12 January 2021

FINAL MINUTES

ICH ASSEMBLY VIRTUAL MEETING

18 NOVEMBER 2020

Please find hereafter the final minutes of the Assembly Virtual meeting held on 18 November 2020.

List of Assembly Participants

Chair: Ms Lenita Lindström-Gommers

Vice-Chair: Dr. Celia Lourenco

ICH Assembly Members Representatives

Mr. Diogo Penha Soares	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Dr. Milton Bonelli	EC, Europe
Dr. Sue Forda	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin	FDA, United States
Ms. Joan Wilmarth Blair	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Mr. Leo Bouthillier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr**.** Kyung Won Seo	MFDS, Republic of Korea
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Dr. Sheng Yang	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Dr. Peter Honig	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Ms. Shiang-Ing (Shirley) Pan	TFDA, Chinese Taipei
Dr. Jo-Feng Chi	TFDA, Chinese Taipei
Ms. Nihan Burul Bozkurt	TITCK, Turkey
Mr. Oguzhan Koyuncu	TITCK, Turkey

ICH Management Committee Member Representatives

Dr. Junko Sato	MHLW/PMDA, Japan

ICH Assembly Coordinators

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Mr. David Dee	BIO
Ms. Jill Alderberg	FDA, United States
Dr. Padmaja Kamath	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichiro Hirose	IGBA
Dr. Manabu Yanagisawa	JPMA
Ms. Miyoung Hyun	MFDS, Republic of Korea
Mr. Hirooki Tanabe	MHLW/PMDA, Japan
Dr. Yang Wang	NMPA, China
Ms. Amanda Roache	PhRMA

Dr. Gabriela Zenhäusern	Swissmedic, Switzerland
Ms. Pin-Tsun Kuo	TFDA, Chinese Taipei
Ms. Nihan Burul Bozkurt	TITCK, Turkey

ICH Assembly Technical Coordinators

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, United States

ICH Assembly Standing Observers Delegates

Ms. Sharon Olmstead	IFPMA
Ms. Angelika Joos	IFPMA
Dr. Samvel Azatyan	WHO
Dr. Petra Doerr	WHO

ICH Assembly Observer Delegates

Dr. Youngju Choi	APEC
Dr. Rainer Fendt	APIC
Dr. Murray Lumpkin	Bill and Melinda Gates Foundation
Ms. Belkis Romeu	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Ms. Margarita Contreras	COFEPRIS, Mexico
Dr. Ofra Axelrod	CPED, Israel
Dr. Susanne Keitel	EDQM
Dr. Hajed M. Hashan	GHC
Ms. Diana Milena Calderon Norena	INVIMA, Colombia
Ms. Janeen Skutnik-Wilkinson	IPEC
Dr. Wesal Haqaish	JFDA, Jordan
Mr. Dumitru Saghin	MMDA, Moldova
Dr. Colette Raidy	MOPH, Lebanon
Dr. Hasenah Ali	NPRA, Malaysia
Dr. Analia Porras	PANDRH
Mr. David Churchward	PIC/S
Dr. Alla Samoylova	Roszdravnadzor, Russia
Ms. Fortunate Ntombi Bhembe	SADC
Ms. Portia Nkambule	SAHPRA, South Africa
Dr. Adel Alharf	SFDA, Saudi Arabia
Mr. Garry Macgregor	TGA, Australia
Dr. Kevin Moore	USP

ICH Invited Participants

Mr. Mick Foy	MedDRA MC Chair; MHRA, UK
Mr. Jerry Stewart	PhRMA

ICH Additional Participants

Dr. Agnes Saint-Raymond	EC, Europe
Ms. Lucy Teng	Health Canada, Canada

Ms. Haruka Yoshimatsu	JPMA
Mr. Ryu Mochizuki	MHLW/PMDA, Japan
Ms. Michelle Rohrer	PhRMA

ICH Secretariat

Ms. Clarisse Bertherat
Mr. Masaki Fujita
Dr. Anne Latrive
Ms. Nikoleta Luludi
Ms. Nadia Myers Biggs
Dr. Dawn Ronan

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Opening of the ICH Assembly Meeting

The ICH Assembly Virtual Meeting, held on 18 November 2020, was chaired by Ms. Lenita Lindström-Gommers (Chair – EC, Europe) and Dr. Celia Lourenco (Vice Chair – Health Canada, Canada).

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda with a minor modification so that MedDRA related matters previously foreseen under items #3 and #4 would be discussed under item #5 which is dedicated to MedDRA.

1. Membership and Observership

The ICH Assembly Chair informed the Assembly that there were no applications for Membership/Observership for Assembly consideration at this meeting.

2. Procedural Matters

Articles of Association, Assembly Rules of Procedure, ICH Management Committee Rules of Procedure and Standard Operating Procedures of ICH Working Groups

The Assembly Chair and the ICH Secretariat presented to the Assembly amendments, proposed for its approval, to the ICH Articles of Association and the Assembly Rules of Procedure (RoP), and updates approved by the ICH MC to the ICH MC RoP and the Standard Operating Procedures (SOP) of ICH Working Groups (WGs), related to the: (1) Process for nominating ad-hoc experts to ICH WGs, (2) Process for revising Assembly/MC minutes/reports, (3) Criteria for Membership related to expert participation in WGs, (4) Process for enabling proxies between ICH Observers, (5) Process for *Step 1* and *3* sign-off when the Topic Leader is not available, (6) Assembly and MC virtual meetings in extraordinary circumstances, (7) Criteria for MC Elected Representatives, (8) Template for Compilation of *Step 3* Public Consultation Comments (see also under item #9), (9) Expedited Process for Membership applications, (10) Use of surplus to offset the MedDRA budget, and (11) the need identified for certain minor clarifications.

Assembly Decisions/Actions:

- The Assembly noted the proposed changes to the ICH Articles of Association v.4.0 and approved the ICH Articles of Association v.5.0, which will be published on the ICH website;

- The Assembly noted the proposed changes to the ICH Assembly Rules of Procedure (RoP) v.8.0, and approved the ICH Assembly Rules of Procedure v.9.0, which will be published on the ICH website;

- The Assembly noted the changes to the ICH MC RoP v9.0 and that the MC approved the ICH MC RoP v.10.0, which will be published on the ICH website;

- The Assembly noted the changes to the SOP of the WGs v9.0 for WGs and that the MC approved the SOP of the WGs v10.0, which will be published on the ICH website.

3. Financial Matters

ICH Finance Committee

The Assembly was informed by the ICH Finance Committee Chair on ongoing work by the newly established ICH Finance Committee, which includes representation from the ICH MC and MedDRA MC, on considerations regarding the sustainable financial management of the ICH Association and the timeframe for implementing the new ICH Membership fee structure presented to the Assembly in May 2020.

Assembly Decisions/Actions:

- The Assembly noted the ongoing activities of the ICH Finance Committee and future plans for proposing a streamlining of ICH and MedDRA budget timelines and processes;
- The Assembly noted considerations that ICH Membership fees should be structured to ensure an equitable distribution of burden to all ICH participants and that they should be predictable over time without dramatic fluctuations, incorporating a mechanism for pre-set adjustment of all fees at an appropriate set frequency;
- The Assembly noted that the new annual ICH Membership fee structure (at present, the following amounts are foreseen: CHF 45 000 Fee for non-Founding/non-Standing Members) and the meeting participation fees for Observers of CHF 1 000 per participant to attend each physical meeting) are proposed for implementation beginning in 2023. The revised fees will be included in the draft 2023 budget which will be for Assembly approval in November 2021.

ICH Financial Matters

The Assembly was informed by the ICH Secretariat on ICH financial matters, including revisions to the 2021 ICH budget and 5-Year ICH budget projection for 2021-2025, as well as the provisional 2022 ICH budget and Membership fees.

Assembly Decisions/Actions:

- The Assembly noted that unspent costs from 2020 for the funding of Regulatory Training events postponed to 2021 and for the organisation of ICH 30th Anniversary postponed to 2021 had been carried over to the 2021 ICH budget;
- The Assembly approved the final 2021 ICH budget, which will be published on the ICH website;
- The Assembly approved the draft 2022 ICH budget and 2022 Membership fees which are kept at the same stable level from 2016.

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

The Assembly was updated by the ICH Secretariat on the 2021 Work Plan and Multi-Annual Strategic Plan of the ICH Association.

Assembly Decision/Action:

- The Assembly approved the 2021 Work Plan and Multi-Annual Strategic Plan of the Association, which will be published on the ICH website.

5. Update on MedDRA

The MedDRA MC Chair reported to the Assembly on items for its approval further to the virtual MedDRA MC meeting held on 4, 10 and 13 November 2020.

The Assembly additionally noted a written report from the MedDRA MC which updated it on MedDRA activities. The Assembly was updated about MedDRA's increasingly global uptake amidst the ongoing COVID-19 pandemic, noting 264 new subscribers in 2020 alone bringing the total number of users to over 6,600 organisations in more than 125 countries. Coupled with this, the Assembly noted continuing efforts by the MedDRA Management Committee to ensure the support to MedDRA users. This has included expanding the numbers and types of MedDRA virtual training offerings available to users, work on targeted mappings with other terminologies such as SNOMED-CT, as well as release of two new Standardised MedDRA Queries (SMQs) on Immune-mediated/autoimmune disorders and COVID-19, included in MedDRA v.23.1. The Assembly was also informed on continuing efforts to support the growing language needs of users, with recent initiation of work on a new Swedish MedDRA translation, planning for initiation of a multi-year project in 2021 which will see the translation of MedDRA into the remaining languages of the European Economic Area in collaboration with European National Regulatory Authorities, as well as release of a number of translations of the MedDRA Points to Consider documents. The Assembly was furthermore informed on a recent IT Assessment which is helping to map out the future strategic direction of MedDRA systems and services, and also noted important work ongoing to leverage technological advancements and improve user experience of MedDRA through the development of tools such as APIs - Application Programming Interfaces - which may be integrated by users into their own tools.

Assembly Decisions/Actions:

- The Assembly approved the 2021 MedDRA Budget, including 2021 MedDRA Subscription Fees (unchanged from 2020), which will be published on the ICH website;
- The Assembly approved the proposed revision to Article 50(3) of the ICH Articles of Association to allow for use of ICH funds to offset the MedDRA budget (see also under item #2);
- The Assembly approved the MedDRA MC Work Plan for 2021, which will be published on the ICH website;
- The Assembly supported that ICH enter into cooperation with SNOMED International for the maintenance and distribution of the bidirectional MedDRA/SNOMED mapping;
- The Assembly supported ICH sign-off of two Amendments to the MSSO Service Provider Agreement.

6. New Topic Process & Strategic Discussions

2021 New Topics Process

The Leads of the ICH MC New Topics Subcommittee informed the Assembly on considerations for the conduct of the New Topics process for the 2021 cycle in view of ICH capacity constraints, as there is currently a high number of topics being developed or already agreed for future development, and in view of competing priorities for ICH Member and Observer resources, some of which may have been allocated to COVID-19-related activities.

Assembly Decisions/Actions:

- The Assembly agreed that, in view of the capacity constraints and competing priorities, a very limited call for New Topics would be launched for the 2021 cycle, focusing only on proposals meeting a need for high-impact and urgent harmonisation;
- The Assembly noted that parties submitting proposals meeting the above criterion should also take into account present and near-term availability of expert resources for ICH work in the Quality, Safety and Efficacy domains;
- The Assembly noted that the deadline for ICH Members and Observers to submit proposals had been set to 11 December 2020, in line with the procedures.

Reflection Paper on Patient-Focused Drug Development

The ICH MC Chair presented to the Assembly the draft Reflection Paper on *Patient-Focused Drug Development* (PFDD), which had been supported by the MC in September 2020. This Reflection Paper identifies key areas where incorporation of the patient's perspective could improve the quality, relevance, safety and efficiency of drug development and inform regulatory decision making.

Assembly Decisions/Actions:

- The Assembly endorsed the Reflection Paper on PFDD and its publication on the ICH website for public comments;
- The Assembly noted that, if proposed Guideline work under this Reflection Paper would later move forward as ICH New Topics and be adopted by the Assembly, the Concept Paper and Business Plans for the WGs should include plans for public consultation and stakeholder engagement similar to the approach being taken for ICH E6(R3), incorporating the learnings and best practices from the E6(R3) pilot experience.

7. Q4B Maintenance

The ICH Representative for EDQM, on behalf of the Pharmacopoeial Discussion Group (PDG), presented to the Assembly an overview of possibilities for stakeholder involvement in the PDG process and PDG's proposed approach for the engagement of the pharmacopoeias of the countries/regions of non-Founding ICH Regulatory Members and in the PDG process for their maintenance/revision which had been approved at the ICH meeting in November 2018.

Assembly Decision/Action:

- The Assembly noted that, as approved by the ICH MC, the PDG would conduct a pilot of their proposal, focusing on three Q4B Annexes, and would report back to the ICH MC on the outcome in order for ICH to determine next steps.

8. Status Update of Working Groups which had been planned to meet

The Assembly was invited to note the Work Plans and the written status (noted below) of the WGs. Furthermore, an oral update was provided by the Coordinator for FDA, United States on the E6(R3) EWG (item #8.4) and M2 EWG (item #8.12), and by the Coordinator for PhRMA on the QDG (item #8.33).

The Assembly was also informed by the ICH Secretariat that, in view of the COVID-19 pandemic preventing any face-to-face meeting, ICH WGs were progressing work remotely and milestones were being achieved electronically.

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

The Standing Paediatric EWG did not receive any 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.

8.2. 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)

Steps 3 and 4 for v1.1. of the Dose Forms and Routes of Administration for Individual Case Safety Reports in the E2B(R3) message were finalised in July 2020.

The E2B(R3) EWG/IWG continues its work, including on the development of the Module II and III training materials, and on the update of the ICSR BFC (Backwards and Forwards Compatibility) Specification document (in view of an error correction and updates needed further to the revision of the EDQM User Guide).

Training Material Module II is expected to be finalised by end 2020.

The voice-over presentation for Training Material Module I is expected to be finalised by March 2021.

Training Material Module III is expected to be finalised by March 2021.

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

At the ICH meeting in November 2019, the MC endorsed the transition of the E2D(R1) informal WG to an EWG.

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 November 2021.

8.4. E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)

In March 2020, the MC approved the E6(R3) Public Engagement Stakeholder Plan proposed by the E6(R3) EWG, which involves both (1) direct engagement with stakeholders during EWG meetings, and (2) the organisation by MC Members of meetings for the engagement of regional stakeholders. In May 2020 a summary version of the plan was published on the ICH website.

The E6(R3) EWG continues its work on the E6(R3) draft Technical Document, including revisions to the overarching general principles guideline, with Annex 1 on traditional interventional trials being developed in parallel.

The Coordinator for FDA, United States updated the Assembly on the status of E6(R3) stakeholder engagement as per the E6(R3) Public Engagement Stakeholder Plan.

Assembly Decision/Action:

- The Assembly noted that the group is engaging directly with stakeholders via teleconferences and emails; and that regional public virtual meetings have been organised in June 2020 by both EC, Europe, and FDA, United States, with the meeting reports publicly available.

Steps 1 and 2 a/b for Annex 1 are expected by January 2022.

Endorsement of the revised E6(R3) Concept Paper updated in regards to Annex 2 is expected by June 2022.

Timeline for Steps 1 and 2 a/b for Annex 2 to be determined (work to be undertaken following reaching of Steps 1 and 2 a/b for Annex 1).

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

The E8(R1) draft Guideline was in public regulatory consultation in the ICH Member regions until end of October 2019.

The E8(R1) EWG held a global public stakeholder meeting as per the GCP renovation plan on 31 October 2019 at the FDA, United States headquarters, and a report was published on the ICH website summarising the discussion from the global public stakeholder meeting on E8(R1).

The E8(R1) EWG continues to address the comments received during the regional public consultation period which ended in October 2019.

Steps 3 and 4 are expected by February 2021.

8.6. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses (Rapporteur: Dr. Petavy – EC, Europe; Regulatory Chair: Dr. Ando – MHLW/PMDA, Japan)

Steps 3 and 4 were reached at the ICH meeting in November 2019, and the E9(R1) EWG is working on the development of training materials and videos.

The E9(R1) EWG continues to work on the development of training materials.

The E9(R1) training materials and videos are expected to be finalised by end of 2020.

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

In October 2017, the MC endorsed the E11A Concept Paper and Business Plan and the transition of the E11A informal WG to an EWG.

The E11A EWG continues its work on the E11A draft Technical Document and the development of examples to be included in an Annex.

Steps 1 and 2a/b are expected by June 2021.

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

Steps 1 and 2a/b of the first stage of Q&As were reached electronically in August 2020 and the document is undergoing public consultation until end of November 2020.

The E14/S7B IWG held its virtual public meeting on the draft E14/S7B Q&As on 15 and 16 October 2020.

Step 3 and 4 of the first stage of Q&As are expected by July 2021.

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

The E19 draft Guideline was in public regulatory consultation in the ICH Member regions until end of September 2019.

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

Steps 3 and 4 are expected by June 2022.

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

At the ICH meeting in November 2019, the MC endorsed the E20 Concept Paper and Business Plan, and the transition of the E20 informal WG to an EWG.

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

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

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

In October 2020, the MedDRA MC approved the development of an additional section of the Companion document on manufacturing quality issues.

V2.0 of the Companion document with a new section on product quality issues was released in November 2020.

The M1 PtC WG continues its work on the update of the Points to Consider documents and on the revision of the Companion document, which is expected to be finalised by March 2021.

Release of updated "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 24.0) in English, Japanese, Chinese, Korean, and Spanish translations is expected in March 2021.

8.12. 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 Assembly was updated by the Coordinator for FDA, United States on the work of the M2 EWG to identify solutions to streamline electronic standards development and mitigate the risk of standards becoming quickly obsolete.

The M2 EWG furthermore continues its work on the development of a technical specification for CeSHarP with the M11 EWG, and on considerations for streamlining of the development of technical standards.

Assembly Decision/Action:

- The Assembly noted that the ICH MC had supported that the M2 EWG develop 1-2 detailed process pilots for streamlining of electronic standards development, further to which the ICH MC would consider next steps for this topic.

8.13. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions (Rapporteur: Dr. Schmuff – FDA, United States)

At the Virtual meeting in May 2020, the Assembly endorsed the proposal "Revision of M4Q(R1) CTD on Quality guidance", with an M4Q(R2) informal WG to be established with a delayed start once the Q13 EWG would reach Steps 1 and 2a/b.

No questions were so far received following the implementation of the revised M4 Granularity Document which would need to be addressed by the M4Q(R1) IWG, and the M4Q(R1) IWG therefore remains in a dormant state until the establishment of the M4Q(R2) informal WG, at which time the MC will confirm whether the M4Q(R1) IWG would be disbanded.

8.14. 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 2 a/b for the M7(R2) Q&As were reached in June 2020. As part of Steps 2a/b, the Assembly Members / Regulatory Members of the Assembly pre-approved a change in the M7(R2) draft Guideline which is referenced in the Q&As, so that the change could be published alongside the M7 Q&As as a support document.

The M7(R2) Maintenance EWG/IWG continues its work on the M7(R2) revision and on the development of the second Addendum.

Steps 1 and 2a/b of the revised M7(R2) draft Guideline and draft addendum are expected by December 2020.

Steps 3 and 4 of the M7(R2) Q&A are expected by April 2021.

8.15. 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 continue its work to monitor the status of implementation of eCTD v4.0.

Further to Change Requests received, Steps 3 and 4 are expected in December 2020 on the eCTD v4.0 Q&As and Specification Change Request Document v1.4.

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

The M10 draft Guideline was undergoing public regulatory consultation in the ICH Member regions until end of September 2019.

The M10 EWG continues to address the comments received during the regional public consultation period.

Steps 3 and 4 are expected by November 2021.

The M10 EWG will develop and finalise training materials within a 6-month timeframe after completion of the M10 Guideline.

8.17. 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 Specification document; as well as on the strategic engagement with other key WGs, such as the E9(R1) EWG regarding statistical elements, and M2 EWG regarding data modelling elements.

Steps 1 and 2 a/b for the Guideline, Template, Basis of Requirements, and Technical Description are expected by September 2021.

Steps 1 and 2 a/b for the Full Technical Specification for Electronic Exchange are expected by February 2022.

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

At the ICH meeting in November 2019, the MC endorsed the M12 Concept Paper and Business Plan, and the transition of the M12 informal WG to an EWG.

The M12 EWG continues its work on the development of the M12 draft Technical Document.

Steps 1 and 2a/b are expected by November 2021.

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

In July 2020, the MC approved the M13 Concept Paper and Business Plan, and the transition of the M13 informal WG to an EWG.

The M13 EWG continues its work on the development of the M13 draft Technical Document.

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

8.20. 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)

As noted at the Assembly meeting in November 2019, the group is working on two separate draft documents (i.e. for Q2(R2) and Q14), with the group to consider at a later stage whether they should be combined into a single draft Technical Document.

The Q2(R2)/Q14 EWG continues its work on the development of the two draft Q2(R2)/Q14 EWG Technical Documents.

Steps 1 and 2a/b are expected by May 2021.

8.21. Q3C(R8) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. McGovern – FDA, United States)

Steps 1 and 2a/b of the Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol were reached in March 2020, and the new PDEs were undergoing public consultations in the ICH Member regions until end of September 2019.

The Q3C(R8) Maintenance EWG continues to address the comments received during the regional public consultation period.

Steps 3 and 4 are expected by end of 2020.

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

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products were reached in September 2020 and the Q3D(R2) Guideline is currently undergoing public consultation in the ICH Member regions.

Steps 3 and 4 are expected by July 2021.

8.23. 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)

The MC approved the Q3E Concept Paper and Business Plan in July 2020, and the transition of the Q3E informal WG to an EWG.

The Q3E EWG continues its work on the development of the Q3E draft Technical Document.

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

8.24. 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)

At the ICH meeting in November 2019, the MC endorsed the Q5A(R2) Concept Paper and Business Plan, and the transition of the Q5A(R2) informal WG to an EWG.

The Q5A(R2) EWG continues its work on the development of the Q5A(R2) draft Technical Document.

Steps 1 and 2a/b are expected by November 2021.

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

In October 2020, the MC endorsed the Q9(R1) Concept Paper and Business Plan and the transition of the Q9(R1) informal WG to an EWG.

The Q9(R1) EWG continues its work on the development of the Q9(R1) draft Technical Document.

Steps 1 and 2a/b are expected by October 2021.

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

Steps 3 and 4 for the Q12 Guideline were reached at the ICH meeting in November 2019.

At the ICH meeting in November 2019, the Assembly approved the development of training material on the Q12 Guideline, and further to the MC endorsement of the Q12 IWG Concept Paper in March 2020, the Q12 IWG was established in May 2020.

The Q12 IWG continues its work on the development of training materials.

The Q12 Training Materials are expected to be finalised by June 2021.

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

The informal regional Continuous Manufacturing site visits which had been organised in Europe and North America for interested Q13 EWG Regulatory Members experts were cancelled due to travel restrictions for some ICH Members related to the COVID-19 pandemic.

The Q13 EWG continues its work on the development of the Q13 draft Technical Document, which would consist of a core document focusing on fundamentals of Continuous Manufacturing, and of five annexes focusing on specific continuous manufacturing technologies.

Steps 1 and 2a/b are expected by May 2021.

8.28. S1(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. Sistare – PhRMA; Regulatory Chair: Dr. Van der Laan – EC, Europe)

The interim face-to-face meeting for S1(R1) Regulatory experts with access to the CADs which was scheduled to be held from 11-13 March 2020 hosted by EC, Europe at the European Medicines Agency (EMA) offices in Amsterdam, the Netherlands was cancelled due to the global COVID-19 situation.

The S1(R1) EWG continues its work on the review of confidential Carcinogenicity Assessment Documents (CADs) and Final Study Reports (FSRs), and on the revisions to the S1B Guideline.

Following *Step 2b*, the Rapporteurship of the group will rotate to a Regulatory Member.

Steps 1 and 2a/b are expected by end 2020.

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

Steps 3 and 4 for the S5(R3) Guideline were reached electronically in February 2020, and the S5(R3) Step 4 training presentation was published on the ICH website in June 2020.

As per the maintenance process endorsed in March 2019, the S5(R4) Maintenance EWG will stay in a dormant state for at least 1 year after Step 4, i.e. until March 2021, and would become active if needed.

8.30. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines (Rapporteur: Dr. Brown – FDA, United States; Regulatory Chair: Dr. van der Laan – EC, Europe)

The S11 Guideline was finalised in April 2020 and Training Materials in August 2020, further to which the S11 EWG was disbanded.

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

At the ICH meeting in November 2019, the MC endorsed the S12 Concept Paper and Business Plan, and the transition of the S12 informal WG to an EWG.

The S12 EWG continues its work on the development of the S12 draft Technical Document.

Steps 1 and 2a/b are expected by May 2021.

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

At the Virtual meeting in May 2020, the MC supported that the term of the GDG be extended by up to one year until June 2021, with a view to disbanding the group earlier if it would finalise its activities sooner, and with the frequency of its TCs to be reduced.

The GDG is working on further scoping of identified topics for potential future harmonisation and to build consensus on their sequencing and timing for any topics identified.

8.33. Quality Discussion Group (QDG) (Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Ms. Kruse – EC, Europe)

The QDG interim meeting, scheduled on 27-30 April 2020 to be hosted by EC, Europe at the State Institute for Drug Control, Prague, Czech Republic, was cancelled due to the global COVID-19 situation.

The Assembly was updated by the Coordinator for PhRMA on the work of the QDG related to ICH New Topic proposals in the Quality area.

Assembly Decision/Action:

- The Assembly noted that the QDG had developed 2 New Topic proposals, which will be submitted as part of the 2021 ICH New Topics cycle (see also item #6).

The MC approved the QDG to operate for a 2-year term beginning on the date of MC approval of the QDG Remit (i.e. November 2018), and, further to the MC approving an extension of its term, the QDG is now expected to finalise its work in August 2021.

8.34. Pharmacoepidemiology Discussion Group (PEpiDG) (Rapporteur: Dr. Uyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Ball – FDA, United States)

The PEpiDG continues its work on the prioritisation of proposed topics based on feasibility, needs and importance for harmonisation.

The MC approved the PEpiDG to operate for a 2-year term. The PEpiDG is expected to have completed its work by early 2022.

9. General Operational Matters

Template for Compilation of Step 3 Public Consultation Comments

The Assembly was informed on the ICH Template for Compilation of *Step 3* Public Consultation Comments, which is to be used by ICH Members to share with the ICH WG the comments received during the public consultation in their region, with the aim to simplify and make WG operations more efficient when reviewing the public comments.

Assembly Decision/Action:

- The Assembly noted that the ICH Template for Compilation of *Step 3* Public Consultation Comments would be made available on the ICH website.

ICH General Operational Matters

The Assembly noted the written report of the ICH Secretariat on general operational matters, including on the level of participation of ICH Members and Observers in ICH WGs.

10. Training

The Training Subcommittee Co-Lead updated the Assembly on ICH Training activities, including on:

- Activities related to ICH Recognised Training Programmes, which are published on the ICH website;
- Revision of the Terms of Reference for Training Providers for an ICH Recognised Training Programme and the ICH Training Programme Provider Application Form which will be shortly published on the ICH website;
- *Step 4* presentations developed by WGs and available on the ICH website;
- Support provided to WGs developing training materials;
- Efforts made on the development of a Training Library and inclusion on the ICH website of links to available translations of training materials and ICH Guidelines,
- Progress made by ICH's first Training Associate on the development of ICH training materials, with the ICH Q1 Introductory Overview Video as a first deliverable published recently on the ICH website and exploration of potentially engaging another ICH Training Associate for the development of training materials on ICH M4 and ICH E2.

11. Implementation of ICH

Implementation survey

The Implementation Co-Lead updated the Assembly on the next steps regarding the 2021 implementation survey developed by a third-party survey provider CIRS and scheduled to be launched in December 2020, which is designed to serve two purposes:

- Inform the elections for Elected MC Representatives to be held in June 2021 (in line with the MC RoP section 2.2.2). For this purpose, the non-Founding and non-Standing Regulatory Members would be surveyed on Tier 2 and 3 Guidelines;
- Provide an opportunity to ICH Observers which are Legislative or Administrative Authorities to participate on a voluntary basis to be surveyed on Tier 1 Guidelines, which would then allow those interested in future ICH Membership to reference the survey findings in support of their application.

12. Collaboration with PIC/S

The Assembly noted that the pilot for collaboration between ICH and the Pharmaceutical Inspection Co-operation Scheme PIC/S on ICH Guideline work with relevance to both Regulatory assessor and Inspector disciplines is ongoing.

13. Communication

ICH 30th Anniversary

The Organising Subcommittee Lead updated the Assembly on considerations regarding the 30th Anniversary Commemorative event, which had been postponed to 2021 in view of the pandemic, where a decision still needs to be taken as to whether or when the event will take place. The Assembly was also informed of the progress made by the Organising Subcommittee, in collaboration with three former

ICH representatives, to develop a publication to commemorate ICH's 30th Anniversary, which would be published in 2021.

Press Release

Assembly Action/Decision:

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

14. Organisation of Next Meetings

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

Assembly Decisions/Actions:

- The Assembly noted that, due to the COVID-19 pandemic, the ICH MC had considered necessary to cancel the next face-to-face meeting planned to be held in May/June 2021. The meeting will be held in a virtual format instead;
- The Assembly noted the dates and locations of its next meetings as per the below:
    - Wednesday 2 June 2021 in a virtual format;
    - Tuesday 16 - Wednesday 17 November 2021 in Vancouver, Canada;
    - Tuesday 24 – Wednesday 25 May 2022 in Athens, Greece (pending final confirmation);
    - Tuesday 15 – Wednesday 16 November 2022 in Asia (location to be confirmed)
    - Tuesday 13 - Wednesday 14 June 2023 or Tuesday 30 - Wednesday 31 May 2023 in the Americas (dates and location to be confirmed)