16 July 2020

FINAL REPORT

ICH ASSEMBLY VIRTUAL MEETING

27 MAY 2020

Please find hereafter the final report of the Assembly Virtual meeting held on 27 May 2020.

List of Assembly Participants

Chair: Ms Lenita Lindström-Gommers

Vice-Chair: Dr. Celia Lourenco

ICH Assembly Member Representatives:

Mr. Gustavo Mendes Lima Santos	ANVISA, Brazil
Mr. Diogo Penha Soares	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Dr. Bruno Sepodes	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Sue Forda	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin	FDA, United States
Dr. Léo Bouthillier	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Dorothy Toh	HSA, Singapore
Ms. Beata Stepniewska	IGBA
Dr. Nick Cappuccino	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Kyung Won Seo	MFDS, Republic of Korea
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Dr. Sheng Yang	NMPA, China
Dr. Peter K. Honig	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Dr. Jo-Feng Chi	TFDA, Chinese Taipei
Ms. Ming-Mei Wu	TFDA, Chinese Taipei
Ms. Hacer Coşkun Çetintaş	TITCK, Turkey[1]

ICH Management Committee Member Representatives:

Dr. Milton Bonelli	EC, Europe
Dr. Junko Sato	MHLW/PMDA, Japan

ICH Assembly Standing Observer Delegates:

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

ICH Assembly Observer Delegates:

Dr. Gi Hyun Kim	APEC
Dr. Rainer Fendt	APIC
Dr. Murray Lumpkin	Bill and Melinda Gates Foundation
Dr. V.G. Somani	CDSCO, India
Dr. Lembit Rägo	CIOMS

[1] At the Assembly Virtual meeting under Agenda item 1, TITCK, Turkey was welcomed as a new ICH Member.

Ms. Margarita Contreras	COFEPRIS, Mexico
Dr. Susanne Keitel	EDQM
Dr. Hajed M. Hashan	GHC
Ms. Janeen Skutnik Wilkinson	IPEC
Mr. Dumitru Saghin	MMDA, Moldova
Dr. Colette Raidy	MOPH, Lebanon[2]
Dr. Hasenah Ali	NPRA, Malaysia
Mr. David Churchward	PIC/S
Ms. Fortunate Ntombi Bhembe	SADC
Mr. Tohlang Sehloho	SAHPRA, South Africa
Dr. Adel Alharf	SFDA, Saudi Arabia
Dr. Richard Hill	TGA, Australia
Dr. Kevin Moore	USP

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
Dr. Manabu Yanagisawa	JPMA
Ms. Miyoung Hyun	MFDS, Republic of Korea
Dr. Yang Wang	NMPA, China
Mr. Ryo Iwase	MHLW/PMDA, Japan
Ms. Janet Vessotskie	PhRMA
Dr. Gabriela Zenhaeusern	Swissmedic, Switzerland
Ms. Pin-Tsun Kuo	TFDA, Chinese Taipei

ICH Assembly Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Ms. Mami Ueda	MHLW/PMDA, Japan

ICH Additional Participants:

Mr. Sebastian Duarte	ANMAT, Argentina
Mr. Gustavo Carballo	ANMAT, Argentina
Ms. Elena Mezquita	EC, Europe
Ms. Christelle Anquez	Global Self-Care Federation
Mr. Sivashen Cunden	Global Self-Care Federation
Ms. Tereza Cervinkova	IFPMA
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Mr. Ryu Mochizuki	MHLW/PMDA, Japan
Ms. Michelle Rohrer	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Hakkı Gürsöz	TITCK, Turkey[1]
Dr. Nihan Burul Bozkurt	TITCK, Turkey[1]

ICH Secretariat:

[2] At the Assembly Virtual meeting under Agenda item 1, MOPH, Lebanon was welcomed as a new ICH Observer.

Dr. Dawn Ronan	ICH Secretariat
Dr. Anne Latrive	ICH Secretariat
Ms. Nadia Myers Biggs	ICH Secretariat
Ms. Nikoleta Luludi	ICH Secretariat

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ICH ASSEMBLY REPORT

Opening of the ICH Assembly Meeting

The ICH Assembly Virtual Meeting, held on 27 May 2020, was chaired by Ms. Lenita Lindström-Gommers (Chair – EC, Europe) and Dr. Celia Lourenco (Vice Chair – Health Canada, Canada).

The Assembly noted the Member Representatives and Observer Delegates as well as Ad-Hoc Observer Delegates from MOPH, Lebanon participating in the Assembly meeting.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. Membership and Observership

The ICH Secretariat presented to the Assembly an overview of applications for Membership/Observership processed since the meeting in Singapore in November 2019 and the ICH MC recommendation on these applications in view of the eligibility criteria.

The applicants were invited to give a short presentation to introduce their organisations.

Assembly Decisions/Actions:

- The Assembly approved the application of TITCK, Turkey for Membership under Article 11(1) of the ICH Articles of Association;
- The Assembly approved the application of MOPH, Lebanon for Observership under Article 17.1(a) of the ICH Articles of Association.

2. Procedural Matters

ICH Management Committee Rules of Procedure

The ICH Secretariat informed the Assembly of an update made by the ICH MC to the ICH MC Rules of Procedure (RoP) to extend the term of office of the MC Chair and Vice-Chair from 1 to 2 years, effectively from November 2021, which will synchronise them with the terms of office of the Assembly Chair and Vice-Chair.

Assembly Decisions/Actions:

- The Assembly noted that the ICH MC approved the ICH MC RoP v9.0 at its Policy 3 TC on 22 April 2020, and that it would be published on the ICH website;
- The Assembly noted that additional changes and opportunities for streamlining ICH procedure documents will be for discussion at the next meeting in November 2020.

3. Update on MedDRA

The Assembly was updated by the MedDRA Secretariat on the outcome of the MedDRA MC meeting held virtually on 20 and 21 May 2020.

Response to the COVID-19 pandemic

The Assembly was updated about MedDRA activities in view of the COVID-19 pandemic which included: an exceptional re-release of MedDRA 23.0 to include ~70 new COVID-19 terms aimed at ensuring that any scientific and medical information from the COVID-19 outbreak can be captured, shared and analysed appropriately; development of a new COVID-19 Standardised MedDRA Query (SMQ); and increased virtual training offerings.

Expansion of MedDRA use worldwide

The Assembly was updated on the continued growth of MedDRA users throughout the world, which currently include over 6200 MedDRA subscribing organisations in 125 countries, reflecting the continued successful adoption of MedDRA as a worldwide standard in the protection of public health.

New Translations

The Assembly was updated on MedDRA MC efforts to support the language needs of users with: release of a new Brazilian Portuguese MedDRA translation in March 2020 which brings to 14 the number of languages in which MedDRA is currently available; and work to begin shortly on a new Swedish MedDRA translation.

Ongoing Activities

The Assembly was furthermore informed on other MedDRA MC efforts to support users, including through the development of targeted mappings with other terminologies such as SNOMED, and ongoing assessment of MSSO IT tools by an external consultant with a view to provide recommendations by November 2020 on a digital transformation.

Assembly Decision/Action:

- The Assembly noted the report on recent MedDRA activities and decisions taken by the MedDRA MC during its meeting on 20-21 May 2020, including the re-election of Mr. Mick Foy (MHRA, UK) as MedDRA MC Chair for a one-year term.

4. Financial Matters

2019 Audited Accounts, 2019 Closing Expense Reports, 2021 ICH budget & 5-Year Plan

The Assembly was informed by the ICH Secretariat on the 2019 Audited Accounts and Financial Statements and the 2019 ICH Closing Expense Report; the 2021 provisional ICH budget; the 5-year 2021-2025 ICH budget projection.

Assembly Decisions/Actions:

- The Assembly approved the 2019 Audited Accounts and Financial Statements of the ICH Association which will be included with the 2019 tax return of the ICH Association to be filed shortly after the meeting;
- The Assembly supported the ICH MC recommendation to appoint the same Auditor again for a further two years for the 2020 and 2021 financial audits;

- The Assembly approved the updated 2021 ICH budget[3], and noted the 5-year 2021-2025 ICH budget projection.

ICH MC Financial Subcommittee

The Assembly was informed by the ICH MC Chair, as Lead of the ICH MC Financial Subcommittee, on ongoing work by the ICH MC Financial Subcommittee in coordination with the MedDRA MC Financial Subcommittee and considerations regarding the sound financial management and sustainable funding of the ICH Association, with ICH Membership Fees to cover the ICH core activities.

Assembly Decisions/Actions:

- The Assembly noted the considerations of the ICH MC on sound financial management of the ICH Association and potential need for adjustments to the Membership Fee structure and model;
- The Assembly noted that this topic will be for further discussion by the Assembly at the next face-to-face meeting in November 2020.

5. New Topic Process & Strategic Discussions

2020 New Topic Proposals

The Assembly was informed by the ICH MC New Topic Subcommittee co-Lead on the New Topic proposals which were submitted by ICH Members in December 2019 and on the outcome of the review and assessment of proposals by the ICH MC.

Assembly Decisions/Actions:

- The Assembly supported in principle the proposals on General Considerations for Model-Informed Drug Development to support Drug Registration and on ICH E4 on Dose Response Information to Support Drug Registration. The Assembly approved as a first step the establishment of a Discussion Group (DG) on Model-Informed Drug Development (MIDD) which would work to finalize the scope of a Guideline on MIDD, and make a recommendation for appropriate sequencing and format for incorporating MIDD concepts into a proposal on ICH E4 (i.e., Revision, Addendum, Q&A). The MIDD DG will develop a work plan for MC approval, with attention to developing a roadmap for integration of MIDD approaches to drug development in existing ICH Guidelines;
- The Assembly endorsed the proposal on *Revision of M4Q(R1) CTD on Quality guidance,* with the M4Q(R2) informal WG to be establish with a delayed start to initiate work in Q4 2020 after the Q13 EWG will have reached *Step 2*. A Concept Paper outline will be provided for Assembly endorsement by November 2020.
- The Assembly endorsed the proposal on *Structured Product Quality Submissions*, with a delayed start to be defined by the ICH MC after the establishment of the M4Q(R2) informal WG, with the M4Q(R2) informal WG being tasked to detail considerations on content and timing for starting work on this topic. A Concept Paper outline will be provided for Assembly endorsement after this exercise.

[3] The ICH Assembly is invited to note that the 2021 ICH Membership Fees remain unchanged as per their approval by the ICH Assembly in Singapore in November 2019 and remain unchanged compared with levels of 2020 Membership Fees.

- The Assembly noted ongoing efforts by the Regulatory Members of the MC on collection of data on the topic of N-Nitrosamines, in order to further prioritise an appropriate ICH action related to N-Nitrosamines;
- The Assembly noted that, as previously agreed, the 3 New Topic proposals which had been submitted on Quality topics had been shared with the Quality Discussion Group (QDG) for their review as part of their larger prioritisation exercise, and would be considered for the 2021 New Topics cycle.

6. Q4B Maintenance

Representatives from the Pharmacopoeial Discussion Group (PDG) informed the Assembly of PDG's revised proposal for the revision of the Q4B Annexes, and on ongoing discussions with the MC regarding opportunities for engagement of the pharmacopoeias of the new ICH Regulatory Members and ICH Industry Members.

Assembly Decision/Action:

- The Assembly noted that PDG would provide the MC with an overview of their proposed process for reviewing the Q4B Annexes, in which the opportunities for engagement of the pharmacopoeias of the non-Founding ICH Regulatory Members and ICH Industry Members would be mapped.

7. 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 Working Groups (WGs) which had been planned to meet face-to-face in Vancouver. Furthermore, an oral update was provided by the Coordinator for FDA, United States on the E6(R3) EWG (item #7.2 below).

7.1. 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.

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

At the ICH meeting in November 2019, the MC endorsed the transition of the E6(R3) informal WG to an EWG.

The Assembly was updated by the Coordinator for FDA, United States on the progress made by the E6(R3) EWG on the E6(R3) draft Technical Document, including revisions to the overarching general principles guideline and Annex 1 on traditional interventional trials being developed in parallel.

Assembly Decisions/Actions:

- The Assembly noted that 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, and that a summary version of the plan was published on the ICH website in May 2020;

- The Assembly noted that as part of the direct engagement process, the EWG had compiled a list of stakeholders, and that in June 2020 the group would start reaching out to stakeholders to invite them to discuss with the group at its TCs;
- The Assembly noted that as part of regional stakeholder engagement process, the following regional public virtual meetings were being organised:
    - 3 June 2020, organised by EC, Europe;
    - 4-5 June 2020, organised by FDA, United States.

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 May 2022.

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).

7.3. E8(R1) EWG: Revision on General Considerations for Clinical Studies (Rapporteur: Dr. LaVange – FDA, United States; Regulatory Chair: Dr. Sweeney – 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 summarizing 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.

The E8(R1) interim meeting which had been originally scheduled in March 2020 was cancelled due to travel restrictions of some ICH Members related to the COVID-19, and the group has set up four teleconferences in March to progress activities.

Steps 3 and 4 are expected by July 2020.

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

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 November 2020.

7.5. 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.

7.6. 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 transition of the E20 informal WG to an EWG.

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

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

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

In October 2019, the ICH MC and Assembly approved the translations in Chinese, Korean, and Spanish (in addition to English and Japanese) of the Points to Consider (PtC) documents; and a change in frequency for the release of the PtC documents from twice to once a year effective March 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 July 2020.

Release of second edition of the 'Companion document', is expected in July 2020.

Release of Chinese, Korean, and Spanish translations of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 23.0) is expected in October 2020.

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

The M10 draft Guideline was in 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 which ended in September 2019.

Steps 3 and 4 are expected by June 2021.

As noted at the Assembly meeting in Singapore in November 2019, the M10 EWG will develop and finalize training materials within a 6-month timeframe after completion of the M10 Guideline.

7.9. 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 2a/b on the Guideline, Template, Basis of Requirements, and Technical Description are expected by September 2021.

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

7.10. 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 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.

7.11. M13 informal WG: Bioequivalence for Immediate-Release Solid Oral Dosage Forms (informal WG Lead: Dr. Zhang - FDA, United States; informal Regulatory Chair: Dr. Welink – EC, Europe)

Further to Assembly approval of the M13 Concept Paper Outline at the ICH meeting in November 2019, the M13 informal WG was established in February 2020.

The M13 informal WG continues its work on the development of the M13 Concept Paper and Business Plan.

7.12. 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 Singapore 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 November 2020.

7.13. Q3E informal WG: Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics (informal WG Lead: Dr. Markovic - PhRMA; informal Regulatory Chair: Dr. Rodriguez – FDA, United States)

Further to Assembly approval of the Q3E Concept Paper Outline at the ICH meeting in November 2019, the Q3E informal WG was established in February 2020.

The Q3E informal WG continues its work on the development of the Q3E Concept Paper and Business Plan.

7.14. 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 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.

7.15. 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 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.

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.

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

7.16. 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 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.

Assembly Decision/Action:

- The Assembly noted that following *Step 2b* the Rapporteurship of the group will rotate to a Regulatory Member.

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.

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

7.17. 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 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. Status Update of Working Groups which had not been planned to meet

The Assembly was invited to note the Work Plans and the written status (noted below) of the WGs which had not been planned to meet face-to-face in Vancouver. Furthermore, an oral update was provided by the Coordinator for FDA, United States on the E14/S7B IWG and GDG (items #8.4 and 8.15 respectively below), and by the Coordinator for EC, Europe on the E9(R1) EWG (item #8.3 below).

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

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.

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)

The E2B(R3) EWG/IWG continues its work, including on the revision of the EDQM User Guide incorporating the mapping table for the Route of Administration (RoA) between ICH and EDQM terms; and on the development of the Module I, II and III training materials.

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

The revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms is expected to be finalised by April 2020.

Training Material Module III is expected to be finalised by September 2020.

The voice-over presentation for Training Material Module I is expected to be finalised by September 2020.

8.3. 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 Singapore, and the E9(R1) EWG is working on the development of training materials and videos.

The Assembly was updated by the Coordinator for EC, Europe on the progress made by the E9(R1) EWG on the development of training materials, and the challenges encountered so far which had resulted in delays in their finalisation.

Assembly Decision/Action:

- The Assembly encouraged the E9(R1) EWG to finalise their training materials as soon as possible.

The E9(R1) training videos are expected to be finalised in the second half of 2020.

8.4. 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)

The Assembly was updated by the Coordinator for FDA, United States on the progress made by the E14/S7B IWG on the development of Q&As and the Integrated Risk Assessment for E14/S7B.

Assembly Decisions/Actions:

- The Assembly noted the group's considerations that once finalised, the Q&As should undergo public consultation, instead of going directly to *Steps 3* and *4* as the group had been initially considering;
- The Assembly noted that the group was additionally preparing a written proposal to the MC to organise a virtual public meeting in October/November 2020 during the public consultation of the first stage of Q&As.

Step 1 and 2 a/b of the first stage of Q&As are expected by July 2020.

8.5. 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 the evaluation of current ICH topics at *Steps 2* and *4* for technical risks and opportunities, the development of a technical specification for CeSHarP with the M11 EWG, and on considerations for streamlining of the development of technical standards.

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

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.

8.7. 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)

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

Steps 1 and 2a/b for the Q&As are expected by June 2020.

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

8.8. 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.

Assembly Decision/Action:

- The Assembly noted that further to finalising the analysis of the M8 EWG/IWG and M2 EWG joint assessment of next steps for the eCTD v4.0 and HL7 FHIR standards, the conclusion of which was presented to the ICH Assembly in Singapore in November 2019, the group prepared a package of the documents related to the analysis, including an overarching assessment document, and that the package was archived on the group's SharePoint as well as in the ICH Secretariat's internal records, and additional reporting or documentation is not envisioned.

Steps 3 and 4 were reached in May 2020 on the eCTD v4.0 Q&As and Specification Change Request Document v1.3.

8.9. M9 EWG: Biopharmaceutics Classification System-based Biowaivers (Rapporteur: Dr. Welink – EC, Europe; Regulatory Chair: Dr. Seo – FDA, United States)

Steps 3 and 4 for the M9 Guideline and the Q&A document were reached at the ICH meeting in Singapore in November 2019.

The M9 EWG finalised the M9 *Step 4* training presentation which was subsequently published on the ICH website.

Assembly Decision/Action:

- The Assembly noted that in view of the completion of the M9 Training Materials, the M9 EWG had been disbanded in March 2020.

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

The Q3C(R6) Guideline was published in October 2019 on the ICH website, effectively reinstating the PDE for ethyleneglycol to 6.2 mg/day (620 ppm), along with a cover statement to explain the reason for the reversion. Furthermore, the revised monograph for the PDE of ethyleneglycol was published on the ICH website in January 2020 as part of Support Document #2.

Step 2b on the Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol was reached in March 2020, and the new PDEs were published for public consultation in the ICH regulatory regions.

Steps 3 and 4 are expected by July 2020.

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

The Q3D(R2) Maintenance EWG continues its work on the finalisation of the draft Addendum on cutaneous and transdermal routes of administration, and is also working on reviewing the PDEs of Gold (all routes), Silver (parenteral) and Nickel (inhalation).

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products are expected by June 2020.

8.12. 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 Singapore in November 2019.

Further to MC approval of the Q12 IWG Concept Paper, the ICH Secretariat begun the process of establishing the Q12 IWG[4].

8.13. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe)

[4] Post-meeting note: Shortly following the Assembly TC, the establishment of the Q12 IWG was finalised.

Steps 3 and 4 for the S5(R3) Guideline were reached electronically in February 2020.

The S5(R3) EWG finalised the *Step 4* training presentation which was published on the ICH website, and the ICH Secretariat will proceed with the establishment of the S5(R4) Maintenance EWG in the second half of 2020.

8.14. 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 draft Guideline reached Step 4 in April 2020.

The S11 EWG continues its work on the finalisation of the S11 Training Materials.

The S11 Training Materials are expected by June 2020.

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

The Assembly was updated by the Coordinator for FDA, United States on the progress made by the GDG, including on 1) the review of ICH Efficacy and Multidisciplinary Guidelines, in consultation with the QDG and finalisation of overall recommendations and prioritization of work areas; and 2) the identification of additional bioequivalence topics for harmonisation.

Assembly Decisions/Actions:

- The Assembly noted that the MC had supported that the term of the GDG be extended by up to one year, with a view to disbanding the group earlier if they would finalize its activities sooner, and with the frequency of its TCs to be reduced to every other month;
- The Assembly noted that the MC had furthermore supported that the GDG's recommendations on the E6(R3) Guideline be shared with the E6(R3) EWG.

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

The QDG continues its work on the review and prioritisation of the proposed new ICH topic proposals.

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 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 the QDG is expected to have completed its work by November 2020 by submitting a set of recommendations to the MC and the Assembly. A 6 month delay is however expected resulting from the situation with COVID-19.

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

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

List of potentially harmonisable areas in ICH is expected by June 2020.

The PEpiDG is expected to have completed its work by Q2/Q3 2021.

9. 2019 Annual Report of the Association

Assembly Decision/Action:

- The Assembly approved the 2019 Annual Report of the Association 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 2019 on behalf of the ICH Association.

10. General Operational Matters

The Assembly was informed by the ICH Secretariat on ICH general operational matters, including on the level of participation of ICH Members and Observers in ICH WGs.

Assembly Decision/Action:

- The Assembly noted the written report of the ICH Secretariat on ICH general operational matters.

11. Training

The Training Co-Lead updated the Assembly on the Training Subcommittee activities, including on activities related to face-to-face and online ICH Recognised Training Programmes, support provided to WGs developing training materials, and considerations of the Training Subcommittee to identify accurate translations of training on ICH Guidelines.

The Training Co-Lead furthermore updated the Assembly on progress made on the engagement of Training Associates to assist ICH in its efforts to address in a strategic manner the training needs of ICH Regulatory and Industry Members and Observers.

Assembly Actions/Decisions:

ICH Recognised Training Programmes:

- The Assembly noted that the MC approved at its MC TC on 26 May 2020 v1.2 of the Procedure for Organisations Interested in Developing an ICH Recognised Training Programme and v1.3 of the Terms of Reference for Training Providers for an ICH Recognised Training Programme, and the publication of these documents on the ICH website;
- The Assembly noted that since the ICH meeting in Singapore in November 2019, the following events which had been endorsed as ICH Recognised Training Programmes were completed:
    - APEC PKU: MRCT & GCP-Related Considerations, Beijing, China, 11-14 November 2019;
    - Northeastern University (NEU): ICH Q1 Drug Stability training, Burlington, MA, USA, 10-12 March 2020.
- The Assembly noted that the following ICH Recognised Training Programmes events had been approved:
    - APEC PKU: Pharmacovigilance Seminar, Beijing, China, May 2020 – date to be determined;
    - USP: Q3 series, Rockville, MD, USA, 8 July 2020;
    - APEC PKU: MRCT & Incorporating GCP-Related Considerations, Beijing, China, September 2020.

- The Assembly noted that the following online training programmes which had been endorsed as ICH Recognised Training Programmes had been finalised with links to these programmes posted on the ICH website:
    - ICH Q7 – Overview of Good Manufacturing Practice, developed by Parenteral Drug Association (PDA), published in November 2019;
    - ICH E6(R2) – Interpretation and Application, developed by Multi-Regional Clinical Trials (MRCT) Center, published in February 2020;
    - ICH Q1 – Introductory Training material, developed by Northeastern University (NEU), published in March 2020.

ICH Working Group Training Activities:

- The Assembly noted that *Step 4* introductory training presentations had been finalised and published on the ICH website on ICH Q12, ICH M9 and ICH S5(R3) Guidelines;
- The Assembly noted that the E9(R1) EWG, E2B(R3) EWG/IWG, E14/S7B IWG and Q12 IWG were developing training materials with FDA, United States Studios.

ICH Training Associates

- The Assembly noted that a first Training Associate agreement had been signed to deliver training on ICH Q1, with the delivery of the first training materials expected in August 2020.

12. Communication

ICH 30th Anniversary

The ICH Secretariat updated the Assembly on the progress made on the planning of the 30th Anniversary Commemorative event to be held on Saturday, 14 November 2020, and the reception to be held on Friday, 13 November 2020, on the margins of the ICH biannual meeting in Athens, Greece.

Assembly Action/Decision:

- The Assembly noted the MC is monitoring the situation with COVID19 and that an update on the organisation of the event in view of the pandemic will be provided to the Assembly within the August timeframe.

Press Release

Assembly Action/Decision:

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

13. Organisation of Next Meetings

- The Assembly noted the dates and locations of the next ICH biannual meetings:
    - Tuesday 17 - Wednesday 18 November 2020 in Athens, Greece (with ICH 30th Anniversary event on Saturday 14 November 2020);
    - Tuesday 1 - Wednesday 2 June 2021 in Incheon, Republic of Korea (final confirmation pending);
    - Tuesday 16 - Wednesday 17 November 2021 in Vancouver, Canada (final confirmation pending);

- Tuesday 24 – Wednesday 25 May 2022 or Tuesday 14 – Wednesday 15 June 2022 in Europe (location & dates to be confirmed);
- Tuesday 12 – Wednesday 16 November 2022 in Asia (location to be confirmed)

Any Other Business

ICDRA Meeting

The representative for WHO informed the Assembly that the International Conference of Drug Regulatory Authorities (ICDRA) meeting scheduled to be held in New Delhi, India on 28 September – 2 October 2020 had been postponed to 2021.