5 August 2019

FINAL MINUTES
ICH Assembly
5 - 6 June 2019, Amsterdam, the Netherlands

Please find hereafter the final minutes of the Assembly meeting held in Amsterdam, the Netherlands on 5- 6 June 2019.

List of Assembly Participants

ICH Assembly Member Representatives:

Dr. Raphael Sanches Pereira	ANVISA, Brazil
Mr. Diogo Penha Soares	ANVISA, Brazil
Mrs. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers (Chair)	EC, Europe
Dr. Georgios Balkamos	EC, Europe
Prof. Bruno Sepodes	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Dr. Léo Bouthillier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Prof. Cheng Leng Chan	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
Dr. Young-Ok Kim	MFDS, Republic of Korea
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Dr. Peter K. Honig	PhRMA
Ms. Camille Jackson	PhRMA
Dr. Petra Doerr (Vice-Chair)	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland
Mr. Ming-Hsun Liu	TFDA, Chinese Taipei
Ms. Shou-Mei Wu	TFDA, Chinese Taipei
Ms. Caroline Mendy	WSMI

ICH Management Committee Member Representatives:

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

ICH Assembly Standing Observer Delegates:

Dr. David Jefferys	IFPMA
Dr. Sharon Olmstead	IFPMA
Ms. Emer Cooke	WHO
Dr. Gabriela Zenhaeusern	WHO

ICH Assembly Observer Delegates:

Dr. Yongseok Ko	APEC
Mrs. Marieke van Dalen	APIC
Dr. Murray Lumpkin	Bill and Melinda Gates Foundation
Dr. S. Eswara Reddy	CDSCO, India
Dr. Celeste Sánchez González	CECMED, Cuba
Dr. Lembit Rägo	CIOMS
Ms. Jane Mashingia	EAC
Dr. Susanne Keitel	EDQM

Dr. Hajed M. Hashan	GHC
Dr. Lucia Ayala	INVIMA, Colombia
Ms. Janeen SkutnikWilkinson	IPEC
Dr. Seetha Ramasamy	NPRA, Malaysia
Dr. Charles Preston	PANDRH
Mr. David Churchward	PIC/S
Ms. Fortunate Ntombi Bhembe	SADC
Mr. Tohlang Sehloho	SAHPRA, South Africa
Ms. Hacer Coşkun Çetintaş	TITCK, Turkey
Dr. Kevin Moore	USP

ICH Assembly Coordinators:

Mr. Sebastian Duarte	ANMAT, Argentina[1]
Dr. Ingrid Markovic	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichiro Hirose	IGBA
Dr. Wesal Haqaish	JFDA, Jordan[1]
Mr. Mitsuo Mihara	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. Mohammed A. Al Quwaizani	SFDA, Saudi Arabia[1]
Ms. Anna Sieg	Swissmedic, Switzerland
Ms. Yi-Jing Kuo	TFDA, Chinese Taipei
Ms. Caroline Mendy	WSMI

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. Mandeep Kumar Bhandari	CDSCO, India
Mrs. Agnès Saint-Raymond	EC, Europe
Ms. Jana Nackberg	EFPIA
Ms. Machiko Sumi	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Mr. Jerry Stewart	PhRMA

ICH Secretariat:

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

[1] At the Assembly meeting in Amsterdam under Agenda 2, ANMAT, Argentina, JFDA, Jordan, and SFDA, Saudi Arabia were welcomed as a new ICH Observers.

Table of Content

ICH ASSEMBLY MINUTES

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

Assembly Vice Chair: Dr. Petra Doerr, Swissmedic, Switzerland

Opening of the ICH Assembly Meeting

The ICH Assembly meeting in Amsterdam, the Netherlands, held on 5 – 6 June 2019, was chaired by Ms. Lindström-Gommers (Chair – EC, Europe) and Dr. Petra Doerr (Vice Chair – Swissmedic, Switzerland).

The Assembly noted the Member Representatives and Observer Delegates as well as Ad-Hoc Observer Delegates from ANMAT, Argentina, JFDA, Jordan and SFDA, Saudi Arabia participating in the Assembly meeting.

The Ad-Hoc Observers Delegates, as well as the representative of CDSCO, India who was attending the first ICH meeting since joining the ICH Assembly as an Observer, were invited to give a short presentation to introduce their organisations.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. 2018 Annual Report of the Association

The ICH Secretariat presented to the Assembly the 2018 ICH Annual Report on the activities of the Association which covered the activities undertaken by the ICH Management Committee (MC), the MedDRA MC and the ICH Secretariat on behalf of the ICH Association.

Assembly Decision/Action:

- The Assembly approved the 2018 Annual Report for publication on the ICH website and the discharge of the ICH MC, MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2018 on behalf of the ICH Association.

2. Membership and Observership

The ICH MC presented to the Assembly an overview of applications for Membership/Observership processed since the meeting in Charlotte, NC, USA, in November 2018 and its recommendation on these applications in view of the eligibility criteria.

Assembly Decision/Action:

- The Assembly approved the following applications for Observership under Article 17.1(a) of the ICH Articles of Association:
  - ANMAT, Argentina;
  - CPED, Israel;
  - JFDA, Jordan;
  - SFDA, Saudi Arabia.

3. Procedural Matters

- ***IFPMA/IGBA expert participation***

The IFPMA and the IGBA delegates updated the Assembly on their respective processes for the selection of experts to ICH Working Groups (WGs) from across their association members and to facilitate the understanding and implementation of ICH Guidelines.

- ***Articles of Association and Assembly Rules of Procedure***

The Assembly Chair and the ICH Secretariat presented to the Assembly amendments proposed to the ICH Articles of Association and Assembly Rules of Procedure (RoP) related to: (1) the management of the size of ICH WGs in view of ICH's growing number of Members and Observers; (2) the definitions of the degrees of implementation of ICH Guidelines approved by the Assembly in Charlotte, NC, USA in November 2018; (3) ICH Cooperation with other organisations; (4) the revision to the training mission statement supported by the MC at its meeting in Charlotte in November 2018, and (5) the need identified for certain clarifications.

Assembly Decisions/Actions:

- The Assembly noted the proposed changes to the ICH Articles of Association v.2.0 and approved the ICH Articles of Association v.3.0, which will be published on the ICH website;
- The Assembly noted the proposed changes to the ICH Assembly Rules of Procedure v.6.0, and approved the ICH Assembly Rules of Procedure v.7.0, which will be published on the ICH website.

- ***ICH Management Committee Rules of Procedure and Standard Operating Procedures of ICH Working Groups***

The ICH MC Chair and the ICH Secretariat presented to the Assembly updates to the ICH MC RoP and the Standard Operating Procedures (SOPs) of the ICH WGs related to the proposed amendments in the ICH Articles of Association and Assembly RoP (see item above), as well as on: (1) the replacement of a WG's Regulatory Chair in the event of their resignation; (2) the process to appoint a Rapporteur; (3) the development of Work Plans by WGs; (4) clarifications on WG quorum; and (5) the need identified for other clarifications, including on templates and forms in the SOPs of the WGs.

Assembly Decisions/Actions:

- The Assembly noted the proposed changes to the ICH MC RoP v6.1 and that the MC approved the ICH MC RoP v.7.0 at its meeting in Amsterdam, which will be published on the ICH website;
- The Assembly noted the proposed changes to the SOP v7.0 for WGs and that the MC approved the SOP v8.0 for WGs at its meeting in Amsterdam, which will be published on the ICH website.

- ***MedDRA Management Committee Rules of Procedure***

The ICH Secretariat informed the Assembly on updates approved by the MedDRA MC to the MedDRA MC RoP for consistency with other ICH procedural documents related to ICH Cooperation with other organisations and the approval process for minutes/reports.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the MedDRA MC RoP v4.0 and that the MedDRA MC approved the MedDRA MC RoP v5.0 at its meeting in Amsterdam, which will be published on the ICH website.

4. General Operational Matters

- ***General***

The Assembly was updated by the ICH Secretariat on general operational matters including: ICH Secretariat implementation of recent Assembly/ICH MC decisions; and statistics regarding the participation of Member and Observer experts in ICH.

Assembly Actions/Decisions:

- The Assembly noted the ICH expert participation statistics presented by the ICH Secretariat and the growing number of ICH Members and Observers, WGs and experts participating in ICH;
- The Assembly was reminded of the fact that experts that have been appointed in WGs are expected to actively participate in and contribute to the work of the WGs on a continuous and regular basis in order to ensure continuity;
- The Assembly acknowledged that Members, Observers, and experts should have knowledge of and adhere to ICH rules, in view of their rights and duties in participating in ICH;
- The Assembly noted that the MC is reflecting on changes towards improving the efficiency of ICH Secretariat operations in view of the increasingly significant impact on resources of the continued growth of ICH, and that the MC will keep the Assembly informed on the outcome of its reflections and any changes being implemented on the operational side.

- ***IPRP Cooperation***

The Assembly was updated by the Chair of the International Pharmaceutical Regulators Programme (IPRP) on IPRP activities and the ICH Secretariat's provision of services to the IPRP since the start of 2018.

Assembly Action/Decision:

- The Assembly approved the renewal of the Memorandum of Understanding (MoU) between ICH and IPRP for the provision of support services by the ICH Secretariat to the IPRP for the period 1 January – 31 December 2020.

5. Update on MedDRA

The Assembly received a report from the ICH Secretariat on the outcome of the MedDRA MC meeting held on 1-2 June 2019. The report included the following matters: the commemoration of MedDRA's 20 year anniversary in 2019; MedDRA MC procedural matters, including the annual election of the MedDRA MC Chair and changes to the MedDRA MC RoP; the expansion of MedDRA use worldwide; and review of the MedDRA 5-year strategic plan in view of the continued growth in MedDRA subscribing organisations.

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

The Assembly was informed on the commemoration of MedDRA's 20 year anniversary, including development of a 20th anniversary logo, presentations at MedDRA User Group meetings, and a special edition of the MedDRA Messenger publication to include 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 5,700 MedDRA subscribing organisations in 122 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.

- ***MedDRA 5-year strategic work plan***

The Assembly was informed on the current MedDRA 5-year strategic work plan which includes a focus on the facilitation of the use of MedDRA in a broader set of countries/regions through (1) new translations; (2) expansion of training and support services; (3) further development of software tools; and (4) work on interoperability with other terminologies. Particularly noteworthy was: the release of a Russian MedDRA translation in March 2019 which had been developed in collaboration with Roszdravadzor, Russia; the conduct of over 98 training courses for MedDRA users in 2018 and new MSSO local support staff in China, India, Latin America and Republic of Korea; the release in April 2019 of a new MedDRA Mobile Browser; and progress of work within the Innovative Medicines Initiative (IMI) WEB-RADR 2 Project to develop a bi-directional MedDRA-SNOMED mapping.

Furthermore, the Assembly was informed on the MedDRA MC's review of the MedDRA 5-year strategic work plan and considerations in view of the scale of growth in MedDRA subscribing organisations worldwide, as well as the need for user support at different levels of scope and maturity.

Assembly Decisions/Actions:

- The Assembly noted the decisions taken by the MedDRA MC at its meeting in Amsterdam on 1-2 June 2018 including the re-election of Mr. Mick Foy (MHRA, UK) as MedDRA MC Chair for a one-year term, and the approval of changes to the MedDRA MC Rules of Procedures (see also item #3 above).
- The Assembly approved in principle the hiring of two additional MSSO local support staff in China to meet current training needs so that the recruitment process could already begin, and noted that the MedDRA MC would come back to the Assembly by September 2019 to seek approval of a revised MedDRA Budget which would include costs associated with this recruitment, in addition to costs related to consultancy support for a digital transformation assessment, and other minor costs anticipated in 2019.

6. Implementation of ICH Guidelines

The Lead of the Implementation Subcommittee of the MC and a representative from the independent third-party which conducted the ICH implementation survey provided the Assembly an update on recent activities as well as the results of the ICH-driven implementation survey for monitoring the adequacy of implementation and adherence to ICH Guidelines which had been completed by Regulators and Industry.

Assembly Decisions/Actions:

- The Assembly noted the outcome of the implementation survey;
- The Assembly approved the 2019 Communication Plan for the publication of the survey results, by which:
    - A publication based on the survey would be prepared during the second half of 2019 in cooperation with the independent third party which had been engaged by ICH to conduct the survey;
    - The data would be presented in aggregated form, grouping Founding and Standing Regulatory Members; Regulatory Members; and Regulatory Observers;
    - Individual Regulatory Members and Observers which decide to publish their data separately should inform the MC on when and where the publication is done. Furthermore, such publications should not make reference to other individual Regulatory Member/Observer results, but could include statements relative to the ICH publication on the survey, in view of which communication by individual Regulatory Members and Observers should only take place after the ICH communication.

- The Assembly noted the MC decision to disband the Implementation Subcommittee, and to appoint two implementation co-Leads, one from a Regulatory and one from an Industry Member, to further consider future mandate, 2020 budget for implementation activities, and an implementation work plan, with the support of the ICH Secretariat to continue activities to support implementation of ICH Guidelines.

7. Training

- ***General***

The Lead of the Training Subcommittee of the MC provided an update to the Assembly on recent activities undertaken by the Training Subcommittee including:

- support provided to ICH WGs developing training materials: E9(R1), E17 and Q11 WGs;
- revision of introductory online training materials to be posted on the ICH website by end 2019;
- recent approval of the following ICH Recognised Training Programmes:
  - APEC PKU Regulatory Sciences CoE: Pharmacovigilance Seminar, Beijing, China, 23-25 April 2019;
  - APEC PKU Regulatory Sciences CoE: MRCT & Incorporating GCP-Related Considerations September 2019;
  - DIA Japan: ICH Day, Tokyo, Japan, 18 April 2019;
  - DIA China: ICH Day, Beijing, China, 20 May 2019;
  - MHLW/PMDA Japan: E8(R1), Tokyo, Japan, July 25, 2019.

The Assembly also noted that the following ICH Recognised Training Programmes took place since the Assembly meeting in Charlotte, NC, USA in November 2018:

- Chinese Pharmaceutical Association: M4 programme in China (May 2019)
- Harvard MRCT B&W with Health Canada: E6(R2)/E17 programme in Ottawa (Feb 2019)
- Duke-NUS: CMC programme in Singapore (March 2019)

The Assembly was also informed on ICH MC approval in February 2019 of: the ICH Recognised Training Programme Online Presentation Template; the revised Terms of Reference for Training Providers; the revised ICH Recognised Training Programme Logo Disclaimer Template; and the revised General Guidance for ICH Training Providers.

The Assembly furthermore noted that an ICH YouTube channel will be created in June 2019 and maintained by the ICH Secretariat to share high resolution ICH Training videos, and that the ICH website would provide links to the videos on YouTube as well as downloadable lower-resolution versions of the videos and PDF version.

- ***ICH Training Associates***

The Assembly was updated by the ICH Secretariat on the conduct of 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. The Assembly noted that 11 organisations had responded to the call, and that a Review

Committee had conducted an anonymised assessment of the applications, based on the eligibility criteria and applicants' ability to meet the statement of work.

Assembly Decisions/Actions:

- The Assembly supported the following next steps:
    - The two organisations which have received the highest scores based on the anonymised assessment would be selected for this round of selection of ICH Training Associates, as they fully meet the eligibility criteria and can cover the full statement of work, and recognizing benefits of contracting two organisations, taking advantage of their different capabilities and expertise;
    - A small subgroup of the MC with support from the ICH Secretariat, would develop more detailed specifications for the scope of work for organisations for the first year of collaboration, which would include as priority the development of online training materials and case studies for Tier 1 and Tier 2 Guidelines, as well as the provision of consultancy services to the ICH WGs developing training materials;
    - After discussion with the organisations on the scope of work, specifications and associated costs, the MC would determine the level of work which can be accommodated within the budget to be approved by the ICH Assembly for this activity;
    - Contract negotiations would be undertaken with a view to contracting Training Associates for an initial 1-year period with an option for possible renewal;
    - Other applicants would be informed in parallel that they have not been selected in this call, but future calls may be organised based on ICH needs.
- The Assembly approved the inclusion of 800'000 CHF in the 2020 budget to support the scope of work with Training Associates;
- The Assembly agreed that the names of the selected organisations would be disclosed to the Assembly shortly after the meeting, following successful discussions and confirmation of work with these organisations.

8. Financial Matters

On behalf of the ICH MC, the ICH Secretariat updated the Assembly on ICH financial matters including: the 2018 Audited Accounts and Financial Statements; updates to the 2020 provisional ICH budget and preparation of the 5-year 2020-2024 ICH budget projection; and MC considerations regarding development of a long-term plan for the strategic use of ICH funds. Regarding the latter, the Assembly was informed on MC considerations regarding the use of surplus funds to: support training, organisation of the annual interim MC meetings; and outreach and communication activities, including those related to the 30th Anniversary of ICH; and noted that the MC would present a more detailed plan by the time of the November 2019 meeting in Singapore.

The Assembly was also informed on MC considerations regarding the current and prospective financial situation of the ICH Association. In view of the forthcoming use of the surplus funds under the long-term plan, once adopted, there is a need to proceed towards a future establishment of a sustainable model for funding of the ICH Association, which may necessitate the increasing of Membership Fees. Related to this, the MC invited Members to seek views internally within their organisations regarding a possible increase to ICH Membership Fees, and for example, whether a doubling of the current CHF 20,000 Membership Fee for Regulatory and Industry Members could be accommodated. It was also mentioned that introducing an increase in the membership fees should allow for sufficient time for implementation in order for the Members to prepare the change in their budget planning. The Assembly also took note that the MC is reflecting about a possible introduction

of a meeting fee for participants from Observers that do not pay membership fees in view of the fact that the growth of the ICH Association has increased the meeting costs.

Assembly Decisions/Actions:

- The Assembly approved the 2018 Audited Accounts and Financial Statements of the ICH Association which will be filed with the 2018 tax return of the ICH Association;
- The Assembly approved the updated provisional 2020 ICH budget to cover new areas of activity related to the support training, organisation of the annual interim MC meetings; and outreach and communication activities;
- While the amount of the current membership fees will remain unchanged, the Assembly Members, with the exception of the Founding Regulatory Members and the Founding Industry Members, were invited to seek views internally within their organisations regarding a possible increase to Membership Fees and provide any comments to the ICH Secretariat for the information of the MC ahead of the Singapore meeting in November 2019.

9. New Topic Process & Strategic Discussions

- ***New Topic Proposals***

The Assembly was informed by the Lead of the New Topics Subcommittee on the 15 New Topic proposals submitted for the 2019 cycle of the New Topic process, and on ICH MC assessment of the proposals.

Assembly Decisions/Actions:

- The Assembly adopted the Concept Paper outline on Revision of ICH Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Quality topic) and agreed on the establishment of an informal WG with the code Q5A(R2) to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2019;
- The Assembly adopted the Concept Paper outline on Revision of ICH E6 Good Clinical Practice (Efficacy topic) and agreed on the establishment of an informal WG with the code E6(R3) to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2019;
- The Assembly adopted the Concept Paper outline on Revision of ICH E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Efficacy topic) and agreed on the establishment of an informal WG with the code E2D(R1) to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2019;
- The Assembly adopted the Concept Paper outline on Biodistribution Studies for Gene Therapy Products (Safety topic) and agreed on the establishment of an informal WG to finalise the Concept Paper and develop a Business Plan ahead of the MC Teleconference to be held in September 2019 – the code for this new ICH Guideline will be confirmed by the MC;
- The Assembly supported that the ICH Secretariat proceed to launch the nomination process amongst ICH Members for the establishment of these informal WGs in line with the revised procedures approved in Amsterdam and noted that ICH Members and Observers interested to participate in the activities of these new WGs would be invited to submit a nomination request within 3 weeks (from the date of the ICH Secretariat's call for nominations);
- The ICH Secretariat will solicit interest via email in the Rapporteurship and Regulatory Chairmanship of these informal WGs in line with the procedures;

- The Assembly adopted the Concept Paper outline on Impurity: Assessment and Control of Extractables and Leachables (E&L) for Pharmaceuticals and Biologics (Quality topic) with a delayed timeframe to establish an informal WG to be determined at a later point by the MC – the code for this new ICH Guideline will also be confirmed by the MC;
- The Assembly supported the new topic proposal in relation to ICH Q9: Quality Risk Management, with a revision or the development of Q&As to be further considered, and agreed that a Concept Paper Outline would be submitted by November 2019 for Assembly consideration of approval;
- The Assembly supported that the IGDG would further work on reviewing the new topic proposal Bioequivalence for Immediate-Release Solid Oral Dosage Forms (Multidisciplinary topic) with a view to submitting a revised topic proposal for Assembly consideration in November 2019;
- The Assembly acknowledged the interest expressed by some ICH Members/Observers on the new topic proposal on Revision of Patient Reported Outcome (PRO) development & validation (Efficacy topic) and supported that a broader Reflection Paper on patient-focused aspects of drug development would be developed in the near future by the EC, Europe in collaboration with FDA, United Sates.
- The Assembly noted the process for the selection of New Topic proposals and that ICH Members and Observers are invited to submit New Topic proposals by the November/December 2019 timeframe (date to be confirmed) to be assessed at the June 2020 meeting.

- ***Strategic Reflection Papers***

The ICH MC presented to the Assembly the status of work regarding development by Members of Reflection Papers on: *Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data*; and *Model Informed Drug Development* (MIDD).

Assembly Decisions/Actions:

- The Assembly endorsed as an ICH Reflection Paper the *Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data* and its publication on the ICH website, and supported the proposed establishment of a Discussion Group (PepiDG) with a 2-year remit;
- The Assembly supported that, as a next step for the establishment of the PepiDG, the ICH Secretariat would issue a call for expression of interest for Members and Observers to nominate experts and to nominate a Rapporteur and a Regulatory Chair, as per the applicable procedures;
- The Assembly noted that once established, the PepiDG would work electronically on the drafting of its Work Plan for finalisation by November 2019;
- The Assembly noted that a revised draft Reflection Paper from PhRMA on *Model Informed Drug Development (MIDD)* would be circulated at a later stage in 2019.

- ***Strategic Discussions***

The Assembly was informed by the ICH MC on the ongoing MC discussion regarding establishing a more formal process for the development and review of Reflection Papers, and developing a framework to help ICH identify near and long-term priorities.

Assembly Decision/Action:

- The Assembly noted that the MC will keep the Assembly informed on amendment of the procedures to reflect this new process.

10. Communication

- ***General***

The ICH Secretariat updated the Assembly on its recent activities aimed at improving ICH communication with stakeholders, including the progress made on improvements to the ICH website.

Assembly Decisions/Actions:

- The Assembly noted the report of the Secretariat on communication activities;
- The Assembly noted the progress of the ICH website improvement project, and that the new features of the ICH website will become operational from the end of June 2019;
- The Assembly noted the next steps planned in the ICH website improvement project.

- ***Commemoration of ICH's 30th Anniversary***

The ICH MC and the ICH Secretariat informed the Assembly on considerations regarding commemoration of the 30th Anniversary of ICH in 2020.

Assembly Decisions/Actions:

- The Assembly noted that the MC had established an Organising Committee for the commemoration of ICH's 30th Anniversary in 2020, to lead work on the:
    - Organisation of an ICH event either back-to-back with an ICH meeting or another event;
    - Development of a video and a publication which would include interviews with key actors in ICH History and new Members.
- The Assembly noted that costs related to the proposed activities for commemorating the 30th Anniversary of ICH in 2020 were included in the revised 2020 budget which was approved by the ICH Assembly in Amsterdam (see item #8 above).

- ***ICH Regional Public Meetings***

Assembly Decision/Action:

- The Assembly noted that the Assembly Members and Observers are invited to inform the ICH Secretariat by email on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Amsterdam in June 2019.

11. WGs Meeting in Amsterdam

The Assembly was informed that requests from WGs to meet at the next ICH meeting in Singapore on 17-20 November 2019 would be taken under consideration by the ICH MC at the end of its meeting in Amsterdam, and that the list of WGs agreed by the ICH MC to meet face-to-face in Singapore will be made available to the Assembly and published on the ICH website.

11.1. 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) Rapporteur reported to the Assembly on the outcome of the meeting of the E2B(R3) EWG/IWG, including the progress made on: the finalisation of the update of the E2B(R3) Q&A document, the Route of Administration (RoA) term mapping between the ICH E2B code list and the EDQM Standard Terms, and training materials for E2B(R3) adopters; as well as on the outcome of the

joint meeting with the M2 EWG regarding the Service Level Understanding on the Standard Operation Procedure to extract and post the EDQM Dose Form (DF) and RoA terminology for E2B(R3) use; and considerations on the update the EDQM DF and RoA Term User Guide.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the E2B(R3) EWG for activities to be undertaken;
- The Assembly noted the outcome of the E2B(R3) EWG/IWG meeting and progress made on the Q&As revision and update of the EDQM DF and RoA Term User Guide;
- The Assembly noted that E2B(R3) EWG/IWG is working on the development of training material modules and that the ICH MC Training Subcommittee could provide support/consultancy on this activity;
- The Assembly noted that the Regulatory Experts had signed-off *Step 3* of the E2B(R3) Q&As, further to which the Regulatory Members of the Assembly adopted the Q&As under *Step 4*;
- The Assembly noted considerations on the future of the E2B(R3) EWG/IWG and the possibility for the group to operate as necessary via a dormant state model, where a membership list would be maintained by the ICH Secretariat, and the group would be activated as and when necessary.

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

The E8(R1) EWG Topic Leader from FDA, United States reported to the Assembly on behalf of the Rapporteur on the outcome of the meeting of the E8(R1) EWG and the progress made on the preparation of the E8(R1) public stakeholder meeting.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the E8(R1) EWG for activities to be undertaken;
- The Assembly noted the outcome of the E8(R1) EWG meeting;
- The Assembly noted that the E8(R1) EWG had finalised the E8(R1) *Step 2* presentation which will be published shortly on the ICH website;
- The Assembly supported the preparations for an E8(R1) public stakeholder meeting to be held on 31 October 2019 at the headquarters of FDA, United States, which aims to present the ICH E8(R1) draft Guideline, get input from a broader range of non-ICH Member/Observer stakeholders, discuss work to-date and planned next steps on E8(R1) development and on GCP renovation, as per the ICH GCP renovation plan;
- The Assembly noted that while this meeting was being organised as an ICH meeting, targeted at global stakeholders, other ICH E8(R1) public stakeholder meetings may be organised in ICH Member countries/regions as per the GCP renovation plan.

11.3. 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)

The E9(R1) EWG Acting Rapporteur reported to the Assembly on the outcome of the meeting of the E9(R1) EWG including on the progress made on analysing and addressing the comments received from the regional public consultations which ended in April 2018, as well as on the development of training materials and the finalisation of the Addendum.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the E9(R1) EWG for activities to be undertaken;
- The Assembly noted the outcome of the E9(R1) meeting and progress made towards finalisation of the E9(R1) Addendum which is expected to reach *Steps 3* and *4* electronically by September 2019;
- The Assembly noted that the E9(R1) EWG is working on an extensive set of training materials in the form of animated videos, previously developed at *Step 2a/b*, which are expected to be finalised by September 2019;
- The Assembly noted considerations regarding communication and dissemination to support implementation of the estimand framework, and that a proposal for a strategic plan would be further put forward in coordination with the MC;
- The Assembly endorsed the nomination of the current Acting Rapporteur as the formal Rapporteur for the E9(R1) EWG in line with the Assembly RoP Section 4.2.

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

The E11A EWG Rapporteur reported to the Assembly on the outcome of the meeting of the E11A EWG including on progress made on the development of the E11A draft Technical Document on Paediatric Extrapolation.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the E11A EWG for activities to be undertaken;
- The Assembly noted the progress made by the E11A EWG on the development of the E11A draft Technical Document and that *Steps 1* and *2 a/b* are expected in November 2020;
- The Assembly noted the positive feedback provided by the E11A EWG on the use of the new collaborative IT platform proposed by the ICH Secretariat.

11.5. 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 IWG Rapporteur reported to the Assembly on the outcome of the meeting of the E14/S7B IWG including on progress made on the development of Q&As.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the E14/S7B IWG for activities to be undertaken;
- The Assembly noted the outcome of the E14/S7B IWG meeting and progress made on the development of the S7B Q&As and on Integrated Risk Assessment for S7B/E14 and that finalisation of the first stage of Q&As is expected by June 2020.

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

The E17 IWG Rapporteur reported to the Assembly on the outcome of the meeting of the E17 IWG including progress made on the development of training material modules.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the E17 IWG for activities to be undertaken;

- The Assembly noted the progress made by the E17 IWG and congratulated the E17 IWG on the finalisation of their training material video;
- The Assembly noted that the E17 Training Materials are expected to be finalised by the end of June 2019, further to which they will be published on the ICH website.

11.7. 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 Co-Rapporteur reported to the Assembly on the outcome of the meeting of the M2 EWG, including the progress made on: the White Paper on the potential of the HL7 Fast Healthcare Interoperability Resources (FHIR) standard for ICH initiatives and on the outcome of the meeting with HL7's Chief Technology Officer to discuss the White Paper; the project opportunity proposal on standardized quality data; and meetings held in Amsterdam with the E2B(R3) EWG/IWG as well as the M11 EWG.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the M2 EWG for activities to be undertaken;
- The Assembly noted the progress made on the White Paper to assess the impact and potential of the HL7 FHIR standard for ICH's own adopted standards, which is expected to be updated in July 2019;
- The Assembly noted that a subgroup composed of experts from the M8 EWG/IWG and the M2 EWG will work together to provide a recommendation by the ICH November 2019 meeting in Singapore regarding assessment of and next steps for eCTD v4 and FHIR standards in order to present a clear rationale for the recommendation on whether to implement eCTD v4; and that the subgroup would submit a detailed work plan for their activities for consideration by the MC in the September 2019 timeframe;
- The Assembly supported that the M2 EWG would share an update on the progress of this assessment with the Assembly before November 2019 and that the M2 EWG would be available to address any related questions from Assembly Members/Observers;
- The Assembly noted that the Service Level Understanding with the E2B(R3) EWG/IWG is expected to be finalised by July 2019;
- The Assembly noted that the publication of the OID maintenance process is expected by November 2019;
- The Assembly noted that the finalisation of the revision of the project opportunities proposal is expected by November 2019.

11.8. M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Honma – MHLW/PMDA, Japan; Regulatory Chair: N/A)

The M7(R2) Maintenance EWG/IWG Topic Leader from EC, Europe reported to the Assembly on behalf of the Rapporteur on the outcome of the meeting of the M7(R2) Maintenance EWG/IWG, including the progress made on the revision of the M7(R1) Guideline for text related to HIV, work on monographs for chemical compounds to be included in the second Addendum, and development of the Q&As document.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the M7(R2) Maintenance EWG/IWG for activities to be undertaken;
- The Assembly noted the outcome of the group's meeting and that *Steps 1* and *2a/b* of the M7(R2) Guideline, the second Addendum and Q&As document are expected by early 2020;
- The Assembly approved the list of chemical compounds to be included in the second Addendum for drafting of monographs, noting that one compound was still subject to confirmation before final inclusion;
- The Assembly endorsed Dr. Roland Frötschl (EC, Europe) as the new Rapporteur of the M7(R2) Maintenance EWG/IWG, who will serve for a 2-year term from the end of the Amsterdam meeting, in line with the M7 maintenance procedure.

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

The M9 EWG Rapporteur reported to the Assembly on the outcome of the meeting of the M9 EWG, including the progress made towards addressing the comments received during regional public consultations.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the M9 EWG for activities to be undertaken;
- The Assembly noted that the final draft of the M9 Guideline would be reviewed by each region especially about rotation speed of dissolution test;
- The Assembly noted the outcome of the M9 EWG meeting and progress made towards the finalisation of the M9 Guideline which is expected to reach *Steps 3* and *4* by November 2019;
- The Assembly supported that the M9 EWG would develop an Annex to the core Guideline to complement the core Guideline , with the aim for the Annex to be finalised by November 2019.

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

The M11 Acting Rapporteur/Rapporteur reported to the Assembly on the outcome of the meeting of the M11 EWG, including the progress made on the M11 draft Technical Document.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the M11 EWG for activities to be undertaken;
- The Assembly noted the progress made by the M11 EWG on the development of the M11 draft Technical Document and that *Steps 1* and *2 a/b* are expected by July 2020;
- The Assembly noted the M11 EWG considerations on the need for additional expertise to support drafting the technical specifications for information exchange;
- The Assembly noted the M11 EWG request to consult with the MC in the June to November 2019 timeframe regarding the strategic engagement strategy with other key WGs, such as the E8(R1) EWG, E9(R1) EWG, and M2 EWG and that the M11 EWG would submit a proposal to the MC;
- The Assembly endorsed the nomination of the current Acting Rapporteur as the formal Rapporteur for the M11 EWG in line with the Assembly RoP Section 4.2.

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

The Q2(R2)/Q14 Rapporteur reported to the Assembly on the outcome of the meeting of the Q2(R2)/Q14 EWG, including the progress made on the Q2(R2)/Q14 draft Technical Document, and the joint meeting with the Q12 EWG with a view to ensuring that both Guidelines are well aligned.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the Q2(R2)/Q14 EWG for activities to be undertaken;
- The Assembly noted the progress made by the Q2(R2)/Q14 EWG on the development of the Q2(R2)/Q14 draft Technical Document and that *Steps 1* and *2 a/b* are expected by June 2020.

11.12. Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: N/A)

Assembly Decisions/Actions:

- The Assembly noted the work plan of the Q3D(R2) Maintenance EWG for activities to be undertaken;
- The Assembly noted that the Q3D(R2) will provide a written report of their meeting on 6-7 June after the ICH meeting in Amsterdam;
- The Assembly endorsed Dr. Akihiko Hirose (MHLW/PMDA, Japan) as new Rapporteur of the Q3D(R2) Maintenance EWG, who will serve for a 2-year term from the end of the Amsterdam meeting, in line with the Q3D maintenance procedure.

11.13. 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 the progress made towards addressing the comments received during the regional public consultation period, the work on the accompanying Annex, and the joint meeting with the Q2(R2)/Q14 EWG.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the Q12 EWG for activities to be undertaken;
- The Assembly noted the outcome of the Q12 EWG meeting and progress made on addressing comments received during the public consultation period and noted that the core Guideline and the Annex are expected to reach *Steps 3* and *4* in November 2019, further to which training materials would be developed;
- The Assembly noted that, as a general point, ICH Members should follow the work of the WGs as they progress and conduct their respective internal legal reviews in a timely manner in order for the WG's work to progress smoothly.

11.14. 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 on the development of the Q13 draft Technical Document.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the Q13 EWG for activities to be undertaken;
- The Assembly noted the progress made by the Q13 EWG on the development of the Q13 draft Technical Document and Annexes, and that *Steps 1* and *2 a/b* are expected by June 2020;
- The Assembly noted the Q13 EWG's considerations on the planning of informal regional Continuous Manufacturing site visits for interested Q13 EWG Regulatory Members experts in Asia, Europe and North America.

11.15. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe; Regulatory Chair: N/A)

The S5(R3) EWG Rapporteur reported to the Assembly on the outcome of the meeting of the S5(R3) EWG, including the progress made to address the comments received during the regional public consultation period and proposal for a maintenance procedure for the S5(R3) Annexes.

Assembly Actions/Decisions:

- The Assembly noted the work plan of the S5(R3) EWG for activities to be undertaken;
- The Assembly noted the outcome of the S5(R3) EWG meeting and progress made on the finalisation of the S5(R3) core Guideline and Annexes and noted that *Steps 3* and *4* are expected prior to November 2019;
- The Assembly endorsed a maintenance procedure for the S5(R3) Annexes, which will be further reflected in an amendment to the SOP and will start, at the earliest, one year after *Step 4*.

11.16. 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 Rapporteur reported to the Assembly on the outcome of the meeting of the S11 EWG, including the progress made to address the comments received during the regional public consultation period.

Assembly Decisions/Actions:

- The Assembly noted the work plan of the S11 EWG for activities to be undertaken;
- The Assembly noted the progress made by the S11 EWG on addressing the comments received during the regional public consultation period, and that *Steps 3* and *4* are expected by November 2019;
- The Assembly supported the clarification of scope provided in the S11 draft Guideline;
- The Assembly noted that S11 Training Materials are expected by June 2020.

12. WGs Not Meeting in Amsterdam

The Assembly noted the status and the work plans of the groups not meeting.

12.1. 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 and 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.

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

The E19 draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions.

12.3. E20 informal Working Group: Adaptive Clinical Trials (Informal Working Group Lead and Regulatory Chair to be determined)

The ICH Secretariat will establish the E20 informal WG shortly after the ICH June 2019 Amsterdam meeting, further to which the informal WG will initiate work on the development of the E20 Concept Paper and Business Plan.

Assembly Action/Decision:

- The Assembly noted that PhRMA, as the Member who proposed the topic, has agreed to lead the informal WG (as per section 1.2 of the SOP).

12.4. 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 on the updating with each MedDRA release of the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents (updated for MedDRA Version 22.1) to be released in September 2019.

12.5. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions (Rapporteur: Dr. Schmuff – FDA, United States; Regulatory Chair: N/A)

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, which remains in a dormant state.

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

No Change Requests were received since the meeting in Kobe, Japan, in June 2018. The M8 EWG/IWG held a teleconference with the M2 EWG in April 2019 to discuss implications of HL7 FHIR and potential paths forward for eCTD.

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

The M10 *Step 2b* draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions.

12.8. M12 informal Working Group: Drug Interaction Studies (Informal Working Group Lead and Regulatory Chair to be determined)

The ICH Secretariat will establish the M12 informal WG shortly after the ICH June 2019 Amsterdam meeting, further to which the informal WG will initiate work on the development of the M12 Concept Paper and Business Plan.

Assembly Action/Decision:

- The Assembly noted that FDA, United States, as the Member who proposed the topic, has agreed to lead the informal WG (as per section 1.2 of the SOP).

12.9. Q3C(R8) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: N/A)

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

Assembly Decisions/Actions:

- The Assembly noted the work plan of the Q3C(R8) EWG for activities to be undertaken;
- The Assembly noted that the Q3C(R7) Guideline would revert to the Q3C(R6) Guideline such that the PDE for ethyleneglycol would revert from 3.1 mg/day (310 ppm) to 6.2 mg/day (620 ppm), effectively reversing the error correction which had occurred on the Q3C(R6) Guideline. Furthermore, the Assembly noted that the Q3C(R8) Maintenance EWG would update the Appendix 5 monograph and provide a cover statement to explain the error correction;
- The Assembly noted that although the Rapporteurship of the group should rotate amongst the Founding Regulatory Members as per the Q3D maintenance procedure included in Annex 4 of the SOP of the WGs, the Founding Regulatory Members were supportive that the Rapporteurship of Q3C(R8) should remain with FDA, United States for the next two years, and the Assembly approved the continued Rapporteurship by FDA, United States.

12.10. Q11 IWG: Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances (Rapporteur: Mr. McDonald – EC, Europe; Regulatory Chair: Dr. Condran – Health Canada, Canada)

The Q11 IWG was disbanded in May 2019, further to the finalisation of the Q11 training materials which will be published shortly on the ICH website.

12.11. 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 drafting revisions to the S1B Guideline.

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

The IGDG continues its work as per the IGDG remit and is working on the development of its work plan.

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

The IQDG continues its work on the development of an Assessment Process establishing criteria to review/triage existing Quality and other relevant Multidisciplinary ICH Guidelines, ICH Guidelines in progress, and newly proposed Quality topics.

13. Q4B Maintenance

The ICH Secretariat updated the Assembly on the Pharmacopeial Discussion Group's (PDG) considerations on the timeframe for the next steps further to the Assembly's approval in November 2018 of the proposal from the PDG for the maintenance procedure of the ICH Q4B Annexes.

Assembly Decision/Action:

- The Assembly noted that the PDG, further to its face-to-face meeting in October 2019, would provide the ICH Secretariat with a timeframe for the next steps regarding both the revision of the Q4B Guideline to align it with the maintenance process approved by the Assembly at the ICH November 2018 meeting, and the revision of the Q4B Annexes as per Annex 5 of the SOP of the WGs.

14. Appointment of ICH Assembly Vice Chair

The Assembly noted the need for the current Assembly Vice-Chair Dr. Petra Doerr (Swissmedic, Switzerland) to step down from the end of the Amsterdam meeting and thanked Dr. Doerr for her chairpersonship since her election in November 2018.

Assembly Decision/Action:

- The Assembly elected Dr. Celia Lourenco (Health Canada, Canada) as Assembly Vice-Chair for a 6-month term until the election of the new Assembly Chair and Vice Chair for a 2-year term at the ICH meeting in November 2019 in line with the applicable procedures.

15. Organisation of Next Meetings

Assembly Decisions/Actions:

- The Assembly noted that the new schedule for the ICH meeting week would be implemented from the next meeting, where the Assembly will meet all day Tuesday and on Wednesday morning, WGs will meet from Sunday to Wednesday (4 days) or Saturday to Wednesday (5 days), and additionally the Coordinators meeting will be held on Saturday evening;
- The Assembly noted that the next ICH Assembly meeting will be held in Singapore, on Tuesday 19 – Wednesday 20 November 2019;
- The Assembly noted the below dates of the next ICH Assembly meetings in 2019-2021:
    - Tuesday 19 – Wednesday 20 November 2019 in Singapore;

- Tuesday 26 – Wednesday 27 May 2020 in Vancouver, Canada;
- Tuesday 17 – Wednesday 18 November 2020 in Athens, Greece (definitive confirmation pending);
- Tuesday 1 – Wednesday 2 June 2021 in Asia (location to be confirmed);
- Tuesday 16 – Wednesday 17 November 2021 in the Americas (location to be confirmed).