9 August 2019

SUMMARY
of
MC SESSION ACTIONS AND DECISIONS

ICH Management Committee Meeting
3 - 6 June 2019, Amsterdam, the Netherlands

List of MC Participants

ICH Management Committee Member Representatives

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Milton Bonelli	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (Chair)	FDA, United States
Ms. Joan Blair	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Dr. Léo Bouthilier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Prof. Cheng Leng Chan	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Kyung Won Seo	MFDS, Republic of Korea
Dr. Young-Ok Kim	MFDS, Republic of Korea
Dr. Nobumasa Nakashima (Vice-Chair)	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Junko Sato	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Dr. Peter K. Honig	PhRMA
Ms. Camille Jackson	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH Assembly Member Representative:

Dr. Bruno Sepodes	EC, Europe

ICH Management Committee Standing Observers Delegates:

Dr. David Jefferys	IFPMA
Dr. Sharon Olmstead	IFPMA
Ms. Emer Cooke	WHO
Ms. Gabriela Zenhaeusern	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
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Ryo Iwase	MHLW/PMDA, Japan
Dr. Yang Wang	NMPA, China
Ms. Camille Jackson	PhRMA
Ms. Anna Sieg	Swissmedic, Switzerland

ICH Management Committee Technical Coordinators:

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

ICH Management Committee Additional Participants:

Mrs. Agnès Saint-Raymond	EC, Europe
Dr. Peter Bachmann	EC, Europe
Ms. Machiko Sumi	JPMA
Ms. Erina Yamada	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Mr. Jerry Stewart	PhRMA

ICH Secretariat:

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

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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 final version of the MC minutes from the Charlotte meeting held in November 2018, dated 5 February 2019;
- The MC noted the final version of the MC minutes from the MC interim meeting held in Brussels in April 2019, dated 16 April 2019;
- The MC noted the Report of the Coordinators teleconference which was held on 5 March 2019, dated 28 March 2019;
- The MC noted the final version of the Report of the MC Technical teleconference held on 25 March 2019, dated 16 April 2019;
- The MC noted the final version of the Report of the MC Policy 1 teleconference held on 30 January 2019, dated 5 March 2019;
- The MC noted the final version of the Report of the MC Policy 2 teleconference held on 12 March 2019, dated 15 April 2019;
- The MC noted the final version of the Report of the MC Policy 3 teleconference held on 12 April 2019, dated 25 April 2019;
- The MC adopted as final the final version of the Report of the MC Policy 4 teleconference held on 8 May 2019, dated 22 May 2019.

B. ICH Membership and Observership Applications

The ICH Secretariat noted the Observership applications received from ANMAT, Argentina; CPED, Israel; JFDA, Jordan; and SFDA, Saudi Arabia.

MC Decision/Action:

- The MC agreed to recommend the following Observership applications to the Assembly for approval:
    - ANMAT, Argentina, noting that as they are member of an RHI which is also an ICH Observer, they are expected to apply for ICH Membership as soon as they meet the eligibility criteria;
    - CPED, Israel;
    - JFDA, Jordan;

- SFDA, Saudi Arabia, noting that as they are member of an RHI which is also an ICH Observer, they are expected to apply for ICH Membership as soon as they meet the eligibility criteria.

C. Financial Matters

The ICH Secretariat provided an update on ICH financial matters including: update on 2018 expense reports and current budget situation; 2018 Financial Audit; 5-Year ICH Budget Plan (2020-2024) and management of ICH funds.

MC Decisions/Actions:

- The MC agreed to recommend a revised 2020 budget to the ICH Assembly in Amsterdam;
- The MC agreed on the need to establish a sustainable model for ICH funding, where expenses are covered by income, and agreed that further consideration should be given to mechanisms such as increasing membership fees and adding a participation fee for meeting participants from ICH Observers;
- The MC supported that Regulatory and Industry Members discuss within their organisation whether a doubling of the membership fee from CHF 20,000 to CHF 40,000 could be accommodated and report to the MC ahead of the next meeting;
- The MC agreed to continue its discussion on the strategic use of surplus funds with the intention of putting forward a more definitive plan for adoption by the ICH Assembly at the next meeting in November 2019 at the latest;
- The MC noted that the MedDRA MC was also in the process of reviewing the 5-year MedDRA strategic plan, particularly in view of the need to support a growing subscriber base, and would be presenting a revised 2019 budget by September to the ICH MC for support for submission to the Assembly for approval, in addition to a revised 2020 budget and updated 5-year budget plan which will then be for Assembly consideration in Singapore in November 2019;
- The MC agreed that active coordination is necessary between the ICH MC and MedDRA MC for the management of ICH funds and that the ICH Secretariat will support these interactions. It was also noted that the new meeting schedule that will be implemented from the Singapore meeting onwards will facilitate the reporting from the MedDRA MC to the Assembly.

D. Training

General

The Lead of the Training Subcommittee provided an update on the Subcommittee's activities since the ICH meeting in Charlotte, NC, USA in November 2018, including on: the status of the requests received from training providers for ICH's approval of training programmes as "ICH Recognised Training Programmes"; the development of online training programmes; support provided to the ICH WGs developing training materials: E9(R1), E17, Q11; and considerations on the publication of training videos developed by ICH WGs.

MC Decisions/Actions:

- The MC noted that an ICH YouTube channel will be created in June 2019 and maintained by the ICH Secretariat to share high resolution ICH Training videos, and that the ICH website would provide links to the videos on YouTube as well as downloadable lower-resolution versions of the videos and PDF versions;
- The MC noted that the above approach will be applied to the Q11 Training video recently finalised by the Q11 IWG.

ICH Training Associates

The MC was updated by the ICH Secretariat on the conduct of the Call for Expression of Interest issued by ICH in April 2019 for ICH Training Associates, aimed at exploring the possibility of contracting appropriate accredited non-profit training organisations/institutions to assist ICH in its efforts to address in a strategic manner the training needs of its Regulatory and Industry Members and Observers. The MC noted that 11 organisations had responded to the call, and that a Review Committee had conducted an anonymised assessment of the applications, based on the eligibility criteria and applicants' ability to meet the statement of work.

MC Decisions/Actions:

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

E. General Operational Matters

The ICH Secretariat provided a report to the MC on: Secretariat staffing; new tasks undertaken by the ICH Secretariat related to ICH and MedDRA activities and support of the growth of ICH; status of the Trademark registration of the ICH logo; considerations for IT support to be provided to the WGs; considerations on the process for responding to technical questions on ICH Guidelines received through the ICH Admin email Box; 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 ICH Secretariat staffing and the allocation of support between ICH, MedDRA and IPRP activities;
- The MC agreed to further reflect on the efficient use of ICH Secretariat resources in the management of the day-to-day operations of the ICH Association and that approaches for improvement would be further considered by the MC;

- The MC noted the status of the registration of the ICH device (logo) Trademark (TM) 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.

WGs IT support

MC Decisions/Actions:

- The MC noted that, as an outcome of the pilot programme to provide the use to a small number of WGs of SharePoint and of the survey amongst WGs to determine their satisfaction with the current IT platform, SharePoint can provide collaborative features important for the WG work, which the current ICH "Groups" platform cannot provide;
- The MC agreed that providing the same IT platform to all WGs would be more efficient in terms of cost and Secretariat administration and that a SharePoint platform would be provided to all WGs in the future;
- The MC agreed that before expanding use of the online SharePoint platform beyond the pilot WGs, the ICH Secretariat should further explore the possibility of setting-up a dedicated SharePoint Server and report to the MC on associated costs and resource constraints as well as on security considerations;
- The MC agreed on the following transition plan to be implemented once the option for the online versus server-based SharePoint platform will be confirmed:
    - New WGs and WGs involved in the pilot will use SharePoint;
    - Current WGs can choose either to finalise their work using the Groups platform for continuity of their activities, or transition to SharePoint upon request;
    - WGs with ongoing mandate (E2B, M2, M8, M1, Q3C, Q3D, M7, Standing Paediatric) will transition to SharePoint upon request and not later than by end 2020.
- The MC agreed that following this transition period, the ICH Groups platform would be shutdown.

Participation of experts in ICH WGs

MC Decisions/Actions:

- The MC noted the level of participation of current Members and Observers in ICH and the growth of ICH in terms of Membership/Observership, number of WGs and number of experts;
- The MC supported that that moving forward, the attendance lists maintained by the Rapporteurs should be made available to the Coordinators;
- The MC supported that on the basis of the attendance lists collected by the Secretariat for January 2019 to May 2019, the Secretariat follow up with the Member Coordinators and Observer Delegates who had experts missing two consecutive teleconferences;
- The MC agreed that the ICH Coordinators are responsible for the management of their respective expert delegations and supported that moving forward the Rapporteurs/Regulatory Chairs should liaise directly with their respective Coordinators to follow-up with other Coordinators and Observer delegates concerning any experts which are not actively participating in the WG, and that in support of this the ICH Secretariat would circulate, as a reminder, the contact details of the Coordinators and Observer Delegates;
- The MC noted that the ICH procedures would be amended to reflect the new process on expert attendance to WGs;
- The MC noted that as per the current procedures, experts who are not participating actively in the WGs may lose their seat in the WG.

Process for Admin Box

MC Decision/Action:

- The MC agreed on the process for responding to technical questions on ICH Guidelines received through the ICH Admin mailbox in an efficient manner, in which:
    - Technical questions from regulatory authorities will be addressed on a case-by-case basis in coordination with ICH Coordinators of the relevant Regulatory Members;
    - Non-Regulatory authorities would be invited to address their technical questions on ICH Guidelines directly to the relevant authority(ies) and the contact address (URL or email address, as appropriate) of the relevant ICH Regulatory Member websites will be indicated on the ICH website on the ICH Contact page;
    - Technical questions from non-regulatory authorities which are clearly in the scope of an active WG would be forwarded to the Coordinator of the Member who holds the Rapporteurship for their consideration on a response to the question and also whether the question should be shared with the Rapporteur for further consideration by the WG.

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

F. Meetings

The ICH Secretariat provided an update on the organisation of ICH meetings in Singapore in November 2019, in Vancouver, Canada in May 2020, in Europe in November 2020, and in Asia in June 2021, as well as on the model for the organisation of ICH meeting and associated financial risks.

Organisation of 2019, 2020 and 2021 Meetings

MC Decisions/Actions:

- The MC noted the process for organisation of ICH meetings with ICH's Professional Conference Organiser (PCO), including signing by the PCO of meeting related contracts (e.g., venue, insurance, AV, translators etc…), with the ICH Secretariat's approval, and that as part of the payment schedule many payments/deposits are made by ICH to the PCO immediately upon signing, some one or two years in advance of the meeting;
- The MC noted that organisation of the November 2019 meeting in Singapore is on track and that 15 meeting rooms will be available for WGs;
- Based on the preference expressed by the majority of Members, the MC agreed that for the November 2020 meeting, the PCO should engage in contract negotiations with the most suitable venue. Exceptionally, the other possibility can be kept, if possible, as a fall-back option should there be any unexpected issue with contract negotiation;
- The MC noted that the PCO had begun the search for venues for the June 2021 meeting in Asia and that several venues have already been put on hold in Japan with the PCO to continue their search

over the summer in other Asian ICH Member countries, to propose a final selection to the MC at a forthcoming TC on venues which best meet ICH meeting requirements.

Designation of 2020 & 2021 Meeting Dates

MC Decisions/Actions:

- The MC agreed on the following dates for the November 2021 meeting in the Americas:
  - Sunday 14 November to Thursday 18 November 2021;
- The MC agreed to hold an MC interim meeting in 2020 and on the following dates:
  - Wednesday 11 March and Thursday 12 March 2020.
- The MC moreover agreed that the ICH Secretariat already proceed to book the venue for the MC interim meeting which it agreed be held in Geneva, Switzerland.

Meeting model

MC Decisions/Actions:

- The MC noted that as part of the current ICH model, ICH books a block of guestrooms at a venue, which includes a financial risk for ICH as ICH commits to guarantee payment for a number of bedrooms;
- The MC supported that, in order to help Members/Observers with logistical preparations for their participants and to obtain better booking conditions for ICH, the MC would aim to take a decision on the majority of WG meetings at the end of each preceding face-to-face meeting, for meetings from November 2019 onwards.

G. 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: progress made on improvements to the ICH website and future planned improvements, and use of the ICH Member logo. The MC was further informed on preparations for the commemoration in 2020 of ICH's 30th Anniversary which was being led by an Organising Committee.

MC Decisions/Actions:

- The MC noted the Secretariat's planned upgrade of the ICH private platform and that a call would be sent out to MC Members to collect any input and suggestions on improvements to be made;
- The MC noted that the ICH public website will be migrated to a new Content Management System in June/July 2019;
- The MC supported that the Members of the Assembly also be invited to appoint representatives to the Organising Committee;
- The MC supported that the Organising Committee convene with the ICH Secretariat via teleconference shortly after the ICH meeting in Amsterdam to prepare the commemoration of ICH's 30th Anniversary, with a focus on the organisation of an ICH event, possibly in the margins of/back-to-back with another event, or following the November 2020 ICH meeting. The Organising Committee would furthermore look into the development of a video and publication to include interviews with key actors in ICH History and new Members, possibly leveraging the ICH event at which interviews could be conducted;

H. Procedural Matters

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

ICH Articles of Association and Assembly Rules of Procedure

MC Decision/Action:

- The MC noted that in Amsterdam, the Assembly adopted the proposed revisions to the Articles of Association (AoA) and Assembly Rules of Procedure (RoP) put forward by the MC.

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

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

MC Decision/Action:

- The MC approved revisions to the ICH MC RoP and to the Standard Operating Procedures (SOP) for Working Groups (WGs), including changes impacting the management of the size of WGs, the amendments to align procedures with the definitions of the degrees of implementation approved by the Assembly at the ICH 2018 November meeting in Charlotte, NC, USA, and clarifications including on ICH cooperation with other organisations.

MedDRA Management Committee Rules of Procedure

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

MC Decision/Action:

- The MC noted the revisions to the MedDRA MC RoP approved by the MedDRA MC at its meeting in Amsterdam, including for efficiency of MedDRA MC operations and for clarification of the respective roles of the Assembly, the MedDRA MC and the ICH MC regarding cooperation with other organisations.

Process for Reflection Papers

The MC was updated on a proposal from FDA, United States to structure the process for development of Reflection Papers as part of a multi-year strategic plan of near and long-term planning for ICH topics, to reflect more linkage to the new topic selection process, and inclusion of a pre-Reflection Paper discussion step to ensure MC input prior to initiation of Reflection Paper development.

MC Decision/Action:

- The MC supported the proposal to structure the process for development of Reflection Papers as part of a multi-year strategic plan of near and long-term planning for ICH Topics, and that work would be undertaken by FDA, United States with the ICH Secretariat to put forward a proposal for amendment of the relevant procedures based on the process discussed in Amsterdam.

General Principles for Discussion Groups

The MC was updated on a proposal from FDA, United States for general principles regarding procedures for establishing and managing ICH Discussion Groups (DGs), including on development of clear remits which would specify specific tasks and timelines for each DG.

MC Decisions/Actions:

- The MC agreed with minor amendments on the proposal for general principles for DGs including on the principle for the DG to operate through email and teleconferences, that the MC would review the number of DGs operating at a given time to ensure appropriate capacity for oversight, and that up to 2 experts per Member may be appointed and up to 1 expert plus 1 alternate per Observer;
- The MC supported that work would be undertaken by FDA, United States with the ICH Secretariat to develop some proposed revisions to the applicable procedures;
- The MC supported that these principles would be applied for DGs established from June 2019 onwards, including the PEpiDG (see also item K: New Topic Proposals and Strategic Discussions).

I. Implementation

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

MC Decisions/Actions:

- The MC noted the outcome of the implementation survey conducted in ICH Regulatory Member and Observer countries/regions;
- The MC supported recommending to the Assembly the 2019 Communication Plan of the survey results, by which:
    - A white paper on the outcome of the survey would be prepared in cooperation with the independent third party engaged by ICH to conduct the survey during the second half of 2019;
    - The data would be presented in aggregated form, grouping Founding and Standing Regulatory Members; Regulatory Members; and Regulatory Observers;
    - Individual Regulatory Members and Observers which decide to publish their data separately should inform the MC on when and where the publication is done. Furthermore, such publications should not make reference to other individual Regulatory Member and Observer results, but could include statements relative to the ICH publication on the survey, in view of which communication by individual Regulatory Members and Observers should only take place after the ICH communication;
    - A publication in a peer-reviewed journal may be considered at a later stage.
- The MC supported that in view of the successful accomplishment of the Implementation Subcommittee mandate, the Subcommittee would be disbanded;

- The MC supported the appointment of Implementation co-Leads, one from a Regulatory and one from an Industry Member, to further consider future mandate and communication activities, 2020 budget for implementation activities, and an implementation work plan, with the support of the ICH Secretariat to continue activities to support implementation of ICH Guidelines;

J. Oversight of Working Groups

Groups Meeting in Amsterdam

- ***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 was informed by the M2 Co-Rapporteurs on the progress made by the EWG on the White Paper titled "HL7 Fast Healthcare Interoperability Resources (FHIR) Considerations for ICH" , and on the outcome of the meeting in Amsterdam with HL7's Chief Technical Officer.

MC Decisions/Actions:

- The MC requested that the updated FHIR White Paper including taking consideration of pros and cons of both FHIR and HL7 v3 would be submitted to the MC shortly after the ICH meeting in Amsterdam;
- The MC supported that a subgroup composed of experts from the M2 EWG and M8 EWG/IWG work together to provide a recommendation well in advance of the ICH November 2019 meeting in Singapore to determine next steps for eCTD v4 and FHIR standards.

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

The MC was informed by the FDA, United States E8(R1) EWG Topic Leader and by the E8(R1) EWG Regulatory Chair on the WG's considerations regarding the planning of the ICH E8(R1) public stakeholder meeting, as per the GCP renovation plan, scheduled for 31 October 2019 at the headquarters of FDA, United States.

The MC was further informed on next steps for the organisation of the ICH E8(R1) public stakeholder meeting.

MC Decisions/Actions:

- The MC noted that while this meeting was being organised as an ICH meeting, targeted at global stakeholders, the MC Regulatory Members are also invited to hold ICH E8(R1) public stakeholder meetings in their countries/regions as per the GCP renovation plan, with the MC already updated on one such meeting planned in Tokyo, Japan on 25 July 2019;
- The MC supported the establishment of a Planning Subcommittee to work with the E8(R1) EWG towards the organisation of the ICH E8(R1) public stakeholder meeting, which will hold its first teleconference on 19 June 2019;
- The MC agreed that the Planning Subcommittee would be responsible for the approval of the final agenda of the meeting, identification of speakers and panellists, identification of invited participants, development of communications strategy, approval of meeting/presentation materials, and any logistical aspects of organisation.

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

MC Decision/Action:

- The MC approved that in view of the Q3D(R2) Maintenance EWG meeting in Amsterdam only from the last day of the ICH Assembly meeting, in the interest of time, the WG would provide a written report on the outcome of their meeting instead of an oral report to the ICH Assembly.

Groups Not Meeting in Amsterdam

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

MC Decisions/Actions:

- The MC noted that in view of recent archival searches related to the Permissible Daily Exposure (PDE) for ethyleneglycol, the Q3C(R8) Maintenance EWG supported the reinstitution of the PDE for ethyleneglycol of 6.2 mg/day (620 ppm) and the update of the Appendix 5 monograph to reflect the correct PDE. To ensure consistent communication at global level, the EWG is to provide a cover statement to the ICH secretariat to explain the error correction.[1]

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

MC Decision/Action:

- The MC agreed that the IGDG should further revise their work plan to prioritise the discussion on the New Topic proposal on Bioequivalence for Immediate-Release Solid Oral Dosage Forms and the review of existing WHO and regional guidelines, publications from IPRP and the Global Bioequivalence Harmonization Initiative (GBHI) related to standards for generic drugs, as well as to review the timeline.

- ***E20 informal Working Group: Adaptive Clinical Trials (Leader: PhRMA representative to be confirmed; Regulatory Chair: Dr. Levin - FDA, United States)***

MC Decision/Action:

- The MC supported the establishment of the E20 informal WG, including requests for nomination from Industry Members and Observers.

- ***M12 informal Working Group: Drug Interaction Studies (Leader: Dr. Madabushi - FDA, United States; Regulatory Chair: Dr. Ishiguro - MHLW/PMDA, Japan)***

MC Decision/Action:

- The MC supported the establishment of the M12 informal WG, including requests to nominate experts from Industry Member IGBA and Observer CIOMS.

[1] Post-meeting note: With the correction of the error, the previous Q3C(R6) version will be reinstated, with the history box and cover statement to explain why Q3(R7) reverted to Q3R(R6). Furthermore, the EWG's current work to develop PDE levels for three solvents: 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol will continue under the code Q3C(R8).

Experts nomination requests

MC Decision/Action:

- The MC reviewed and approved requests received from ICH Members to nominate Deputy Topic Leaders as well as requests from Observers for new Observer experts on several Working Groups.

Plenary Working Parties

MC Decision/Action:

- The MC postponed the discussion on the establishment of Plenary Working Parties for current WGs.

K. New Topic Proposals and Strategic Discussions

2018 New Topic proposals with a delayed start

MC Decisions/Actions:

- The MC supported that, as agreed in November 2018, both E20 and M12 informal WGs would initiate work in June 2019.

2019 New Topic proposals process

The Lead of the New Topic Subcommittee informed the MC on the feedback received from: the IQDG on proposals #1 (Revision of ICH Q5A), #3 (Extractables and Leachables) and #4 (Revision of ICH Q9); the IGDG on proposal #12 (Bioequivalence for Immediate-Release Solid Oral Dosage Forms); and MC Industry parties on proposal #14 (Biodistribution Studies for Gene Therapy Products).

MC Decisions/Actions:

- The MC agreed that, in view of the feedback provided, the following assessment would be shared with the Assembly:
  - #1 (Revision of ICH Q5A: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin): general support from the MC;
  - #6 (Revision of ICH E6(R2): Good Clinical Practice): general support from the MC;
  - #8 (Revision of ICH E2D Post-Approval Safety Data Management): general support from the MC;
  - #14 (Biodistribution Studies for Gene Therapy Products): general support from the MC;
  - #3 (Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics): general support from the MC, with a delayed starting timeframe;
  - #12 (Bioequivalence for Immediate-Release Solid Oral Dosage Forms): need for further discussion by the IGDG for the development of a Concept Paper Outline for Assembly consideration at the November 2019 meeting;
  - #4 (ICH Q9: Quality Risk Management – revision or development of Q&As to be further considered): need for additional work for development of a Concept Paper Outline for Assembly consideration at the November 2019 meeting;
  - Other topics are not supported by the MC.
- The MC agreed that the 2020 New Topics process would begin earlier than the previous year in view of the MC interim meeting, when any proposals would be discussed, being held earlier in 2020.

Strategic Reflection Papers

- ***Draft ICH 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***

MC Decision/Action:

- The MC noted that the revised 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 as a Draft ICH Reflection Paper ahead of the meeting for consideration for endorsement in Amsterdam and establishment of the Pharmacoepidemiology Discussion Group (PEpiDG).

- ***Revised draft PhRMA Reflection Paper: Model Informed Drug Development (MIDD)***

The MC was informed by PhRMA on revisions made to their draft Reflection Paper on MIDD and considerations on alternative approaches to the establishment of a Discussion Group to discuss further their draft Reflection Paper seeking input from relevant MC parties.

MC Decision/Action:

- The MC agreed that PhRMA would send a call for interested MC parties to join ad-hoc calls to advance this topic further.

- ***Draft Reflection Paper: Patient-Focused Drug Development***

MC Decision/Action:

- The MC noted that FDA, United States and EC, Europe would further share a draft Reflection Paper on Patient-Focused Drug Development with the MC in the second half of 2019 timeframe.

Strategic Framework

The MC was informed on a proposal for a multi-year strategic plan of near and long-term planning for ICH topics.

MC Decision/Action:

- The MC generally supported the proposed structure of the framework and agreed to further discuss at the meeting in Singapore, the topic areas to populate strategic framework to serve as an internal planning tool to help ICH identify near and long-term priorities in each topic.

ICH and WHO

MC Decision/Action:

- The MC postponed the discussion on the areas of work and complementarities of ICH and WHO which should be considered in ICH Guideline development to the next meeting.

L. Working Groups meeting in Singapore in November 2019

MC Decisions/Actions:

- The MC agreed on 15 WGs which will meet in Singapore in November 2019. The MC supported that the list will be made available to the Assembly and also on the ICH website following the meeting and noted that the ICH Secretariat will send shortly registration information for Singapore to support the making of travel arrangements by participants to the meeting;

- The MC noted that E8(R1) EWG and M2 EWG had also requested to meet in Singapore and agreed to further consider approval of these requests electronically after the meeting once the ICH Secretariat has confirmed whether there would be additional meeting rooms available at the venue or in a hotel nearby;
- The MC also recalled that WGs should as a general rule not hold interim meetings as they entail additional costs which are not foreseen in the annual budget planning.
- The following table summarises MC decisions regarding the WGs to meet.

List of Current ICH Working Groups		Meeting	Not meeting	To be confirmed after the meeting
Efficacy Groups	Standing Paediatric EWG		X	
	E2B(R3) EWG/IWG		X	
	E8(R1) EWG			X (5 days)
	E9(R1) EWG		X	
	E11A EWG	X (5 days)		
	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) Maint. EWG/IWG		X	
	M8 EWG/IWG		X	
	M9 EWG		X	
	M10 EWG	X		
	M11 EWG	X		
	M12 informal WG	X		
Quality Groups	Q3C(R8) Maint. EWG		X	
	Q3D(R2) Maint. EWG		X	
	Q12 EWG	X (5 days)		
	Q2(R2)/Q14 EWG	X		
	Q13 EWG	X		
Safety Groups	S1(R1) EWG	X		
	S5(R3) EWG		X	
	S11 EWG		X	
Discussion Groups	IGDG		X	

List of Current ICH Working Groups		Meeting	Not meeting	To be confirmed after the meeting
	IQDG		X	
New Topics	Q5A(R2)	X		
	E6(R3)	X		
	E2D(R1)	X		
	S12	X		
TOTAL		**15**	**15**	**2**

M. Press release

MC Decision/Action:

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

N. Dates of Next meetings

Teleconferences

MC Decisions/Actions:

- The MC noted the below dates of the next teleconferences:
  - Policy 1: 10 September 2019;
  - Policy 2: 7 October 2019;
  - Policy 3: 23 October 2019;
  - Technical: 13 September 2019;
  - Coordinators (for information): 3 September 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 that the new schedule for ICH week is implemented for meetings from November 2019 onwards, with the ICH MC and MedDRA MC to meet on Sunday and Monday, and the ICH Assembly to meet on Tuesday and Wednesday; additionally the Coordinators meeting will be held on Saturday evening and WGs meeting for 4(5) days will meet from Sunday (Saturday) to Wednesday;
- The MC noted the dates of the next face-to-face meetings:
  - Saturday 16 – Wednesday 20 November 2019 Singapore
  - Saturday 23 - Wednesday 27 May 2020 Vancouver, Canada
  - Saturday 14 - Wednesday 18 November 2020 Athens, Greece (definitive confirmation pending)
  - Saturday 29 May – Wednesday 2 June 2021 Asia (location to be confirmed)
  - Saturday 13 - Wednesday 17 November 2021 The Americas (location to be confirmed)