To:
ICH Assembly

22 January 2018

FINAL MINUTES
ICH Assembly
Geneva, Switzerland
15-16 November 2017

Please find hereafter the final minutes of the Assembly meeting held in Geneva, Switzerland on 15-16 November 2017.

List of Assembly Participants

ICH Assembly Member Representatives:

Ms. Bianca Zimon	ANVISA, Brazil
Ms. Tatiana Cambraio Sa Lowande	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Mr. Xiaoling Qin	CFDA, China
Mr. Siyuan Zhou	CFDA, China
Ms. Lenita Lindström-Gommers (*Chair*)	EC, Europe
Dr. Tomas Salmonson	EC, Europe
Dr. Georgios Balkamos	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin	FDA, US
Ms. Joan Wilmarth Blair	FDA, US
Ms. Catherine Parker	Health Canada, Canada
Dr. Celia Lourenco	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore[1]
Ms. Beata Stepniewska	IGBA
Dr. Nick Cappuccino	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Dae Cheol Kim	MFDS, Republic of Korea
Dr. Toshiyoshi Tominaga (*Vice-Chair*)	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Dr. Peter K. Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland
Dr. Christelle Anquez-Traxler	WSMI
Ms. Caroline Mendy	WSMI

ICH Management Committee Member Representatives:

Prof. Spiros Vamvakas	EC, Europe
Ms. Pujita Vaidya	FDA, US

ICH Assembly Standing Observer Delegates:

Dr. David Jefferys	IFPMA
Dr. Sarah Adam	IFPMA
Dr. Gabriela Zenhäusern	WHO
Ms. Emer Cooke /Mr. Michael Ward /Dr. SamvelAzatyan	WHO

ICH Assembly Observer Delegates:

Dr. Eun Hee Kim	APEC
Mrs. Marieke van Dalen	APIC
Ms. Charunee Krisanaphan	ASEAN

[1] At the Assembly meeting in Geneva under Agenda 2, HSA, Singapore was welcomed as a new ICH Member.

Dr. Murray Lumpkin	Bill & Melinda Gates Foundation[2]
Dr. Lembit Rägo	CIOMS
Mr. Cuauhtémoc Ruiz Toledo	COFEPRIS, Mexico
Dr. Susanne Keitel	EDQM
Dr. Hajed M. Hashan	GHC
Ms. Janeen SkutnikWilkinson	IPEC
Mrs. Aliya Kessikova	National Center, Kazakhstan
Mr. David Churchward	PIC/S
Mrs. Fortunate Ntombi Fakudze	SADC
Ms. Chao-Yi Wang	TFDA, Chinese Taipei
Dr. Kevin Moore	USP

ICH Assembly Ad-hoc Observer Delegates:

Ms. Carol Zhu	DIA

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Dr. Wei Zhou	CFDA, China
Dr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Ms. Camille Jackson	PhRMA
Ms. Cordula Landgraf	Swissmedic, Switzerland
Ms. Caroline Mendy	WSMI

ICH Assembly Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, US
Ms. Chieko Hirose	MHLW/PMDA, Japan

ICH Assembly Additional Participants:

Mr. Xiangyu Wang	CFDA, China
Dr. Agnès Saint-Raymond	EC, Europe
Mr. Martin Harvey Allchurch	EC, Europe
Dr. Stephan Rönninger	EFPIA
Ms. Machiko Sumi	JPMA
Ms. Erina Yamada	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Ms. Han Vit Yu	MFDS, Republic of Korea
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan

ICH Secretariat:

Dr. Véronique Kuntzelmann
Dr. Anne Latrive
Dr. Dawn Ronan

[2] At the Assembly meeting in Geneva under Agenda 2, the Bill & Melinda Gates Foundation was welcomed as a new ICH Observer.

Table of Contents

ICH Assembly Meeting

Opening Discussions

The ICH Assembly meeting in Geneva, Switzerland held on 15-16 November 2017 was chaired by Mrs. Lindström-Gommers (Chair, EC, Europe) and Dr. Tominaga (Vice-Chair, MHLW/PMDA, Japan).

Adoption of the Agenda

- The Assembly agreed that the election of Elected MC Representatives (which had been scheduled under item 14) would be postponed until the next ICH meeting in Kobe, Japan, in June 2018, as noted below under agenda item 14.

- The Assembly supported that further clarification on the eligibility criteria for Elected MC Representatives would be shortly provided by the ICH Management Committee (MC) within the MC Rules of Procedure (RoP) in preparation of the meeting in Kobe, Japan, in June 2018.

The agenda was adopted without further modification.

1. Procedural Matters

Standard Operating Procedures for EWGs/IWGs

The MC presented to the Assembly the v4.0 of the SOP for Working Groups (WGs) approved by the MC in Geneva, including revisions to the Business Plan and Work Plan templates as well as to the EWG/IWG Assembly presentation template, and newly added text for clarification of rules related to: confidentiality; the official names of ICH Members and Observers; information published on the ICH website including the names and parties of experts of all ongoing WGs; the size of WGs; the role of Additional Expert; and the process for nomination of a Regulatory Chair.

Assembly Actions/Decisions:

- The Assembly noted the proposed changes to the SOP v3.0 for WGs that the MC had approved at its meeting in Geneva;

- The Assembly supported that the SOP v4.0 for WGs will be published on the ICH website.

Management Committee Rules of Procedures

The ICH Secretariat presented to the Assembly the amendments proposed to the MC RoP on granting the use of the ICH Member logo to third-party representative agencies of ICH Members and the policy on translation of the ICH Member logo.

Assembly Actions/Decisions:

- The Assembly noted the changes to the MC RoP that the MC had approved at its meeting in Geneva;

- The Assembly supported that the revised MC RoP will be published on the ICH website.

2. Membership and Observership

The MC presented to the Assembly an overview of applications for Membership/Observership processed since the Montreal meeting in May/June 2017 and its recommendations on these applications.

Assembly Actions/Decisions:

- The Assembly approved the following Membership application:
  - HSA, Singapore.

- The Assembly approved the following Observership applications:
  - Bill & Melinda Gates Foundation;
  - INVIMA, Colombia.

The Assembly Chair noted that this brings the total number of Members to 15 and the number of Observers to 24 in ICH.

3. Financial Matters

The MC updated the Assembly on financial matters including the revised 2018 ICH Budget and the development of a 5-Year ICH Budget Plan (2018-2022) including incorporation of: projected annual membership fees; cost to contract a Professional Conference Organiser (PCO); increased IT expenses for ICH websites; trademark registrations costs for the ICH logo; costs associated with a MC interim meeting; and costs associated to adding 1 FTE for the ICH Secretariat.

Assembly Actions/Decisions:

- The Assembly noted that the ICH meeting held in Montreal in May/June 2017 came within budget and that the meeting in Geneva in November 2017 was expected to be within budget;

- The Assembly noted the decision taken by the MC on the organisation of an interim meeting of the New Topic MC Subcommittee in March 2018, potentially along with other MC Subcommittees, and supported the associated budget impact related to Secretariat travel;

- The Assembly noted the decision taken by the MC to contract a Professional Conference Organiser (PCO) for the organisation of future ICH meetings as of June 2019, and supported the associated budget impact;

- The Assembly noted the decision taken by the MC related to ICH logo trademark registration, and supported the associated 2018 budget impact and ongoing budgeted costs from 2019 onwards;

- The Assembly noted that the concept of participation fees to meetings for non-Membership fee paying attendants was not being implemented at this time, but could be re-assessed for future meetings;

- The Assembly approved the revised 2018 Budget, including costs added related to: website major upgrades; ICH logo trademark registration; Secretariat travel to the interim MC meetings; funding of the ICH meeting reception; and an additional Secretariat staff of 1 FTE to account for the growing need of ICH for Secretariat support in particular for training activities, and supported its publication on the ICH website;

- The Assembly supported the assumptions and predictions of the 5-year budget;

- The Assembly approved the 2018 MedDRA budget which included the 2018 Subscription rates and supported its publication on the ICH website.

4. New Topics Process & Strategic Discussions

Processes for New Topics, Reflection Papers and Strategic Discussions

The MC presented to the Assembly the updated process for the selection of New Topics proposals integrated with the process for Reflection Papers and Strategic discussions.

Assembly Actions/Decisions:

- The Assembly supported the updated process for the submission and selection of new topics for harmonisation, including the following timelines:
    - The capacity for new topics to start is determined in September-October by the MC and the New Topics Subcommittee, the deadline for submission of New Topic proposals is set as 15 December 2017 for all ICH Members and Observers;
    - The new topics proposals are circulated to the Assembly during December 2017;
    - The MC New Topics Subcommittee Q&A teleconferences (with Experts) take place between 15 January and 15 February 2018;
    - The MC New Topics Subcommittee meets at an interim meeting in March 2018 to prioritise the New Topics proposals and make a recommendation to the Assembly ahead of the June 2018 face-to-face meeting;

Strategic Reflection Papers

The Assembly was updated on the development of a Quality Reflection Paper on *Advancing Pharmaceutical Quality Standards* which is still under discussion by the MC.

Assembly Actions/Decisions:

- The Assembly noted the ongoing MC Strategic discussions regarding a draft Quality Reflection Paper on *Advancing Pharmaceutical Quality Standards* and that the establishment of an *ad-hoc* Quality Discussion Group was being considered by the MC with the MC still to consider the remit and participants of such a group;
- The Assembly was invited to submit any comments on the draft Quality Reflection Paper to the ICH Secretariat no later than 15 December 2017;

Strategic Discussions

The MC updated the Assembly regarding its discussion of other topics put forward as potential future strategic priorities for the ICH Association.

Assembly Actions/Decisions:

- The Assembly noted the MC's intention to develop a Strategic Topic Framework encompassing strategic priorities for ICH, which would frame new topics adopted for development.

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

The MC presented to the Assembly the 2018 ICH Work Plan and Multi-Annual Strategic Plan, while the MedDRA MC Chair's delegate presented the MedDRA 2018 Annual Work Plan.

Assembly Actions/Decisions:

- The Assembly approved the 2018 Work Plan and Multi-Annual Strategic Plan for the Association and supported their publication on the ICH website;

- The Assembly approved the MedDRA 2018 Annual Work Plan and supported its publication on the ICH website.

6. Communication

Communication Activities

The MC provided an update to the Assembly on current communication activities including the implementation of the agreed transparency policy and 2017-2018 stakeholder engagement plan, as well as recent updates to the ICH website.

Assembly Actions/Decisions:

- The Assembly noted the implementation of the Transparency Policy agreed at the Montreal meeting in June 2017 including the publication on the ICH website of the photos and short biographies of the MC and Assembly Member Representatives and Observer Delegates, as well as information on the funding of ICH;

- The Assembly noted that the next steps for the implementation of the Transparency Policy will be to publish on the ICH website photos and short biographies of the MedDRA MC Representatives, the ICH Coordinators and the ICH Secretariat;

- The Assembly noted plans by the MC Communication Subcommittee, in collaboration with the E8(R1) EWG, to develop a "GCP Stakeholder Engagement Plan". The Assembly will be further updated on this activity at the next ICH meeting in June 2018;

- The Assembly noted plans to develop a proposal for webcasting from parts of the Assembly meetings that could be of potential interest to external stakeholders. The Assembly will be further updated on this activity at the next ICH meeting in June 2018;

- The Assembly noted that the Concept Paper and Business Plan templates were updated (as also described under agenda item 1. Procedural Matters) to include a specific section on Training and Stakeholder engagement needs;

- The Assembly acknowledged the shared responsibility of the ICH Members and Observers on "communicating ICH" according to the Articles of Association and agreed to encourage the ICH Members to use the ICH Member logo on their website or any communications to denote their participation to ICH;

- The Assembly supported that information on the various MC Subcommittees which have been established be provided to the Assembly and could also be communicated via the ICH website on the page regarding the MC;

- The Assembly supported the update of the "ICH History" page of the ICH website to include notably the statistical information on the evolution of ICH WGs which now includes participation from a growing number of new ICH Members, as well as of ICH Observers.

ICH Regional Public Meetings

The Assembly was invited to share information on any ICH Regional Public Meetings in their respective regions prior to/following the ICH meeting in Geneva.

The Assembly noted the organisation of a joint FDA, US and Health Canada, Canada public regional meeting on ICH on 6 April 2018 and that this meeting will be webcast live, recorded and the presented slides published on the FDA, US website.

The Assembly noted the organisation of a joint FDA, US and PhRMA session on ICH at the DIA meeting in Massachusetts, US on 23-28 June 2018.

The Assembly noted the organisation of the DIA Euro meeting on 17-19 April 2018 in Basel, Switzerland and that it will include a half-day on ICH Information.

The Assembly noted that JPMA and MHLW/PMDA, Japan will organise a joint meeting to report on the outcome of the ICH meeting in Geneva on 15 December 2017.

The Assembly noted that JPMA and MHLW/PMDA, Japan will also organise two workshops on Q12 on 15 March 2018 in Osaka and 29 March 2018 in Tokyo.

The Assembly noted the organisation by IGBA of conference which includes Q11 and Q12 on 25-26 January 2018.

The Assembly noted that IGBA will organise its annual conference on 13 June 2018 including the update on ICH in the programme.

The Assembly noted that DIA China will organise a conference in China in May 2018 which will include a workshop on ICH.

Assembly Actions/Decisions:

- The Assembly agreed to keep the ICH Secretariat informed on the organisation of any ICH Regional Public Meetings for communication via the ICH website.

7. Implementation of ICH Guidelines

The Assembly noted the implementation table, maintained by the ICH Secretariat, which reflects the current state of play of the implementation of ICH Guidelines, based on the information provided by all Regulatory Members to the ICH Secretariat.

The Assembly was updated by a representative of the European Medicines Agency ('EMA') on behalf of EC, Europe on the benefits and challenges of implementing E2B for the electronic transmission of Individual Case Safety Reports (ICSRs). The specific implementation measures enabling smaller companies with limited portfolio to remain compliant was noted.

The Founding Industry Members presented on a survey conducted amongst their members by a third-party regarding ICH Guideline implementation in their countries/regions of activity.

Assembly Actions/Decisions:

- The Regulatory Members of the Assembly noted that they are invited to keep the ICH Secretariat informed of any updates on the implementation of ICH Guidelines in their respective countries/regions;

- The Assembly noted that ICH Guideline implementation information (both on Implemented Guidelines and on Guidelines undergoing Public Regulatory Consultation) for Founding and Standing Regulatory Members is published on the ICH website under each ICH Guideline section and that the ICH Secretariat will shortly be including the information provided by the new Regulatory Members;

- The Assembly noted that, in preparation of the next ICH meeting in June 2018, Members and Observers are invited to submit to the ICH Secretariat suggestions for ICH guidelines or topics which could be a focus for discussion under the Agenda item on implementation.

- The Assembly noted the survey conducted by the Founding Industry Members amongst their members regarding ICH Guideline implementation in their countries/regions of activity;

- The Assembly supported the principle of a more holistic and granular ICH-driven survey led by an independent third party on ICH Guideline implementation and noted that the MC planned to further define the scope accordingly. The MC will report back on the outcomes of this scoping exercise to the Assembly.

8. Training

The MC updated the Assembly on the outcome of the 2017 pilot which was conducted by the ICH MC Training Subcommittee by partnering with a small group of training providers and presented training strategy considerations.

Assembly Actions/Decisions:

- The Assembly noted the outcomes of the APEC Harmonization Center online training pilot on the E2 series of ICH Guidelines that was conducted between August 2016 and August 2017;

- The Assembly noted the outcome of the 2017 Training Pilot conducted by the ICH MC Training Subcommittee and supported the continuation of work with training partners, including DIA, RAPS, NEU, Duke-NUS, Harvard MRCT, AHC, according to the Revised Terms of Reference for this activity;

- The Assembly noted the eligibility criteria for training partners and the selection process;

- The Assembly agreed on the proposal for the MC Training Subcommittee to assist ICH WGs in the development of training material;

- The Assembly supported the allocation of funds in the budget for Training purposes for the next 5 years, as already agreed in the 2018 ICH budget;

- The Assembly supported that the Training Subcommittee would develop online training programmes that would be published on the ICH website..

9. Update on MedDRA

The Assembly received a report from the MedDRA Management Committee (MC) Chair's delegate on the ICH MedDRA MC meeting held on 11-12 November 2017. The Assembly noted that further to the transfer of MedDRA's ownership to the new ICH Association from IFPMA as trustee of the former ICH (International Conference on Harmonisation), the MedDRA Management Board had been disbanded and the MedDRA MC was now fully responsible for MedDRA issues. The Assembly also noted that Ms. Sophie Sommerer (Health Canada, Canada) had been appointed in Geneva as MedDRA MC Chair with the unanimous support of the Committee to serve until November 2018.

The report covered the following matters: expansion of MedDRA use; training; cooperation effort with WHO; tools to facilitate MedDRA's use; and development of Standardised MedDRA Queries (SMQs) including status of SMQ development and collaboration with CIOMS.

The Assembly was updated on the continued growth of MedDRA users throughout the world, with currently over 4,000 organisations in 111 countries, reflecting the successful adoption of MedDRA as a worldwide standard in the protection of public health. The Assembly noted the importance of training in helping to facilitate the use of MedDRA and that the MSSO provides free training to Regulators and other MedDRA users as part of their MedDRA subscription package, with training available in several forms: face-to-face training; webinars; and e-learning tools/videocasts. The Assembly heard that in 2017 the MSSO provided free training to over 3,000 people which included 63 face-to-face training courses provided to 965 participants in multiple locations worldwide, including Brazil, Canada, China, Europe, Japan, Mexico, Russia and the United States. It was noted that a similar scale of training is planned for 2018, with all training offerings advertised on the website **www.meddra.org**.

The Assembly was also updated on plans to release a Korean MedDRA translation and to initiate development of a Russian MedDRA translation.

The Assembly also noted the cooperating effort with the WHO and its Collaborating Centre, the Uppsala Monitoring Centre (UMC), which resulted in a joint MSSO MedDRA and UMC WHODrug user group meeting in China (September 2017), and a MedDRA presentation at the 2017 WHO Annual Meeting of National Pharmacovigilance Centres (NPCs) in Uganda (November 2017).

The Assembly was informed of the success of the new Self-Service application launched in April 2017 which is a web-based application which allows users to obtain subscription information; add/delete/change point of contact; and change of password. The Assembly was also informed on the development of a Patient Friendly MedDRA term list (~1,500 LLTs) as a part of the WEB-RADR project under the Innovative Medicines Initiative (IMI) in Europe, which will be posted on the MedDRA website and for future use in apps and web portals.

The Assembly was also updated on ICH's work with CIOMS to develop Standardised MedDRA Queries (SMQs). In Geneva, the MedDRA MC acknowledged the significant contributions of the CIOMS SMQ Working Group and the development to-date of 102 SMQs, as well as one new SMQ on Dehydration that will go into production in v21.0 on 1 March 2018. The MedDRA MC also renewed the Memorandum of Understanding between ICH and CIOMS for a further year of development of new SMQs.

Assembly Actions/Decisions:

- The Assembly noted the decisions taken by the MedDRA MC, including the granting of a 5% reduction for the 2018 subscription rates for lower-revenue users (commercial levels 0 to 3), and the provision of MSSO local support in countries and regions with an increasing number of subscribers, namely the Republic of Korea and Central America in 2018, and China in 2019;

10. General Operational Matters

ICH General operational matters

The ICH Secretariat updated the Assembly on items including: completion of the transfer of assets from IFPMA as trustee of the former ICH (International Conference on Harmonisation) to the new ICH Association; implementation of recent Assembly/MC decisions and support of growth of ICH by the ICH Secretariat; approach for report development and clarification of rules; and overview of the participation of current Members and Observers in ICH.

Assembly Actions/Decisions:

- The Assembly noted the completion of the formal transfer to the new ICH Association of assets (including MedDRA) which had been held by IFPMA as trustee of the former ICH (International Conference on Harmonisation);

- The Assembly noted the implementation by the ICH Secretariat of the Transparency Policy, including the publication on the ICH website of the photos and short biographies of all ICH Assembly Members Representatives and Observers Delegates, as well as the list of experts' names for active WGs;

- The Assembly acknowledged the need to adhere to the current agreed procedures to ensure the smooth functioning of the Assembly, including respecting the maximum number of representatives/delegates who should attend the ICH meetings;

- The Assembly also acknowledged the need for ICH experts to adhere to ICH policy, including on confidentiality regarding ongoing WG discussions, and that all ICH Members and Observers should make their experts aware of ICH rules, in particular through the SOP for WGs;

- The Assembly noted that meeting minutes drafted by the ICH Secretariat are intended to reflect the current state of Assembly discussions and consensus decisions, and not intended to capture individual views expressed during the meeting.

IFPMA role

The Assembly was updated on the process agreed in Montreal in May/June 2017 to facilitate the participation of IFPMA National Industry Association experts in EWG/IWGs.

Assembly Actions/Decisions:

- The Assembly noted the process launched by IFPMA to facilitate the participation of IFPMA National Association experts in ICH WGs and that to-date five experts have been nominated in the following WGs: M9, M10, E8(R1), E19 and E11A.

IPRF/IGDRP Cooperation

The IPRF Chair updated the Assembly on the work being undertaken regarding the arrangement to be put in place with ICH for the provision of Secretariat support services to the forthcoming consolidated IPRF-IGDRP.

Assembly Actions/Decisions:

- The Assembly noted that the consolidated IPRF-IGDRP initiative would take effect as of 1 January 2018 under the new name IPRP (International Pharmaceutical Regulators Programme) and that the ICH Secretariat would begin the transition to providing services to IPRP from 1 January 2018. The Assembly noted that support of IPRP activities will be conducted and financed separately from support of ICH activities.

11. EWGs/IWGs/Discussion Groups Meeting in Geneva

Regarding requests from EWGs/IWGs to meet at the next ICH meeting in Kobe, Japan on 2-7 June 2018, the Assembly noted that any such requests would be taken under consideration by the MC and that a list of EWG/IWGs agreed by the MC to meet face-to-face in Kobe will be made available to the

Assembly, and also on the ICH website, following the MC technical teleconference to be held at least 8 weeks ahead of the meeting. It was also agreed that in order to facilitate logistics and organisation, confirmation of face-to-face meeting of EWGs/IWGs may occur sooner via mailing.

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

The Rapporteur reported to the Assembly on the outcome of the first E8(R1) informal WG meeting held on 13-16 November 2017 and the progress made towards finalising the Concept Paper and the Business Plan.

Assembly Actions/Decisions:

- The Assembly noted that the E8(R1) EWG finalised the Concept Paper and the Business Plan and that the MC endorsed these documents on 14 November 2017;

- The Assembly supported that the E8(R1) EWG would organise a meeting with stakeholders at the end of the *Step 2b*, probably in June 2019 and independently of the ICH meeting;

- The Assembly supported that the E8(R1) EWG would be involved in the development of a *GCP Stakeholder Engagement Plan* in collaboration with the Communication Subcommittee;

- The Assembly noted that the E8(R1) EWG will provide a work plan to the MC ahead of its Technical teleconference for activities to be undertaken.

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

The Rapporteur reported to the Assembly on the outcome of the E9(R1) EWG meeting held on 13-15 November 2017 and the progress made on the current activities of the E9(R1) EWG including: the development of an extensive training slide deck including examples and case studies and the planned development of a video explaining the Estimand concept.

Assembly Actions/Decisions:

- The Assembly noted the progress made by the group on the development of a script and illustrations in view of the production of a video to present the Estimand concept, and agreed that the development of this video be supported by both the ICH MC Communication and Training Subcommittees;

- The Assembly endorsed the work plan of the E9(R1) EWG for activities to be undertaken.

11.3. M1 PtC WG: MedDRA Points to Consider *(Rapporteur: Dr. Winter – EFPIA; Regulatory Chair: Dr. Brajovic – FDA, US)*

The Rapporteur reported to the Assembly on the outcome of the M1 PtC WG meeting held on 13-15 November 2017 and the progress made by the group on the development of the Companion Document and on the update of the PtC document to be included with the next MedDRA release.

Assembly Actions/Decisions:

- The Assembly noted the progress made by the group on the development of the Companion Document, which is expected to be submitted to the MedDRA MC for sign-off in early 2018, and

work on the update of the PtC document to be included with the next MedDRA release v21.0 on 1 March 2018;

- The Assembly endorsed the work plan of the M1 PtC WG for activities to be undertaken, including the release of the Condensed PtC by end 2018.

11.4. M10 EWG: Bioanalytical Method Validation *(Rapporteur/Regulatory Chair: Dr. Ishii-Watabe – MHLW/PMDA, Japan)*

The Rapporteur reported on the outcome of the meeting of the M10 EWG held on 11-15 November 2017 and progress made towards developing the draft Technical Document.

Assembly Actions/Decisions:

- The Assembly endorsed the work plan of the M10 EWG for activities to be undertaken and noted that *Step 2* is expected by November 2018 and *Step 4* by June 2020.

11.5. 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, US)*

The Rapporteur reported on the outcome of the E2B(R3) IWG meeting held on 13-16 November 2017 and the joint meeting held with the M2 EWG on 14 November 2017, and progress made on developing the EDQM Dose Form and Route of Administration Term User Guide.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Experts signed-off *Step 3* of the EDQM Dose Form and Route of Administration Term User Guide, further to which the Regulatory Members of the Assembly adopted the documents under *Step 4*;

- The Assembly noted that the group had agreed and signed-off on the E2B Code lists #9 and #14, further to which the lists were also endorsed by the Assembly;

- The Assembly endorsed the work plan of the E2B(R3) EWG/IWG for activities to be undertaken.

- The Assembly noted that the current E2B(R3) EWG/IWG focus is on E2B(R3) issues, not E2B(R2) issues which are out of the scope of E2B(R3)'s Concept paper.

11.6. E11A EWG: Paediatric Extrapolation *(Rapporteur: Dr. Yao – FDA, US)*

The Rapporteur reported to the Assembly on the outcome of the first E11A EWG meeting held on 13-16 November 2017 and the progress made towards developing the draft Technical Document.

Assembly Actions/Decisions:

- The assembly noted that the E11A EWG proposed a change in the timeline compared to the Business Plan and that *Step 2* is now expected to be reached in November 2020;

- The Assembly endorsed the work plan of the E11A EWG for activities to be undertaken.

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

The Rapporteur reported on the outcome of the meeting of the M9 EWG held on 13-16 November 2017 and progress made towards developing the draft Technical Document.

Assembly Actions/Decisions:

- The Assembly noted the progress made by the group on the draft Technical document, expected to reach *Step 1* and *Step 2* by early 2018;
- The Assembly endorsed the work plan of the M9 EWG for activities to be undertaken.

11.8. E19 EWG: Optimization of Safety Data Collection *(Acting Rapporteur: Dr. Unger – FDA, US; Regulatory Chair: Mr. Mol - EC, Europe)*

The acting Rapporteur reported the outcome of the meeting of the E19 EWG held on 13-16 November 2017 and the progress made toward developing the draft Technical Document.

Assembly Actions/Decisions:

- The Assembly endorsed the work plan of the E19 EWG for activities to be undertaken;
- The Assembly endorsed the nomination of Dr Mary Thanh Hai, FDA, US as the new Rapporteur.

11.9. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) *(Co-Rapporteurs: Mr. Kampmeijer – EC, Europe, Ms. Slack – FDA, US, Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Mr. Srivastava – Health Canada, Canada)*

The Rapporteur reported to the Assembly on the M2 EWG meeting held on 12-16 November 2017 and joint meetings with the E2B(R3) EWG/IWG and M8 EWG on 14 November 2017, and the progress made towards developing the ICH project opportunities proposal, defining the maintenance process for external terminologies and evaluating existing ICH topics for technical opportunities.

Assembly Actions/Decisions:

- The Assembly noted the concept proposal on CPT, renamed CeSHarP - Clinical electronic Structured Harmonized Protocol, developed by the group, and that this proposal would be submitted to the Assembly as a New Topic by 15 December 2017 in line with the new topic process;
- The Assembly noted the progress made by the group on the eCTA project opportunity, renamed eCCTS – electronic Common Clinical Trial Submission, and supported that M2 engage with SMEs in order to develop an updated proposal to be provided at the next ICH meeting in Kobe in June 2018;
- The Assembly noted the group's activities on the review of emerging project opportunities and terminologies maintenance, in particular for E2B;
- The Assembly endorsed the new PDF specification agreed by M2 EWG experts in Geneva and noted that it would be published on the ICH ESTRI website;
- The Assembly endorsed the work plan of the M2 EWG for activities to be undertaken.

11.10. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) *(Acting Rapporteur: Mr. Gray – FDA, US; Regulatory Chair: Dr. Menges – EC, Europe)*

The Rapporteur reported to the Assembly on the M8 EWG/IWG meeting held on 13-16 November 2017 and joint meeting with the M2 EWG on 14 November 2017, and the progress made by the group

on developing the eCTD v4.0 Implementation Package and the eCTD v4.0 Change Request/Q&A document v1.1.

Assembly Actions/Decisions:

- The Assembly supported that the Acting Rapporteur would continue to serve as Acting Rapporteur until the nomination of a new Rapporteur can be put forward;
- The Assembly noted that the group will continue to review the eCTD v4.0 Implementation Package and collaborate with the M2 EWG to finalise this document in order to reach *Steps 3* and *4* by the next meeting in Kobe in June 2018;
- The Assembly noted that the Regulatory Topic Leaders of the M8 EWG had signed-off under *Step 3* the eCTD v4.0 Change Request/Q&A document v1.1, further to which the Assembly adopted the document under *Step 4*;
- The Assembly noted the group's activities on developing a recommendation for process change to ICH Guidelines, to be implemented in collaboration with the ICH Secretariat;
- The Assembly endorsed the work plan of the M8 EWG/IWG for activities to be undertaken.

11.11. E17 EWG: Multi-Regional Clinical Trials *(Rapporteur: Dr. Uyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Dunder – EC, Europe)*

The Rapporteur reported to the Assembly on the outcome of the E17 EWG meeting held on 11-16 November 2017 and the progress made towards finalising the E17 Guideline.

Assembly Actions/Decisions:

- The Assembly noted that the Regulatory Topic Leaders of the E17 EWG signed-off under *Step 3* the E17 Draft Guideline, further to which the Regulatory Members of the Assembly adopted under *Step 4* the final Harmonised E17 Guideline;

  The Assembly supported the establishment in principle of an Implementation Working Group (IWG) to develop training materials (and Q&As), noting that the final decision regarding the scope and remit of the IWG would be taken by the MC further to the endorsement of a Concept Paper.

11.12. Q3D(R1) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities *(Rapporteur: Dr. McGovern – FDA, US; Regulatory Chair: N/A)*

The Rapporteur reported to the Assembly on the outcome of the Q3D(R1) Maintenance EWG meeting held on 13-16 November 2017 and the progress made on the revision/error correction procedures and on the development of the draft Addendum.

Assembly Actions/Decisions:

- The Assembly noted the progress made on the revision of the Cadmium inhalation PDE for consistency with the oral and parenteral PDE calculations, and that *Steps 1* and *2* are expected by early 2018;
- The Assembly noted the progress made on the addendum to the Q3D Guideline to include PDEs for cutaneous and transdermal products, and that *Steps 1* and *2* are expected by mid-2018;
- The Assembly noted that a minor error correction had been undertaken to remove a reference to a missing documentin Module 8 of the Training package;
- The Assembly endorsed the work plan of the Q3D(R1) Maintenance EWG for activities to be undertaken.

11.13. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines *(Rapporteur: Dr. Keller – PhRMA; Regulatory Chair: Dr. van der Laan – EC, Europe)*

The Rapporteur reported to the Assembly on the S11 EWG meeting held on 12-16 November 2017 and the progress made towards developing the draft Technical Document.

Assembly Actions/Decisions:

- The Assembly noted that the S11 *Step 1* sign-off is now expected by March 2018;
- The Assembly endorsed the work plan of the S11 EWG for activities to be undertaken.

12. EWGs/IWGs/Discussion Groups Not Meeting in Geneva

12.1. S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals *(Rapporteur/Regulatory Chair: Dr. Leighton – FDA, US)*

The Rapporteur updated the Assembly on the current activities of the S9 IWG and the progress made by the group on analysing and addressing comments received on the draft Q&As from the regional public consultations, and that the Assembly will be invited to adopt under *Step 4* the final S9 Q&As in early 2018.

12.2. E14/S7B Discussion Group (DG): The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs *(Acting Rapporteur: Dr. Leishman – PhRMA; Regulatory Chair: Dr. Prasad – EC, Europe)*

The E14/S7B DG is monitoring the progress of the discussion of the Comprehensive *in vitro* Proarythmia Assessment (CiPA) Initiative in view of issuing a recommendation on whether to reopen the E14 Guideline for a complete revision by early 2018.

12.3. E18 EWG: Genomic Sampling and Management of Genomic Data *(Rapporteur: Dr. Grimstein – FDA, US; Regulatory Chair: N/A)*

Further to the adoption under *Step 4* of the E18 final Guideline in August 2017, the E18 EWG was disbanded.

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

The M4Q(R1) IWG remains in a dormant state in case questions are raised while the eCTD v4.0 Implementation Guide, including the Granularity document, is being implemented in the ICH Regions.

12.5. M7(R2) Maintenance EWG: 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 will list the new set of compounds to be evaluated in the second Addendum by December 2017.

12.6. Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents *(Rapporteur: Dr. McGovern – FDA, US; Regulatory Chair: N/A)*

The Q3C(R7) Maintenance EWG is working on developing Permitted Daily Exposure (PDE) levels for the 3 solvents agreed on at the meeting in Montreal, Canada, in May/June 2017, which are 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol. *Steps 1* and *2* are anticipated the first quarter of 2018. Q3C(R7) will be undertaking an error correction for the Permitted Daily Exposure for ethyleneglycol.

12.7. 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 IWG has worked on the generation of the slide deck to be published on the ICH website along with the *Step 4* Q&A document and will work in liaison with the MC Training Subcommittee on developing other training material (slides and webinar materials) to be disseminated in the ICH regions.

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

Assembly Actions/Decisions:

- The Assembly endorsed the Q12 Technical Document (including Annexes) under *Step 2a* and noted that the Industry Members did not support the additional text included to allow some regional flexibility on the implementation of Q12 due to regulatory requirements, which was put forward by the MC;
- The Regulatory Members adopted the Q12 draft guideline (including the additional text) under *Step 2b*;
- The Assembly supported that the public consultation period would be extended to 12 months.

12.9. 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) has progressed with the collection and review of confidential submissions of Carcinogenicity Assessment Documents (CADs) and summary report submissions by sponsors to Drug Regulatory Authorities within each region.

12.10. S3A IWG: Q&As on Note for Guidance on Toxicokinetics *(Rapporteur/Regulatory Chair: Dr. Saito – MHLW, Japan*

The ICH Coordinator for MHLW/PMDA, Japan reported to the Assembly on the progress made towards finalising the S3A Q&As.

Assembly Actions/Decisions:

- The Assembly noted that the S3A IWG Regulatory Topic Leaders signed-off under *Step 3* the S3A Q&As (via written postal procedure) in advance of the Assembly meeting, further to which the Regulatory Members of the Assembly adopted under *Step 4* the S3A Q&As;
- The Assembly supported the disbandment of the S3A IWG further to the completion of its work.

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

The S5(R3) EWG is currently awaiting the closure of public regulatory consultation in the ICH Member regions on the *Step 2b* document which will close in Q2 2018. The group will work via teleconference and email exchange and will present an updated work plan in advance of the MC TC on technical topics ahead of the Kobe meeting.

12.12. Standing Paediatric EWG *(Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, US)*

Further to the adoption under *Step 4* of the E11(R1) Addendum, the E11(R1) EWG proposed the creation and maintenance of a standing Paediatric EWG, which was endorsed by the MC in September 2017. This standing Paediatric EWG will act as a continuous resource available for expert consultation and guidance to WGs charged with developing new or revised Guidance which may by of relevance to paediatric drug development. The standing Paediatric EWG will work by mail and teleconferences on an ad-hoc basis as needed.

Assembly Actions/Decisions:

- The Assembly noted that any issue raised by a WG on paediatric considerations should be forwarded to the ICH Secretariat which would then submit it to the standing Paediatric EWG;
- The Assembly acknowledged the need to inform their experts of the mandate of the standing Paediatric EWG so that they can seek any guidance on any paediatric issues as needed;
- The Assembly agreed that the experts who had been nominated to the previous E11(R1) EWG would automatically be integrated in the standing Paediatric EWG as per the E11(R1) proposal endorsed by the MC.

13. Organisation of Next Meetings

Assembly Actions/Decisions:

- The Assembly noted the that the next ICH meeting will be held in Kobe, Japan, on 6-7 June 2018, and that the following ICH meeting will be held in the US (location to be confirmed) on 10-15 November 2018;
- The Assembly noted that the June 2019 meeting would be held in Europe, with dates and location to be confirmed. This would be the first ICH meeting to be organised by the PCO which ICH MC plans to engage.

14. Appointment of Elected MC Representatives

Assembly Action/Decision:

- The Assembly supported postponing the elections for Elected MC Representatives until the next ICH meeting in Kobe, Japan in June 2018.

15. Election of Assembly Chair and Vice Chair

Assembly Action/Decision:

- The Assembly unanimously elected Ms. Lenita Lindström-Gommers (EC, Europe) as Assembly Chair and Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan) as Assembly Vice-Chair and noted that they would serve for a two-year mandate.