5 February 2019

SUMMARY
of
MC SESSION ACTIONS AND DECISIONS

ICH Management Committee Meeting
12 - 15 November 2018, Charlotte, NC, USA

List of MC Participants

ICH Management Committee Members Representatives

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin (Chair)	FDA, United States
Ms. Pujita Vaidya	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

ICH Assembly Member Representative:

Dr. Tomas Salmonson	EC, Europe

ICH Management Committee Standing Observers Delegates:

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

ICH Management Committee Coordinators:

Dr. Ingrid Markovic	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
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

ICH Management Committee Technical Coordinators:

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

ICH Management Committee Additional Participants:

Mr. William Lewallen	FDA, United States
Dr. Léo Bouthilier	Health Canada, Canada
Mr. Tsuyoshi Kobayashi	JPMA
Ms. Machiko Sumi	JPMA
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

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 MANAGEMENT COMMITTEE MEETING
MINUTES

MC Chair: Dr. Theresa Mullin, FDA, United States

MC Vice Chair: Dr. Nobumasa Nakashima, MHLW/PMDA, Japan

Welcome & Adoption of the Agenda

Dr. Mullin (MC Chair, FDA, United States) and Dr. Nakashima (MC Vice Chair, MHLW/PMDA, Japan) welcomed MC Member Representatives and Standing Observer delegates.

MC Decision/Action:

- The MC adopted the agenda without any modification.

A. Adoption of Reports of the Previous Teleconferences

MC Decisions/Actions:

- The MC noted the MC minutes from the Kobe meeting held in June 2018, dated 3 August 2018;
- The MC noted the Report of the Coordinators teleconference which was held on 22 August 2018, dated 25 September 2018;
- The MC noted the Report of the MC Technical teleconference held on 19 September 2018, dated 4 October 2018;
- The MC noted the Report of the MC Policy 1 teleconference held on 20 September 2017, dated 4 October 2018;
- The MC noted the Report of the MC Policy 2 teleconference held on 10 October 2018, dated 1 November 2018;
- The MC noted the Report of the MC Policy 3 teleconference held on 22 October, dated 29 October 2018.

B. ICH Membership and Observership Applications

The ICH Secretariat confirmed that, besides the recent Observership application received from NRA, Iran, no other applications had been received since the meeting in Kobe in June 2018.

MC Decision/Action:

- The MC agreed to recommend the following Observership application to the Assembly for approval :
    - NRA, Iran, for Observership under Article 17.1(a) of the ICH Articles of Association.

C. General Operational Matters

The ICH Secretariat provided a report to the MC on: Secretariat staffing; updates to the ICH Employee Handbook; new tasks undertaken by the ICH Secretariat in 2018 related to ICH, MedDRA and IPRP activities; status of the Trademark registration of the ICH logo; ICH Secretariat's support of MC operations and efficiency; considerations for IT support to be provided to the WGs; and an overview of the participation of current Members and Observers in ICH Assembly and Working Groups (WGs).

ICH Secretariat

MC Decisions/Actions:

- The MC noted the current status of the ICH Secretariat staffing and the allocation of support between ICH, MedDRA and IPRP activities;
- The MC noted the status of the registration of the ICH device (logo) Trademark in ICH Member and Observer countries and the actions undertaken by the ICH Secretariat in support of this activity in coordination with ICH's lawyers;
- The MC supported the additional revisions to the MC Rules of Procedures (RoP) section 7.2 for alignment with the current approach for efficiency of MC operations;
- The MC confirmed its support of the proposed revisions to the ICH Employee Handbook, including the revised approach for signature of contracts and agreements on behalf of the ICH Association;
- The MC agreed that, when a new project/task is assigned to the Secretariat, consideration should be given by the ICH MC and/or MedDRA MC, as applicable, on whether the workload can be accommodated within the work plan of the Secretariat within the desired timeframe;
- The MC noted the steps undertaken by the Secretariat as supported by the MedDRA MC for the ICH Association to become a partner in the IMI WEB-RADR 2 project which will in particular develop a proof-of-concept bidirectional mapping between MedDRA and SNOMED;
- The MC gave its general approval for the ICH logo to be used within the WEB-RADR 2 project to communicate ICH's involvement in the project, and agreed that the Secretariat would ensure the appropriate use of the logo on a case-by-case basis;
- The MC supported that the Secretariat would conduct a survey amongst ICH WGs to determine their satisfaction with the current IT platform, as well as interest in any additional features, with a view to informing considerations on future WG IT support;
- The MC supported that the Secretariat would conduct a pilot programme to provide the use to a small number of ICH WGs of a new IT platform which would include MS SharePoint;
- The MC agreed to further discuss ICH WG use of IT platforms at its next meeting in June 2019 and to take a decision on next steps based on the outcome of the pilot;
- The MC noted the ICH expert participation statistics presented by the ICH Secretariat including the yearly rate of expert turnover;
- The MC supported that the ICH Secretariat coordinate with Rapporteurs to follow closely the attendance of experts to WG face-to-face meetings and teleconferences in line with the rules set in the Standard Operating Procedures (SOPs) for ICH WGs section 1.5.4 and Annex 2.

IPRP

The Vice Chair of the International Pharmaceutical Regulators Programme (IPRP) MC updated the ICH MC on the work of the IPRP and on ICH's provision of Secretariat support services to the IPRP since the start of 2018.

MC Decision/Action:

The MC supported the revision and provision to the Assembly for approval of the Memorandum of Understanding between ICH and IPRP for the provision of Secretariat support services for the period 1 January – 31 December 2019 to include the contributions of an additional five parties to cover meeting costs.

D. Training

The Lead of the Training Subcommittee provided an update on the Subcommittee's activities including: the status of the 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 of 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; the development of online training programmes; and use of the allocated ICH training budget.

MC Decisions/Actions:

- The MC endorsed the list of Tier 3 ICH Guidelines prioritised for training purposes, noting that the list should be revised by the Training Subcommittee and submitted for MC approval on a yearly basis;
- The MC supported the revisions to the ICH mission statement and its subsequent publication on the ICH website;
- The MC approved the revised ICH Training Programme Providers' Eligibility Criteria;
- The MC approved the Procedures for Organisations Interested in Developing an ICH Recognised Training Programme;
- The MC approved the ICH Training Provider application form;
- The MC noted the ongoing development of a new process for identification of ICH Training Partners, in addition to the ICH Training Provider process, where ICH would fund and own the training material developed by partners;
- The MC agreed to further discuss the terminology to be used with regards to ICH Training "Partners";
- The MC supported that ICH use surplus funds to support various training activities;
- The MC agreed that a call should be made to the Assembly to see if ICH Regulatory members and/or Observers may have requests for ICH funding of regional training which they would like the MC to consider.

E. Financial Matters

The ICH Secretariat provided an update on ICH financial matters including: update on 2018 membership fee payments and current budget situation; final 2019 ICH budget for Assembly approval in Charlotte; provisional 2020 ICH budget and 2020 ICH Membership Fees for Assembly approval in Charlotte; 5-Year ICH Budget Plan (2019-2023); management of ICH funds; and organisation of the 2018 Financial Audit.

The ICH Secretariat also provided an update on MedDRA financial matters including: draft 2019 MedDRA budget, including the proposed 2019 MedDRA Subscription Fees for Assembly approval at the meeting, and the 5-Year MedDRA Budget Plan (2019-2023).

MC Decisions/Actions:

- The MC noted that the Charlotte meeting was expected to come in over budget and was supportive that the ICH Secretariat reimburse PhRMA for the additional costs incurred beyond the approved meeting budget. Further to this, the MC supported a revision to the ICH meeting budget from 2019 on (see item F below for details);
- The MC supported the MedDRA MC's proposal to submit a revised 2019 MedDRA Budget to the ICH Assembly for approval in Charlotte to include work associated with a Brazilian Portuguese MedDRA translation, the development of which the MedDRA MC supported in Charlotte;

- The MC agreed the need to put in place a clear plan to spend surplus funds on strategic activities such as training, outreach and stakeholder engagement and agreed that a small MC subgroup develop a plan.

F. Meetings

The ICH Secretariat provided an update on the organisation of ICH meetings including: implementation of the new schedule for the ICH week; work undertaken with ICH's contracted Professional Conference Organiser (PCO) in preparation of the 2020 and 2021 meetings; status of organisation of the meeting in Amsterdam, the Netherlands, in June 2019; and contracting of a venue in Singapore for the meeting in November 2019.

Scheduling of the ICH Week

MC Decision/Action:

- The MC noted that the new schedule of the ICH week would be implemented for meetings starting from November 2019.

Designation of 2020 and 2021 Meeting Locations and Dates

MC Decisions/Actions:

- The MC agreed on the following dates for the June 2021 meeting:
    - From Sunday 30 May to Thursday 3 June, 2021.
- The MC noted that as part of the selection process, ICH meetings will be held with a three-region rotation (North America / South America, Europe / Africa, Asia) and that within a region with more than one ICH Member, the Professional Conference Organiser (PCO) is tasked with identifying the three best options (based on the agreed selection criteria) looking across ICH Member countries / regions, with one of the options to come from the country / region of a Founding or Standing ICH Member, with the MC to take a final decision;
- The MC agreed that, in view of the growth of the size of ICH meetings, the budget for ICH meetings would be revised (see also under item E);
- The MC agreed that, based upon the revised budget, the PCO would conduct a further search of venues for the June 2020 meeting in the Americas focusing on Canada (in view of its accessibility to a higher number of ICH attendees from the perspective of visa requirements), and agreed that further options be brought forward for MC decision by early 2019 at latest;
- The MC noted that the envisioned timeframe for selection of the location of the November 2020 meeting in Europe is April 2019 and for the June 2021 meeting is June 2019;
- The MC noted that for meetings from 2021 onwards, the date would be confirmed 30 months in advance, and the location 24 months in advance.

Organisation of June 2019 & November 2019 Meetings

MC Decisions/Actions

- The MC noted that the organisation of the June 2019 meeting in the Amsterdam, the Netherlands is on track and that the registration process would be simplified via the use of the PCO's online platform;
- The MC noted that the venue for the November 2019 would be contracted after the inspection carried out by the PCO in Singapore by the end 2018.

G. Oversight of Working Groups

Groups Meeting in Charlotte

MC Decisions/Actions:

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

- The MC 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 organized with the E8(R1) EWG and interested ICH internal stakeholders to answer questions regarding the draft Technical Document;
- The MC agreed on the below process in line with the communication pilot:
    - The final draft Technical Document is shared 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, for a 3-week comment period*;*
    - The E8(R1) EWG reviews comments and questions received;
    - A teleconference between the E8(R1) EWG and the interested ICH internal stakeholders is organised 2 weeks later;
    - The E8(R1) EWG debriefs the discussion and finalises the Technical Document for *Step 1* sign-off.

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

- The MC approved the revised Concept Paper and, pending Assembly endorsement of the new area of work at the meeting in Charlotte, the subsequent establishment of the E14/S7B IWG;
- The MC noted that the membership of the E14/S7B DG would be transferred to the E14/S7B IWG;
- The MC agreed to recommend to the Assembly Dr. Strauss (FDA, United States) as Rapporteur of the E14/S7B IWG;
- The MC noted that the Regulatory Members of the MC approved the appointment of Dr. Shinagawa (MHLW/PMDA, Japan) as Regulatory Chair of the E14/S7B IWG.

- ***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 MC noted the current status of work and expertise available within the M7(R2) Maintenance EWG/IWG.

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

- The MC approved the M11 Concept Paper and Business Plan and the subsequent establishment of the M11 EWG;
- The MC noted that the membership of the M11 informal WG would be transferred to the EWG;

- The MC agreed that in line with the concept of continuity outlined in section 4.2 of the Assembly RoP, the MC would recommend to the Assembly to appoint the M11 informal Group Leader, Ms. Vanderslice (PhRMA), as M11 Rapporteur;
- The MC noted that in line with the concept of continuity outlined in section 1.5.2 of the SOP of the WG, the Regulatory Chair of the M11 informal WG, Dr. Fitzmartin (FDA, United States), would assume the role of Regulatory Chair of the M11 EWG.

- ***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 MC approved the Q2(R2)/Q14 Concept Paper and Business Plan and the subsequent establishment of the Q2(R2)/Q14 EWG;
- The MC noted that the membership of the Q2(R2)/Q14 informal WG would be transferred to the Q2(R2)/Q14 EWG;
- The MC agreed that in line with the concept of continuity outlined in section 4.2 of the Assembly RoP, the MC would recommend to the Assembly to appoint the Q2(R2)/Q14 informal Group Leader WG, Dr. Hiyama (MHLW/PMDA, Japan) as Q2(R2)/Q14 Rapporteur;
- The MC noted that in line with the concept of continuity outlined in section 1.5.2 of the SOP of the WG, the Regulatory Chair of the Q2(R2)/Q14 informal WG would assume the role of Regulatory Chair of the Q2(R2)/Q14 EWG.

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

- The MC approved the Q13 Concept Paper and Business Plan and the subsequent establishment of the Q13 EWG;
- The MC noted that the membership of the Q13 informal WG would be transferred to the Q13 EWG;
- The MC agreed that in line with the concept of continuity outlined in section 4.2 of the Assembly RoP, the MC would recommend to the Assembly to appoint the Q13 informal Group Leader, Dr. Lee (FDA, United States) as Q13 Rapporteur;
- The MC noted that in line with the concept of continuity outlined in section 1.5.2 of the SOP of the WG, the Regulatory Chair of the Q13 informal WG, Dr. Matsuda (MHLW/PMDA, Japan), would assume the role of Regulatory Chair of the Q13 EWG.

Groups Not Meeting in Charlotte

MC Decision/Action:

- ***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 MC confirmed its support in principle for the approach of the Terminology List Management Process put forward by the M2 EWG and agreed that in the future the M2 EWG should be allowed to make minor amendments to the process without seeking MC approval.

Q4B Annexes Maintenance

The MC 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.

MC Decision/Action:

- The MC noted the proposal from the Pharmacopeial Discussion Group (PDG) for the maintenance procedure of the Q4B Annexes and supported its circulation to the Assembly for consideration;
- The MC noted that, if the proposal is approved by the Assembly, the SOP of the ICH WGs would be revised accordingly.

H. Procedural Matters

Management of ICH Working Groups Size

The MC was informed on the proposals and comments shared by MC Members ahead of the meeting regarding the future management of the size of ICH WGs.

MC Decisions/Actions:

- The MC noted the various proposals brought forward by individual MC Members for managing the size of WGs and noted that the MC Chair and Assembly Chair would further develop a new proposal reflecting current discussions, for MC consideration at one of the next teleconferences;
- The MC approved EC, Europe's request to appoint a third expert to the M11 informal Working Group;
- The MC approved APIC's request to appoint an Observer expert to the M7(R2) EWG.

ICH Assembly Rules of Procedure

MC Decision/Action:

- The MC noted that in Charlotte, the Assembly would be invited to adopt the proposed revisions to the ICH Assembly Rules of Procedure (RoP) put forward by the MC.

ICH Management Committee Rules of Procedure

MC Decisions/Actions:

- The MC noted that it had approved revisions to the ICH MC RoP at its MC Policy 2 TC, pending Assembly approval in Charlotte of the revised Assembly RoP;
- The MC approved additional minor revisions to section 9.2.1 of the MC RoP which were made for consistency with the current approved process for the selection of New Topic proposals (see also under item L), as well as additional minor revisions to section 7.2 for alignment with the current MC decision-making process (see also under item C), and supported its circulation to Assembly as part of the MC RoP v6.1.

Standard Operating Procedures for Working Groups

MC Decision/Action:

- The MC noted that it had approved revisions to the Standard Operating Procedures (SOP) for Working Groups at its MC Policy 2 TC, pending Assembly approval in Charlotte of the revised Assembly RoP.

I. Election of MC Chair and Vice Chair

MC Decision/Action:

- Dr. Mullin (FDA, United States) and Dr. Nakashima (MHLW/PMDA, Japan) were elected as MC Chair and Vice Chair, to serve for a 1-year term from the end of the Charlotte meeting.

J. Communication

The ICH Secretariat provided an overview of the update it planned to make to the ICH Assembly regarding its activities aimed at improving ICH communication with stakeholders including: planned improvements to the ICH website, maintenance of the ICH transparency policy, ICH presence on online platforms, 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 MC was also informed of the upcoming publication in the journal *Clinical Pharmacology & Therapeutics* of an article on ICH authored by the ICH Assembly Chair and ICH MC Chair.

MC Decision/Action:

- The MC supported the ICH Secretariat's planned update to the Assembly.

K. Implementation

The Leads of the Implementation Subcommittee provided an update on the Subcommittee's activities including: the terminology to be used with respect to the degrees of implementation; next steps for phase 2a of the implementation survey, as well as prioritisation of Tier 3 ICH Guidelines for implementation purposes.

MC Decisions/Actions:

- The MC approved the Work Plan of the ICH Implementation Subcommittee;
- The MC noted that in Charlotte the Assembly would be invited to approve the final definitions for the degrees of implementation;
- The MC agreed that the scope of the survey would include Tier 1 and Tier 2 ICH Guidelines, as well as Tier 3 ICH Guidelines identified as a priority in terms of the Implementation survey (M3, M8 and E17);
- The MC approved the survey questionnaire and the design notes for the Data Collection Tool (DCT), with minor amendments to ensure alignment with the ICH Procedures, as well as to clarify that responses for ICH Member EC, Europe would only relate to the Centralised Procedure;
- The MC supported the subsequent circulation to the Assembly of the survey questionnaire and design notes for the DCT for a comment period of two weeks after the Charlotte meeting, and agreed that following consideration of Assembly comments by the Implementation Subcommittee, the survey would be initiated;
- The MC noted that the results of the survey would be presented to the MC and to the Assembly at the next ICH meeting in Amsterdam in June 2019;

- The MC agreed that following completion of the Implementation Survey, a report summarizing aggregated results would be made available to the public.

L. New Topic Proposals and Strategic Discussions

New Topics Subcommittee Lead

MC Decision/Action:

- The MC appointed a co-Lead for the New Topics Subcommittee, and noted that further consideration could be given in the future on whether to appoint an additional co-Lead.

2018 New Topic proposals with a delayed start

MC Decision/Action:

- The MC 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 the call for expression of interest to nominate experts, further to which the MC will be invited to 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 MC.

2019 New Topic proposals process

MC Decisions/Actions:

- The MC noted that based on an ICH Secretariat's poll, approximately 15 New Topic proposals are currently expected for the 2019 cycle;
- The MC agreed to postpone until the end of November 2018, the decision on whether or not to hold an interim meeting to discuss New Topic proposals received;
- The MC noted that, if an interim meeting was to be held, Swissmedic, Switzerland would be able to host it in Bern or Zürich, Switzerland or EC, Europe would be able to host it in Brussels, Belgium;
- The MC agreed that, if an interim meeting was to be held, it would to be held over 2 days preferably during the week of 1 to 5 April 2019;
- The MC agreed that, if an interim meeting was to be held, it would be an interim meeting of the MC, and not of the Subcommittees, and would cover not only discussion of New Topic proposals, but also other topics to be determined, including work of other Subcommittees.

Strategic Reflection Papers

- ***Informal Quality Discussion Group (IQDG)***

The MC was updated on the revisions made to the remit document for the Informal Quality Discussion Group (IQDG) further to comments received.

MC Decisions/Actions:

- The MC approved the revised IQDG remit document;

- The MC confirmed that as a next step for the establishment of the IQDG, the Secretariat would issue a call for expression of interest to nominate experts as well as a Rapporteur and a Regulatory Chair, as per the applicable procedures;
- The MC noted that once established, the IQDG would work electronically on the drafting of its Work Plan by March 2019 and on the development of a survey of existing ICH Quality Guidelines, for presentation to the MC by June 2019;
- The MC confirmed support for publication on the ICH public website of the approved ICH Quality Reflection Paper on Advancing Pharmaceutical Quality Standards, including the updated IQDG remit.

- ***Reflection Paper: Further Opportunities for Harmonization of Standards for Generic Drugs***

The MC was informed by FDA, United States on comments received from the ICH Assembly on its Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drug*, which had been circulated to the Assembly for comments ahead of the Charlotte meeting.

MC Decisions/Actions:

- The MC endorsed the FDA, United States revised Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drugs* including minor amendments made during the meeting, and agreed that the Assembly would be invited to endorse the paper as an ICH Reflection Paper;
- The MC supported that FDA, United States also provide a short remit document for the Informal Generic Drug Discussion Group (IGDDG), which would be established for a 1-year duration on the basis of Assembly approval of the Reflection Paper and MC approval of the remit;
- The MC agreed that following Assembly endorsement of the Reflection Paper and following MC endorsement of the remit document for the IGDDG, the Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drugs* including the remit document would be published on the ICH website;
- The MC agreed on the need to further consider the respective roles of IGBA and WHO for coordination with stakeholders of the generic drugs industry and to raise awareness of Regulators worldwide, and agreed that IGBA should provide a written report to the Assembly ahead of the next meeting, in addition to provision of a presentation at the Assembly meeting in June 2019, on its process for selecting ICH experts and consulting its membership on ICH matters.

- ***Reflection Paper: 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***

The MC was informed by MHLW/PMDA, Japan on revisions made to its 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,* which had been circulated to the MC and Assembly in October 2018.

MC Decisions/Actions:

- The MC noted the revisions made by MHLW/PMDA, Japan to its 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*, including for clarification of the schedule of the proposed Discussion Group (DG);
- The MC supported that MHLW/PMDA, Japan further revise its Reflection Paper by end of November 2018 to narrow the focus of work for the DG from that proposed and include a step-wise approach;

- The MC noted that the revised Reflection Paper would be for MC tacit approval and subsequent Assembly tacit approval electronically, with the aim of initiating the work of the DG in early 2019.

- ***Draft Reflection Paper: Model Informed Drug Development (MIDD)***

MC Decision/Action:

- The MC noted that PhRMA would provide a draft Reflection Paper on Model Informed Drug Development (MIDD) for MC consideration by end of 2018.

- ***Reflection Papers Process***

The MC was informed by FDA, United States on considerations for clarification of the process for the development and endorsement of Reflection Papers as outlined in a draft flow chart.

MC Decision/Action:

- The MC agreed on the need to further review and clarify the process for the development and endorsement of Reflection Papers and noted that a revised flow chart would be provided for MC consideration at one of the next teleconferences.

Future Strategic Priorities

MC Decision/Action:

- The MC noted the ongoing development by BIO of a draft Reflection Paper on Advanced Therapies (Cell and Gene Therapies) to be shared with the MC within the March 2019 timeframe.

M. Working Groups meeting in Amsterdam

MC Decisions/Actions:

- The MC agreed to finalise the list of WGs which will meet in Amsterdam, the Netherlands in June 2019 at the latest at the Technical Topic MC teleconference (TC). This list will be made available to the Assembly and also on the ICH website following the MC TC;
- The MC supported that the list of WGs already approved in Charlotte by the MC to meet could obtain the final approval electronically, following the Coordinators TC;
- The MC supported that the E17 IWG would hold an interim meeting in the first half of 2019 (dates and locations to be determined)[1];
- The following table summarises MC preliminary considerations regarding the WGs to meet.

[1] Post-meeting note: At its TC on 30 January 2019, the ICH MC agreed to cancel the interim meeting of the E17 IWG in view of difficulties raised by a couple of ICH MC Members regarding participation, which would present an issue for the reaching of the necessary Member quorum for the meeting to proceed.

List of Current ICH Working Groups		Meeting	Not meeting	For decision at MC TC
Efficacy Groups	Standing Paediatric EWG		x	
	E2B(R3) EWG/IWG			x
	E8(R1) EWG		x	
	E9(R1) EWG	x (4 days)		
	E11A EWG	x		
	E14/S7B IWG	x		
	E17 IWG			x
	E19 EWG		x	
	E20 informal WG		x	
Multidisciplinary Groups	M1 PtC WG		x	
	M2 EWG			x
	M4Q(R1) IWG		x	
	M7(R2) EWG/IWG	x		
	M8 EWG/IWG		x	
	M9 EWG			x
	M10 EWG		x	
	M11 EWG	x (5 days)		
	M12 informal WG		x	
Quality Groups	Q3C(R8) Maintenance EWG		x	
	Q3D(R1/2) Maintenance EWG			x
	Q11 IWG		x	
	Q12 EWG	x (5 days)		
	Q2(R2)/Q14 EWG	x (4 days)		
	Q13 EWG	x (4 days)		
Safety Groups	S1(R1) EWG		x	
	S5(R3) EWG	x		
	S11 EWG			x
TOTAL		**9**	**12**	**6**

N. Any Other Business

MC Decision/Action:

- The MC named the newly elected Assembly Vice-Chair Dr. Petra Doerr (Swissmedic, Switzerland) as an additional ICH signatory, alongside existing signatories Mrs. Lenita Lindström-Gommers (EC, Europe), and Dr. Dawn Ronan, Dr. Anne Latrive and Ms. Emilie Macara (ICH Secretariat).

O. Press release

MC Decision/Action:

- The MC noted the process for the development and approval of the ICH Press release in line with the revised Assembly RoP requiring publication within one week of the ICH meeting.

P. Dates of Next meetings

Teleconferences

MC Decisions/Actions:

- The MC noted the below dates of the next teleconferences and supported that an additional date be identified end of January / beginning of February:
  - Coordinators: Tuesday 5 March 2019;
  - MC Policy: Tuesday, 12 March 2019;
  - MC Technical: Monday, 25 March 2019;
  - MC Policy: Friday, 12 April 2019;
  - MC Policy: Wednesday, 8 May 2019.
- The MC noted that the Secretariat would shortly circulate the timeline for the next cycle.

Face-to-face Meetings

MC Decisions/Actions:

- The MC noted the dates of the next face-to-face meetings:

• 1-6 June 2019	Amsterdam, The Netherlands
• 17-21 November 2019*	Singapore (to be confirmed)
• 24-28 May 2020*	The Americas (location to be confirmed)
• 15-19 November 2020*	Europe (location to be confirmed)
• 30 May-3 June 2021*	Asia (location to be confirmed)

** New schedule is implemented for meetings from November 2019 onwards, with the ICH meeting week starting on Sunday.*