To:
ICH Assembly Members & Observers

22 June 2022

FINAL MINUTES

ICH Assembly Hybrid Meeting

24-25 May 2022, Athens

Please find hereafter the final minutes of the Assembly hybrid meeting held in Athens on 24-25 May 2022.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICH, Route de Pré-Bois 20, P.O. Box 1894, 1215 Geneva, Switzerland
Telephone: +41 (22) 710 74 80 - *admin@ich.org, http://www.ich.org*

List of Assembly Participants

Chair: Ms. Lenita Lindström-Gommers
Vice-Chair: Dr. Gabriela Zenhäusern

ICH Assembly Member Representatives:

Mr. Gustavo Santos	ANVISA, Brazil
Mr. Diogo Soares	ANVISA, Brazil
Dr. Wassim Nashabeh	BIO
Ms. Khushboo Sharma*	BIO
Ms. Miriam Loera*	COFEPRIS, Mexico
Ms. Lenita Lindström-Gommers (Chair)	EC, Europe
Dr. Georgios Balkamos	EC, Europe
Dr. Bruno Sepodes	EC, Europe
Dr. Susan Forda	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin	FDA, United States
Dr. Michelle Limoli*	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Dr. Leo Bouthillier*	Health Canada, Canada
Mr. Bruce Randall*	Health Canada, Canada
Ms. Siew Wei Chua*	HSA, Singapore
Dr. Dorothy Toh*	HSA, Singapore
Dr. Nick Cappuccino*	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Manabu Yanagisawa	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Younjoo Park	MFDS, Republic of Korea
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Ms. Gavia Taan*	MHRA, UK[1]
Dr. Sheng Yang*	NMPA, China
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
Dr. Gabriela Zenhäusern (Vice-Chair)	Swissmedic, Switzerland
Dr. Jo-feng Chi*	TFDA, Chinese Taipei
Mr. Kevin Ming-hsun Liu*	TFDA, Chinese Taipei
Dr. Elif İnci Ergönül*	TITCK, Turkey
Ms. Handan Öztunca*	TITCK, Turkey

ICH Management Committee Member Representatives:

Dr. Milton Bonelli	EC, Europe
Mr. Teruyoshi Ehara	MHLW/PMDA, Japan

* Virtual attendance
[1] At the Assembly meeting under Agenda item 8, MHRA, UK was welcomed as a new ICH Member

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Dr. Katherine Donigan*	BIO
Ms. Margarita Contreras Olvera*	COFEPRIS, Mexico
Dr. Georgios Balkamos	EC, Europe
Dr. Jyothsna Krishnan	EFPIA
Ms. Jill Adleberg	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Ms. Junhan Shang*	HSA, Singapore
Dr. Shinichiro Hirose*	IGBA
Ms. Mariko Kato	JPMA
Ms. Minjung Lee**	MFDS, Republic of Korea
Ms. Mao Yanagisawa*	MHLW/PMDA, Japan
Mr. Baoshu Wen*	NMPA, China
Ms. Amanda Roache	PhRMA
Mr. Yahya Alnujaym	SFDA, Saudi Arabia
Dr. Gabriela Zenhäusern	Swissmedic, Switzerland
Ms. Pao-Hsuan Huang*	TFDA, Chinese Taipei
Dr. Elif İnci Ergönül*	TITCK, Turkey

ICH Assembly Technical Coordinators:

Dr. Kevin Cunningham	EC, Europe
Dr. Michelle Limoli*	FDA, United States
Dr. Ayako Ono (Sakaguchi)	MHLW/PMDA, Japan

ICH Assembly Standing Observer Delegates:

Ms. Angelika Joos	IFPMA
Ms. Judith Macdonald	IFPMA
Dr. Samvel Azatyan	WHO
Ms. Marie Valentin	WHO

ICH Assembly Observer Delegates:

Mr. Farid Hasanov*	AEC, Azerbaijan
Dr. Matias Gomez*, **	ANMAT, Argentina
Dr. Kamel Mansouri*	ANPP, Algeria[2]
Dr. Kyung Won Seo	APEC
Dr. Rainer Fendt	APIC
Ms. Charunee Krisanaphan*	ASEAN
Dr. Murray Lumpkin*	Bill and Melinda Gates Foundation
Dr. Venugopal Girdharilal Somani*	CDSCO, India
Dr. Celeste Aurora Sánchez González*	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Dr. Ofra Axeldrod*	CPED, Israel
Ms. Asmaa Fouad	EDA, Egypt
Ms. Helene Bruguera *, **	EDQM
Dr. Hajed Mohammad Hashan	GHC

* Virtual attendance

** Replacement for Athens meeting only

[2] At the Assembly meeting under Agenda item 8, ANPP, Algeria was welcomed as a new ICH Observer

Ms. Mimin Jiwo Winanti*	Indonesian FDA, Indonesia
Ms. Yenny Suarez	INVIMA, Colombia
Ms. Janeen Skutnik-Wilkinson	IPEC
Ms. Anastasia Nikitina*	Roszdravnadzor, Russia
Ms. Portia Nkambule*	SAHPRA, South Africa
Ms. Aida Malkhasyan*	SCDMTE, Armenia
Dr. Kevin Moore	UPS

ICH Additional Participants:

Dr. Varley Sousa	ANVISA, Brazil
Dr. Peter Bachmann	EC, Europe
Mr. Martin Harvey Allchurch	EC, Europe
Ms. Andreea Iordache	EFPIA
Mr. Ian Urquhart	Global Self-Care Federation
Ms. Christelle Anquez Traxler	Global Self-Care Federation
Ms. Olivia Suarez-Milan*	Health Canada, Canada
Ms. Tereza Cervinkova	IFPMA
Ms. Machiko Sumi*	JPMA
Ms. Minyoung Lim	MFDS, Republic of Korea
Dr. Risa Ishitani*	MHLW/PMDA, Japan
Ms. Nannan Li*	NMPA, China
Dr. Sean Curtis*	PhRMA

ICH Secretariat:

Mr. Brian Boyle	ICH Secretariat
Ms. Olga Frei	ICH Secretariat
Ms. Nikoleta Luludi	ICH Secretariat
Ms. Anca Matei	ICH Secretariat
Dr. Dawn Ronan	ICH Secretariat

* Virtual attendance

TABLE OF CONTENT

ICH ASSEMBLY MINUTES

Assembly Chair: Ms. Lenita Lindström-Gommers, EC, Europe

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

Opening of the ICH Assembly Hybrid Meeting

The ICH Assembly hybrid meeting in Athens, held on 24 – 25 May 2022, was chaired by Ms. Lenita Lindström-Gommers (Chair – EC, Europe) and Dr. Gabriela Zenhäusern (Vice Chair – Swissmedic, Switzerland).

The Assembly noted the Member Representatives and Observer Delegates participating in the Assembly meeting which was held in a hybrid in-person / virtual format, with all virtual attendees joining for "core hours" when decision-making items were taken and with several virtual attendees participating throughout. The ICH Association keeps growing and in this context, the Chair drew the attention to the fact that the ICH rules include limitations as regards the maximum number of in-person participants in ICH Assembly meetings, and all Member and Observers are therefore invited to verify those rules before making any travel arrangements for future meetings.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda with a modification of the order in which some agenda items were taken.

1. Training

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

- Activities related to ICH Recognised Training Programmes, which are published on the ICH website;
- ICH Working Group (WG) training materials, including: ICH E8(R1) *Step 4* Introductory Training Presentation, ICH E11A and ICH Q2(R2)/Q14 *Step 2* presentations recently published on the ICH website; as well as E9(R1), E2B(R3) and Q12 WG materials under development with FDA, United States Studios thanks to a grant it has provided for the development of ICH training materials, with the development of materials with other WGs also under discussion;
- Progress made by ICH's two Training Associates to develop online training materials on ICH Q1 Stability Guidelines (Introductory Overview Video already published on ICH website, to be shortly followed by additional Online Training Modules), in addition to materials on the ICH M4 Common Technical Document and ICH E2 Pharmacovigilance Guidelines (with ongoing work on development of Introductory Overview Videos for both), and progress on multi-year agreements with three Training Associates for development of training materials on ICH Q3 series, ICH Q5 series, ICH Q8-12, ICH E6, ICH E8 and ICH E17 Guidelines.

The ICH Secretariat also informed the Assembly on the status of 2022 Regulatory Training Funding applications.

Assembly Decisions/Actions:

- The Assembly noted the update and the ICH Training activities;

- The Assembly noted that the multi-year agreements with three Training Associates will be finalised shortly after the meeting in Athens with work beginning in 2022;
- The Assembly noted the status of 2022 Regulatory Training Funding applications approved by the MC at the interim meeting in March 2022, and that eligibility to submit requests was extended from ICH Regulatory Members and Regulatory Observers, to also include other ICH Observers representing or constituted by Regulators, namely Regional Harmonisation Initiatives (RHIs) and PIC/S, starting from the 2023 Call for Expression of Interest. The expansion of the budget in 2023 of the ICH Regulatory Funding Training will be considered in due time taking into consideration the extension of eligibility to RHIs and PIC/S.

2. Implementation of ICH Guidelines

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.

3. Communication

ICH 30th Anniversary Publication and Leaflet

Assembly Decision/Action:

- The Assembly noted the finalisation of printed copies of ICH 30th Anniversary Publication and Leaflet available for each in-person participant to the Assembly meeting in Athens, and that further copies will be shipped to ICH Members and Observers shortly after the meeting, as per requests submitted to the ICH Secretariat.

Communication Activities

Assembly Decision/Action:

- The Assembly noted the recent ICH website developments to improve ICH communication with stakeholders.

ICH Regional Public Meetings

Assembly Decision/Action:

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

Approaches for Patient Stakeholder Engagement in ICH

Assembly Decision/Action:

- The Assembly noted ICH MC discussions regarding considerations for patient stakeholder engagement in ICH and next steps upon which the Assembly will be kept informed.

ICH Award

Assembly Decision/Action:

- The Assembly noted the status of submissions and the upcoming closing of nominations on 1 June for ICH awards to be conferred at the Assembly meeting in November 2022.

4. General Operational Matters

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 708 experts from amongst the 19 ICH Members and 35 ICH Observers.

5. Update on MedDRA

The MedDRA MC Chair reported to the Assembly on MedDRA activities and items for approval further to the MedDRA MC Hybrid meeting held on 22 and 23 May 2022.

The Assembly was updated on the steady increase in the global uptake of MedDRA, with a total number of subscribers close to 7,500 organisations in almost 130 countries. The Assembly was updated on the recent release of Swedish and Latvian MedDRA translations in Version 25.0, making MedDRA available in 16 languages in support of users' language needs. Ongoing work to translate MedDRA into Arabic, Greek, Polish, Maltese, Estonian, Icelandic and Norwegian was also noted; increasing the volume and types of MedDRA virtual trainings available to users; continued work on targeted mappings with other terminologies; the release of the second production of the SNOMED CT – MedDRA mappings, development of new SMQs (Standardised MedDRA Queries) on *Noninfectious myocarditis*/*pericarditis*. The Assembly was furthermore informed on ongoing IT activities including development of tools such as APIs (Application Programming Interfaces) to improve user experience of MedDRA which are expected for official release to users mid-2022.

The Assembly was also updated on activities related to oversight of MedDRA, including an upcoming study looking at long-term MedDRA operations, and a study conducted to gain a better understanding of the potential numbers of new MedDRA users in countries/regions which are moving towards MedDRA's use.

Assembly Decision/Action:

- The Assembly noted the decisions taken by the MedDRA MC during its meeting on 22 and 23 May 2022, including the re-election of Mr. Mick Foy (MHRA, UK) as MedDRA MC Chair for a further one-year term.

6. WGs Not Meeting in Athens

The Coordinator for each Member holding the Rapporteurship provided an update on the status of work of the WG, with the Assembly also being informed on any requests from WGs to meet in-person at the next ICH meeting in Incheon in November 2022. To be noted that all requests would be taken under consideration by the ICH MC at the end of its meeting in Athens.

The Assembly additionally noted that in the case of some WGs, delays had been experienced in the reaching of *Steps 1* and *2* and/or *Steps 3* and *4*, which was noted as being attributable to the COVID-19 pandemic due to elements including competing priorities and not having had an opportunity to meet face-to-face.

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

The Standing Paediatric EWG did not receive any recent request for paediatric advice, 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.

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

Following the *Steps 3* and *4* milestones reached in March 2022 for the update of the ICSR BFC (Backwards and Forwards Compatibility) Specification document, the E2B(R3) EWG/IWG continues its work, including considering updates to Q&As as needed and the development of Training Module III and the voice over for Training Module I and which are expected to be finalised by November 2022.

Assembly Decision/Action:

- The Assembly noted that the MC supported changes proposed by the E2B(R3) EWG to the procedures related to the approval process for its documents.

6.3 E2D(R1) EWG: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Rapporteur: Ms. Edwards – EFPIA)

Established in November 2019, the E2D(R1) EWG continues its work on the development of the E2D(R1) draft Technical Document.

Steps 1 and 2a/b are expected by May 2023. The E2D(R1) draft Technical document should be shared with the E2D(R1) Plenary Working Party (PWP) ahead of Step 1 sign-off, and is expected to be shared by February 2023.

6.4 E8(R1) EWG: Revision on General Considerations for Clinical Studies (acting Rapporteur: Dr. Levenson – FDA, United States; Regulatory Chair: Dr. Kirisits – EC, Europe)

The E8(R1) EWG recently concluded its work on the development of *Step 4* Training Presentation.

Assembly Decision/Action:

- The Assembly noted that the E8(R1) EWG has concluded its activities and is now disbanded.

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

Established in October 2017, the E11A EWG`s draft Technical Document reached *Steps 1* and *2 a/b* in April 2022, and is currently undergoing public regulatory consultation. The EWG is working to develop initial training material case examples for publication on the ICH website.

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

Following the E14/S7B IWG`s first stage Q&As document reaching *Steps 3* and *4* in January and February 2022, and finalisation in April 2022 of initial training materials for the first stage Q&As, the E14/S7B IWG continues to work on the development of comprehensive training material for the first stage Q&As and on recommendations for the second stage Q&As.

6.7 E19 EWG: Optimization of Safety Data Collection (Rapporteur: Dr. Hai – FDA, United States; Regulatory Chair: Dr. Mol - EC, Europe)

The E19 EWG continues to address the comments received during the public regulatory consultation period which ended in September 2019.

The Assembly noted that more time was needed to complete with reviews, with a request from some Members for additional time, which would see the timeline for *Steps 3* and *4* being potentially delayed by a couple of months from June 2022.

Assembly Decisions/Actions:

- The Assembly supported the updated timeline for reaching *Steps 3* and *4*;
- The Assembly noted that the E19 EWG would be disbanded upon reaching *Step 4* and providing its *Step 4* Introductory Training Presentation for publication on the ICH website.

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

The E20 EWG continues its work on the E20 draft Technical Document.

Steps 1 and 2a/b are expected by June 2023. The E20 draft Technical document should be shared with the E20 PWP ahead of Step 1 sign-off, and is expected to be shared by March 2023.

6.9 M1 PtC WG: MedDRA Points to Consider (Rapporteur: Dr. Winter – EFPIA; Interim Regulatory Chair: Mr. De – FDA, United States)

The M1 PtC WG continues its work on the updating with each MedDRA release of the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents, having most recently released translations in English, Japanese, Chinese, Korean, Russian and Spanish in March 2022.

Assembly Decision/Action:

- The Assembly noted the updated work plan of the M1 PtC WG reflected the decision taken with the support of the MedDRA MC to pause work on the companion section on product quality issues during manufacturing pending the completion of work on ICH Q9(R1).

6.10 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 to work on: exploring/identifying technological risks or opportunities by discussing with ICH WGs at *Step 1* and reviewing *Step 3-4* documents; development of a report on the potential to innovate regulatory process through technology; considering the need to update recommendations for streamlining ICH standards development process; and development of a technical specification document for CeSHarP with the M11 EWG.

6.11 M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Froetschl – EC, Europe)

Steps 1 and 2a/b for the revised Guideline and Addendum to M7(R2) were reached in October 2021 and underwent public regulatory consultation until February 2022.

Steps 3 and 4 of the M7(R2) revised Guideline and the Addendum are expected by June 2022.

Assembly Decision/Action:

- The Assembly noted that the M7(R2) Q&As had reached *Step 4* electronically in parallel of the Assembly meeting, and that the Q&As will be published on the ICH website alongside the revised Guideline and the Addendum once they also reach *Step 4*.

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

The M8 EWG/IWG continues its work to monitor the status of implementation of eCTD v4.0.

Assembly Decision/Action:

- The Assembly noted that the Regulatory Topic Leaders had signed off at *Step* 3, the eCTD v4.0 Q&As and Specification Change Request Document v1.7 and eCTD v4.0 Implementation Package v1.5, further to which they were adopted by Regulatory Members of the Assembly under *Step 4*.

6.13 M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Ms. Combs – PhRMA; Regulatory Chair: Dr. Fitzmartin – FDA, United States)

The M11 EWG continues its work on the development of the M11 draft Technical Document, the clinical protocol template and the Technical Implementation Guide.

Steps 1 and 2 a/b for the Guideline, Template, and Technical Implementation Guide are expected by July 2022. Steps 3 and 4 for Guideline, Template, and Technical Implementation Guide are expected by July 2023.

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

Assembly Decision/Action:

- The Assembly noted that *Step 1* of the M12 draft Technical Document was signed-off by the Topic Leaders of the M12 EWG ahead of the Athens meeting, and took the decision to adopt *Step 2a*, further to which the Regulatory Members of the Assembly took the decision to adopt *Step 2b*.

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

Established in July 2020, the M13 EWG continues its work on the development of the first M13 draft guideline in the series (M13A).

Steps 1 and 2a/b are expected by December 2022.

6.16 M14 EWG: General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of a Medicine (Rapporteur: Mr. Moeny – FDA, United States; Regulatory Chair: Dr. Kajiyama – MHLW/PMDA, Japan)

Following its establishment in April 2022, the M14 EWG continues its work on the development of the M14 draft Technical Document.

6.17 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)

Steps 1 and 2 a/b of the Q2(R2) and Q14 draft Guidelines were reached in March 2022, and the draft Guidelines are currently undergoing public regulatory consultation.

While published as two separate draft Guidelines, it should be noted that the EWG developed a combined Q2(R2)/Q14 *Step 2* Training Presentation.

Steps 3 and 4 of the Q2(R2) and Q14 draft Guidelines are expected by May 2023.

6.18 Q3C(R9) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

Steps 3 and *4* of the Q3C(R8) Guideline including the Permitted Daily Exposure (PDE) levels for the solvents 2-2-Methyltetrahydrofuran, Cyclopentyl methyl ether and Tertiary butyl alcohol were reached in April 2021.

The Q3C(R9) Maintenance EWG remains in a dormant state until proposals for revisions are received.

6.19 Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

The Q3D(R2) Maintenance EWG addressed the comments received during the public regulatory consultation period ending in June 2021, and *Steps 3* and *4* were reached in April 2022.

Assembly Decision/Action:

- The Assembly noted that in line with the previous decision of the Assembly, the Rapporteurship of the WG will rotate to Dr. Roland Froetschl (EC, Europe) in line with Annex 4 of the SOP on rotation of Rapporteurship once the *Step 4* Introductory Training Presentation has been reached.

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

Established in July 2020, the Q3E EWG continues its work on the development of the Q3E draft Technical Document.

Steps 1 and 2a/b are expected by May 2023. The Q3E draft Technical Document should be shared with the Q3E PWP ahead of Step 1 sign-off and is expected to be shared by March 2023.

Assembly Decision/Action:

- The Assembly noted that the MC had supported an interim meeting of the Q3E EWG for September 2022, noting that since the meeting would be hosted in the US, the meeting would be held in-person only and not as a hybrid meeting with virtual component.

6.21 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 IWG is working on the finalisation of Training Material Module 8 (case studies) as well as on a broad audience video with the support of the FDA, United States studios.

The Q12 Training Material Module 8 (case studies) is expected to be finalised shortly.

Assembly Decision/Action:

- The Assembly noted that the MC was discussing the future of the Q12 EWG following completion of its Training Module (Module 8) and how best to support expected future implementation questions.

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

Steps 3 and *4* for the S5(R3) Guideline were reached electronically in February 2020, with no proposals for revisions of Annex 1 or 2 received at this time and therefore the group remains in a dormant state.

6.23 S12 EWG: Biodistribution Studies for Gene Therapy Products (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Serabian – FDA, United States)

Following public regulatory consultation, ending December 2021, the S12 EWG continues to address the comments received during the public regulatory consultation period.

Steps 3 and 4 on the S12 Guideline are expected by May 2023.

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

Having finalised its recommendations in 2021, the GDG is dormant until the ICH MC requests or directs them to resume work.

6.25 Quality Discussion Group (QDG) (Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Dr. Barry – EC, Europe)

At the end of 2021, the QDG submitted its report on the finalisation of its activities and its recommendations were published on the ICH website. Further to this, it was agreed to keep the QDG as a DG with low activity.

6.26 Model-Informed Drug Development Discussion Group (MIDD DG) (Rapporteur: Dr. Marshall - PhRMA; Regulatory Chair: Dr. Karlsson – EC, Europe)

The MIDD DG recently finalised its "roadmap" including appropriate sequencing and format for incorporating MIDD concepts into a proposal on ICH E4 (i.e., Revision, Addendum, Q&A).

Assembly Decision/Action:

- The Assembly noted that the roadmap has been published on the ICH website further to MC support, and the MIDD DG has been disbanded.

7. 2021 Annual Report of the Association

The ICH Secretariat presented to the Assembly the 2021 ICH Annual Report on the activities of the Association which covered the activities undertaken by the ICH Management Committee (MC), the MedDRA MC and the ICH Secretariat on behalf of the ICH Association.

Assembly Decision/Action:

- The Assembly approved the 2021 Annual Report for publication on the ICH website and the discharge of the ICH MC, MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2021 on behalf of the ICH Association.

8. Membership and Observership

The ICH Secretariat presented to the Assembly an overview of the applications for Membership and Observership processed since the last virtual ICH Assembly meeting in November 2021 and shared the ICH MC's recommendations on these applications in view of the eligibility criteria.

Assembly Decisions/Actions:

- The Assembly approved the following application for Membership under Article 11(1) of the ICH Articles of Association under an expedited procedure:
    - MHRA, UK;
- The Assembly approved the following application for Observership under Article 17.1(a) of the ICH Articles of Association:
    - ANPP, Algeria.

9. New Topics & Strategic Discussions

2022 New Topics Proposals

The Assembly was informed by the ICH MC New Topic Subcommittee co-Leads on the New Topic proposals which were submitted by ICH Members and Observers in December 2021 as part of the limited call only for New Topics in specific areas on the basis of pre-defined criteria; and on the outcome of the review and assessment of proposals by the ICH MC.

Assembly Decisions/Actions:

- The Assembly endorsed the proposal for a new Efficacy Topic (E21) on "Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials" and the related Concept Paper outline, with an informal WG to be established by the end of 2022;
- The Assembly supported that a proposal on "General Considerations for Patient-Centric Product Information" should be revised and resubmitted seeking further input from other Members and Observers to be provided to the proposing party directly and also giving consideration as to whether the topic proposal could be more suitable to be submitted as another ICH work product, such as a Reflection Paper.

Strategic Framework

Assembly Decision/Action:

- The Assembly noted the revised ICH Strategic Framework document.

Q1/Q5C informal WG on Targeted Revisions of the ICH Stability Guideline Series

Assembly Decision/Action:

- The Assembly approved PhRMA's nomination of Dr. Megan McMahon as the informal WG Leader (and subsequent Rapporteur) of the new Q1/Q5C informal WG which is in the process of establishment further to Assembly approval of this new topic in June 2021.

10. Financial Matters

ICH Finance Committee

The Assembly was informed by the ICH Finance Committee Chair on the ongoing activities of the ICH Finance Committee which includes representation from the ICH MC and the MedDRA MC on: approaches to reducing surplus funds, including through the recently approved multi-year training project; inclusion of the asset preservation policy in the MC Rules of Procedure and incorporation of its related implementation procedure into the working procedures of the Finance Committee which is moving forward in line with this asset preservation strategy; decision to postpone indefinitely the introduction of meeting participation fees and exploration of potential grants; and Finance Committee Work Plan.

Assembly Decision/Action:

- The Assembly noted the report of the ICH Finance Committee and actions undertaken in line with working procedures and with the support of the ICH MC.

2021 Financial Statements

The Assembly was informed by the ICH Secretariat on the 2021 Audited Accounts and Financial Statements, and the 2021 ICH Closing Expense Report.

Assembly Decisions/Actions:

- The Assembly approved the 2021 Audited Accounts and Financial Statements of the ICH Association which will be filed with the 2021 tax return of the ICH Association;
- The Assembly approved the re-appointment of the current auditor to audit the ICH annual financial statements for the years 2022 and 2023.

11. Procedural Matters

Assembly Rules of Procedure

The ICH Secretariat presented to the Assembly amendments proposed to the Assembly Rules of Procedure (RoP) related to: shortening the time period for review of draft and revised reports and minutes; and clarification of the expert appointment and participation process.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the ICH Assembly RoP v10.0, and approved the ICH Assembly RoP v11.0, which will be published on the ICH website.

ICH Management Committee Rules of Procedure

The ICH Secretariat presented to the Assembly updates made to the ICH MC RoP related to: shortening the time period for review of draft and revised reports and minutes; and addition of a new Annex 1: Asset Preservation Policy for ICH Reserve Funds.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the ICH MC RoP v10.0, and that the MC had approved the ICH MC RoP v11.0 at its hybrid meeting in Athens, which will be published on the ICH website.

SOPs of the WGs

The ICH Secretariat presented to the Assembly updates made to the SOPs of the WGs related to: clarification on the expert appointment and participation process; reflection of recent ICH MC decisions regarding Discussion Groups; and clarification of the error correction procedure.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the SOPs of the WGs v11.0, and that the MC had approved the SOPs of the WGs v12.0 at its hybrid meeting in Athens, which will be published on the ICH website.

12. WGs Meeting in Athens

The Assembly was informed that requests from WGs to meet in-person at the next ICH meeting in Incheon in November 2022 would be taken under consideration by the ICH MC at the end of its meeting in Athens.
The Assembly additionally noted that in the case of some WGs, delays had been experienced in the reaching of *Steps 1 and 2* and/or *Steps 3* and *4* milestones which was noted as being attributable to the COVID-19 pandemic due to elements including competing priorities and not having had an opportunity to meet face-to-face.

12.1 E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. ElZarrad – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)

The E6(R3) EWG Rapporteur reported to the Assembly on the outcome of the meeting of the E6(R3) EWG including on the progress made on the revision of the Guideline and active collaboration with E6 stakeholders in line with the E6 Stakeholder Engagement Plan.

Steps 1 and 2 a/b for Principles and Annex 1 are expected by November 2022. The E6(R3) draft Technical document should be shared with the E6(R3) Plenary Working Party (PWP) ahead of Step 1 sign-off, and is expected by August 2022.

Endorsement of the revised E6(R3) Concept Paper updated in regards to Annex 2 is expected by October 2022. Timeline for Steps 1 and 2 a/b for Annex 2 is to be determined.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the E6(R3) EWG for activities to be undertaken;
- The Assembly noted that the ICH MC had supported a request from the E6(R3) EWG to hold a face-to-face (hybrid) ad-hoc meeting on 26-29 September 2022 hosted by EC, Europe at EMA offices in Amsterdam;
- The Assembly noted E6(R3) EWG interest to invite six additional experts for a 1-day meeting during the ad-hoc meeting in Amsterdam; these academic experts were previously appointed by

the different ICH regions to provide input to the E6(R3) Stakeholder Meeting held in May 2021 in accordance with the E6(R3) EWG Stakeholder Engagement Plan;

- The Assembly noted that the current Regulatory Chair, Dr. Fergus Sweeney (EC, Europe) would be stepping down after the meeting, and would be replaced by Dr. Spiros Vamvakas (EC, Europe), in line with Section 1.5.2. of the Standard Operating Procedure of the ICH Working Groups.

12.2 M4Q(R2) EWG: Revision of M4Q(R1) CTD on Quality guidance (Rapporteur: Dr. Yu - FDA, United States)

The M4Q(R2) Rapporteur reported to the Assembly on the outcome of the meeting of the M4Q(R2) EWG and the progress made on the draft Technical document, including reaching agreement on the overall outline.

Steps 1 and 2 a/b are expected by July 2023.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the M4Q(R2) EWG for activities to be undertaken;
- Regulatory Members of the MC at the Assembly meeting supported the proposal from the WG for the appointment of Mr. Antonius Johannes (Ton) van der Stappen (EC, Europe) as Regulatory Chair for this WG.

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

The M10 Rapporteur reported to the Assembly on the outcome of the meeting of the M10 EWG, including the progress made on revisions following the public regulatory consultation including a proposed Guideline title change from "Bioanalytical Method Validation" to "Bioanalytical Method Validation and Study Sample Analysis", and the development of Frequently Asked Questions (FAQs) to supplement the Guideline as part of a package of training materials.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the M10 EWG meeting including the finalisation of the Guideline, a FAQs document, and initiation of work on training materials;
- The Assembly noted that the Regulatory Experts had signed-off *Step 3* of the M10 Guideline, further to which the Regulatory Members of the Assembly adopted the Guideline including its title change under *Step 4*;
- The Assembly noted the work plan of the M10 EWG for activities to be undertaken.

Training materials are expected by November 2022.

12.4 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 the revision of the Guideline, and reaching agreement on timing and plan for final editorial correction and formatting ahead of *Step 1*, expected now by July 2022.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the Q5A(R2) EWG meeting and progress made on the Guideline revision;
- The Assembly noted the work plan of the Q5A(R2) EWG for activities to be undertaken.

Steps 1 and 2a/b are expected by July 2022, with Steps 3 and 4 by November 2023.

12.5 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) EWG, including the progress made on addressing the comments received to-date during the public regulatory consultation, which the Assembly noted had not yet been concluded in all Member regions.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the Q9(R1) EWG meeting and progress made on the Guideline revision and noted an expected 6 months delay in future key milestones due to the delayed start of the public regulatory consultation in one region;
- The Assembly agreed that once new training materials have been developed by the EWG for the Q9(R1) Guideline, consideration would need to be given to either removing or updating the existing Q9 training materials on the ICH website which date back to 2006;
- The Assembly noted the Q9(R1) EWG request for an interim meeting in Q1 2023 to complete its work on the development of training materials and that this request would be for the consideration of the ICH MC;
- The Assembly noted the work plan of the Q9(R1) EWG for activities to be undertaken.

Steps 3 and 4 are expected by March 2023.

The Q9(R1) draft Guideline should be shared with the Q9(R1) PWP ahead of Step 3 sign-off and is expected to be shared by November 2022.

Training materials are expected by February 2023.

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

The Q13 Rapporteur reported to the Assembly on the outcome of the meeting of the Q13 EWG, including the progress made at the meeting to address comments received during the public regulatory consultation period.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the Q13 EWG meeting and progress made on addressing the comments received during the public regulatory consultation period;
- The Assembly noted that in line with a proposal in its Business Plan, the Q13 EWG planned to come back to the ICH MC and Assembly regarding interest to establish an Implementation Working Group (IWG) to develop Q13 training materials after *Steps 3* and *4* are reached;
- The Assembly noted the work plan of the Q13 EWG for activities to be undertaken.

Steps 3 and 4 are expected by November 2022.

12.7 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 S1B(R1) Rapporteur reported to the Assembly on the outcome of the meeting of the S1B(R1) EWG, including the progress made at the meeting to address comments received during the public regulatory consultation period.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the S1B(R1) EWG meeting and progress made on addressing comments received during the public regulatory consultation period, and that *Steps 3* and *4* are expected to be reached shortly;
- The Assembly supported the approach of updating a placeholder footnote – footnote 2 of the Addendum – after *Step 4* is reached to include reference to a scientific paper which is currently pending publication;
- The Assembly additionally noted EWG considerations on monitoring the impact and outcomes of the Addendum recommendations after *Step 4* is reached, with this to be further considered by the ICH MC;
- The Assembly noted the work plan of the S1B(R1) EWG for activities to be undertaken.

Steps 3 and 4 on the S1B(R1) Guideline are expected by June 2022.

13. Organisation of Next Meetings

Assembly Decisions/Actions:

- The Assembly noted that in view of the difficulties of conducting meetings in a hybrid format when the biannual ICH meeting occurs in the Americas, or in Asia due to the difference in time zones, the Incheon meeting in November 2022 will be an in-person meeting, with a hybrid/core hours format available only for the ICH Assembly or as a fallback as necessary, and with all other meetings, including the ICH MC, MedDRA MC meetings and WG meetings to be organised as in-person meetings only;
- The Assembly noted the below dates of next ICH Assembly meetings:
    - Tuesday 15 – Wednesday 16 November 2022 in Incheon, Republic of Korea;
    - Monday 12 – Tuesday 13 June 2023 in Vancouver, Canada;
    - Tuesday 31 October –Wednesday 1 November or Tuesday 14 – Wednesday 15 November 2023 in Europe (dates & location do be confirmed);
    - Tuesday 4 – Wednesday 5 June 2024 or Tuesday 21 – Wednesday 22 May 2024 in Asia (dates & location to be confirmed).

14. Press Release

Assembly Decision/Action:

- The Assembly noted the development of a Press Release to be issued shortly after the meeting in line with the usual process.