q(R2) EWG recommendation to implement the M4Q(R2) guideline in the eCTD 4.0;
- The Assembly recommended that the M4Q(R2) EWG adhere to the May 2025 timeline to reach *Steps 1* and *2 a/b*.

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

The M11 Rapporteur and Regulatory Chair reported progress to the Assembly on the M11 EWG Meeting. Before meeting in Montreal, the M11 EWG completed the adjudication of 2300 comments received, conducted a regional party review and updated the M11 draft Guideline, M11 Clinical Protocol Template and M11 Technical Specification. In collaboration and per the MoU, CDISC conducted a public review of the terms, definitions, and valid value sets for M11 documents. During the meeting in Montreal, the M11 EWG reached a consensus on regional party comments for the M11 Template and progressed on the adjudication and consensus of a substantial number of regional party comments for the Technical Specification and terms, definitions, and valid value sets. The M11 EWG put forward preliminary considerations for a proposed maintenance process for the M11 Clinical Protocol Template content and the Technical Specifications and foreseen expertise for a small expert group.

In addition, the M11 EWG has continued the discussion with a Training Associate to develop training materials with ICH M11 to be published on the ICH website. The M11 EWG also advanced

the discussion with the M2 EWG on developing the technical implementation guide for Fast Health Interoperability Resources (FHIR).

Assembly Actions/Decisions:

- The Assembly noted no changes to the Work Plan of the M11 EWG, noting the draft M11 Guideline, M11 Template and M11 Technical Specification are expected to reach Steps 3 and 4 by November 2025;
- The Assembly noted the M11 EWG has requested a 4-day meeting in Madrid, Spain in May 2025;
- The Assembly noted a regulatory public consultation for the complete, updated Technical Specification is expected in Q1 2025;
- The Assembly noted that considerations towards the maintenance process for the M11 Clinical Protocol Template and Technical Specification content will be discussed with the ICH MC.

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

The M13 Rapporteur and Regulatory Chair reported to the Assembly on the progress of the M13 EWG meeting, which is developing a series of guidelines: M13A, M13B, and M13C. Following the completion of M13A in July 2024, the M13 EWG recommenced work on the M13B draft technical document, which is on track to be completed by January 2025, at which point work on M13C will commence. During the meeting in Montreal, the M13 EWG finalised the M13B draft Technical Document, which will be submitted for internal clearance following the Montreal meeting and will determine the need for M13B Q&As following the M13B public consultation. Finally, the M13 EWG has initiated the development of a draft of the M13C Concept Paper Supplement.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan for the M13 EWG, noting the draft M13B Technical Document is expected to reach *Steps 1* and *2 a/b* in January-February 2025;
- The Assembly noted the M13 EWG has requested a 5-day meeting in Madrid, Spain in May 2025;
- The Assembly noted the M13 EWG will put forward an M13C Concept Paper Supplement for MC approval.

13.9. Q1/Q5C EWG: Targeted Revisions of the ICH Stability Guideline Series (Rapporteur: Ms. McMahon – PhRMA; Regulatory Chair: Dr. Rao – FDA, United States)

The Q1/Q5C Rapporteur and Regulatory Chair reported to the Assembly on the outcome of the Q1/Q5C EWG meeting. The Q1/Q5C EWG addressed 2900 comments received during a second constituents review following the Fukuoka, Japan meeting and identifying 10% of the comments as critical. The Q1/Q5C EWG agreed on strategies to address critical themes such as minimum data recommendations and differentiation of stress and forced stability conditions, aligned on key topics and those requiring the development of training material. The Q1/Q5C EWG has ongoing discussions on stability data to support multiple manufacturing facilities and content placement for development studies under stressed and forced conditions. Based on the comments received, the Q1/Q5C Technical Document has undergone restructuring in the product lifecycle and photostability sections. Following the Montreal, Canada meeting, the Q1/Q5C EWG will finalize the Technical document for submission.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan of the Q1/Q5C EWG, noting the draft Technical Document is expected to reach *Steps 1* and *2a/b* by January 2025 and be shared with the PWP in December 2024;
- The Assembly noted the Q1/Q5C EWG will begin development of training material in March 2025 during *Step 3* public consultation;
- The Assembly noted the Q1/Q5C EWG has requested 5-day meeting in Madrid, Spain in May 2025.

13.10. Q3E EWG: Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics (Rapporteur: Dr. Parris – PhRMA; Regulatory Chair: Dr. Rodriguez – FDA, United States)

The Q3E Rapporteur and Regulatory Chair reported to the Assembly on the progress of the Q3E EWG meeting since the Fukuoka, Japan meeting. The Q3E EWG has developed a draft Technical Document consistent with the Concept Paper and has addressed the comments received from the constituent review, which took place in May 2024. Based on the comments, the Q3E EWG has reformatted and streamlined the Technical Document. The Threshold Project has progressed, with 77% of the PDEs commissioned and received from the vendors and currently projected to remain under the budget allocated to the Q3E EWG. The Q3E EWG is in the process of reviewing the PDEs received and will review any remaining PDEs over the next 8 months, to determine their inclusion into the Technical document as Class 1 (high risk) and Class 3 (low risk) compounds based on preliminary results from the Threshold Project dataset. Furthermore, during the meeting, the Q3E EWG reached a consensus on text for low-risk scenarios included in the Appendix for manufacturing components/systems and discussed low-risk scenarios for packaging components/systems.

Assembly Actions/Decisions:

- The Assembly noted no changes to the Work Plan of the Q3E EWG noting the draft Technical Document is expected to reach *Steps 1* and *2a/b* June 2025 and to be shared with the PWP in March 2025;
- The Assembly noted the Q3E EWG has requested a 4-day meeting in Madrid, Spain in May 2025.

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

The Q6(R1) Co-Rapporteurs and Regulatory Chair reported to the Assembly on the outcome of the Q6(R1) EWG meeting. The Q6(R1) EWG Technical document will be developed building on ICH Q8-Q14 and leveraging ICH Q6A and ICH Q6B, noting there would be a considerable expansion of biological modalities and merging common unifying principles applicable to all product types. Before the Montreal, Canada meeting, gap analysis and mapping were conducted on ICH Q6A and ICH Q6B to identify topics for development. During the meeting, the Q6(R1) EWG agreed not to introduce new terminologies in ICH Q6(R1) unless it is necessary and support concepts developed in ICH Q8-Q14. The EWG reached this conclusion as new terminology could lead to misinterpretation and increase complexity, and the approaches used in ICH Q8-Q14 cover patient-centric concepts. However, the Q6(R1) EWG acknowledges that the application of science and risk-based principles are essential elements for the modernisation of specification setting and has begun discussing examples to illustrate the concepts which require further refinement by the EWG. In addition, high-level topics were identified, and the role of Pharmacopoeias in setting specifications will be included in the Technical Document.

Assembly Actions/Decisions:

- The Assembly noted the Q6(R1) EWG Work Plan, noting the draft Technical Document is expected to reach *Steps 1* and *2a/b* June 2026;
- The Assembly noted the Q6(R1) EWG has put forward a request for the allocation of a Technical Writer to be approved by the ICH MC;
- The Assembly noted the Q6(R1) EWG has requested a 5-day meeting in Madrid, Spain, in May 2025.

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

The CGTDG Rapporteur and Regulatory Chair reported to the Assembly on the progress of the CGTDG meeting. The work of CGTDG is focused on mature product classes such as *ex vivo* genetically modified cells and *in vivo* viral vector-based gene therapies with a scope to address the interdependencies in the Clinical, Nonclinical, and Quality disciplines. The CGTDG will develop six deliverables over the 2-year remit. Before meeting in Montreal, the CGTDG completed work on a high-level principles document, an overview of the global regulatory frameworks and a mapping of areas of divergence and harmonization in regulatory expectations. Currently, the CGTDG continues to work on a review of existing ICH guidelines for applicability to ATMPs and a holistic ATMP roadmap. Building on the ATMP roadmap and high-level principles document, the CGTDG will develop a Recommendation Paper as a final deliverable to be completed in October 2025. Additionally, during the meeting in Montreal, the CGTDG met with Q1/Q5C EWG and the Q6(R1) EWG to share considerations towards relevant sections where CGT products are in scope. Finally, during the meeting, the CGTDG has identified priority topics to be submitted as a multidisciplinary new topic proposal towards the 2025 New Topics Cycle.

Assembly Actions/Decisions:

- The Assembly noted the CGTDG Work Plan, noting the final CGTDG Recommendation Paper is expected to be completed in October 2025;
- The Assembly noted the CGTDG will put forward a new topic proposal towards the 2025 New Topics Cycle;
- The Assembly noted the CGTDG may request an interim meeting in Geneve, Switzerland, if required to complete the CGTDG Recommendation Paper by October 2025.

14. WGs not Meeting in Montreal

14.1. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports (Rapporteur: Dr. Yamaguchi– MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, United States)

The E2B(R3) EWG/IWG continues the development of updates to code list 8, a collaborative Information Paper with E2D(R1) EWG and E2B(R3) EWG/IWG Training Materials I, II and III which are expected to be finalised shortly.

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

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

The E11A EWG continues to develop E11A training materials expected to be finalised in August

2025.

14.3. E14/S7B IWG: Questions & Answers: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential (Rapporteur: Dr. Leishman –PhRMA)

The E14/S7B IWG was established in March 2024.

The E14/S7B IWG continues the development of second-stage Q&As, which is expected to reach *Steps 3* and *4* in November 2025.

14.4. E20 EWG: Adaptive Clinical Trials (Rapporteur: Dr. Zhong – PhRMA; Regulatory Chair: Dr. Levin – FDA, United States)

The E20 EWG continues the development of the E20 Technical Document, which is expected to reach *Steps 1* and *2* shortly.

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

The M1 PtC WG continues to work on the update toward the March MedDRA release the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents, having most recently released language versions in English, Japanese, Chinese, Korean, Russian and Spanish in March 2025.

14.6. M7(R3) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Atrakchi – FDA, United States)

No proposals for revisions have been received at this time; therefore, the M7(R3) Maintenance EWG remains dormant.

14.7. 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 continues work on the development of the Concept Paper.

14.8. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) (Rapporteur: Mr. McCormick – FDA, United States; Regulatory Chair: Ms. Puusaari – EC, Europe)

The M8 EWG/IWG continues the development of updates to eCTD 3.2.2 Q&A to v1.34 and eCTD 4.0 Q&A to v1.9 and recommendations for eCTD evolution.

Steps 3 and 4 for eCTD 3.2.2 Q&A to v1.34 and eCTD 4.0 Q&A to v1.9 are expected in November 2024.

14.9. M14 EWG: General Principles on Plan, Design and Analysis of Pharmacoepidemiological 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 Technical Document were reached in May 2024.

The M14 EWG public consultation was concluded in October 2024.

The M14 EWG continues to address comments received and the development of M14 Training Materials and the M14 draft Guideline expected to reach *Steps 3 and 4* in June 2025.

14.10. M15 EWG: General Principles for Model-Informed Drug Development (Rapporteur: Dr. Karlsson – EC, Europe; Regulatory Chair: TBD)

The M15 Technical Document reached *Step 1* Sign-off from all Topic leaders on 2 November 2024.

Steps 3 and 4 for the M15 draft Guideline are expected by Q4 2025.

Assembly Actions/Decisions:

- The Assembly noted that the Topic Leaders of the M15 EWG have signed off at *Step 1* for the M15 Technical Document, further to which ICH Assembly Members and Regulatory Members of the Assembly endorsed the draft Guideline under *Step 2a/b*;
- The Assembly noted the M15 draft Guideline now enters into *Step 3* for public consultation;
- The Assembly endorsed the rotation of the Rapporteurship for the M15 EWG from PhRMA to Dr. Kristin Karlsson, EC, Europe, in line with Annex 4 of the SOPs on rotation of Rapporteurship at *Steps 2a/b.*

14.11. Q2(R2)/Q14 IWG: Training on Validation of Analytical Procedures and Analytical Procedure Development (Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)

The Q2(R2)/Q14 IWG continues the development of the Q2(R2)/Q14 training materials expected to be finalised by March 2025.

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

Step 4 for Q3C(R9) "Guideline for Residual Solvents", was reached in January 2024 for a revision to include consideration of solvent volatility for analytical methods.

Q3C(R10) Maintenance EWG continues to work on revisions of monographs of Di-methyl-formamide, Di-chloro-methane and Ethylene-glycole.

14.13. Q3D(R3) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. Froetschl – EC, Europe)

Steps 3 and *4* of the Q3D(R2) revision for the cutaneous and transdermal products were reached in April 2022.

The Q3D(R3) Maintenance EWG remains in a dormant state until proposals for revisions are received.

14.14. Q5A(R2) IWG: Training on Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Rapporteur: Dr. Welch – FDA, United States; Regulatory Chair: Dr. Blumel – EC, Europe)

The Q5A(R2) IWG continues the development of the Q5A(R2) training materials expected to be finalised in December 2024.

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

Updated Q8/Q9/Q10 training material published on the ICH website in November 2024.

The Q9(R1) Training Group continues revising the Q9 Briefing Pack expected to be finalised by September 2025.

14.16. Q12 IWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)

The Q12 Training Material Module 8 (case studies) and broad-audience video developed by the FDA United States studios were published in February 2024.

The Q12 IWG remains in a low activity state until prompted by the ICH MC.

14.17. Q13 IWG: Continuous Manufacturing of Drug Substances and Drug Products (Rapporteur: Dr. Lee – FDA, United States; Regulatory Chair: Dr. Matsuda – MHLW/PMDA, Japan)

The Q13 EWG transitioned to an IWG in January 2023.

The Q13 IWG continues the development of training materials, which are expected to be finalised shortly. Following completion of training materials the Q13 EWG will be disbanded.

14.18. S1B(R1) IWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. McGovern – 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 IWG continues work monitoring the implementation of the S1B(R1) Guideline.

14.19. S5(R4) Maintenance EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe)

Expected to be disbanded shortly.

14.20. 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.

The ICH MC approved the S13 Concept Paper in November 2024 and will be published on the ICH website.

14.21. Standing Paediatric EWG (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, United States)

The Standing Paediatric EWG did not receive any request for paediatric advice from WGs and the group remains available for expert consultation and guidance to WGs charged with developing new or revised guidance which may be of relevance to paediatric drug development.

14.22. Quality Discussion Group (QDG) (Rapporteur: Dr. Miksinski – PhRMA; Regulatory Chair: Dr. Barry – EC, Europe)

The QDG remains available for expert consultation upon the ICH Management Committee's request.

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:
  - 10 - 14 May 2025 in Madrid, Spain
  - 15 - 19 November 2025 in Singapore
  - 30 May - 3 June 2026 in Rio de Janeiro, Brazil
  - 14 - 18 November 2026 in Europe, Africa and the Middle East Region (location to be confirmed)

16. Press Release

Assembly Action/Decision:

- 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.