Dated 28 May 2024

ICH ASSEMBLY FUKUOKA MEETING

AGENDA

Tuesday 4 June and Wednesday 5 June 2024

Fukuoka, Japan

Opening of the ICH Assembly Meeting

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

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

Mr. Yasunori Yoshida (Councillor for pharmaceutical affairs, Ministry of Health, Labour and Welfare, Japan) will be invited to deliver some opening remarks.

The ICH Secretariat will provide a brief presentation to the Assembly on the use of the online platform for Members and Observers to have access to the agenda papers and background documents during the meeting.

Adoption of the Agenda

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

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1. Membership and Observership

The ICH Secretariat will inform the Assembly of any Membership and/or Observership application(s) processed by the ICH Management Committee (MC) since the Assembly Meeting in October/November 2023.

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

- The Assembly is invited to share its views and take a **decision** regarding any applications for ICH Membership and/or Observership recommended by the ICH MC.

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2. General Operational Matters

ICH Modernisation & ICH Procedural/Process Changes

The ICH Assembly Chair and ICH MC Chair will provide an update on recent Chair and MC discussions concerning the modernisation of the ICH Secretariat, including procedural and process changes supported by the ICH MC aimed at improving the overall efficiency of ICH operations, as well as allowing the ICH Secretariat more time to focus on modernisation activities.

ICH Operational Efficiency

The Leads for work on ICH Operational Efficiency will provide an update on the status of activities, including the outcome of the recent Request for Proposals to identify and contract a Technical Writer Provider.

ICH Secretariat Report

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

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

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3. Update on MedDRA

The MedDRA MC Chair will provide an update on current MedDRA activities.

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

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4. Financial Matters

The ICH Finance Committee Chair will provide an update on ongoing activities of the ICH Finance Committee, which includes representation from the ICH MC and MedDRA MC.

The ICH Secretariat will provide an update on the 2023 Audited Accounts and Financial Statements.

- The Assembly is invited to share its views on the update and provide any input requested;
- The Assembly is invited to take a **decision** to approve the 2023 Audited Accounts and Financial Statements of the ICH Association which will then be filed with the 2023 tax return of the ICH Association;
- The Assembly is invited to take a **decision** on the appointment of auditor to audit the ICH annual financial statements for the years 2024 and 2025;
- The Assembly is invited to take a **decision** to approve any proposed updates to the current 2024 ICH budget further to recent discussions by the ICH Finance Committee and/or ICH MC.

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5. 2023 Annual Report of the Association

The ICH Secretariat will present to the Assembly the 2023 Annual Report of the Association developed by the ICH Secretariat with the input of the ICH MC and MedDRA MC.

- The Assembly is invited to take a **decision** to approve the 2023 Annual Report and the discharge of the ICH MC, MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2023 on behalf of the ICH Association.

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6. New Topics & Strategic Discussions

2024 New Topics Process

The Leads of the ICH MC New Topics Subcommittee will present the MC assessment of the New Topic Proposal that was submitted by ICH Members in December 2023.

- The Assembly is invited to share its views and to take a **decision** to approve the New Topic proposal, associated Concept Paper Outline and proposal for Rapporteurship, confirming any next steps.

Reflection Paper on Pursuing Opportunities for Harmonisation in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines

The Leads for the Reflection Paper approved by the ICH Assembly for a 3-month public consultation in June 2023, will provide an update on the outcome of public consultation and the updated ICH Reflection Paper.

- The Assembly is invited to share its views and take a **decision** on next steps.

7. Implementation of ICH Guidelines

General

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

Implementation Survey

The ICH MC will inform the Assembly on Implementation activities, including on the Implementation survey, which was conducted, as in previous years, by the Center for Innovation in Regulatory Science ('CIRS') on behalf of ICH. The purpose of the Survey is to provide an overview of the status of implementation by ICH Regulatory Members, inform the elections for Elected MC Representatives and to provide an opportunity to ICH Observers interested in future ICH Membership to reference the survey findings in support of their application.

The Representative(s) from CIRS will present to the Assembly the results of implementation survey launched by CIRS in January 2024.

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

8. Appointment of ICH Management Committee Elected Representatives

The Assembly Members will note the applications put forward for ICH MC Elected Representatives and the considerations of the MC regarding eligibility based on the criteria defined in Articles 30(1) and 31(1) of the ICH Articles of Association and ICH MC RoP Sections 2.2.1 and 2.3.1.

The applicants for the positions of ICH MC Elected Representatives will be invited to provide a brief introduction and present their interest in joining the ICH MC.

- The Assembly Members are invited to **vote** via secret ballot on the appointment of any MC Elected Representatives in line with the Assembly RoP Section 3.6.4;
- The Assembly is invited to note the results of the elections for the appointment of MC Elected Representatives.

9. Training

General

The ICH MC Lead for Training Activities, will update the Assembly on the work which was accomplished by the ICH MC Training Subcommittee and its three sub-groups, and the recent decision of the ICH MC to disband the Subcommittee and sub-groups for the time being in order to allow the ICH secretariat to focus on the modernisation project, and for the Leads to continue to oversee core and prioritised training activities with support from the MC Coordinators and the ICH Secretariat.

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

ICH Training Associates

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

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

ICH Funding of Regulatory Training

The ICH Secretariat will update the Assembly on: the 2024 call for expressions of interest from ICH Regulatory Members and Observers for training funding in 2024; the status of trainings previously approved by the ICH

Management Committee as part of process for ICH Funding of Regulatory Training; and ICH MC support to change the annual process to a rolling process.

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

10. ICH Collaboration with PIC/S

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

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

11. Communication

ICH Regional Public Meetings

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

Approaches for Patient Stakeholder Engagement in ICH

The ICH MC Chair will provide a brief update on recent activity in relation to patient stakeholder engagement in ICH.

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

12. ICH PQKM Task Force

ICH PQKM Task Force

The ICH MC Chair will provide the Assembly with a brief update on the activities of the ICH Pharmaceutical Quality Knowledge Management System (PQKM) Task Force recently established by the ICH MC.

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

ICMRA PQ KMS Working Group

The Representative of the ICH MC participating on behalf of ICH in the activities of the ICMRA Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group will provide an update on recent activities.

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

13. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) will be invited to provide an update on the status of activities related to the new maintenance approach to both the ICH Q4B Guideline and Annex 5 of the ICH Standard Operating Procedures (SOP) for WGs on the Q4B maintenance process.

- The Assembly is invited to share its views on the report and to take a **decision** to support the PDG proposed revisions to the ICH Q4B Guideline and Annex 5 of the ICH SOPs for WGs.

14. WGs Meeting in Fukuoka

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

14.1. E6(R3) EWG: 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) EWG held an interim meeting in Basel, Switzerland in March 2024.

The E6(R3) Annex 2 Sub-group was established in April 2023 following the MC approval of the Annex 2 E6(R3) Concept Paper.

The Rapporteur will report on the meeting of the E6(R3) EWG, including progress made on the development of the E6(R3) Principles and Annex 1.

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

The E6(R3) Annex 2 draft was shared in April 2024 with the E6(R3) PWP ahead of Step 1 Sign-off. Steps 1 and 2a/b for the E6(R3) Annex 2 draft Technical Document are expected by August 2024.

The E6(R3) Principles and Annex 1 are expected to be shared with the E6(R3) PWP by July 2024 ahead of Step 3 Sign-off. Steps 3 and 4 for the E6(R3) Principles and Annex 1 are expected by October 2024.

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

The E20 EWG was established in November 2019.

The Rapporteur will report on the meeting of the E20 EWG, including progress made on the development of the E20 draft Technical Document.

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

The E20 draft Technical Document is expected to be shared with the E20 PWP by October 2024 ahead of Step 1 sign-off. Steps 1 and 2a/b are expected by November 2024.

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

The E21 EWG was established in June 2023.

The Rapporteur will report on the meeting of the E21 EWG, including progress made on the development of the E21 draft Technical Document.

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

Steps 1 and 2a/b for the E21 draft Technical Document are expected by Q2 2025.

14.4. 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 was established in November 2021.

The Rapporteur will report on the meeting of the M4Q(R2) EWG, including progress made on the M4Q(R2) draft Technical Document.

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

The M4Q(R2) draft Technical Document was shared with the M4Q(R2) PWP in April 2024 ahead of Step 1 sign-off. Steps 1 and 2a/b are expected by November 2024.

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

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

The M11 Step 3 public regulatory consultation concluded in March 2023.

The Rapporteur will report on the meeting of the M11 EWG, including progress on the M11 draft Guideline, Template, and Technical specification.

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

Steps 3 and 4 are expected by November 2025 for the M11 Guideline, Template, and Technical Specification.

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

Steps 1 and 2a/b for the ICH M13A draft Guideline were reached in December 2022.

The M13A Step 3 public regulatory consultation concluded in May 2023.

The Rapporteur will report on the meeting of the M13 EWG, including progress made to address comments received on the M13A draft Guideline, and work on the M13A Q&As and M13B draft Technical Document.

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

Steps 3 and 4 for M13A and Step 4 for M13A Q&As are expected by August 2024.

Steps 1 and 2a/b for M13B are expected by December 2024.

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

The M15 EWG was established in November 2022.

The Rapporteur will report on the meeting of the M15 EWG, including progress made on the M15 draft Technical Document.

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

The M15 draft Technical Document is expected to be shared with the M15 PWP by July 2024 ahead of Step 1 Sign-off. Steps 1 and 2a/b are expected by September 2024.

14.8. 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 EWG was established in November 2022.

The Rapporteur will report on the meeting of the Q1/Q5C EWG including progress made on the Q1/Q5C draft Technical Document.

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

Steps 1 and 2a/b are expected by December 2024.

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

The Q2(R2)/Q14 IWG was established in February 2024.

The Rapporteur will report on the meeting of the Q2(R2)/Q14 IWG including progress made on the development of training modules.

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

The Q2(R2)/Q14 training materials are expected to be finalised by November 2024.

14.10. 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 EWG was established in July 2020.

The Rapporteur will report on the Q3E EWG meeting, including progress made with the Threshold Project and development of the Q3E draft Technical Document.

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

The Q3E draft Technical Document is expected to be shared with the Q3E PWP by January 2025 ahead of Step 1 Sign-off. Steps 1 and 2a/b are expected by June 2025.

14.11. 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 was established in February 2024.

The Rapporteur will report on the Q5A(R2) IWG meeting, including progress made on the development of the Q5A(R2) training materials.

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

The Q5A(R2) IWG training materials are expected to be finalised in December 2024.

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

The Q6(R1) informal WG was established in February 2024.

The Co-Rapporteurs will report on the Q6(R1) informal WG meeting, including progress made on the development of the Q6(R1) Concept Paper.

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

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

The Q9(R1) EWG transitioned to an IWG in September 2023 to work on training materials and revise the quality risk management concepts within the existing training materials published on the ICH website.

The Rapporteur will report on the Q9(R1) IWG meeting, including progress made on revising the Q8/Q9/Q10 training material and the conclusions of the gap analysis of the Q9 Briefing Pack.

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

The Q9(R1) IWG is expected to finalise the revised Q8/Q9/Q10 training material in June 2024 with the materials to be published shortly after. The revision of the Q9 Briefing Pack is expected to be completed within 12-18 months after that.

15. WGs not Meeting in Fukuoka

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

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

15.1. 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 completed the voice-over presentation of Training Module I in January 2023.

The E2B(R3) EWG/IWG continues its work on the development of Training Module III and is considering comments received in January 2024 related to Appendix I(G), and whether this would entail a further revision, to be potentially included in this cycle of maintenance.

Training Modules I and II are expected shortly, and Training Module III is expected by June 2024.

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

The E2D(R1) Technical Document reached Steps 1 and 2a/b in February 2024.

The E2D(R1) EWG continues developing the draft Guideline in liaison with the E2B(R3) EWG/IWG to update code lists, other documents, and an E2D(R1)/E2B(R3) Information Paper.

The E2D(R1) draft Guideline is expected to be shared with the E2D(R1) PWP by January 2025 ahead of Step 3 Sign-off. Steps 3 and 4 are expected by May 2025.

15.3. E11A EWG: Paediatric Extrapolation (Rapporteur: Dr. Yao – FDA, United States; Regulatory Chair: Mr. Thomson – EC, Europe)

Steps 1 and 2a/b for the E11A draft Guideline were reached in April 2022.

The E11A Step 3 public regulatory consultation concluded in October 2022.

The E11A EWG held an interim meeting in Lisbon, Portugal in March 2024.

The E11A EWG continues its work developing the draft Guideline.

Steps 3 and 4 for the draft Guideline are expected in Q2 2024.

15.4. E14/S7B IWG: Questions & Answers: the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Acting Rapporteur: Dr. Leishman – PhRMA)

The E14/S7B DG transitioned to an IWG in March 2024 to develop second stage Q&As.

The E14/S7B IWG continues its work on the second stage Q&As.

- The Assembly is invited to take a **decision** to endorse Dr. Derek Leishman (PhRMA) for the role of Rapporteur for the E14/S7B IWG.

E14/S7B IWG second stage Q&As are expected to be finalised by September 2025.

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

The E22 informal WG was established in February 2024.

The E22 informal WG continues its work on developing the E22 EWG Concept Paper.

15.6. 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 updating with 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 2024.

The M1 PtC WG continues work on a new section on product quality issues during manufacturing and revision of other sections of the Companion Document v3.0 which is expected October 2024.

15.7. 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)

In May 2024, the Assembly endorsed the M2 JSON Recommendation for publication on the ICH website.

The M2 EWG continues its work on the development of recommendations for eCTD evolution, eCTD implementation activities), AI Proof of Concept and a collaborative framework between M2 and M4Q(R2).

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

Steps 3 and 4 of the eCTD v.3.2.2 Q&A Document v.1.33; eCTD V3.2.2 Valid Values v6.0; eCTD v4.0 Q&A v1.8;eCTD v4.0 Implementation Guide v1.6 and eCTD v4.0 Controlled Vocabulary Package v1.0 were reached in May 2024.

- The Assembly is invited to note the recent decision of the ICH MC to decouple M8 as a sub-group of the M2 EWG and reform a standalone M8 EWG;
- The Assembly is invited to take a **decision** to endorse Mr. Chris McCormick (FDA, United States) for the role of Rapporteur for the M8 EWG.

The M8 EWG has commenced engagement with eCTD v4.0 vendors to discuss the implementation of eCTD v4.0.

15.9. 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)

Steps 3 and 4 for the M7(R2) 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.

15.10. M14 EWG: General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine (Rapporteur: Dr. Moeny – FDA, United States; Regulatory Chair: Dr. Kajiyama – MHLW/PMDA, Japan)

The M14 EWG was established in April 2022.

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

Steps 3 and 4 for the M14 draft Guideline are expected in June 2025. The M14 EWG will also develop training materials expected to be finalised in June 2025.

15.11. 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.

No proposals for revisions have been received at this time and therefore the Q3C(R10) Maintenance EWG remains in a dormant state.

15.12. 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.

15.13. 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 Materials Modules 0-7 were finalised in June 2021, and Module 8 (case studies) was finalised in February 2024.

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

15.14. 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 EWG held an interim meeting in Tokyo, Japan in January 2024.

The Q13 IWG continues development of training materials.

The Q13 IWG training materials are expected to be finalised by June 2024.

15.15. S1B(R1) IWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. McGovern – FDA; Regulatory Chair: Dr. Van der Laan – EC, Europe)

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

The IWG commences work monitoring the implementation of the S1B(R1) Guideline.

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

No proposals for revisions of Annex 1 or 2 have been received at this time and therefore the group remains in a dormant state.

15.17. S13 EWG: Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics (Rapporteur - TBD)

The ICH Assembly endorsed this new topic in 2023, and the EWG will be established shortly to commence work.

- The Assembly is invited to take a **decision** to endorse the proposal put forward for the role of Rapporteur for the S13 EWG.

15.18. Generic drug Discussion Group (GDG) (Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)

The GDG has been dormant pending an ICH MC request to resume work.

15.19. 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.

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

The QDG continues its work on the "Knowledge Management Strategy for Quality Topics", expected in May 2024.

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

The CGTDG was established in September 2023.

The CGTDG continues its work developing high-level principles document for: *ex vivo* genetically modified immune cell products (including both autologous and allogeneic), and *in vivo* viral vector-based gene therapy products.

16. Organisation of Next Meetings

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

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

- 2 - 6 November 2024 in Montreal, Canada
- 10 - 14 May 2025 in Madrid, Spain
- 1 - 5 November or 15 - 19 November 2025 in Asia (dates & location to be confirmed)

- 30 May to 3 June 2026 in the Americas (location to be confirmed)

Any Other Business

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

Press Release

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