8 January 2019

FINAL MINUTES
ICH Assembly
14-15 November 2018, Charlotte, NC, USA

Please find hereafter the final minutes of the Assembly meeting held in Charlotte, NC, USA on 14-15 November 2018.

List of Assembly Participants

List of participants

ICH Assembly Member Representatives:

Ms. Patrícia Pereira Tagliari	ANVISA, Brazil
Dr. Raphael Sanches Pereira	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Lenita Lindström-Gommers (Chair)	EC, Europe
Dr. Tomas Salmonson	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
Ms. Catherine Parker	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Dorothy Toh	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nakyung Kim	MFDS, Republic of Korea
Ms. Chieko Hirose	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima (Vice-Chair)	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Xiaoling Qin	NMPA, China
Dr. Peter K. Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland
Dr. Jo-Feng Chi	TFDA, Chinese Taipei
Mr. Ming-Hsun Liu	TFDA, Chinese Taipei
Ms. Caroline Mendy	WSMI

ICH Management Committee Member Representatives:

Ms. Pujita Vaidya	FDA, United States

ICH Assembly Standing Observer Delegates:

Dr. David Jefferys	IFPMA
Dr. Sharon Olmstead	IFPMA
Ms. Emer Cooke	WHO
Mr. Mike Ward	WHO

ICH Assembly Observer Delegates:

Dr. Eun Hee Kim	APEC
Mrs. Marieke van Dalen	APIC
Ms. Charunee Krisanaphan	ASEAN
Dr. Murray Lumpkin	Bill and Melinda Gates Foundation
Dr. Lembit Rägo	CIOMS
Dr. Mario Alanis Garza	COFEPRIS, Mexico

Ms. Jane Mashingia	EAC
Dr. Susanne Keitel	EDQM
Dr. Hajed M. Hashan	GHC
Ms. Janeen SkutnikWilkinson	IPEC
Dr. Charles Preston	PANDRH
Mr. David Churchward	PIC/S
Ms. Fortunate Ntombi Bhembe	SADC
Mr. Tohlang Sehloho	SAHPRA, South Africa
Ms. Aida Malkhasyan	SCDMTE, Armenia
Ms. Hacer Coşkun Çetintaş	TITCK, Turkey
Dr. Kevin Moore	USP

ICH Assembly Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Ms. Lila Feisee	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Dr. Wei Zhou	NMPA, China
Ms. Camille Jackson	PhRMA
Ms. Anna Sieg	Swissmedic, Switzerland
Ms. Yi-Jing Kuo	TFDA, Chinese Taipei
Ms. Caroline Mendy	WSMI

ICH Assembly Technical Coordinators:

Dr. Michelle Limoli	FDA, United States
Ms. Chieko Hirose	MHLW/PMDA, Japan

ICH Ad-Hoc Observer Delegate:

Dr. Jared Auclair	NorthEastern University

ICH Additional Participants:

Mr. William Lewallen	FDA, United States
Dr. Léo Bouthillier	Health Canada, Canada
Ms. Erina Yamada	JPMA
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan
Dr. Churn-Shiouh Gau	TFDA, Chinese Taipei

ICH Secretariat:

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

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ICH ASSEMBLY MINUTES

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

Assembly interim Vice Chair: Dr. Nobumasa Nakashima - MHLW/PMDA, Japan

Opening of the ICH Assembly Meeting

The ICH Assembly meeting in Charlotte, NC, USA, held on 14-15 November 2018, was chaired by Ms. Lindström-Gommers (Chair - EC, Europe) and Dr. Nobumasa Nakashima (interim Vice Chair - MHLW/PMDA, Japan).

The Assembly noted the Member Representatives and Observer Delegates participating in the Assembly meeting in Charlotte, NC, USA.

Adoption of the Agenda

Assembly Decision/Action:

- The Assembly adopted the agenda without any modification.

1. Procedural Matters

- ***General***

The ICH Secretariat presented to the Assembly ICH MC considerations regarding changes to ICH procedural documents in view of recent ICH MC and Assembly discussions, as well as necessary clarifications identified by the ICH Secretariat.

- ***Assembly Rules of Procedure***

The Assembly Chair and the ICH Secretariat presented to the Assembly amendments proposed to the Assembly Rules of Procedure (RoP) which were last updated and approved by the Assembly in Kobe, Japan in June 2018. The revisions related to: (1) the process for the replacement of Assembly Chair and Vice-Chair in the event of his/her resignation, and which would result in the synchronisation of the terms of the Assembly Chair and Vice-Chair; (2) clarifications regarding confidentiality; (3) the timing of the press release; and (4) clarification of the process for appointment of Rapporteurs and Regulatory Chairs.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the Assembly RoP, and approved the Assembly RoP v.6.0, which will be published on the ICH website.

- ***ICH Management Committee Rules of Procedure***

The Assembly was informed by the ICH MC on updates made by the ICH MC to the ICH MC RoP which were last updated and approved by the ICH MC in December 2017. The revisions related to various items including: (1) clarifications regarding the participation of Assembly Members/Observers to Discussion Groups; (2) the process for the replacement of ICH MC Chair and Vice-Chair in the event of his/her resignation; (3) clarification of the process for appointment of Rapporteurs and Regulatory Chairs; and (4) the recording and communication of decisions of the ICH MC.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the ICH MC RoP and that the ICH MC approved the ICH MC RoP v6.1 at the meeting in Charlotte, which will be published on the ICH website.

- ***Standard Operating Procedures of ICH Working Groups***

The Assembly was informed by the ICH MC on updates made by the ICH MC to the Standard Operating Procedures (SOPs) of ICH Working Groups (WGs) which were last updated and approved by the ICH MC in Kobe, Japan in June 2018. The revisions related to various items including: (1) clarifications regarding the participation of Assembly Members to Discussion Groups; (2) the management of the size of Working Groups; (3) the process for endorsement of new activities; and (4) clarification of the process for appointment of Rapporteurs and Regulatory Chairs.

Assembly Decision/Action:

- The Assembly noted the proposed changes to the SOP for WGs and that the MC approved the SOP v6.0 for WGs on 10 October 2018, which will be published on the ICH website.

2. Membership and Observership

The ICH Secretariat presented to the Assembly the application for Observership processed by the ICH MC following the Kobe, Japan meeting in June 2018 and the ICH MC's recommendation in view of the eligibility criteria.

Assembly Decisions/Actions:

- The Assembly approved the application of NRA, Iran for Observership under Article 17.1(a) of the ICH Articles of Association;
- Further to the above approval, the Assembly noted that ICH is now constituted by 16 Members and 28 Observers.

3. Update on MedDRA

The Assembly received a report from the ICH Secretariat on the outcome of the MedDRA MC meeting held on 10-11 November 2018. The report included the following matters: the expansion of MedDRA use worldwide; the current MedDRA 5-year strategic plan to facilitate the use of MedDRA through MedDRA translations, MedDRA training, and the maintenance and development of tools by the Maintenance and Support Services Organisation (MSSO).

The Assembly was updated on the continued growth of MedDRA users throughout the world, which currently has over 5,500 MedDRA subscribing organisations in 120 countries, reflecting the continued successful adoption of MedDRA as a worldwide standard in the protection of public health for almost 20 years since its first release in 1999.

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 with new translations and expanded training and support services; further development of software tools; and exploring interoperability with other terminologies. The Assembly also took note of the 5-year budget projection regarding how costs are expected to evolve.

The Assembly was informed that as part of the efforts to facilitate the use of MedDRA, translations of MedDRA into Korean and Russian are due for release in 2019. Furthermore, the Assembly noted that at the meeting in Charlotte, the MedDRA MC supported the development of a Brazilian Portuguese MedDRA translation.

Regarding efforts made to facilitate the use of MedDRA though training, the Assembly was informed that in 2018, the MSSO conducted over 90 training courses for MedDRA users, including 71 face-to-face training courses in multiple locations worldwide, such as Canada, Central America, Colombia, Europe, Mexico, Turkey, UK and USA, as well as courses conducted by JMO in Japan. The Assembly was further informed that 115 classes are scheduled for 2019, which will be provided with the assistance of new local support staff in China, India, Latin America and the Republic of Korea.

The Assembly was also informed on MedDRA workshops held in conjunction with The XV International Pharmacovigilance Meeting of the Americas in Santiago, Chile; the Conference on Pharmacovigilance, Challenges and Opportunities, in Moscow, Russia; and the WHO Annual Meeting of Representatives of National Pharmacovigilance Centres, in Geneva, Switzerland, which was attended by over 190 participants from 82 countries.

As part of efforts made to facilitate the use of MedDRA through IT tools, the Assembly was informed on work to maintain and develop software tools, noting that in October 2018, a new version of the MedDRA Web-Based Browser (WBB) with increased functionalities was released, and that in Charlotte the MedDRA MC had supported the development of a MedDRA Mobile WBB for release mid-2019.

Furthermore, as part of the efforts to facilitate the use of MedDRA through mapping with other terminologies, the Assembly was informed that in August 2018, the ICH MedDRA MC supported that ICH become a partner in the Innovative Medicines Initiative (IMI) WEB-RADR 2 Project, which is a project composed of several Work Packages (WP). ICH will participate specifically in WP4, which focuses on a bi-directional mapping between MedDRA and SNOMED terminologies. Furthermore, the MedDRA MC also supported that a discussion be initiated with WHO for the development of a mapping between MedDRA and ICD 10/11.

Regarding the development of Standardised MedDRA Queries (SMQs), the Assembly noted that the MedDRA MC in Charlotte supported the renewal of the Memorandum of Understanding with ICH Observer CIOMS for an additional year until 31 October 2019.

Finally, the Assembly noted that the condensed version of the Points to Consider (PtC) Documents, intended to support the global implementation and use of MedDRA, was published on the MedDRA website in November 2018 in all languages except English and Japanese (as these versions will continue to be maintained as the full reference documents). Furthermore, the consolidated MedDRA Best Practices document, intended to provide MSSO recommendations for implementation of MedDRA in relation to primary System Organ Class allocation rules, versioning, and use of supplemental terms, was also published on the MedDRA website.

Assembly Action/Decision:

- The Assembly noted the decisions taken by the MedDRA MC at its meeting in Charlotte on 10-11 November 2018 including the updated 5-year strategic work plan with activities to be funded from the surplus funds (see also item #4 below).

4. Financial Matters

- ***ICH Financial Matters***

The Assembly was updated by the ICH Secretariat on items including the draft 2019 ICH budget and draft 5-Year ICH budget projection for 2019-2023, as well as the provisional 2020 ICH budget and Membership Fees.

Assembly Actions/Decisions:

- The Assembly approved the updated 2019 ICH budget and provided formal confirmation, for the records, of the amount of the 2019 Membership fees which is unchanged compared to 2018 and their publication on the ICH website;

- The Assembly approved the provisional 2020 ICH budget and 2020 Membership Fees, the latter of which is unchanged compared to 2019.

- ***MedDRA Financial Matters***

The Assembly was updated by the ICH Secretariat on MedDRA financial matters, including the updated draft 2019 MedDRA budget and the 2019 MedDRA subscription fees; and the 5-year MedDRA budget projection.

Assembly Action/Decision:

- The Assembly approved the updated 2019 MedDRA budget, including the 2019 MedDRA subscription fees, reflecting a 5% decrease across all subscription fee levels, and use of surplus funds for publication on the ICH website.

5. General Operational Matters

- ***ICH General Operational Matters***

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

Assembly Action/Decision:

- The Assembly noted that the ICH Secretariat will conduct a pilot programme to provide the use of a new IT platform to a small number of WGs (E11A, E14/S7B, M10 and Q2(R2)/Q14), with the aim of discussing the outcome and next steps for future ICH WG IT support at the meeting in June 2019.

- ***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 Actions/Decisions:

- The Assembly noted the update on IPRP activities;
- The Assembly approved the revision and ICH sign-off of the Memorandum of Understanding (MoU) between ICH and IPRP for the provision of Secretariat support services for the period 1 January – 31 December 2019 to include the additional financial contributions to the IPRP budget of five IPRP Members and Observer.

6. New Topic Process & Strategic Discussions

- ***New Topic Process***

The ICH MC provided an update to the Assembly on the New Topic process for the 2019 cycle, including on the cut-off date for submission of any New Topics proposals by Assembly Members and Observers, as well as on considerations on the timeframe to initiate work on the two New Topic Proposals adopted by the Assembly in June 2018 on *Drug Interaction Studies* (M12) and *Adaptive Clinical Trials* (E20).

Assembly Decisions/Actions:

- The Assembly noted that the cut-off date for submission of any New Topic proposals to the ICH Secretariat by Assembly Members and Observers is 14 December 2018;
- The Assembly noted that the ICH MC had confirmed the below timeframe for initiation of work on *Drug Interaction Studies* (M12) and *Adaptive Clinical Trials* (E20):
    - By March 2019: The Secretariat will issue a call for expression of interest for Members and Observers to nominate experts, further to which the ICH MC will confirm the membership for each group;
    - By June/July 2019: The groups will start their work on drafting their respective Concept Paper and Business Plan;
    - In November 2019: The groups will hold their first face-to-face meeting, if approved by the ICH MC.

- ***Strategic Reflection Papers***

Informal Quality Discussion Group (IQDG)

The Assembly was updated by the ICH MC on the status of the establishment of the Informal Quality Discussion Group (IQDG).

Assembly Decisions/Actions:

- The Assembly noted that following Assembly endorsement of the Reflection Paper on *Advancing Pharmaceutical Quality Standards* at the meeting in June 2018, the remit document for the Informal Quality Discussion Group (IQDG) had been revised and subsequently approved by the ICH MC in Charlotte;
- The Assembly noted that as a next step for the establishment of the IQDG, 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 IQDG would work electronically on the drafting of its Work Plan for finalisation by March 2019;
- The Assembly noted that the approved ICH Quality Reflection Paper on *Advancing Pharmaceutical Quality Standards*, including the updated IQDG remit, will be published shortly on the ICH website.

Reflection Papers

The ICH MC presented to the Assembly the status of work regarding development by Members of Reflection Papers on: *Further Opportunities for Harmonization of Standards for Generic Drugs*; *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 FDA, United States' Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drugs*, including minor amendments made during the meeting, and agreed that its publication on the ICH website would be deferred until the approval of the remit of the Informal Generic Drug Discussion Group (IGDDG);
- The Assembly supported that with the MC's support of the remit, the IGDDG would be established for a 1-year term and a call for expression of interest for Members and Observers to nominate experts would be issued, in line with the applicable procedures;

- The Assembly agreed on the need to consider the involvement of relevant stakeholders in the field of generic drugs during the course of this work, and that IGBA would further inform the Assembly on this at its next meeting;
- The Assembly noted that the MHLW/PMDA, Japan Reflection Paper 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* had been circulated to the Assembly ahead of the meeting, and that a revised document with a narrower focus would be further provided that includes a proposal for establishment of a DG;
- The Assembly noted that a draft Reflection Paper from PhRMA on *Model Informed Drug Development (MIDD)* was expected to be circulated to the ICH Assembly in 2019.

- ***Strategic Discussions***

The Assembly noted ongoing considerations by the ICH MC on the need to clarify the process for development of ICH Reflection Papers and the complementarity between Reflection Papers and New Topic proposals, in order to provide a better view of the global work of ICH in harmonisation for better health.

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

- ***ICH Annual Work Plan and Multi-Annual Strategic Plan***

The ICH Secretariat presented to the Assembly the 2019 Work Plan and Multi-Annual Strategic Plan of the Association.

Assembly Decisions/Actions:

- The Assembly approved the 2019 ICH Work Plan with minor amendments related to the updating of the expected timeframes for completion of WG work further to the Charlotte meeting, and its publication on the ICH website;
- The Assembly approved the Multi-Annual Strategic Plan for the Association, and its publication on the ICH website.

- ***MedDRA Annual Work Plan***

The ICH Secretariat presented to the Assembly the 2019 MedDRA MC Work Plan.

Assembly Decision/Action:

- The Assembly approved the 2019 MedDRA MC Work Plan and its publication on the ICH website.

8. Communication

- ***Communication Activities***

The ICH Secretariat updated the Assembly on its recent activities aimed at improving ICH communication with stakeholders including: planned improvements to the ICH website to be implemented in early 2019, maintenance of the ICH transparency policy for publication of agendas, reports and other WG documents on the ICH website, ICH presence on online platforms such as Wikipedia, as well as future work on the update of the ICH history webpage and on the development of a flyer about ICH for dissemination purposes. The Assembly was also informed of the upcoming publication of an article entitled “ICH: Recent Reforms as a Driver of Global Regulatory Harmonization and Innovation in Medical Products" in the journal *Clinical Pharmacology & Therapeutics*, which is authored by Mrs. Lenita Lindström-Gommers (ICH Assembly Chair) and Dr. Theresa Mullin (ICH MC Chair).

Assembly Decision/Action:

- The Assembly noted the report of the ICH Secretariat on recent work aimed at improving ICH communication with stakeholders, as well as plans for future communication activities.

- ***ICH Regional Public Meetings***

The Assembly shared information on ICH Regional Public Meetings in their respective regions prior to and following the ICH meeting in Charlotte, NC, USA in November 2019:

- On 18 July 2018, JPMA and MHLW/PMDA, Japan held a joint meeting to report on the outcome of the Kobe, Japan ICH meeting in June 2018;
- On 17 October 2018, FDA, United States and Health Canada, Canada held a joint public consultation meeting to solicit public input on current work under ICH in view of the upcoming ICH meeting in Charlotte, NC, USA on 10-15 November;
- On 17 October 2018, ANVISA, Brazil held an event to raise awareness and share information on the advances achieved by ICH Working Groups and the process of implementation of ICH Guidelines by ANVISA, Brazil;
- On 24 October 2018, MFDS, Republic of Korea held a public meeting in the Republic of Korea to share with Regulators and Industry the main results of the Kobe, Japan ICH meeting in June 2018, and to present the major agenda items for the Charlotte, NC, USA ICH meeting;
- On 27-30 November 2018, MFDS, Republic of Korea will host a training event on ICH Guidelines for the Korean industry;
- On 28 November 2018, ANVISA, Brazil will host an event to raise awareness of the ICH M9 draft Guideline as part of its public consultation process in Brazil;
- On 14 December 2018, JPMA and MHLW/PMDA, Japan will hold a joint meeting to report on the outcome of the Charlotte, NC, USA ICH meeting in November 2018;
- On 7 February 2019, an ICH info day will be held during the DIA meeting in Vienna, Austria;
- On 29 April 2019, FDA, United States and Health Canada, Canada will hold a joint meeting at the FDA, United States offices which will also be publicly broadcasted.

9. Implementation of ICH Guidelines

The Lead of the Implementation Subcommittee provided to the Assembly an update on recent activities undertaken the Implementation Subcommittee.

Assembly Decision/Action:

- The Assembly noted the status of implementation of ICH Guidelines by ICH Regulatory Members.

- ***Definitions of degrees of implementation***

The Lead of the Implementation Subcommittee provided to the Assembly an update on the final version of the definitions to be used with respect to the degrees of implementation of and adherence to ICH Guidelines.

Assembly Decision/Action:

- The Assembly approved the final version of the definitions of the degrees of implementation.

- ***Implementation survey***

The Lead of the Implementation Subcommittee and a representative from the independent third-party conducting the ICH implementation survey provided to the Assembly an update on recent activities including the progress made to the ICH-driven implementation survey for monitoring the adequacy of implementation and adherence to ICH Guidelines for Regulators and Industry, including the progress made to the survey questionnaire and the design notes for the online Data Collection Tool (DCT), and the expected timeline for the initiation of the survey.

Assembly Decisions/Actions:

- The Assembly noted the reports of the Implementation Subcommittee and the independent third party engaged by ICH on the survey questionnaire and design notes for the online DCT;
- The Assembly noted the 30 November 2018 deadline for the Assembly to provide feedback on the survey questionnaire and design notes for the online DCT, and agreed that following consideration of Assembly comments by the Implementation Subcommittee, the survey would be initiated;
- The Assembly noted that ICH Observers were invited to express their interest to volunteer to participate in the survey by 30 November 2018, further to which GHC expressed interest to participate along with previously confirmed ICH Observers: NPRA, Malaysia, COFEPRIS, Mexico and SAHPRA, South Africa;
- The Assembly noted that the results of the survey would be presented to the Assembly at the next ICH meeting in Amsterdam in June 2019.

10. Training

The Lead of the Training Subcommittee provided an update to the Assembly on recent activities, including the status of requests received from training providers for ICH's approval of training programmes as "ICH Recognised Training Programmes"; considerations on eligibility criteria and a draft procedure for approval of training providers interested in developing an ICH Recognised Training Programme; prioritisation of Tier 3 ICH Guidelines for training purposes; considerations related to the Subcommittee's mission statement; and the development of online training programmes.

The Assembly also noted a report from Dr. Auclair (NorthEastern University) who had been invited to participate in the Assembly meeting in Charlotte as an ad-hoc Observer;

Assembly Decisions/Actions:

- The Assembly noted the update made to the ICH WG templates for *Step 2* informational materials and *Step 4* online slide presentations;
- The Assembly acknowledged that the ICH MC had in Charlotte supported the ICH Training Programme Providers Eligibility Criteria; the Procedures for Organisations Interested in Developing an ICH Recognised Training Programme; the ICH Training Provider Application Form; and the list of priority Tier 3 ICH Guidelines for training purposes which will be reviewed annually;
- The Assembly noted that the Training Subcommittee had recently approved: the Chinese Pharmaceutical Association (CPA)'s application to provide an ICH Recognised Training Programme on the ICH M4 Guideline; Duke NUS CoRE Singapore's request to provide an ICH Recognised Training Programme on Chemistry, Manufacturing and Control (CMC); and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) request to provide an ICH Recognised Training Programme on ICH E6(R2) and ICH E17;
- The Assembly noted that the ICH MC/Training Subcommittee was reflecting on how ICH might further leverage the expertise of training providers in a consultant-type role.

11. WGs Meeting in Charlotte

Regarding requests from WGs to meet at the next ICH meeting in Amsterdam, the Netherlands on 1-6 June 2018, the Assembly noted that any such requests would be taken under consideration by the ICH MC. A list of WGs agreed by the ICH MC to meet face-to-face in Amsterdam will be made available to the Assembly, and also on the ICH website, following the ICH MC 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 WGs may occur sooner via mailing.

11.1. 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 Rapporteur reported to the Assembly on the outcome of the E8(R1) EWG meeting and the progress made on the development of the draft E8(R1) Technical Document on the Revision on General Considerations for Clinical Trials.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the E8(R1) EWG for activities to be undertaken;
- The Assembly noted that the draft Technical Document will be completed by November 2018, and that *Steps 1* and *2a/b* are expected to be reached electronically between January and February 2019;
- The Assembly noted that as agreed in Kobe in June 2018, and as per the E8(R1) communication pilot, the E8(R1) EWG will share the final draft Technical Document prior to *Step 1* with interested ICH internal stakeholders (i.e. those Members which had expressed interest but had not been able to nominate experts due to the large size of the group), and that a teleconference will be organised with the E8(R1) EWG and interested ICH internal stakeholders to answer questions regarding the draft Technical Document;
- The Assembly acknowledged that the intent of the pilot was to communicate with the internal ICH stakeholders rather than to revise the draft Technical Document;
- The Assembly noted that an ICH public stakeholder meeting would take place after the closure of the public consultation phase, as per the GCP renovation plan, and that FDA, United States had proposed to host the meeting;
- The Assembly noted that the ICH MC would further consider the timing and need for additional stakeholder meetings in further regions, as well as the timeframe for these meetings;
- The Assembly supported that the E8(R1) EWG would liaise with the Training Subcommittee to receive guidance regarding the development of training materials.

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

Assembly Decisions/Actions:

- The Assembly supported the work plan of the E9(R1) EWG for activities to be undertaken;
- The Assembly noted that *Steps 3* and *4* are expected by June 2019;

- The Assembly noted that a video animation and voice over for Module 1 of the training material are expected to be finalised by June 2019.

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

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

Assembly Decisions/Actions:

- The Assembly supported the work plan of the E11A EWG for activities to be undertaken;
- The Assembly noted the group's process for management of additional ad-hoc experts in line with the applicable SOP;
- The Assembly noted the progress made on the draft Technical Document and that *Steps 1* and *2a/b* are expected by November 2020.

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

Dr. Leishman (PhRMA), Rapporteur of the former E14/S7B DG, reported to the Assembly on the outcome of the E14/S7B DG / IWG meeting and progress made by the group, including on the review of the CiPA (Comprehensive *in vitro* Proarrhythmia Assessment) validation data and the finalisation of a Concept Paper for the development of Q&A for S7B / E14.

Assembly Decisions/Actions:

- The Assembly noted the report on the progress of the E14/S7B DG / IWG;
- The Assembly endorsed the new area of work of the E14/S7B DG as outlined in the Concept Paper which was approved by the MC at the meeting in Charlotte, and the subsequent establishment of the E14/S7B IWG;
- The Assembly appointed Dr. Strauss (FDA, United States) as Rapporteur of the E14/S7B IWG to serve from the end of the meeting at Charlotte;
- The Assembly noted that the Regulatory Members of the MC had appointed Dr. Shinagawa (MHLW/PMDA, Japan) as Regulatory Chair of the E14/S7B IWG.
- The Assembly noted that *Steps 1* and *2a/b* are expected by June 2020.

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

The E17 IWG Rapporteur reported to the Assembly on the outcome of the E17 IWG meeting and progress made on the finalisation of the Training Materials, with case studies supportive of harmonised implementation activities of the recently released E17 ICH Guideline on General Principles for Planning and Design of Multi-Regional Clinical Trials.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the E17 IWG for activities to be undertaken;
- The Assembly noted that the E17 IWG is liaising with the Training Subcommittee for the development of training materials and case studies, and that the publication on the ICH website of training materials is expected by June 2019.

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

The E19 EWG Rapporteur reported to the Assembly on the outcome of the meeting of the E19 EWG and the progress made on the development of the E19 draft Technical Document on Optimisation of Safety Data Collection.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the E19 EWG for activities to be undertaken;
- The Assembly noted the progress made towards the finalisation of the *Step 1* Technical Document and that *Steps 1* and *2a/b* are expected to be reached electronically by March 2019.

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

The M7(R2) Maintenance EWG Rapporteur reported to the Assembly on the outcome of the M7(R2) Maintenance EWG meeting, including its progress on the development of a list of compounds to be evaluated in the second Addendum, the update of the M7(R1) Guideline text regarding the treatment for HIV (Human Immunodeficiency Virus), and on the development of a Q&A document to clarify and address Quality and Safety issues.

Assembly Decisions/Actions:

- The Assembly endorsed the new area of work of the M7(R2) Maintenance EWG as outlined in the revised Concept Paper which was approved by the ICH MC, further to which the group's code was changed to M7(R2) Maintenance EWG/IWG;
- The Assembly supported the work plan of the M7(R2) Maintenance EWG/IWG for activities to be undertaken;
- The Assembly noted that Dr. Honma (MHLW/PMDA, Japan) would continue to assume the role of M7(R2) Rapporteur until June 2019, further to which the Rapporteurship would rotate as per the maintenance procedure outlined in Annex 4 of the SOP of the ICH WGs;
- The Assembly noted that *Steps 1* and *2a/b* are expected by November 2019.

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

The M10 EWG Rapporteur reported to the Assembly on the outcome of the M10 EWG meeting and progress made towards developing the M10 draft Technical Document on Bioanalytical Method Validation.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the M10 EWG for activities to be undertaken;
- The Assembly noted the appointment by the Regulatory Members of the MC of Dr. Booth from FDA, United States as Regulatory Chair of the M10 EWG;
- The Assembly noted the progress made towards the finalisation of the Technical Document and that *Steps 1* and *2a/b* are expected to be reached electronically by December 2018.

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

The PhRMA deputy topic Leader, Ms. Vivian Combs, replacing in Charlotte the M11 EWG Acting Rapporteur, reported to the Assembly on the outcome of the M11 informal WG / EWG meeting and progress made by the group, including the finalisation of the M11 Concept Paper and Business Plan.

Assembly Decisions/Actions:

- The Assembly noted the report of the M11 informal WG / EWG;
- The Assembly noted that the ICH MC had in Charlotte endorsed the M11 Concept Paper and Business Plan, and the subsequent establishment of the M11 EWG;
- The Assembly supported the work plan of the M11 EWG for activities to be undertaken;
- The Assembly appointed the M11 informal WG Leader and M11 EWG Acting Rapporteur, Ms. Vanderslice (PhRMA), as M11 EWG Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP;
- The Assembly noted that in line with section 1.5.2 of the SOP, the M11 informal WG Regulatory Chair Dr. Fitzmartin (FDA, United States) will continue as Regulatory Chair of the M11 EWG;
- The Assembly noted that *Steps 1* and *2a/b* are expected by June 2020.

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

The Q2(R2)/Q14 EWG Acting Rapporteur reported to the Assembly on the outcome of the Q2(R2)/Q14 informal WG / EWG meeting and progress made by the group, including on the finalisation of a Concept Paper and Business Plan.

Assembly Decisions/Actions:

- The Assembly noted the report of the Q2(R2)/Q14 informal WG / EWG;
- The Assembly noted that the ICH MC had in Charlotte endorsed the Q2(R2)/Q14 Concept Paper and Business Plan, and the subsequent establishment of the Q2(R2)/Q14 EWG;
- The Assembly supported the work plan of the Q2(R2)/Q14 EWG for activities to be undertaken;
- The Assembly appointed the Q2(R2)/Q14 informal WG Leader and Q2(R2)/Q14 EWG Acting Rapporteur, Dr. Hiyama (MHLW/PMDA, Japan) as Q2(R2)/Q14 EWG Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP;
- The Assembly noted that in line with section 1.5.2 of the SOP, the Q2(R2)/Q14 informal WG Regulatory Chair Dr. Keire (FDA, United States) will continue as Regulatory Chair of the Q2(R2)/Q14 EWG;
- The Assembly noted that *Steps 1* and *2a/b* are expected by June 2020.

11.11. Q13 EWG: Continuous Manufacturing *(Rapporteur: Dr. Lee – FDA, United States; Regulatory Chair: Dr. Matsuda – MHLW/PMDA Japan)*

The Q13 Acting Rapporteur reported to the Assembly on the outcome of the Q13 informal WG / EWG meeting and the progress of the group, including on the finalisation of a Concept Paper and Business Plan.

Assembly Decisions/Actions:

- The Assembly noted the report of the Q13 informal WG / EWG;
- The Assembly noted that the ICH MC had in Charlotte endorsed the Q13 Concept Paper and Business Plan, and the subsequent establishment of the Q13 EWG;
- The Assembly supported the work plan of the Q13 EWG for activities to be undertaken;
- The Assembly appointed the Q13 informal WG Leader and Q13 EWG Acting Rapporteur, Dr. Lee (FDA, United States) as Q13 EWG Rapporteur, in line with the concept of continuity outlined in section 4.2 of the Assembly RoP;
- The Assembly noted that in line with section 1.5.2 of the SOP, the Q13 informal WG Regulatory Chair, Dr. Matsuda (MHLW/PMDA, Japan) will continue as Regulatory Chair of the Q13 EWG.
- The Assembly noted that *Steps 1* and 2a/*b* are expected by June 2020.

11.12. 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 Rapporteur reported to the Assembly on the outcome of the S1(R1) EWG meeting and progress made towards developing the S1(R1) draft Addendum.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the S1(R1) EWG for activities to be undertaken;
- The Assembly noted that *Steps 1* and *2a/b* are expected to be achieved electronically by March 2020 following a possible face-to-face meeting in November 2019, and *Steps 3* and *4* by June 2021.

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

The S5(R3) EWG Rapporteur reported to the Assembly on the outcome of the S5(R3) EWG meeting and progress made towards developing the S5(R3) draft Guideline, as well as on the proposal for a maintenance procedure of S5(R3) Annexes.

Assembly Decisions/Actions:

- The Assembly supported the work plan of the S5(R3) EWG for activities to be undertaken;
- The Assembly noted that a draft Concept Paper defining the Maintenance Procedure is expected to be submitted to the MC by March 2019, with the aim of submitting it for Assembly endorsement at the meeting in June 2019;
- The Assembly noted that *Steps 3* and *4* are expected by November 2019.

12. WGs/DGs Not Meeting in Charlotte

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

The Assembly noted that the Standing Paediatric EWG had received a request for paediatric advice from the S11 EWG and continues to remain available for new requests 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. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports *(Rapporteur: Dr. Misu – MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, United States)*

The E2B(R3) EWG/IWG continues its work, including on the Route of Administration (RoA) term mapping between E2B(R2) and EDQM; the Service Level Understanding (SLU) regarding the SOP to extract and post the EDQM Dose Form (DF) and RoA terminology list for E2B(R3) use; and plans for developing training materials for E2B(R3) adopters.

12.3. 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 regarding the updating with each MedDRA release of the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents. The Condensed Versions of "these documents, translated into all MedDRA languages (except English and Japanese), have been released in November 2018.

Release of next versions of the MedDRA Term Selection: Points to Consider and MedDRA Data Retrieval and Presentation: Points to Consider documents (updated for MedDRA Version 22.0) are expected in March 2019.

12.4. M2 EWG Electronic Standards for the Transfer of Regulatory Information *(Co-Rapporteurs: Dr. Okada – MHLW/PMDA, Japan; Ms. Slack – FDA, United States, Regulatory Chair: Dr. Jaermann – Swissmedic, Switzerland)*

The M2 EWG continues its work, including the development of a White Paper on the potential of the HL7 Fast Healthcare Interoperability Resources (FIHR) standard for ICH initiatives; and the consultation of subject matter experts to confirm interest and concerns with Common Clinical Trial submission (eCCTS).

Assembly Decisions/Actions:

- The Assembly noted that the Regulatory Members of the ICH MC had appointed Dr. Jaermann (Swissmedic, Switzerland) to the role of M2 EWG Regulatory Chair;
- The Assembly noted that the MC confirmed its support in principle for the approach of the Terminology List Management Process put forward by the M2 EWG, and that in the future the M2 EWG would be tasked with maintaining the document by making minor amendments to the process as appropriate without seeking MC approval.

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

The M4Q(R1) IWG is in a dormant state since the meeting in Osaka, Japan in November 2016, and no questions have been raised to-date following the implementation of the M4 Granularity Document which would need to be addressed by the M4Q(R1) IWG.

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

Further to the eCTD v4.0 Q&As and Specification Change Request Document v1.2, as well as the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 reaching *Steps 3* and *4* at the meeting in Kobe, Japan, in June 2018, the M8 EWG/IWG did not receive any new Change Requests which would require an update of these documents.

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

Further to Assembly endorsement of *Step 2b* at the meeting in Kobe, Japan in June 2018, the M9 Draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions until the beginning of 2019.

Steps 3 and 4 are expected by November 2019.

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

The most recent revision of the ICH Q3C Guideline, ICH Q3C(R7), reflecting an error correction of the Permitted Daily Exposure (PDE) for ethyleneglycol in the ICH Q3C(R6) Guideline, and the Q3C Support Documents 1, 2 and 3, which contain the summaries of the toxicity data from which the PDEs were derived for the original ICH Q3C Guideline, were published on the ICH website in October 2018.

As a result of the publication of ICH Q3C(R7), the code of the Maintenance Expert Working group (EWG) has been changed to Q3C(R8) Maintenance EWG as it continues its work.

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

Steps 1 and 2a/b of ICH Q3C(R8) are expected by March 2019.

12.9. Q3D(R1)/(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities *(Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: N/A)*

The Q3D(R1)/(R2) EWG continues to address comments received on the revision Q3D(R1) regarding the Cadmium inhalation PDE from the regional public consultation period which was completed end of September 2018.

The Q3D(R1)/(R2) EWG continues its work on the development of the Q3D(R2) draft Technical Document for cutaneous and transdermal RoA PDEs.

Steps 3 and 4 of the Q3D(R1) revision to the Cadmium inhalation PDE are expected by early 2019.

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products are expected by November 2019.

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 continues its work on the development of the script for the narrated slide deck.

The finalisation of the Training Material in the form of a video with the narrated slide deck is expected by end of 2018.

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

Further to Assembly endorsement of *Step 2b* at the meeting in Geneva in November 2017, the Q12 Draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions until December 2018.

The group will hold an interim meeting from 11 to 15 February 2019 in Tokyo, Japan.

Steps 3 and 4 are expected by November 2019.

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

Further to Assembly electronic endorsement of *Step 2b* of the S11 draft Guideline on 18 September 2018, the draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions.

Assembly Decision/Action:

- The Assembly endorsed the nomination of the current Acting Rapporteur as the formal Rapporteur for the S11 EWG in line with the SOP Section 1.5.2.

Steps 3 and 4 are expected by November 2019.

12.13. Maintenance of Q4B Annexes

The Assembly was informed on the proposal received from the Pharmacopeial Discussion Group (PDG) for the maintenance procedure of the ICH Q4B Annexes in view of revisions made to PDG General Chapters and the involvement in ICH of more countries/regions. Under this proposal, the PDG would be responsible for the maintenance of the current ICH Q4B Annexes following a new process. The need to revise a Q4B Annex would be triggered by PDG's sign-off of a revised text which is the subject of a Q4B Annex. The PDG will then compare the corresponding current ICH Q4B Annex, the PDG sign-off text as well as the corresponding European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP) and United States Pharmacopoeia (USP) chapters as published in the respective Pharmacopoeias. Other pharmacopoeias will be informed of the ongoing review via the contact list of the International Meeting of World Pharmacopoeias (IMWP). Following this review, the PDG will prepare a revised Q4B annex which will enter the usual ICH *Step* process: endorsement by the ICH Assembly under *Step 2 a* and by the ICH Assembly Regulatory Members under *Step 2b*; *Step 3* public consultation; adoption by the ICH

Assembly Regulators Members under *Step 4*. Under *Step 5*, the Q4B Annex will move to the regional regulatory implementation step and the corresponding PDG chapter will move to PDG stage 5 (inter-regional acceptance). Other pharmacopoeias will be informed via the contact list of the IMWP.

Assembly Decisions/Actions:

- The Assembly approved the proposal from the Pharmacopeial Discussion Group (PDG) for the maintenance procedure of the ICH Q4B Annexes;
- The Assembly noted that a revision to the SOP of the ICH WGs would be undertaken to align with the new procedure.

13. Appointment of ICH Assembly Vice Chair

Assembly Action/Decision:

- The Assembly unanimously elected Dr. Petra Doerr (Swissmedic, Switzerland) as Assembly Vice Chair and noted that she would serve for a one-year term.

14. Organisation of Next Meetings

Assembly Actions/Decisions:

- The Assembly noted that the next ICH Assembly meeting will be held in Amsterdam, the Netherlands, on Wednesday 5 – Thursday 6 June 2019;
- The Assembly noted the below dates of the next ICH Assembly meetings:
    - Tuesday 19 – Wednesday 20 November 2019 in Singapore (to be confirmed);
    - Tuesday 26 - Wednesday 27 May 2020 in the Americas (location to be confirmed);
    - Tuesday 17 - Wednesday 18 November 2020 in Europe (location to be confirmed);
    - Tuesday 1 - Wednesday 2 June 2021 in Asia (location to be confirmed).