

10 February 2020

FINAL MINUTES
ICH Assembly Meeting
19 - 20 November 2019, Singapore

Please find hereafter the final minutes of the Assembly meeting held in Singapore on 19 – 20 November 2019.



List of Assembly Participants

ICH Assembly Member Representatives:

Mr. Diogo Penha Soares	ANVISA, Brazil
Mr. Gustavo Mendes Lima Santos	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers (Chair)	EC, Europe
Dr. Georgios Balkamos	EC, Europe
Dr. Harald Enzmann	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Susan Forda	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin	FDA, United States
Ms. Caroline Mendy	Global Self-Care Federation
Dr. Celia Lourenco (Vice-Chair)	Health Canada, Canada
Dr. Léo Bouthillier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Ms. Jessica Teo	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
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Dr. Sheng Yang	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Dr. Peter K. Honig	PhRMA
Mr. Richard Moscicki	PhRMA
Dr. Jörg Schläpfer	Swissmedic, Switzerland
Mr. Ming-Hsun Liu	TFDA, Chinese Taipei
Mrs. Jo-Feng Chi	TFDA, Chinese Taipei

ICH Management Committee Member Representatives:

Dr. Milton Bonelli	EC, Europe
Dr. Junko Sato	MHLW/PMDA, Japan
Ms. Camille Jackson	PhRMA

ICH Assembly Standing Observer Delegates:

Dr. David Jefferys	IFPMA
Dr. Sharon Olmstead	IFPMA
Dr. Samvel Azatyan	WHO
Ms. Marie Valentin	WHO

ICH Assembly Observer Delegates:

Dr. Matías Gómez	ANMAT, Argentina
Dr. Yongseok Ko	APEC
Dr. Rainer Fendt	APIC
Dr. Tharnkamol Chanprapaph	ASEAN
Dr. David Mukanga	Bill and Melinda Gates Foundation
Mr. Arun Kumar Pradhan	CDSCO, India
Dr. Celeste Sánchez González	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Dr. Ofra Axelrod	CPED, Israel

Ms. Jane Mashingia	EAC
Dr. Susanne Keitel	EDQM
Dr. Adel Alharf	GHC
Ms. Janeen SkutnikWilkinson	IPEC
Mr. Dumitru Saghin	MMDA, Moldova
Ms. Aida Haryati Abdul Rahim	NPRA, Malaysia
Dr. Analía Porrás	PANDRH
Mr. David Churchward	PIC/S
Ms. Fortunate Ntombi Bhembe	SADC
Dr. Adel Alharf	SFDA, Saudi Arabia
Ms. Jenny Burnett	TGA, Australia
Ms. Hacer Coşkun Çetintaş	TITCK, Turkey
Dr. Kevin Moore	USP

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Dr. Ingrid Markovic	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Ms. Caroline Mendy	Global Self-Care Federation
Mr. Nick Orphanos	Health Canada, Canada
Ms. Chua Siew Wei	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
Dr. Manabu Yanagisawa	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Ryo Iwase	MHLW/PMDA, Japan
Dr. Yang Wang	NMPA, China
Ms. Camille Jackson	PhRMA
Dr. Gabriela Zenhäusern	Swissmedic, Switzerland
Ms. Pin-Tsun Kuo	TFDA, Chinese Taipei

ICH Assembly Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, United States
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

ICH Additional Participants:

Dr. Agnès Saint-Raymond	EC, Europe
Ms. Shang Junhan	HSA, Singapore
Ms. Erina Yamada	JPMA
Ms. Minjung Lee	MFDS, Republic of Korea
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Ms. Le Shi	NMPA, China
Mr. Jerry Stewart	PhRMA

ICH Secretariat:

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

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ICH ASSEMBLY MINUTES

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

Assembly Vice Chair: Dr. Celia Lourenco, Health Canada, Canada

Opening of the ICH Assembly Meeting

The ICH Assembly meeting in Singapore, held on 19 – 20 November 2019, was chaired by Ms. Lindström-Gommers (Chair – EC, Europe) and Dr. Celia Lourenco (Vice Chair – Health Canada, Canada).

The Assembly noted the Member Representatives and Observer Delegates participating in the Assembly meeting.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. 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 experts to the 3 additional industry seats, (2) Process for development of Reflection Papers, (3) General Principles for Discussion Groups, (4) Attendance of experts to their WG meetings, (5) Synchronization of the terms of office of the MC Elected Representatives, (6) Replacement of MC Elected Representatives, (7) Clarification on the synchronization of the terms of office of the Assembly Chair and Vice-Chair, (8) Synchronization of the terms of office of the MC Chair and Vice-Chair, (9) S5 Annexes Maintenance Procedure, (10) Streamlining of procedures, 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.3.0 and approved the ICH Articles of Association v.4.0, which will be published on the ICH website;
- The Assembly noted the proposed changes to the ICH Assembly Rules of Procedure (RoP) v.7.0, and approved the ICH Assembly Rules of Procedure v.8.0, which will be published on the ICH website;
- The Assembly noted the changes to the ICH MC RoP v7.0 and that the MC approved the ICH MC RoP v.8.0 at its meeting in Singapore, which will be published on the ICH website;
- The Assembly noted the changes to the SOP of the WGs v8.0 for WGs and that the MC approved the SOP of the WGs v9.0 at its meeting in Singapore, which will be published on the ICH website.

2. Membership and Observership

The ICH Secretariat informed the Assembly that no applications for Membership or Observership were received for Assembly consideration since the ICH meeting in Amsterdam, the Netherlands in June 2019.

3. Update on MedDRA

The Assembly received a report from the MedDRA MC Chair, Mr. Mick Foy (MHRA, UK), on the outcome of the MedDRA MC meeting held on 17-18 November 2019. The report included the following matters: the commemoration of MedDRA's 20-year anniversary in 2019; the expansion of MedDRA use worldwide; 2020 MSSO MedDRA Subscription Fees; 2020 MedDRA MC Work Plan and update on ongoing activities.

- ***MedDRA's 20-year anniversary***

The Assembly was informed on the commemoration of MedDRA's 20-year anniversary in 2019, including development of a 20th anniversary logo, presentations at MedDRA User Group meetings, and a special edition of the MedDRA Messenger publication in September 2019 which included reflections of MedDRA MC Member Representatives.

- ***Expansion of MedDRA use worldwide***

The Assembly was updated on the continued growth of MedDRA users throughout the world, which currently include over 6,000 MedDRA subscribing organisations in 125 countries, reflecting the continued successful adoption of MedDRA as a worldwide standard in the protection of public health for 20 years since its first release in 1999.

- ***2020 MedDRA Budget & Subscription Fees***

The Assembly was informed on MedDRA MC plans for conducting a market analysis for 2020 with the support of an external consultant with the objective of developing a comprehensive plan for future activities and associated multi-year budget needs. The Assembly was invited to approve the 2020 MedDRA Budget and stable 2020 MedDRA Subscription Fees, unchanged compared to 2019.

- ***2020 MedDRA MC Work Plan & Ongoing Activities***

The Assembly was invited to approve the 2020 MedDRA MC Work Plan aimed at (1) facilitating the use of MedDRA in a broader set of countries/regions with new translations, with plans to release a Brazilian Portuguese MedDRA translation in early 2020, and expanded training & support services assisted by local support staff in Europe, India, China, Republic of Korea, Latin America, the United States of America and other regions; (2) interoperability with other terminologies, including ongoing activities focusing on mapping MedDRA with SNOMED, ICD and IMDRF terms; and (3) further development of software tools, which will be accompanied in 2020 by a digital transformation assessment by an external IT consultant.

The Assembly was also invited to give its support to items including: (1) the process for MedDRA MC approval of additional translations of MedDRA Points to Consider (PtC) documents; (2) establishment of a Memorandum of Understanding (MoU) with the International Medical Device Regulators Forum (IMDRF) in support of the maintenance of a mapping developed between MedDRA and the IMDRF's terminology: Annex E: Health Effects – Clinical Signs, Symptoms and Conditions Terms and Codes; and the ending of the current phase of Standardised MedDRA Query (SMQ) development in collaboration with ICH Observer CIOMS which had been successful in the development of 105 SMQs since work began in 2003.

Assembly Decisions/Actions:

- The Assembly noted the decisions taken by the MedDRA MC during its meeting in Singapore on 17-18 November 2019;

- The Assembly supported the process for approval of any new translations of PtC documents by the MedDRA MC by which any translations into additional MedDRA languages would be considered and approved on a case-by-case basis by the MedDRA MC based on need expressed and feasibility, with the Assembly being informed of any new translation;
- The Assembly supported that the MedDRA MC proceed to finalise and establish a MoU with IMDRF concerning cooperation on the maintenance of a mapping between MedDRA and IMDRF's terminology: terminology: Annex E: Health Effects – Clinical Signs, Symptoms and Conditions Terms and Codes;
- The Assembly supported the completion of the current phase of SMQ development between ICH and CIOMS following the successful development of over 100 SMQs since work was initiated in 2003.

4. Financial Matters

The Assembly noted the ICH and MedDRA budgets submitted for its approval and received a report from ICH MC Chair, Dr. Theresa Mullin regarding ICH MC exploration of options towards a future sustainable ICH budget.

Assembly Decisions/Actions:

- The Assembly approved the revised 2020 ICH budget for publication on the ICH website;
- The Assembly approved the provisional 2021 ICH budget and 2021 Membership Fees;
- The Assembly noted work by the MC to consider options towards a future sustainable ICH funding model which the MC would further work on in coordination with the MedDRA MC, with a view to making a proposal to the Assembly for the next meeting in Vancouver, Canada in May 2020;
- The Assembly approved the 2020 MedDRA budget, including 2020 MedDRA subscription fees unchanged from 2019 rates, for publication on the ICH website;
- The Assembly noted MedDRA MC plans for a market analysis in 2020 with the support of an external consultant and plans to work together with the ICH MC to develop a comprehensive plan for multi-year budget needs for future activities.

5. Collaboration with PIC/S

The Assembly was informed by the ICH MC Chair on the ICH MC's considerations and proposal for interactions between ICH and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on ICH Guideline work with relevance to both Regulatory assessor and Inspector disciplines. As part of this proposal and in line with ICH processes, PIC/S would be involved in ICH Guideline work during the public consultation following *Step 2b* and additionally, as an ICH Observer, PIC/S could also request to be part of Plenary Working Parties (PWPs) which would allow an involvement prior to *Step 1*.

Assembly Decisions/Actions:

- The Assembly noted that in September 2019 the MC had shared with PIC/S a proposal for more routine engagement with PIC/S on ICH Guideline work with relevance to both Regulatory Assessor and Inspector disciplines, further to which the ICH MC Chair had met with the PIC/S Executive Bureau;
- The Assembly supported that a pilot process for this proposal would be developed by the ICH MC for sharing with PIC/S and noted that it would be informed on progress at its next meeting;

- The Assembly noted that the PIC/S Delegate in ICH, Dr. David Churchward, would be the PIC/S point of contact for ICH in this project;
- The Assembly noted that, complementary to this approach, ICH Regulatory Members and Observers should continue to coordinate internally with their inspectorate groups to provide feedback into ICH documents as appropriate.

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

The Assembly noted the 2020 Work Plan and Multi-Annual Strategic Plan of the ICH Association developed by the ICH MC, as well the 2020 MedDRA MC Work Plan developed by the MedDRA MC.

Assembly Decisions/Actions:

- The Assembly approved the 2020 Work Plan and Multi-Annual Strategic Plan of the Association, and its publication on the ICH website;
- The Assembly approved the 2020 MedDRA MC Work Plan, and its publication on the ICH website.

7. 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 ICH Assembly and WGs.

Assembly Actions/Decisions:

- The Assembly noted the participation in 32 ongoing WGs of 723 experts from amongst the 16 ICH Members and 32 ICH Observers;
- The Assembly was reminded that appointed experts are expected to participate actively in their WG on a continuous and regular basis and that changes of experts should be avoided as much as possible in order to ensure continuity of a WG's work;
- The Assembly noted that as a general rule ICH aims for 25 ongoing WGs and the hosting of up to 15 WGs meeting in parallel at ICH biannual meetings;
- The Assembly acknowledged the need and challenge to balance ICH's interest in pursuing new topics and ICH's capacity in terms of the number of WGs operating in parallel.

8. New Topic Process & Strategic Discussions

2019 New Topics Process

The Assembly was informed on pending items from the 2019 New Topic process, including: the Concept Paper outline on the revision of ICH Q9: *Quality Risk Management*; the revised New Topic proposal and Concept Paper outline on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*; and timeframe for initiation of work on the New Topic approved in June 2019 on *Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics*

Assembly Actions/Decisions:

- The Assembly approved the Concept Paper Outline for the revision of ICH Q9 and noted that the timeframe for establishment of a Q9(R1) informal WG, to be led by EC, Europe as the party who proposed the topic, will be further determined by the MC;

- The Assembly approved the New Topic proposal and the Concept Paper Outline on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*, further to which a M13 informal WG will be established, to be led by FDA, United States as the party who proposed the topic;
- The Assembly noted that work would initiate after the meeting on the New Topic proposal adopted by the Assembly in June 2019 on *Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics* with the establishment of a Q3E informal WG, to be led by PhRMA as the party who proposed the topic.

2020 New Topics Process

The Assembly was updated on the New Topics process for the 2020 cycle, including the cut-off date for submission of any New Topics proposals by Assembly Members and Observers.

Assembly Actions/Decisions:

- The Assembly noted that the deadline for submission of New Topic proposals for the 2020 process by Assembly Members and Observers is 13 December 2019 and that the Assembly would receive thereafter in December 2019 the New Topic proposals submitted, followed by the MC's assessment of proposals in April 2020;
- The Assembly noted that, to avoid duplication of work, any New Topic proposals received on Quality topics would be redirected by the MC to the Quality Discussion Group (QDG) which would review the topics falling within its remit and report with a recommendation for the 2021 New Topic process, including considerations on the expert capacity for Quality related topics.

Reflection Papers

The ICH MC presented to the Assembly the status of work regarding Member development of Reflection Papers on *Model Informed Drug Development (MIDD)* and on *Patient-Focused Drug Development (PFDD)*.

Assembly Actions/Decisions:

- The Assembly noted that a Reflection Paper on MIDD would be further shared with the Assembly for consideration at its meeting in Vancouver, Canada in May 2020;
- The Assembly noted the ongoing work on a draft Reflection Paper on PFDD which would also include considerations on engagement of external stakeholders with an interest in, and/or impacted by this topic, and noted that an update on progress would be given at the meeting in Vancouver, Canada in May 2020.

ICH and WHO

The Assembly was informed on considerations on the areas of work and complementarities of ICH and WHO to be considered in ICH Guideline development.

Assembly Action/Decision:

- The Assembly noted WHO's considerations shared on the areas of work and complementarities of ICH and WHO which should be considered in ICH Guideline development.

9. Implementation of ICH Guidelines

The Implementation Co-Leads of the MC updated the Assembly on the publication in November 2019 on the ICH website of the outcome of the ICH implementation survey for monitoring the adequacy of

implementation and adherence to ICH Guidelines for Regulators and Industry, as well as on considerations for future ICH implementation activities.

Assembly Actions/Decisions:

- The Assembly noted the report of the Implementation Co-Leads, including the publication of the 2019 implementation survey report on the ICH website in November 2019; considerations for conducting a trend analysis/text-mining of free text entries collected during the 2019 survey; and the planned next steps for the Implementation Co-Leads to draft a proposal for the next Implementation survey, including objectives, timing and scope;
- The Assembly noted that it was invited to provide any feedback on the 2019 implementation survey report to the Implementation Co-Leads via the ICH Secretariat;
- The Assembly noted that the status of implementation of ICH Guidelines by all ICH Regulatory Members is published on the ICH website, and that Regulatory Members of the Assembly are invited to inform directly the ICH Secretariat of any updates.

10. Training

The Co-Leads of the Training Subcommittee of the MC provided an update to the Assembly on recent activities undertaken by the Training Subcommittee, including:

- Recent approval of the following programmes as ICH Recognised Training Programmes:
 - Northeastern University: ICH-Q1 Training, Burlington, MA, USA, 16-18 October 2019;
 - APEC PKU Regulatory Sciences CoE: MRCT & Incorporating GCP-Related Considerations, Beijing, China, 11-14 November 2019.
- Recent publication on the ICH website of the Q7 online training material developed by the Parenteral Drug Association (PDA), and which had been approved by the Training Subcommittee as an ICH Recognised Training Programme;
- Ongoing considerations to provide support to the E2B(R3) EWG/IWG and the Q12 EWG for development of training materials via the FDA, United States Studios.

The Assembly was also informed of the:

- recent publication on the ICH website of training videos developed by ICH WGs on Q11 Q&As and E17;
- progress made further to the Call for Expression of Interest issued by ICH in April 2019 for ICH Training Associates aimed at exploring the possibility of contracting appropriate accredited non-profit training organisations/institutions to assist ICH in its efforts to address in a strategic manner the training needs of its Regulatory and Industry Members and Observers.

Assembly Actions/Decisions:

- The Assembly noted the appointment by the MC a new industry Co-Lead of the Training Subcommittee;
- The Assembly supported the development of an ICH Training Library on the ICH website which would provide in one location the links to all training materials published on the ICH website;

- The Assembly noted the progress made further to the Call for Expression of Interest issued by ICH in April 2019 for ICH Training Associates, and that the two organisations which had been short-listed further to an anonymised assessment of applications had been informed of ICH's interest to engage with them for further discussion on the basis of more detailed ICH specifications and contracts were currently being discussed with both organisations.

11. Communication

Commemoration of ICH's 30th Anniversary

The Assembly was informed by the Lead of the Organising Committee on preparations for the commemoration in 2020 of ICH's 30th Anniversary.

Assembly Actions/Decisions:

- The Assembly noted the planning by the Organising Committee of a commemorative ICH event for ICH 30th Anniversary in Athens, Greece on Saturday, 14 November 2020 which would be preceded by a reception on Friday, 13 November 2020 and to which all ICH Assembly Members and Observers are invited;
- The Assembly noted that the Organising Committee would develop a draft programme for the event with options for various topics, including past ICH achievements as well as future ICH focus and challenges, and that the draft programme would be shared with the Assembly for input ahead of the next meeting in Vancouver, Canada in May 2020;
- The Assembly noted that, in addition to the event, the commemoration of the ICH 30th Anniversary will include a short promotion video, filmed at the meeting in Singapore, and that consideration is also being given to an anniversary publication.

Communication Activities

The Assembly was updated by the ICH Secretariat on the recent changes made to the ICH website to improve ICH communication with stakeholders.

Assembly Actions/Decisions:

- The Assembly noted the new functionalities of the upgraded ICH website launched in October 2019, including a new search tool to allow easy retrieval of information on the status of implementation of ICH Guidelines by ICH Regulatory Members;
- The Assembly noted that the Secretariat would build a Training Library on the ICH website to provide more visibility to the training materials of ICH WGs so that stakeholders can more easily access them.

ICH Regional Public Meetings

Assembly Action/Decision:

- The Assembly noted that Members are invited to inform the ICH Secretariat on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Singapore in November 2019, for publication on the ICH website.

12. Appointment of ICH Management Committee Elected Representatives

The Assembly was informed that in line with the ICH Articles of Association, up to two Elected MC Representatives representing up to one Regulatory Member could be elected to fill two seats currently

vacant. Furthermore, it was noted that as per Article 26(9) of the ICH Articles of Associations the election should be conducted by secret ballot.

The Assembly was informed that ANVISA, Brazil had submitted an application, and ANIVSA, Brazil subsequently provided a brief introduction and presented their interest in joining the ICH MC. The ICH MC confirmed to the Assembly the Applicants' eligibility.

Assembly Actions/Decisions:

- The Assembly elected Mr. Diogo Penha Soares and Mr. Gustavo Lima Mendes Santos from ANVISA, Brazil, as ICH MC Elected Representatives, to serve until the next ICH MC elections in June 2021;
- The Assembly noted that the new elected MC Representatives would be given the opportunity to also participate in any Subcommittees set-up under the MC.

13. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) updated the Assembly on (1) activities performed, including the review and categorisation of the Q4B Annexes, to assess the timeframe for the revision of the Q4B Annexes as per the maintenance process described in Annex 5 of the SOP of the WGs; and (2) considerations regarding the revision of the Q4B Guideline to align it with the Q4B Annexes maintenance process approved by the Assembly at its meeting in Charlotte, NC, USA in November 2018.

Assembly Actions/Decisions:

- The Assembly noted that the PDG would submit:
 - by the ICH meeting in May 2020, 14 Q4B annexes, revised to align them with the current editions of the three pharmacopoeias for endorsement by the Assembly under *Step 2a/b*;
 - by the ICH meeting in November 2020, a proposed revision to the Q4B Guideline to align it with the Q4B Maintenance Procedure approved at the Assembly meeting Charlotte, NC, USA in November 2018.
- The Assembly noted that the process would involve PDG communication with other global Pharmacopoeias regarding the revision of the Q4B Annexes.

14. WGs Meeting in Singapore

The Assembly was informed that requests from WGs to meet at the next ICH meeting in Vancouver, Canada on Sunday 24 – Wednesday 27 May 2020 would be taken under consideration by the ICH MC at the end of its meeting in Singapore, and that the list of WGs agreed by the ICH MC to meet face-to-face in Vancouver will be made available to the Assembly and published on the ICH website.

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

Assembly Actions/Decisions:

The E2D(R1) Acting Rapporteur reported to the Assembly on the outcome of the meeting of the E2D(R1) informal WG /EWG, including finalisation of the E2D(R1) Concept Paper and Business Plan.

- The Assembly noted that the ICH MC had in Singapore endorsed the E2D(R1) Concept Paper and Business Plan, and the subsequent establishment of the E2D(R1) EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly supported the work plan of the E2D(R1) EWG for activities to be undertaken and supported efforts to expedite work;
- The Assembly noted that the E2D(R1) EWG would interact with the E19 EWG regarding handling of safety data;
- The Assembly appointed the former E2D(R1) informal WG Leader, and current E2D(R1) EWG Acting Rapporteur, Dr. Edwards (EFPIA) as E2D(R1) Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP.

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

The E6(R3) Acting Rapporteur reported to the Assembly on the outcome of the meeting of the E6(R3) informal WG /EWG, including finalisation of the E6(R3) Concept Paper and Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the ICH MC had in Singapore endorsed the E6(R3) Concept Paper and Business Plan, and the subsequent establishment of the E6(R3) EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly noted the work plan of the E6(R3) EWG for activities to be undertaken, noting that the group would first work on the Guideline and Annex 1, and when *Step 1* of these documents is reached, the group would revise the E6(R3) Concept Paper regarding the revision of Annex 2 based on an increased understanding at that time;
- The Assembly noted the considerations of the group to submit by early 2020 to the MC a proposal for external stakeholder engagement, including organisation of regional outreach activities such as workshops or surveys;
- The Assembly appointed the former E6(R3) informal WG Leader, and current E6(R3) EWG Acting Rapporteur, Dr. M. El Zarrad (FDA, United States) as E6(R3) Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP.

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

The E11A Rapporteur reported to the Assembly on the outcome of the meeting of the E11A EWG and the progress made on the E11A draft Technical Document.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the E11A EWG for activities to be undertaken, noting that *Steps 1* and *2a/b* are expected by November 2020;
- The Assembly supported the continued involvement of subject matter experts as *ad hoc* experts to support development of the E11A Technical Document;
- The Assembly noted the consideration of the group to develop an Annex with illustrative examples, and the Assembly further invited the E11A EWG to include, in their subsequent presentation to the Assembly, an example developed by the group.

14.4 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: Dr. Shinagawa – MHLW/PMDA, Japan)

The E14/S7B Rapporteur reported to the Assembly on the outcome of the meeting of the E14/S7B IWG and the progress made on the development of Q&As and the Integrated Risk Assessment for E14/S7B.

Assembly Action/Decision:

- The Assembly noted the work plan of the E14/S7B IWG for activities to be undertaken and noted that finalisation of the first stage of Q&As is expected by May 2020.

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

The E19 Rapporteur reported to the Assembly on the outcome of the meeting of the E19 EWG and the progress made on reviewing the comments received during the regional public consultations which ended in September 2019.

Assembly Action/Decision:

- The Assembly noted the work plan of the E19 EWG and that although *Steps 3 and 4* are expected by June 2021, the type/extent of comments received on the draft Guideline which need to be further considered by the EWG may impact the expected timeframe.

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

The E20 Acting Rapporteur reported to the Assembly on the outcome of the meeting of the E20 informal WG, including finalisation of the E20 Concept Paper and Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the ICH MC had endorsed in Singapore the E20 Concept Paper and Business Plan, and the subsequent establishment of the E20 EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly agreed that the work plan of the E20 EWG may be further updated in view of considerations on the timeline for completion of the work;
- The Assembly supported that that the E20 EWG should interface with other ongoing WGs of relevance such as the M11 EWG;
- The Assembly appointed the former E20 informal WG Leader, and current E20 EWG Acting Rapporteur Dr. Zhong (PhRMA) as E20 Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP.

14.7 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 and the progress made on reviewing the comments received during the regional public consultations which ended in September 2019.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the M10 EWG for activities to be undertaken and that *Steps 3 and 4* are expected by November 2020;

- The Assembly noted considerations of the group to develop training materials after completion of the M10 Guideline, and the Assembly further noted that the development of training materials should remain within a 6-month timeframe following *Step 4*.

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

The M11 Rapporteur reported to the Assembly on the outcome of the meeting of the M11 EWG and the progress made on the development of the M11 Technical Document, the protocol template and the technical specification document, as well as on strategic engagement with other key WGs, and the progress made on early engagement of external stakeholders.

Assembly Actions/Decisions:

- The Assembly noted the M11 EWG’s interactions with the E6(R3) EWG, the M2 EWG, and the E9(R1) EWG, and supported that the group should also interact with the E20 EWG;
- The Assembly noted that the M11 EWG would submit an updated proposal for early engagement of external stakeholders to the MC based on the E8(R1) EWG’s approach for a comprehensive engagement;
- The Assembly noted that the finalisation on the M11 Technical Document, template content and data model had been delayed and that *Steps 1* and *2* are now expected in November 2020.

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

The M12 Acting Rapporteur reported to the Assembly on the outcome of the meeting of the M12 informal WG, including finalisation of the M12 Concept Paper and Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the ICH MC had in Singapore endorsed the M12 Concept Paper and Business Plan, and the subsequent establishment of the M12 EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly supported the work plan of the M12 EWG for activities to be undertaken and noted that *Steps 1* and *2a/b* are expected by November 2021;
- The Assembly appointed the former M12 informal WG Leader, and current M12 EWG Acting Rapporteur, Dr. Madabushi (FDA, United States) as M12 Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP.

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

The Q2(R2)/Q14 Rapporteur reported to the Assembly on the outcome of the meeting of the Q2(R2)/Q14 EWG and the progress made in the development of the Q2(R2)/Q14 Technical Document.

Assembly Actions/Decisions:

- The Assembly noted the progress made by the group in the development of two separate draft documents, and that the group would further consider whether they should be combined into one document;
- The Assembly noted the progress made towards the finalisation of the *Step 1* Technical Document and that *Steps 1* and *2a/b* are expected to be reached by May 2020.

14.11 Q5A(R2) EWG: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Rapporteur: Dr. Welch - FDA, United States)

The Q5A(R2) Acting Rapporteur reported to the Assembly on the outcome of the meeting of the Q5A(R2) informal WG, including finalisation of the Q5A(R2) Concept Paper and Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the ICH MC had in Singapore endorsed the Q5A(R2) Concept Paper and Business Plan, and the subsequent establishment of the Q5A(R2) EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly supported the work plan of the Q5A(R2) EWG for activities to be undertaken and noted that that *Steps 1* and *2a/b* are expected to be reached by June 2021;
- The Assembly appointed the former Q5A(R2) informal WG Leader, and current Q5A(R2) EWG Acting Rapporteur, Dr. Welch (FDA, United States) as Q5A(R2) Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP;
- The Assembly noted that the Regulatory Members of the MC would be invited electronically to appoint a Regulatory Chair to the group.

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

The Q12 Rapporteur reported to the Assembly on the outcome of the meeting of the Q12 EWG, including finalisation of the Q12 draft Guideline.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Topic Leaders of Q12 EWG signed-off *Step 3* of the Q12 draft Guideline, further to which the Regulatory Members of the Assembly adopted the Guideline under *Step 4*;
- The Assembly supported, in principle, the Q12 EWG request for development of training materials, and the Assembly further noted that the Q12 EWG had submitted to the MC a Concept Paper for approval regarding the development of training materials by November 2020. Pending MC endorsement of the Concept Paper, the Q12 EWG would transition to an IWG;
- The Assembly noted considerations to include Q12 in the draft pilot proposal for more routine engagement with PIC/S on ICH Guidelines;
- The Assembly noted that the implementation of this Guideline by the Regulatory Members will require considerable efforts and will take some time and that changes in national/local regulations are being envisaged by several ICH Regulatory Members.

14.13 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 in the development of the Q13 Technical Document, and the planning of informal regional Continuous Manufacturing site visits for interested Q13 EWG Regulatory Member experts.

Assembly Actions/Decisions:

- The Assembly noted that interested Regulatory Member experts had visited a continuous manufacturing site for chemical entity drug substance in Asia, and that the Q13 EWG was in the process of organising further informal regional Continuous Manufacturing site visits across Asia, Europe and the United States;
- The Assembly noted the progress made on the *Step 1* Technical Document and Annexes on specific Continuous Manufacturing topics including the fact that considerations are being given to regional differences in respect of regulatory aspects and that *Steps 1* and *2a/b* are expected to be reached by May 2020, although a risk was identified of a possible extension of this timeline.

14.14 S12 informal WG: Non-clinical Biodistribution Considerations for Gene Therapy Products (Lead: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Serabian – FDA, United States)

The S12 Acting Rapporteur reported to the Assembly on the outcome of the meeting of the S12 informal WG, including on the finalisation of the S12 Concept Paper and Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the ICH MC had in Singapore endorsed the S12 Concept Paper and Business Plan, and the subsequent establishment of the S12 EWG, and subject to interest and need from Members and Observers not represented in the EWG, the potential establishment of an associated PWP;
- The Assembly supported the work plan of the S12 EWG for activities to be undertaken and supported efforts to expedite work while noting that regulatory issues are being taken into account;
- The Assembly appointed the former S12 informal WG Leader, and current S12 EWG Acting Rapporteur, Dr. Hirata (MHLW/PMDA, Japan) as S12 EWG Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP.

15. WGs Not Meeting in Singapore

15.1 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.

15.2 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 training materials.

15.3 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) EWG continues its work on reviewing the comments received during the regional public consultations which ended in October 2019.

The Coordinator for FDA, United States updated the Assembly on the outcome of the E8(R1) global public stakeholder meeting held as per the GCP renovation plan on 31 October 2019 at the FDA, United States headquarters.

Assembly Actions/Decisions:

- The Assembly noted that a video recording of the E8(R1) public meeting would be made available;
- The Assembly noted that the E8(R1) EWG would submit a report on the feedback received during the E8(R1) public meeting.

The E8(R1) EWG will hold an interim meeting on 27-30 March 2020 in Tokyo, hosted by MHLW/PMDA, Japan and JPMA.

Steps 3 and 4 are expected by June 2020.

15.4 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)

The E9(R1) continues its work on the development of training materials and videos.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Topic Leaders of the E9(R1) EWG signed-off *Step 3* of the E9(R1) draft Guideline, further to which the Regulatory Members of the Assembly adopted the Guideline under *Step 4*;
- The Assembly noted the E9(R1) EWG's ongoing considerations for development of training materials.

The E9(R1) training videos are expected to be finalised by early 2020.

15.5 E17 IWG Multi-Regional Clinical Trials (Rapporteur: Dr. Dunder – EC, Europe; Regulatory Chair: Mr. Otsubo – MHLW/PMDA, Japan)

Further to the completion of the E17 training materials in August 2019 and their publication on the ICH website and YouTube, the E17 IWG was disbanded in September 2019.

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

The M1 PtC WG continues its work, including on the update of the Points to Consider documents with the MedDRA release in March of each year and additional translations of the Points to Consider documents into Chinese, Korean and Spanish (see also item #3).

Release of a second edition of the Companion Document is expected by December 2019.

Release of next versions of the “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 23.0 and available in English, Japanese, Chinese, Korean and Spanish) are expected in March 2020.

15.7 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: 1) the finalisation of a Service Level Understanding for terminology list management with the E2B EWG/IWG; 2) the development of a technical specification with the M11 EWG; 3) the development of an opportunity proposal on standardized quality data; 4) the evaluation of new ICH topics (i.e. which are at *Step 1*) for technical risks and opportunities; and 5) consideration on rapid technology advancement of electronic standards impacting harmonisation activities and continued monitoring of FHIR development.

Assembly Action/Decision:

- The Assembly noted the White Paper developed by the M2 EWG on *HL7 Fast Healthcare Interoperability Resources (FHIR) Considerations for ICH*.

The publication of the OID maintenance process and the finalisation of the revision of the project opportunities proposal is expected by November 2019.

15.8 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.

15.9 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 revised M7(R2) Draft Guideline (including the revised second Addendum) and Q&As are expected by January 2020.

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

The Coordinator for FDA, United States updated the Assembly on activities of the M8 EWG/IWG, including the finalisation of the assessment on next steps for eCTD v4.0 and FHIR standards.

Assembly Actions/Decisions:

- The Assembly noted the presentation on the M8 EWG/IWG and M2 EWG joint assessment of next steps for the eCTD v4.0 and HL7 FHIR standards, and that the M8 EWG/IWG and M2 EWG would provide a formal report;
- The Assembly approved the recommendation to move forward with the eCTD v4.0 implementation;
- The Assembly noted that the M8 EWG/IWG would monitor the status of implementation of eCTD v4.0 with a view to providing a status update on a biannual basis;
- The Assembly noted that the M8 EWG is working on eCTD v4.0 Change Requests.

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

Further to the finalisation of the M9 draft Guideline and the Q&As document, the M9 EWG is working on the development of the *Step 4* Training Presentation.

Assembly Action/Decision:

- The Assembly noted that the Regulatory Topic Leaders of the M9 EWG signed-off *Step 3* of the M9 draft Guideline and the Q&As document, further to which the Regulatory Members of the Assembly adopted the Guideline and Q&As document under *Step 4*.

15.12 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.

The revised monograph to Q3C(R6) for the PDE of ethyleneglycol is also planned for publication on the ICH website as a support document.

The Q3C(R8) Maintenance EWG continues its work on the development of Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol.

Q3C(R8) is expected to reach Steps 1 and 2a/b by early 2020.

15.13 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 draft Addendum on cutaneous and transdermal routes of administration.

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

15.14 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 third S1 Status Report was published on the ICH website in September 2019.

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

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

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

The S5(R3) EWG continues its work on the finalisation of the S5(R3) Guideline.

Steps 3 and 4 are expected by early 2020.

15.16 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 EWG continues its work on the finalisation of the S11 Guideline.

Steps 3 and 4 are expected by early 2020.

The S11 training materials are expected by June 2020.

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

Following the finalisation of the GDG's recommended revisions to the topic proposal on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*, the GDG continues its work on: 1) the identification of additional bioequivalence topics for harmonisation and communication with the BEWGG (Bioequivalence WG for Generics) of the IPRP (International Pharmaceutical Regulators programme); 2) review of ICH Efficacy and Multidisciplinary Guidelines, with consultation with the QDG; and 3) finalisation of overall recommendations and prioritization of work areas by the end of the GDG's terms anticipated by April/May 2020.

Assembly Action/Decision:

- The Assembly noted that further to the approval of the amendments to the ICH procedures regarding general principles on discussion Groups, the name and abbreviated name of the Informal Generic drug Discussion Group (IGDG) would change to Generic drug Discussion Group or GDG.

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

The QDG continues its work on the review of the ICH Quality and Multidisciplinary Guidelines.

Assembly Action/Decision:

- The Assembly noted that further to the approval of the amendments to the ICH procedures regarding general principles on discussion Groups, the name and abbreviated of the Informal Quality Discussion Group would change to Quality Discussion Group or QDG.

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

The PEpiDG continues its work, including on developing its Work Plan.

16. Election of Assembly Chair and Vice-Chair

Assembly Action/Decision:

- The Assembly re-elected Ms. Lenita Lindström-Gommers (EC, Europe) as Assembly Chair and Dr. Celia Lourenco (Health Canada, Canada) as Assembly Vice-Chair and noted that they would serve for a two-year mandate.

17. Organisation of Next Meetings

Assembly Action/Decision:

- The Assembly noted the below dates of the next ICH Assembly meetings:
 - Tuesday 26 - Wednesday 27 May 2020 in Vancouver, Canada;
 - Tuesday 17 - Wednesday 18 November 2020 in Athens, Greece;
 - Tuesday 1 - Wednesday 2 June 2021 in Incheon, Republic of Korea (final confirmation pending);
 - Tuesday 16 - Wednesday 17 November 2021 in the Americas (location to be confirmed).

18. AOB

- The Assembly thanked Dr David Jefferys/representative of IFPMA who is rotating off IFPMA for his contribution to ICH over the past years and especially for the efforts to involve experts from national industry associations that are members of IFPMA in ICH, noting that there are at present 28 such experts in ICH EWGs.