28 November 2023

FINAL MINUTES

ICH ASSEMBLY PRAGUE MEETING

31 OCTOBER – 1 NOVEMBER 2023

Please find hereafter the final minutes of the Assembly Meeting held in Prague, Czech Republic on 31 October and 1 November 2023.

List of Assembly Participants

Chair: Ms. Lenita Lindström

ICH Assembly Member Representatives:

Mr. Nélio Cezar De Aquino	ANVISA, Brazil
Ms. Bianca Zimon	ANVISA, Brazil
Dr. Wassim Nashabeh	BIO
Ms. Miriam Jackeline Loera Rosales	COFEPRIS, Mexico
Mr. Raùl Romàn Flores Linares**	COFEPRIS, Mexico
Dr. Georgios Balkamos	EC, Europe
Dr. Bruno Sepodes	EC, Europe
Ms. Asmaa Fouad	EDA, Egypt
Prof. Aiman El-Khatib**	EDA, Egypt
Mr. Raun Kupiec	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Michelle Limoli	FDA, United States
Dr. Theresa Mullin	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Dr. Souha Mekary**	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua*	HSA, Singapore
Dr. Nick Cappuccino*	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Manabu Yanagisawa	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Younglim Kim	MFDS, Republic of Korea
Mr. Daisuke Koga	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Ms. Catherine Lenihan**	MHRA, UK
Mr. Julian Beach**	MHRA, UK
Mr. Siyuan Zhou	NMPA, China
Ms. Michelle Rohrer	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Adel Al Harf	SFDA, Saudi Arabia
Dr. Abdullah AL-Hatareshah	SFDA, Saudi Arabia
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Dr. Yi-Ju Lin	TFDA, Chinese Taipei
Ms. Elif Inci Ergonul	TITCK, Turkey
Ms. Handan Oztunca	TITCK, Turkey

ICH Management Committee Member Representative:

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

* Virtual attendance

** Replacement for Prague meeting only

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Ms. Casey Rosner	BIO
Dr. Georgios Balkamos	EC, Europe
Dr. Sondos Moshtohry*	EDA, Egypt
Dr. Jyothsna Krishnan	EFPIA
Ms. Jill Adleberg	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
Dr. Hyun Song	MFDS, Republic of Korea
Ms. Mao Yanagisawa	MHLW/PMDA, Japan
Ms. Grace Harman	MHRA, UK
Mr. Baoshu Wen	NMPA, China
Ms. Amanda Roache	PhRMA
Mr. Yahya Al-Nujaym	SFDA, Saudi Arabia
Ms. Sarah Koechlin	Swissmedic, Switzerland
Dr. Jo-Feng Chi	TFDA, Chinese Taipei
Ms. Handan Öztunca	TITCK, Turkey

ICH Assembly Technical Coordinators:

Dr. Kevin Cunningham	EC, Europe
Dr. Takashi Misu	MHLW/PMDA, Japan

ICH Assembly Standing Observer Delegates:

Ms. Angelika Joos	IFPMA
Ms. Judith Macdonald	IFPMA
Dr. Samvel Azatyan	WHO
Mr. Hiiti B. Sillo	WHO

ICH Assembly Observer Delegates:

Ms. Yanina Rodriguez	ANMAT, Argentina
Dr. Amel Bensedira	ANPP, Algeria
Mr. Hyungok Chun**	APEC
Dr. Rainer Fendt	APIC
Dr. Celeste Sánchez González	CECMED, Cuba
Dr. Lembit Ragö	CIOMS
Dr. Vered Ben-Naim**	CPED, Israel
Prof. Abderrazek Hedhili*	DPM, Tunisia
Mr. Felchism Apolnary	EAC

* Virtual attendance

** Replacement for Prague meeting only

Dr. Petra Doerr	EDQM
Dr. Hajed M. Hashan	GHC
Ms. Janeen Skutnik-Wilkinson	IPEC
Dr. Wesal Haqaish	JFDA, Jordan
Prof. Christianah Mojisola Adeyeye	NAFDAC, Nigeria
Ms. Suhailah Abu Bakar	NPRA, Malaysia
Mr. Jeffrey Hodgson**	PIC/S
Mr. Frank Chan Ling Fung	PPBHK, Hong-Kong, China[1]
Ms. Anastasia Nikitina*	Roszdravnadzor, Russia
Ms. Fortunate Ntombi Bhembe	SADC
Ms. Silverani Padayachee**	SAHPRA, South Africa
Dr. Kevin Moore	USP

ICH Additional Participants:

Dr. Varley Sousa	ANVISA, Brazil
Dr. Peter Bachmann	EC, Europe
Ms. Miyako Okayama	JPMA
Ms. Minyoung Lim	MFDS, Republic of Korea
Ms. Kaori Ogawa	MHLW/PMDA, Japan
Ms. Nannan Li	NMPA, China
Ms. Akanksha Kaushal	PhRMA

ICH Secretariat:

Mr. Sivashen Cunden
Ms. Nikoleta Luludi
Ms. Anca-Elena Matei
Dr. Dawn Ronan

[1] At the Assembly meeting under Agenda item 2, PPBHK, Hong-Kong, China was welcomed as a new ICH Observer

* Virtual Attendance

** Replacement for Prague meeting only

TABLE OF CONTENT

ICH ASSEMBLY FINAL MINUTES

Assembly Chair: Ms. Lenita Lindström, EC, Europe

Opening of the ICH Assembly Meeting

The ICH Assembly Meeting, held on 31 October and 1 November 2023 in Prague, Czech Republic, was chaired by Ms. Lenita Lindström (Chair – EC, Europe).

The Assembly noted the Member Representatives and Observer Delegates as well as the Ad hoc Observer delegate participating in the Assembly meeting.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. Procedural Matters

The ICH Secretariat presented to the Assembly amendments proposed to the Assembly Rules of Procedure (RoP) regarding the procedure for notification by Members of any additional participants to ICH meetings. The Assembly noted a similar change had been made to the ICH Management Committee (MC) RoP.

The Secretariat additionally informed the Assembly on a change made to the MedDRA MC RoP related to the organisation of executive sessions and Member consultations.

Assembly Decisions/Actions:

- The Assembly noted the proposed changes to the ICH Assembly RoP v13.0, and approved the ICH Assembly RoP v14.0, which will be published on the ICH website;
- The Assembly noted the changes to the ICH MC RoP v13.0, with v14.0 approved by the ICH MC for publication on the ICH website;
- The Assembly noted the changes to the MedDRA MC RoP v7.0, with v8.0 approved by the MedDRA MC for publication on the ICH website.

2. 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 June 2023 and shared the ICH MC's recommendations on these applications in view of the eligibility criteria.

The applicant was invited to give a short presentation to introduce their organisation.

Assembly Decision/Action:

- The Assembly approved the following application for Observership under Article 17.1(a) of the ICH Articles of Association:
    - PPBHK, Hong Kong, China.

3. Update on MedDRA

A Representative of the MedDRA MC reported to the Assembly on MedDRA activities further to the MedDRA MC meeting held in Prague on 29 and 30 October 2023.

The Assembly was updated on the continued growth in MedDRA subscribers, with over 600 new subscribers since the start of the year, the MedDRA user community has grown to over 8,900 subscribing organisations in 138 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 a new Estonian MedDRA translation released in September 2023, and with a new Arabic MedDRA translation released in January 2023, making MedDRA now available in 20 languages; MedDRA training opportunities, which in 2023 saw in-person events resume globally, and a higher number of classes conducted in countries such as Brazil and China; the continuity of work on targeted mappings with other terminologies such as SNOMED-CT, IMDRF and ICD 10/11; the development of a new SMQ (Standardised MedDRA Query); and the ongoing IT activities including potential future use of Artificial Intelligence (AI) / Machine Learning (ML). The Assembly was also updated on the progression of the MedDRA Business Continuity Assessment in the face of various scenarios to ensure the current high level of functionality which MedDRA users have come to expect.

The Assembly was also updated on the 2024 budget and subscription fees, as well as the 2024 MedDRA MC Work Plan (see also items #4 and #5 below).

Finally, the Assembly noted that Dr. Barbee Whitaker (FDA, United States) and Dr. Craig Simon (Health Canada, Canada) were elected as MedDRA Management Committee Chair and Vice-Chair to serve respectively for a two-year and one-year term.

Assembly Decision/Action:

- The Assembly noted the decisions taken by the MedDRA MC during its meeting on 29 and 30 October 2023.

4. Financial Matters

The ICH Finance Committee Chair updated the Assembly on the ongoing activities of the ICH Finance Committee, including: strategic revisions to the 5-year budget projection to decrease surplus ahead of seeking ICH Assembly approval in Prague of the 2024 ICH Association Budget and 2024 MedDRA MSSO subscription fees; and work on the process for funding of Regulatory Observers to attend meetings in line with November 2022 ICH Assembly decision. The Assembly noted the updating of the budget plan to reflect additional costs related to items including future training needs, use of technical writers, and PCO (professional conference organiser) fee for planning of Interim ICH MC and WG meetings.

Assembly Decisions/Actions:

- The Assembly approved the 2024 ICH Association Budget, including 2024 MedDRA subscription fees with a redefining of the definitions of Level 2 and Level 3 subscribers and a 10% reduction in fees across all subscriber levels;
- The Assembly approved the 2025 ICH Membership Fees which are kept at the same level as for 2024;
- The Assembly noted the 5-year budget projection, including a decrease of the surplus, for the ICH Association;
- The Assembly supported the proposed process for the funding of Regulatory Observers to attend ICH meetings, including eligibility criteria; funding coverage; and administration, with development by the Secretariat of an application form with a view to beginning the process in 2024;

- The Assembly supported the inclusion in the 2024 budget of costs related to the Interim Meeting of MC and WGs, with PCO support to be sought for this meeting via an update to the current agreement.

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

The Assembly was updated by the ICH Secretariat on the 2024 Work Plan and Multi-Annual Strategic Plan of the ICH Association and by the MedDRA MC Chair (under agenda item 3) on the 2024 MedDRA MC Work Plan.

Assembly Decisions/Actions:

- The Assembly approved the 2024 ICH Work Plan and Multi-Annual Strategic Plan of the Association, which will be published on the ICH website;
- The Assembly approved the 2024 MedDRA MC Work Plan, which will be published on the ICH website.

6. New Topics & Strategic Discussions

2024 New Topics Process

The Assembly was informed by the ICH MC New Topic Subcommittee Co-Leads on the considerations for the 2024 New Topics New Topic selection process, including on the: overall number of active WGs; ongoing discussions on EWGs transitioning to IWG; and topics with delayed start date.

Assembly Decisions/Actions:

- The Assembly noted initial interest to submit a new topic proposal received and presented to the ICH MC in Prague by a few ICH Members/Observers, with the two following initial topic proposals considered as urgent and of potential high public health interest:
    - Proposal on Real World Data Evidence (RWE) terminology;
    - Proposal on Non-clinical nitrosoamines;
- The Assembly noted that in view of a high ICH WG-related workload and important backlog of approved topics to start (mainly due to the Covid-19 pandemic), as well as increased interest of WGs in pursuing training/implementation activities (IWGs), only the two aforementioned topics proposals are welcomed to be submitted by 4 December 2023 for the 2024 selection process, while the other topics may be re-submitted for the 2025 selection cycle;
- The Assembly noted that a proposal on General Considerations for Materials Used in the Manufacture of Human Cell and Gene Therapy Products is recommended for discussion with the ICH Cell and Gene Therapy Discussion Group (CGTDG) established in August 2023.

Reflection Paper on Harmonisation of Real-world Evidence Terminology, and Convergence of General Principles Regarding Planning and Reporting of Studies Using Real-world Data, with a Focus on Effectiveness of Medicines

The Assembly was updated on the initial outcome of the public consultation for the Reflection Paper on Harmonisation of Real-World Evidence (RWE) terminology, approved by the Assembly for public consultation in June 2023.

Assembly Decision/Action:

- The Assembly noted the initial outcome of recent public consultations on the Reflection Paper on RWE terminology, which took place from July to September 2023, with the proposing parties to

review comments received in November 2023 with a view of submitting the revised Reflection Paper for approval in June 2024.

7. Implementation of ICH Guidelines

The Assembly was informed by the Co-Leads for the next Implementation Survey on the status of a preparatory work towards the development of the survey foreseen ahead of the June 2024 MC elections, with main goals to: (1) inform the MC elections; (2) support ICH training work; (3) advance ICH's mission for regulatory harmonisation; and (4) provide ICH Members/Observers information/data for internal consideration. The Assembly was also updated on the implementation status of ICH Guidelines by ICH Regulatory Members.

Assembly Decisions/Actions:

- 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;
- The Assembly noted the timeline of the survey to be launched early December 2023 and high-level survey results to be available to the MC in March/April 2024, with a final report available in May 2024 at the latest in time for the MC Elections;
- The Assembly noted that the scope of the survey will be based on the 2021 survey, with the participation of all ICH non-Standing non-Founding Regulatory Members on Tier 2 and Tier 3 Guidelines; participation of Standing and Founding Regulatory Members on 7 newer Tier 3 Guidelines; and voluntary participation of ICH Regulatory Observers on Tier 1 Guidelines;
- The Assembly noted participation of up to 40 industry companies.

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 E6(R3) *Step 2* presentation and ICH Q9(R1) training materials developed by Working Groups recently published on the ICH website; as well as ICH E2B(R3) and ICH Q12 WG materials under development with FDA, United States Studios thanks to a grant it has provided for the development of ICH training materials, as well as the development of an ICH E19 video module by FDA, United States with FDA, United States Studios;
- Progress made by ICH's Training Associates to develop online training materials on ICH Q3 series, ICH M4, ICH E8(R1), ICH E17 and ICH Q8-12 Guidelines;
- Activities of 3 Training Subcommittee Sub-groups, focusing their work on the following key areas since their formation in December 2022: renovation and organisation of the ICH Training Website; development of a training evaluation process; and assessment of needs / benefits of the ICH Training Subcommittee outputs.

Assembly Decisions/Actions:

- The Assembly noted the update and the ICH Training activities;
- The Assembly noted the progress of work of Sub-group 1 since the last meeting in Vancouver, focusing on the development of an interactive training web page and infographic for onboarding new ICH Members and Observers, which will be finalised after the meeting in Prague, as well as

development of an ICH Training Subcommittee onboarding slide deck and Training Materials Inventory with categories for the existing ICH training materials;

- The Assembly noted the progress of work of Sub-group 2 since the last meeting in Vancouver, with a pilot evaluation process of the in-person and hybrid regulatory trainings co-funded by ICH launched in August 2023 for Regulators participating on a voluntary basis, and ongoing work on identifying tools to evaluate ICH online training materials, including materials developed by ICH WGs and Training Associates;
- The Assembly noted the recent activities of Sub-group 3, with a launch of the Survey on ICH Training Needs between July – September 2023 among all ICH Regulatory Members and Observers on a voluntary basis, as well as Industry Trade Associations, with an objective to provide direction on prioritisation of ICH training efforts on developing criteria and prioritising training needs related to content and/or implementation of ICH Guidelines with a more targeted approach. The Assembly noted the results of the survey, with 17 high priority needs identified based on both Regulatory and Industry assessment, and acknowledged the Sub-group 3 recommendations to focus on high priority needs with training gaps identified via the survey;
- The MC noted ongoing discussions on work of ICH Training Associates, as well as ICH Working Groups in developing training materials, with a pilot process supported by the MC in Prague, where the Training Associate could be engaged with the EWG early in the Guideline development process (e.g., at *Step 2*), and could help in developing *Step 4* training materials, and case studies, in cooperation with the EWG (or subgroup of Experts), to be piloted for the development of E6(R3) training materials by Training Associate.

ICH Funding of Regulatory Training

The ICH Secretariat provided an update on the status of requests approved for the 2023 ICH Funding of Regulatory training, as well as applications postponed from 2020 – 2022 to 2023, and the planning of the 2024 Call of Expression of Interest for the ICH Regulatory Training Funding.

Assembly Decisions/Actions:

- The Assembly noted that Members/Observers who wish to postpone their training to 2024, have the possibility to do so, by communicating a clear timeline for the training to the ICH Secretariat. In case no clear timeline is provided, the application will be considered withdrawn, and no further postponement will be granted;
- The Assembly noted that the next Call of Expression of interest for ICH-funded Regulatory Training will be launched on 15 December 2023 and a deadline for application on 15 February 2024, with Revised Forms and Process documents to be provided by the ICH Secretariat at the launch of the call;
- The Assembly also noted ongoing discussions on the alternative approaches and/or additions to the current Regulatory Training process, in order to create a more sustainable model and reach more Regulators.

9. ICH Collaboration with PIC/S

The ICH MC Chair informed the Assembly on the status of activities regarding collaboration with PIC/S, including on the Memorandum of Understanding (MoU) with PIC/S.

Assembly Decisions/Actions:

- The Assembly noted the sign off of the final MoU by both ICH and PIC/S in October 2023, with an announcement of the collaboration to be included in the Press Release from the ICH meeting in Prague on the ICH website, and a reciprocal publication on the PIC/S website in the near future;

- The Assembly noted the ongoing collaboration with PIC/S in particular in the field of training, as a part of the PIC/S Inspectorates' Academy (PIA), with ICH financially supporting development by PIC/S of training on ICH Quality Guidelines, to be available for ICH Members and Observers.

10. ICH Work to Progress a PQ KM Capability

The Representative of ICH participating on behalf of ICH in the activities of the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group updated the Assembly on recent activities, including on the finalisation of a Joint ICMRA-ICH-PICS-IPRP PQ KMS WG Work Plan detailing the work of each participating organisation, which will be shortly published on the ICMRA website; as well as the "PQKM Platform Governance Reflection Paper" developed by the ICMRA PQ KMS WG Technology Platform Sub-Working Group for ICH MC consideration.

Assembly Decision/Action:

- The Assembly noted the update on the status of work with the ICMRA PQ KMS WG and next steps further to the "PQKM Platform Governance Reflection Paper".

11. Communication

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 Prague in November 2023, including meetings organised by: FDA, United States and Health Canada, Canada; and MHLW/PMDA, Japan and JPMA.

Assembly Decision/Action:

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

Approaches for Patient Stakeholder Engagement in ICH

The ICH MC Chair provided an update on the status of activities regarding ICH Patient Engagement, including on the outcome of an ICH session at the DIA Global Annual Meeting at the end of June 2023, in Boston, the United States, and initial considerations on the ICH involvement in the 2024 DIA Annual Meeting.

Assembly Decisions/Actions:

- The Assembly noted the outcome of an ICH session at the DIA Annual Meeting at the end of June 2023 in Boston, and DIA request on whether ICH would be interested in holding an ICH Patient session during the June 2024 DIA Annual Meeting which will mark DIA's 60th anniversary, with more information to be given at the next ICH meeting;
- The MC noted EC, Europe planned involvement in two sessions at the DIA Europe meeting in Brussels in March 2024, with a first session providing an update on key ICH Guidelines (one from each category Q, S, E, M) and a second session focusing on explaining ICH patient engagement.

12. General Operational Matters

ICH Operational Efficiency

The Assembly was updated on the status of activities related to operational efficiency, including on the following items: (i) reflection on Implementation Working Groups (IWGs), including identification of sub-categories of IWGs; (ii) use of technical writers, including plans to launch a Request for Proposals (RFP) to identify and contract a Technical Writer Provider; and (iii) consideration of enhancements to the Plenary Working Party (PWP) process.

Assembly Decisions/Actions:

- The Assembly noted the identification of 4 IWG sub-categories – 1-Clarifying, 2-Implementing, 3-Training, and 4-Monitoring/ Discussion and supported the next steps for consideration of differing specificities regarding workflow including: pairing discussion on training efforts to the time of *Step 2* sign-off and preloading the IWG work avoiding the need for the transition of an EWG to an IWG; not requiring that IWGs developing training materials include a full membership; scoping the interaction between an EWG/IWG and Training Associates; and updating of relevant documents and internal process in view of these considerations;
- The Assembly noted the planned launch between November 2023 and February 2024 of a RFP to identify and contract a technical writer provider with a view to using technical writers to help to advance the work of WGs more efficiently, and plans to set-up a funding mechanism to support use of technical writers, with a further update to be provided to the Assembly in June 2023 as informed by the RFP;
- The Assembly noted changes which the ICH MC had supported be made to the ICH Standard Operating Procedures (SOPs) for WGs including increasing the number of Experts per party in a PWP to include a PWP Topic Lead and Alternate, and aligning the timing of the PWP consultation with that of EWG constituency review.

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 31 ongoing WGs of 760 experts from amongst the 21 ICH Members and 36 ICH Observers.

13. ICH Award

The ICH Secretariat presented 6 nominations recommended by the ICH MC as meeting the eligibility criteria for the 2023 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 6 recommended nominees with the 2023 *Award for Outstanding Contribution to ICH Harmonisation for Better Health*, with one awardee present in Prague in-person, and few others joining virtually;
- The Assembly noted that with the consent of awardees, their names would be published on the ICH website as recipients of the 2023 Award.

14. Q4B Maintenance

A Representative from the Pharmacopeial Discussion Group (PDG) presented proposed revisions to the Q4B Guideline and Annex 5 of the SOPs for WGs in line with the approach to Q4B maintenance previously agreed by the ICH Assembly.

Assembly Decision/Action:

- The Assembly noted that more time was needed for ICH Member review of the proposed revisions and supported the postponement of a decision regarding these changes.

15. Election of ICH Assembly Chair and Vice Chair

Assembly Action/Decision:

- The Assembly re-elected Ms. Lenita Lindström (EC, Europe) as Assembly Chair and Dr. Gabriela Zenhäusern (Swissmedic, Switzerland) as Assembly Vice-Chair and noted that they would serve for a two-year mandate.

16. Organisation of next MC election

The ICH Secretariat briefly presented a process for appointment of MC Elected Representatives by the Assembly Members, with next elections to take place in June 2024 in Fukuoka.

Assembly Actions/Decisions:

- The Assembly noted the election process and eligibility criteria for MC Elected Representatives, both for Regulatory and Industry Members, and that candidatures should be submitted to the ICH Secretariat in writing at least 4 months prior to the next Assembly meeting, with a deadline of 1 February 2024 for decision in June 2024;
- The Assembly noted that the Implementation survey to support MC Elections for Regulatory Members will take place from December 2023 – February 2024 (see also item #7).

17. WGs meeting in Prague

The Assembly received reports from each of the 16 WGs meeting in Prague. The Assembly was informed that requests from the ICH WGs to meet at the next ICH meeting in Fukuoka, Japan on Saturday, 1 June – Wednesday, 5 June 2024 would be taken under consideration by the ICH MC at the end of its meeting in Prague, and that the list of WGs agreed by the ICH MC to have interim meetings and/or to meet face-to-face in Fukuoka will be made available to the Assembly in due course.

17.1. 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) Rapporteur reported to the Assembly on the outcome of the meeting of the E2B(R3) EWG/IWG. The E2B(R3) EWG/IWG progressed reconciliation of the Implementation Guide and Q&A, revised Code list 25, finalised the Appendix I(G) and aligned content for Training Material Module III.

In a joint meeting with the E2D(R1) EWG, alignment was reached for the integration of new E2B(R3) values in E2D(R1) after *Step 3* and the development of an "Information Paper" by the E2B(R3) EWG/IWG to support the transition of the new values to be published with E2D(R1) at *Step 4*.

In a joint meeting with the M2 EWG, the E2B(R3) EWG/IWG discussed ongoing considerations with regards to the international standardization efforts and ongoing topics that may impact the ICSR to be discussed in future activities with the M2 EWG.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the E2B(R3) EWG/IWG noting a minor revision as per the E2B(R3) maintenance procedure will be made to the Implementation Guideline Package (including updated IG, code list & Appendix I(G)) and Q&A and is expected to be published in January 2024;
- The Assembly noted Training Material Module III is expected to be published in March 2024;
- The Assembly noted further activities with the E2D(R1) EWG and M2 EWG will be held regarding reaching a common position on external standard development activities and development of the Information Paper.

17.2. E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Dr. Twomey – EC, Europe; E6(R3) Annex 2 Sub-group Regulatory Chair: Dr. Thompson – EC, Europe)

The E6(R3) Rapporteur and Annex 2 Sub-group Regulatory Chair reported to the Assembly that over 5000 comments were received during the public consultation of the Draft E6(R3) Guideline, including Principles and Annex 1, and that the E6(R3) EWG has begun a regional review of these comments to determine major trends.

The E6(R3) Annex 2 Sub-group made significant progress drafting the majority of the document and work on refining content within key sections with convergence on critical areas 1) Informed consent considerations, 2) Utilisation of healthcare settings and 3) Alternative approaches to IP management.

Assembly Actions/Decisions:

- The Assembly noted the updated Work Plan and a 2-month delay for the E6(R3) Annex 2 Sub-group, noting E6(R3) Annex 2 is expected to reach *Step 1* and *Step 2a/b* between June and August 2024;
- The Assembly noted the E6(R3) EWG have requested an Interim Meeting in 2024 exceptionally outside of the ICH MC Interim Meeting period to progress comments review for the Principles and Annex 1;
- The Assembly noted the E6(R3) EWG is continuing discussion regarding how to develop a targeted updates mechanism which would allow for agile updates to annexes in a 6 to 12-month period.

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

The E11A Rapporteur reported to the Assembly on the progress of the E11A EWG meeting at which the E11A EWG addressed 65% of the 1182 comments received from the *Step 3* public consultation which were previously triaged by 3 internal Sub-groups. In addition, consensus was reached on several technical aspects of the guidance (e.g., model-informed approaches, statistics) within the framework of existing ICH and regional guidances.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan of the E11A EWG, noting that to prevent a delay in the timeline the E11A EWG have requested an Interim Meeting in Q1 2024 parallel to the ICH MC Interim Meeting;

- The Assembly noted the E11A EWG will develop training materials within 6 months after the publication of the final ICH E11A Guideline;
- The Assembly noted that the E11A EWG may request additional Subject Matter Experts (SMEs) who would have industry experience to aid development of training materials.

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

The E20 Rapporteur reported to the Assembly on the progress of the E20 EWG meeting. The E20 EWG continues to work on the E20 draft Technical Document. While progress has been made, challenges for alignment on specific topics have been identified and next steps to address the challenges to reach consensus have been planned to address core principles and Bayesian methods applied to adaptive designs. The E20 EWG requested a 6-month extension in the timeline to reach *Step 1* and *Step 2a/b*, with input from the ICH MC to be sought if needed prior to reaching *Step 1* and *Step 2a/b*.

Assembly Action/Decision:

- The Assembly noted the updated Work Plan and the 6-month extension for the E20 EWG, and supported the new timeline for the draft Technical Document to reach *Steps 1 and 2a/b* in November 2024.

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

The E21 Rapporteur reported to the Assembly on the progress of the E21 EWG meeting. The E21 EWG continues work on the draft Technical Document. The E21 EWG will conduct 2 rounds of constituents review of the draft Technical Document in Q3 and Q4 2024.

Assembly Actions/Decisions:

- The Assembly noted the Work Plan for the E21 EWG, noting the draft Technical Document will reach *Steps 1* and *2 a/b* in Q1-Q2 2025;
- The Assembly noted that collaboration with other ICH WGs will be requested after relevant EWGs have been identified;
- The Assembly noted the request to appoint a Technical Writer to assist drafting of the Technical Document and that the process for Technical Writer allocation is being finalised by the ICH MC.

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

The M1 PtC Rapporteur reported to the Assembly on the progress of Day 1 of the planned 3-day meeting, noting the EWG had commenced discussion regarding the Medication errors, Off label use and Pregnancy exposures, with work on the new "Manufacturing and Quality System Issues" section of the Companion Document which would be finalised and published in 2024.

Assembly Action/Decision:

- The Assembly noted an updated Work Plan for the M1 PtC EWG, noting the Companion Document v3.0 with new section on Manufacturing and Quality System Issues and revised section on Medication errors will be released in April 2024.

17.7. M4Q(R2) EWG: Revision of M4Q(R1) CTD on Quality guidance (Rapporteur: Dr. Yu – FDA, United States; Regulatory Chair: Mr. van der Stappen – EC, Europe)

The M4Q(R2) Rapporteur reported to the Assembly on the progress of the M4Q(R2) EWG meeting at which alignment was reached on the design of Module 2 leveraging the mock examples, provided by ICH Members, which laid the foundation for Module 2 and 3. Module 2 will be the basis for Regulatory Assessment and will be supported by Module 3, which will be structured to retain the information and data repository (reports, data, protocols, descriptions). Due to the time needed to reach alignment for Module 2 structure, the M4Q(R2) EWG have requested a 6-month extension to reach *Step 1* and *Step 2a/b*.

Assembly Action/Decision:

- The Assembly noted the updated Work Plan for the M4Q(R2) EWG and supported the 6-month extension to reach *Step 1* and *Step 2a/b* by November 2024 with the draft Technical Document to be shared with the PWP in April 2024.

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

The M11 Rapporteur reported to the Assembly on the outcome of the meeting of the M11 EWG. In addition to progress on the M11 draft Guideline, the M11 EWG progressed work on the M11 Template and M11 Technical Specification. The M11 EWG progressed addressing the comments received during *Step 3* public consultation and the joint industry-regulator statistics Sub-group recommendations. The M11 EWG also initiated discussion on the need for the development of training materials, which will be determined in Q2 2024. Based on the extensive workload and deliverables, the M11 EWG requested technical writing support to not delay the timeline.

Assembly Actions/Decisions:

- The Assembly noted an updated Work Plan for the M11 EWG will be provided after the Prague Meeting, noting the draft Guideline, Template and Technical Specification will reach *Steps 3* and *4* in Q3 2025;
- The Assembly noted that consistent M11 EWG and M2 EWG interaction and collaboration is required to for the Technical Specification and to determine a mechanism for updating the Technical Specification after completion of M11 EWG work;
- The Assembly noted the request to appoint a Technical Writer and that the process for Technical Writer allocation is being finalised by the ICH MC.

17.9. M12 EWG: Drug Interaction Studies (Rapporteur: Dr. Madabushi – FDA, United States; Regulatory Chair: Dr. Ishiguro – MHLW/PMDA, Japan)

The M12 Rapporteur reported to the Assembly on the outcome of the meeting of the M12 EWG. The M12 EWG continues to work on the M12 draft Guideline addressing the comments received during the *Step 3* Public Consultation and reaching alignment on major elements of the guideline including on the emerging areas of Endogenous Biomarkers and Protein Binding. The M12 EWG considered the need for the development of training materials to be determined by December 2023 prior to the M12 Sign-off.

Assembly Actions/Decisions:

- The Assembly noted the M12 EWG is on track for M12 to reach *Steps 3* and *4* in Q1 2024;
- The Assembly noted that during the development of training materials, the M12 EWG will also develop clarifying Q&As.

17.10. 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 reported to the Assembly on the progress of the M13 EWG who are developing a series of guidelines M13A, M13B and M13C. Work on M13A and M13B is currently ongoing and the M13 EWG is addressing all comments received during M13A public consultation and in parallel the M13B Technical Document sections are being drafted and reviewed. The M13 EWG have also commenced drafting of M13A **"**Clarification Document". Regarding the demanding workload to remain on target with the projected timeline, the M13 EWG requested an Interim Meeting within 2024 Spring or a 4–6-month extension for the development of M13B to ensure completion of both M13A and the M13A **"**Clarification Document" in June/July 2024.

Assembly Action/Decision:

- The Assembly noted the updated Work Plan for the M13 EWG and that the necessity of the Interim Meeting will be further discussed by the MC based on further clarification of contents of the "Clarification Document".

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

The M15 Rapporteur reported to the Assembly on the outcome of the meeting of the M15 EWG including the progress on the development of the draft Technical Document triaging and addressing key comments and topics and aligning on structure, terminology, language and principles to be addressed in the M15 Guideline. The M15 EWG will also seek comments from constituent Subject Matter Experts (SMEs) to ensure resolution of any language queries before finalisation of the Technical Document.

Assembly Action/Decision:

- The Assembly noted the Work Plan of the M15 EWG and that the draft Technical Document is expected to reach *Steps 1* and *2a/b* by September 2024.

17.12. 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 reported to the Assembly on the outcome of the meeting of the Q1/Q5C EWG. The Q1/Q5C EWG further progressed the development of the draft Technical Document and reached consensus on multiple sections. The Q1/Q5C EWG also considered the need for transitioning to an IWG to develop targeted training materials to support implementation after *Step 4* is reached for Q1/Q5C.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the Q1/Q5C EWG and that the draft Technical Document is expected to reach *Steps 1* and *2a/b* by Q4 2024 with constituent review to be carried out in Q1 2024;
- The Assembly noted the request to transition to an IWG to develop targeted training materials to support implementation after *Step 4* is reached for Q1/Q5C;
- The Assembly noted the Q1/Q5C EWG have requested an Interim Meeting between June and November 2024 to reach consensus on complex issues requiring alignment;
- The Assembly supported the Q1/Q5C EWG interaction with the CGTDG to leverage and engage Advanced Therapy Medicinal Products experts to support the development of the Technical Document and align on topics discussed.

17.13. Q2(R2)/Q14 EWG: Analytical Procedure Development and Revision of Q2(R1) Validation of Analytical Procedures (Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)

The Q2(R2)/Q14 Rapporteur reported to the Assembly on the outcome of the meeting of the Q2(R2)/Q14 EWG, including the progress made on conducting a line-by-line review and the reaching of consensus on the final draft Guidelines and *Step 3* sign-off at the meeting in Prague.

Furthermore, as approved by the ICH MC, the Q2(R2)/Q14 EWG will transition to an IWG to develop training material. The training material is to support the implementation of the Q2(R2) and Q14 Guidelines respectively and will consist of 7 modules. The IWG would primarily work virtually within a 1-year period of time and would not require the full EWG membership and 1 Expert per party to reach quorum would be needed. However external expertise maybe also required to support the development of the training materials.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Topic Leaders of the Q2(R2)/Q14 EWG had signed off *Step 3* of the Q2(R2) and Q14 draft Guidelines, further to which the Guidelines were adopted by Regulatory Members of the Assembly under *Step 4*;
- The Assembly supported the smaller size of the IWG composition to free resources for other Quality Topics, and noted that further to ICH MC discussions regarding IWGs in Prague, the procedure for the establishment of the IWG would be modified accordingly;
- The Assembly noted that the Q2(R2)/Q14 IWG Work Plan will be updated by the Q2(R2)/Q14 EWG prior to transition to an IWG.

17.14. 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 Rapporteur reported to the Assembly on the progress of the Q3E EWG meeting at which the Safety Team Members of the Q3E EWG begun the review of the first batch of PDE Reports from work with vendors. The Q3E EWG also outlined a workflow to review the PDEs and developed a checklist for PDE review to standardize review, capture comments on individual PDEs, and to decide on the need for further EWG discussion. Alignment was also reached on derivation of Qualification Thresholds, approaches for assessment of compounds that lack existing bioavailability studies and challenges and feasibility of deriving dermal PDEs. Currently the Threshold Project will prioritize oral and parenteral routes. The Q3E EWG have begun initial discussion as to how the final PDEs will be published with initial considerations to share PDE values as a table to be published with the final Q3E Guideline. With regard to the Q3E timeline due to the vendor agreements being finalised only prior to the Prague meeting, the Q3E EWG requested a 6-month extension.

Assembly Actions/Decisions:

- The Assembly noted the updated Work Plan of the Q3E EWG and supported the 6-month extension to enable completion of the Threshold Project with *Steps 1* and *2a/b* now expected by June 2025;
- The Assembly recommended the Q3E EWG review the Q3D(R2) Guideline Appendix regarding dermal routes of administration.

17.15. Q5A(R2) EWG: 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) Rapporteur reported to the Assembly on the outcome of the meeting of the Q5A(R2) EWG, including the progress made on addressing the comments received, line-by-line review and the reaching of consensus on the final draft guideline and *Step 3* sign-off at the meeting in Prague. In addition, the Q5A(R2) EWG requested an extension of approximately 12 months to develop training materials which will include written case studies, slides, and virtual webinars to support implementation of Q5A(R2). The topics addressed in the case studies include 1) New Product Types, 2) Viral Safety of Continuous Manufacturing Processes and 3) Prior Knowledge / Platforms. It was noted that alignment with Q13 will be required to ensure Continuous Manufacturing Processes are adequately addressed.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Topic Leaders of the Q5A(R2) EWG had signed-off *Step 3* of the Q5A(R2) draft Guideline, further to which the Guideline was adopted by Regulatory Members of the Assembly under *Step 4*;
- The Assembly noted the request to extend the EWG timeline to develop training materials as an IWG within a 12-month period which would be further discussed by the ICH MC determining the composition and size of the proposed IWG.

17.16. Q9(R1) EWG: Quality Risk Management (Rapporteur: Mr. O'Donnell – EC, Europe; Regulatory Chair: Mr. Viehmann – FDA, United States)

The Q9(R1) Rapporteur reported to the Assembly on the outcome of the meeting of the Q9(R1) IWG. The Q9(R1) IWG commenced the review of the initial training materials developed by an ICH Training Associate and updating the 2006-2010 Q8/Q9/Q10 training materials currently published on the ICH website. Based on the initial review, the Q9(R1) recommended pausing the review work of the remaining Training Associate materials so that consideration can be given to changes identified, and next steps, with suggestion of a gap analysis to be performed such that the materials developed are additive in value and compatible with other ICH training materials. The Q9(R1) IWG will be reviewing the IWG Concept Paper with regard to the work on the Training Associate materials to determine if an update would be required.

Assembly Action/Decision:

- The Assembly noted the work plan of the Q9(R1) IWG and the expectation of the IWG to complete review of the 2006-2010 training materials and update by June 2024.

18. WGs not Meeting in Prague

18.1. E2D(R1) EWG: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Rapporteur: Ms. Edwards – EFPIA; Regulatory Chair: Dr. Ball – FDA, United States)

The E2D(R1) EWG continues to work on the E2D(R1) draft Technical Document.

The E2D(R1) draft Technical Document is expected to reach *Steps 1* and *2a/b* by January 2024.

18.2. E14/S7B DG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Rapporteur: Dr. Strauss – FDA, United States)

With the E14/S7B DG close to the conclusion of its one-year term, the DG will recommend to the ICH MC the development of a second stage of Q&As, with further consideration needed regarding the next steps.

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

The M2 EWG continues its work on: exploring/identifying technological risks or opportunities by discussing with ICH WGs at *Step 1* and reviewing *Step 3-4* documents; M2 EWG continues work on the development of a New ESTRI Recommendation; and working on CeSHarP documentation.

18.3.1. M8 Sub-group of M2: The Electronic Common Technical Document (eCTD) Ms. Slack – FDA, United States / Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Ms. Puusaari – EC, Europe)

The M8 Sub-group of the M2 EWG continues its work to monitor the status of implementation of eCTD v4.0.

18.4. 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.

18.5. M10 EWG: Bioanalytical Method Validation (Rapporteur: Dr. Ishii-Watabe – MHLW/PMDA, Japan; Regulatory Chair: Dr. Booth – FDA, United States)

Steps 3 and *4* were reached for the M10 Guideline in May 2022. *Steps 3* and *4* were reached for the M10 Q&As in November 2022.

The M10 EWG continues its work to finalise training materials which are to be expected shortly.

18.6. 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 continues to work on the M14 draft Technical Document, which is expected shortly.

18.7. Q3C(R9) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Acting Rapporteur: Dr. Froetschl – EC, Europe)

The Q3C(R9) Maintenance EWG proposed a minor revision using the Minor Revision Procedure captured in V.13 of the ICH Standard Operating Procedure of ICH WGs.

Assembly Action/Decision:

- The Assembly approved revision of ICH Q3C(R9) using the Minor Revision Procedure captured in V.13 of the ICH Standard Operating Procedure.

18.8. 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.

18.9. 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. The Q12 Training Material Module 8 (case studies) is expected to be finalised in 2024. The Q12 IWG is working on the finalisation of a broad-audience video with the support of the FDA, United States studios.

18.10. 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 IWG continues to work on the development of training materials expected to be finalised by June 2024.

Assembly Action/Decision:

- The Assembly noted the Q13 IWG will hold an interim meeting in Tokyo, Japan in January 2024.

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

The Regulatory S1B(R1) EWG experts continue to write a final evaluative paper of the complete dataset as the result of the Prospective Evaluation Period.

18.12. 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.

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

A disbandment of the GDG is foreseen at the conclusion of a 2-year dormant period in November 2023.

18.14. 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.

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

The QDG continues as a DG with low activity.

18.16. 18.16. 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 remit of CGTDG will focus on high maturity modalities linked to broader global clinical development plans and existing approved products, with the DG to identify and recommend topics for potential harmonisation as part of a roadmap development including prioritisation.

19. 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:
    - 1 - 5 June 2024 in Fukuoka, Japan
    - 2 - 6 November 2024 in the Americas (location to be confirmed soon)
    - 10 - 14 May 2025 in Europe (location to be confirmed)
    - 1 - 5 November or 15 - 19 November 2025 in Asia (dates & location to be confirmed)

20. 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.