10 February 2020

SUMMARY
of
MC SESSION ACTIONS AND DECISIONS

ICH Management Committee Meeting
17-20 November 2019, Singapore

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

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List of MC Participants

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Ms. Lila Feisee	BIO
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Dr. Milton Bonelli	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Susan Forda	EFPIA
Ms. Joan Blair	FDA, United States
Dr. Theresa Mullin (Chair)	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Dr. Léo Bouthilier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Ms. Jessica Teo	HSA, Singapore
Ms. Beata Stepniewska	IGBA
Dr. Nick Cappuccino	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Kyung Won Seo	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. Sheng Yang	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Ms. Camille Jackson	PhRMA
Dr. Peter K. Honig	PhRMA
Dr. Jörg Schläpfer	Swissmedic, Switzerland

ICH Assembly Member Representative:

Dr. Harald Enzmann	EC, Europe
Mr. Richard Moscicki	PhRMA

ICH Management Committee Standing Observers Delegates:

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Dr. Sharon Olmstead	IFPMA
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ICH Management Committee Coordinators:

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Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Ms. Chua Siew Wei	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
Dr. Manabu Yanagisawa	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Ryo Iwase	MHLW/PMDA, Japan
Dr. Yang Wang	NMPA, China
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Dr. Gabriela Zenhäusern	Swissmedic, Switzerland

ICH Management Committee Technical Coordinators:

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Dr. Michelle Limoli	FDA, United States
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

ICH Management Committee Additional Participants:

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Dr. Peter Bachmann	EC, Europe
Dr. Clare Louise Rodrigues	HSA, Singapore
Ms. Machiko Sumi	JPMA
Mr. Tsuyoshi Kobayashi	JPMA
Ms. Eunkyoung Lee	MFDS, Republic of Korea
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Ms. Le Shi	NMPA, China
Mr. Jerry Stewart	PhRMA

ICH Secretariat:

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

Table of Content

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 Action/Decision:

- The MC adopted the agenda without any modification.

A. Adoption of Reports of the Previous Teleconferences

MC Actions/Decisions:

- The MC noted the final version of the MC minutes from the Amsterdam meeting held in June 2019, dated 9 August 2019;
- The MC noted the Report of the Coordinators teleconference which was held on 3 September 2019, dated 1 October 2019;
- The MC noted the final version of the Report of the MC Technical teleconference held on 13 September 2019, dated 8 November 2019;
- The MC noted the final version of the Report of the MC Policy 1 teleconference held on 10 September 2019, dated 1 October 2019;
- The MC noted the final version of the Report of the MC Policy 2 teleconference held on 7 October 2019 2019, dated 24 October 2019;
- The MC noted the final version of the Report of the MC Policy 3 teleconference held on 23 October 2019, dated 6 November 2019.

B. ICH Membership and Observership Applications

The ICH Secretariat informed the MC on the status of ICH Membership and Observership applications.

MC Action/Decision:

- The MC noted that since the meeting in Amsterdam in June 2019, the Secretariat received two applications which did not meet the eligibility criteria, as one application was for an individual company and the other was for an individual person, and that in line with the ICH procedures, the applicants were directly informed by the ICH Secretariat that their applications did not meet the eligibility criteria

C. Meetings

The ICH Secretariat provided an update on the organisation of next ICH meetings in Vancouver, Canada in May 2020, in Athens, Greece in November 2020, and in Incheon, Republic of Korea in June 2021, as well as on organisation of future ICH meetings in 2022 and beyond and on contract with the PCO.

Organisation of Next Meetings

MC Actions/Decisions:

- The MC noted that the ICH meeting in June 2019 in Amsterdam, the Netherlands had been the largest ICH biannual meeting in ICH history with close to 500 participants and had come in under budget;
- The MC agreed that for the organisation of the ICH MC interim meeting in March 2020 in Brussels, Belgium, the Secretariat would go ahead with instructing the PCO to book the preferred venue fulfilling ICH needs and costs requirements;
- The MC noted that the organisation of next meetings is on track, including that the contract had been signed with the November 2020 meeting venue in Athens, Greece which will also host the ICH 30th Anniversary event on Saturday, 14 November 2020 to be preceded by a reception on Friday, 13 November in place of the usual ICH week reception;
- The MC noted that a decision on the location for the November 2021 meeting in the Americas will be taken by the MC at an upcoming teleconference in early 2020;
- The MC agreed on the following dates as possible options for the May/June 2022 meeting to be held in Europe:
    - Option A: From Saturday 21 May to Wednesday 25 May;
    - Option B: From Saturday 11 June to Wednesday 15 June.

PCO Support of ICH Meetings

MC Actions/Decisions:

- The MC noted the status of the ICH Secretariat's support for the organisation of meetings and that an important part of the Secretariat's time had been invested to train the PCO to fully understand ICH meeting requirements, meaning that time for Secretariat support was expected to decrease in subsequent years of work with the same PCO;
- The MC noted that to-date the current PCO had supported the selection of venues for 5 ICH meetings (June 2019 – June 2021) and the logistical organisation of 1 complete meeting (June 2019), and had also covered additional projects such as the ICH 30th Anniversary event;
- The MC noted the current PCO's offer for renewal of the contract for 2022 meetings;
- In view of the above, the MC agreed to renew the contract with the current PCO as per the contract's renewal clause for one additional year (i.e., organisation of May/June and November 2022 ICH meetings);
- The MC noted that it would be invited to take a decision in November 2020 on the contracting of a PCO for the organisation of ICH meetings from 2023 and beyond;
- The MC supported that a call for tenders would be conducted by the Secretariat to receive offers for the organisation of ICH meetings from 2023 and beyond, which may also include an offer from the current PCO;
- The MC agreed that, in the current model for selection of ICH meeting locations, options should also be considered where some Working Group (WG) meeting rooms would be in a separate nearby venue within walking distance from the main ICH meeting location;
- The MC agreed that it would further discuss the model and process for selection of ICH meeting locations, including considerations for going back to the same venue(s) and any consultation with/ support from ICH MC Members in the shortlisting of venues in their countries/regions.

D. General Operational Matters

ICH General Operational Matters

The ICH Secretariat provided a report to the MC on: overview of participation of ICH Members and Observers in ICH Assembly and WGs, follow-up on participation of experts in WGs, status of ICH trademarks, status of work on the websites/database project, use of webconference system, and ICH Secretariat operational changes in 2019-to-date to increase efficiency.

MC Action/Decision:

- The MC noted the written report of the ICH Secretariat.

E. New Topic Proposals and Strategic Discussions

The MC was informed by the Co-Lead of the New Topic Subcommittee on pending items from the 2019 New Topic process, including: the Concept Paper outline on the revision of ICH Q9: *Quality Risk Management*; the revised New Topic proposal and Concept Paper outline on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*; and timeframe for initiation of work on the New Topic approved in June 2019 on *Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics*.

2019 New Topic proposals

MC Actions/Decisions:

- The MC noted that the Concept Paper outline on the revision of ICH Q9: *Quality Risk Management* and the revised New Topic proposal and Concept Paper outline on *Bioequivalence for Immediate-Release Solid Oral Dosage Forms* had been submitted to the Assembly for approval in Singapore;
- The MC agreed that, if supported by the Assembly, a M13 informal WG would be established shortly after the meeting on the topic of *Bioequivalence for Immediate-Release Solid Oral Dosage Forms*;
- The MC agreed that a Q3E informal WG would be established shortly after the meeting on the topic of *Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics* which had been approved in Amsterdam in June 2019;
- The MC agreed that in view of concerns expressed by a MC Member on resource constraints in the quality area that the starting time for the Q9(R1) topic would be delayed and further determined by the MC at a later point, with the aim of establishing an informal WG at the latest by November 2020.

2020 New Topic proposals process

The MC was informed by the Co-Lead of the New Topic Subcommittee on the 2020 New Topic proposals process.

MC Actions/Decisions:

- The MC noted that the deadline for submission of New Topic proposals by Assembly Members and Observers is 13 December 2019 and that teleconferences of the New Topics Subcommittee would be scheduled shortly by the Secretariat to take place in the second half of January/early February 2020;
- The MC agreed that any New Topic proposals received on Quality topics would be redirected by the MC to the Quality Discussion Group which would review the topics as per its remit and report to the MC with a recommendation for the 2021 New Topic process;

- The MC noted that at least 10 New Topic proposals are expected to be submitted as part of the 2020 New Topic process;
- The MC noted that it will review the New Topic proposals at its interim meeting in March 2020, including to ensure they are in line with the scope of ICH, in order to share an assessment with the Assembly in April 2020.

Reflection Papers

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

The MC was updated on the status of work on the revision of the PhRMA Reflection Paper on *Model-Informed Drug Development* (MIDD).

MC Action/Decision:

- The MC noted that an informal group of MC Members, with PhRMA as lead, would further discuss the draft Reflection Paper on MIDD, with a view to providing a revised draft for MC consideration by March 2020.

- ***Draft Reflection Paper: Patient-Focused Drug Development (PFDD)***

The MC was updated on the status of development of a draft Reflection Paper on *Patient-Focused Drug Development* (PFDD).

MC Actions/Decisions:

- The MC noted that MC Members are invited to provide comments by mid-January 2020 on the draft Reflection Paper on PFDD developed by FDA, United States and EC, Europe;
- The MC agreed that the Assembly would be informed in Singapore on the work being undertaken in this area and that a Reflection Paper, including a stakeholder engagement plan, may be submitted at a later stage.

- ***Draft BIO proposal for Reflection Paper: Strategic Approach to Gene Therapy Harmonization***

The MC was informed on a BIO proposal to develop a Reflection Paper on *Strategic Approach to Gene Therapy Harmonization*.

MC Actions/Decisions:

- The MC noted the proposal brought forward by BIO on a *Strategic Approach to Gene Therapy Harmonization* and comments provided by some MC Members concerning its scope which should be well defined to fit within ICH scope of harmonisation of scientific and technical requirements;
- The MC agreed to keep this topic on hold for possibly one year in view of expertise currently available within MC Members, during which time BIO could consider the development of any associated topic proposals.

Strategic Framework

The MC was informed on the strategic framework internal planning tool designed to help ICH identify near and long-term priorities in each topic.

MC Actions/Decisions:

- The MC supported the use of the strategic framework as a useful planning tool to provide an overview of strategic areas on Quality (Q), Safety (S), Efficacy (E) and/or Multidisciplinary (M) topics;
- The MC agreed that only already agreed-upon topics should be included so that work would not be duplicated with the work of the New Topic Subcommittee in the review of New Topics;
- The MC agreed that this tool would be used to assess only topics in the Q, S, E and M areas (and related reflection papers if applicable) and not other ICH activities such as implementation and training, so that work would not be duplicated with the priorities listed in the ICH Association work plan and multi-annual strategic plan;
- The MC agreed that needs and priorities for training activities could be identified as a separate exercise;
- The MC agreed that topics should be categorised as either short-term or long-term priorities;
- The MC noted that a revised version of the strategic framework incorporating the above comments would be shared with the MC ahead of a next teleconference;
- The MC supported that going forward the strategic framework would be maintained by the Secretariat with input from the MC.

ICH and WHO

The MC was informed on considerations on the areas of work and complementarities of ICH and WHO to be considered in ICH Guideline development.

MC Actions/Decisions:

- The MC noted WHO's considerations shared on the areas of work and complementarities of ICH and WHO which should be considered in ICH Guideline development and supported that these should also be presented to the Assembly in Singapore;
- The MC agreed on the necessity to clearly communicate on the functioning of ICH since the organisational changes undertaken in 2015;

F. Implementation

The MC was updated by the Co-Leads for Implementation on the publication in November 2019 on the ICH website of the outcome of the ICH implementation survey for monitoring the adequacy of implementation and adherence to ICH Guidelines for Regulators and Industry; and on considerations for future ICH implementation activities, including the organisation of subsequent surveys regarding implementation of ICH Guidelines.

MC Actions/Decisions:

- The MC noted that, ahead of its next teleconference, the Implementation Co-Leads would submit a proposal to the MC regarding objectives, timeframe/periodicity, and scope of the next Implementation survey(s), taking into consideration:
    - the eligibility criteria applicable from 2021 for Elected Management Committee Representative candidates for the election to be held in June 2021, which includes adequate implementation of 50% of ICH Tier 3 Guidelines;
    - the potential for the survey results to inform the prioritisation of ICH Guidelines in regards to the need for training materials;
    - the potential for collaboration with IFPMA to broaden input to the survey from industry.

- The MC agreed in view of cost considerations an implementation survey should not be conducted on an annual basis;
- The MC noted that, in view of their methodology, the cost of a subsequent survey run by CIRS (the independent third party which conducted the survey in 2019) would not be impacted by the number of ICH Guidelines in the survey or by the number of responders to the survey;
- The MC supported that the Implementation Co-Leads would liaise with CIRS to determine the costs of an analysis, per ICH Guideline, of the free-text entries provided by industry in the Implementation survey;
- The MC noted the work undertaken by the WHO on its Benchmarking Tool on implementation and agreed that WHO would be involved in the development of any future ICH survey;
- The MC noted that ICH Regulatory Members are invited to inform the Secretariat when a status of implementation has been updated so that the ICH website can be updated accordingly.

G. Training

Training Subcommittee

The MC was updated by the Co-Lead of the Training Subcommittee on the Subcommittee's activities since the ICH meeting in Amsterdam, the Netherlands in June 2019, including on the status of requests received from training providers for approval to develop ICH Recognised Training Programmes, and considerations on further support to provide to ICH WGs developing training materials.

MC Actions/Decisions:

- The MC appointed a new industry co-Lead of the Training Subcommittee;
- The MC noted the recent approval by the Training Subcommittee of the following ICH Recognised Training Programmes:
    - Northeastern University: ICH-Q1 Training, Burlington, MA, USA, 16-18 October 2019;
    - APEC PKU Regulatory Sciences CoE: MRCT & Incorporating GCP-Related Considerations, Beijing, China, 11-14 November 2019.
- The MC additionally noted the recent publication on the ICH website of the Q7 online training material developed by the Parenteral Drug Association (PDA), which had been approved as an ICH Recognised Training Programme.
- The MC noted ongoing considerations to provide support to the E2B(R3) EWG/IWG and the Q12 EWG for development of training materials via the FDA, United States Studios.

ICH Training Associates

The MC was updated by the Co-Lead of the Training Subcommittee on the status of work further to 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, and on considerations on next steps.

MC Actions/Decisions:

- The MC noted the status of work to engage ICH Training Associates and that discussions are ongoing with the selected organisations to finalise contracts, including on the scope of work which will follow a step-wise approach;

- The MC noted that it would be invited to confirm support once the contracts are finalised;
- The MC agreed to further discuss how to assess the outcome of the first phase of work with Training Associates.

ICH Funding of Training by Regulatory Members

The MC was updated by the ICH Secretariat on post-training reports received on ICH Guideline training events from ICH Regulatory Members who received funding for ICH training activities in 2019.

MC Actions/Decisions:

- The MC supported proposing to the ICH Assembly repeating the process for ICH funding of ICH Regulatory training events on ICH Guidelines in 2020, agreeing to extend the process to Regulatory Observers in addition to Regulatory Members;
- The MC supported proposing to the ICH Assembly that ICH training budget would be used to support the funding of Regulatory Training events in 2020, for an equivalent amount to the funding allocated in 2019;
- The MC Chairs will provide input to the ICH Secretariat on practical refinements to the application process in preparation of launch of the application process in early 2020;
- The MC agreed that funding training activities may be time limited as long as ICH has surplus funds available and would likely not be possible in the future as part of the sustainable ICH budget model under development.

H. Financial Matters

General

The ICH Secretariat provided an update on ICH financial matters including: final 2020 ICH budget for Assembly approval in Singapore; provisional 2021 ICH budget and 2021 ICH Membership Fees for Assembly approval in Singapore; 5-Year ICH Budget Plan (2020-2024); management of ICH funds; and organisation of the 2019 Financial Audit.

MC Actions/Decisions:

- The MC noted that in Singapore the ICH Assembly would be invited to approve the final 2020 ICH budget, as well as the provisional 2021 ICH budget and membership fees;
- The MC noted that as approved by the ICH Assembly, Audit firm Moore Stephens will conduct the 2019 ICH Audit and that this would be performed on a similar schedule to the previous year's audit.

ICH Funding Model

MC Action/Decision:

- The MC agreed on the need for further MC consideration towards establishment of a sustainable ICH funding model, including further reflection on options such as introducing fees for Observers as well as increasing membership fees for some Members, and agreed to launch a call for volunteers from the ICH MC to participate in a Financial Subcommittee which will work towards the development of a sustainable ICH funding model for further discussion at the ICH MC interim meeting in March 2020.

I. MedDRA Financial Matters (joint session ICH MC & MedDRA MC)

The ICH MC welcomed the MedDRA MC for a joint session on MedDRA financial matters.

MC Actions/Decisions:

- The ICH MC supported the MedDRA MC's proposal for (1) a revised 2020 MedDRA budget to include additional MedDRA Secretariat support; and (2) keeping 2020 MSSO Subscription Fees stable;
- The ICH MC supported that its new Financial Subcommittee (see item H above) hold joint sessions with a new MedDRA MC Financial Subcommittee (call for volunteers to be launched by the Secretariat), supported by the ICH/MedDRA Secretariat, to review together overall ICH and MedDRA multi-year budget planning, surplus needs and the appropriate level of reserve to maintain in view of overall ICH Association activities;
- The ICH MC furthermore supported MedDRA MC proposals to the ICH Assembly in Singapore regarding the establishment of a Memorandum of Understanding (MoU) with IMDRF and the end of the current phase of SMQ development with CIOMS which would see the MoU with CIOMS not being renewed further to its end in October 2019.

J. Collaboration with PIC/S

The MC was informed by the ICH MC Chair, Dr. Theresa Mullin (FDA, United States), on the status of follow-up with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on considerations for interactions between ICH and PIC/S on ICH Guideline work with relevance to both Regulatory Assessor and Inspector disciplines. Further to the sharing of an ICH MC proposal with PIC/S in September 2019, the ICH MC Chair attended a meeting of the PIC/S Executive Bureau on 13 November 2019 to discuss this proposal and the possible initiation of a pilot.

MC Actions/Decisions:

- The MC noted that, at the ICH MC Chair's meeting with the Executive Bureau of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), PIC/S had provided positive feedback to the proposal of the ICH MC for more routine engagement with PIC/S on ICH Guideline work with relevance to both Regulatory Assessor and Inspector disciplines, focusing on Quality topics;
- The MC noted that, as part of this proposal and in line with ICH process, PIC/S would be involved in ICH Guideline work during the public consultation following *Step 2b* and that additionally, as an ICH Observer, PIC/S could also request to be part of Plenary Working Parties (PWP) which would allow an involvement prior to *Step 1*;
- The MC agreed that PIC/S could share this proposal with a broader audience within PIC/S;
- The MC supported that as a next step the ICH MC Chair will develop a proposal for a pilot process focusing on a few relevant Quality Guidelines, to be shared with the ICH MC by the end of the year for a commenting period of a few weeks, with the aim of sharing a final proposal with PIC/S by end January 2020;
- The MC noted that the PIC/S Delegate in ICH, Dr. David Churchward, would be the PIC/S point of contact for ICH in this project;
- The MC agreed to inform the Assembly on this proposal and way forward at its meeting in Singapore.

K. Election of MC Chair and Vice Chair

MC Action/Decision:

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

L. Communication

Commemoration of ICH 30th Anniversary

The MC was updated by the Lead of the Organising Committee on preparations for the commemoration in 2020 of ICH's 30th Anniversary.

MC Actions/Decisions:

- The MC supported plans for the organisation of a commemorative ICH event in Athens, Greece on Saturday, 14 November 2020 which would be preceded by a reception on Friday, 13 November 2020 and to which all ICH Assembly Members and Observers are invited;
- The MC agreed to review the initial list of potential invitees put together by the Organising Committee and consider their respective former representatives who should be invited (i.e. MC Representatives, Coordinators, etc.) along with former / current experts (up to four, i.e. one expert per ICH Q/S/E/M topics, and up to four alternate experts). The Secretariat will send a call to the MC with the deadline to input;
- The MC also agreed to provide input on the draft list of external organisations which might also be invited;
- The MC noted the excellent response of ICH Member Representatives and Observer Delegates willing to be filmed in the development of a short (<5 minute) video in Singapore which would be used to promote ICH activities and the 30th Anniversary event;
- The MC noted that next steps for the Organising Committee would include development of a draft programme for the 30th Anniversary event and consideration of the development of a publication, as well as considerations for special sessions to be held at DIA meetings in 2020 in the Americas, Europe and Asia.

ICH Speaker Participation at Key Events

MC Action/Decision:

- The MC noted the participation of Ms. Lenita Lindström-Gommers (ICH Assembly Chair, EC, Europe) as an ICH speaker at the 13th Middle East Regulatory Conference (MERC) held in October 2019 in Cairo, Egypt.

M. Procedural Matters

The ICH Secretariat updated the MC on the status of proposed amendments to the ICH Articles of Association, the Assembly Rules of Procedure (RoP), the ICH MC RoP and the Standard Operating Procedures (SOP) of ICH WGs, including on the (1) Process for nominating experts to the 3 additional industry seats, (2) Process for development of Reflection Papers, (3) General Principles for Discussion Groups, (4) Attendance of experts to their WG meetings, (5) Synchronization of the terms of office of the MC Elected Representatives, (6) Replacement of MC Elected Representatives, (7) Clarification on the synchronization of the terms of office of the Assembly Chair and Vice-Chair, (8) Synchronization

of the terms of office of the MC Chair and Vice-Chair, (9) S5 Annexes Maintenance Procedure, (10) Streamlining of procedures, and (11) the need identified for certain minor clarifications.

MC Actions/Decisions:

- The MC agreed not to amend the template for ICH Topic Proposals (Annex 8 of the SOP of the WGs), noting that the MC should take into consideration, typically during the New Topic Selection Process and the review of Concept Papers, that proposed new topics should not impact ICH Member regulations. The MC noted that it is important that, when selecting topics for harmonisation and subsequently throughout the guideline development process, notably the ICH Regulatory Members need to monitor developments closely to ensure that the ICH guidelines focus on technical and scientific requirements and do not enter into legal framework issues.
- The MC approved the amendments to the ICH MC RoP and SOP of ICH WGs, with amendments linked with those proposed to the ICH Articles of Association and Assembly Rules of Procedures pending Assembly approval of these related amendments before being considered final.

N. Oversight of Working Groups

Groups Meeting in Singapore

The MC was updated by the ICH Secretariat and MC Coordinators of the progress made by informal WGs on the development of Concept Papers and Business Plans, as well as other items regarding WGs meeting in Singapore requiring MC input.

- ***E2D(R1) EWG: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Rapporteur: Dr. Edwards – EFPIA)***

MC Actions/Decisions:

- The MC approved the E2D(R1) Concept Paper and Business Plan and the subsequent establishment of the E2D(R1) EWG;
- The MC noted that the membership of the E2D(R1) informal WG would be transferred to the EWG;
- The MC noted that the E2D(R1) EWG would liaise with the E19 EWG during the course of its work.

- ***E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)***

MC Actions/Decisions:

- The MC approved the E6(R3) Concept Paper and Business Plan and the subsequent establishment of the E6(R3) EWG, noting that the group should work first on the Guideline and Annex 1, and when *Step 1* on is reached, the group would revise the E6(R3) Concept Paper regarding the revision of Annex 2 based on an increased understanding at that time;
- The MC noted that the membership of the E6(R3) informal WG would be transferred to the EWG;
- The MC supported the principle that the E6(R3) EWG would develop a stakeholder engagement plan, to be further submitted to the MC for consideration.

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

MC Actions/Decisions:

- The MC approved the request from the E11A EWG to leave to the discretion of the experts of the group, in coordination with their Rapporteur, the approval of ad-hoc experts from Members and

Observers already represented in the group, noting that the addition of any new ad-hoc experts from Members and Observers not represented in the group should still be approved by the MC;

- The MC agreed that the ICH procedures would be amended to generalise this approach to WGs, noting additionally that ad-hoc experts should not be included in the headcount of WGs, but that the Secretariat should periodically update the MC on the numbers of new ad-hoc experts in WGs.

- ***E20 EWG: Adaptive Clinical Trials (Rapporteur: Dr. Zhong - PhRMA; Regulatory Chair: Dr. Levin – FDA, United States)***

MC Actions/Decisions:

- The MC approved the E20 Concept Paper and Business Plan and the subsequent establishment of the E20 EWG;
- The MC noted that the membership of the E20 informal WG would be transferred to the EWG.

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

MC Action/Decision:

- The MC acknowledged the challenge for the M10 EWG to address the substantial number of comments (~2,500) received during the public consultation period, and supported the proposal from ICH Coordinators to develop a standard template for the collection of comments to help facilitate review of comments by WGs in general.

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

The M11 Rapporteur and Regulatory Chair presented to the MC the updated M11 EWG proposal for early engagement of external stakeholders.

MC Action/Decision:

- The MC noted the revised M11 EWG proposal and supported that the M11 EWG revise their proposal further in view of the feedback from the MC.

- ***M12 EWG: Drug Interaction Studies (Rapporteur: Dr. Madabushi - FDA, United States; Regulatory Chair: Dr. Ishiguro – MHLW/PMDA, Japan)***

MC Actions/Decisions:

- The MC approved the M12 Concept Paper and Business Plan and the subsequent establishment of the M12 EWG;
- The MC noted that the membership of the M12 informal WG would be transferred to the EWG.

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

The MC held a general exchange of views regarding what would be considered to be a reasonable timeframe for implementing ICH guidelines after their adoption in view of the fact that no specific timelines are mentioned in the ICH procedures. The Industry Members of the MC explained that they expect the ICH guidelines to be implemented as soon as possible but recognised that the timing depends on the guideline as some are more transformational and may require longer time, e.g. up to 5 years to be adequately implemented. The EC, Europe pointed out that ICH guidelines should complement legislation and not require legislative/statutory changes as such changes are not entirely under the control

of the ICH Regulatory Members who are thus not in a position to commit to introducing changes in the legislation for the purpose of implementing ICH guidelines. The EC, Europe stated the importance that ICH guidelines remain focused on technical and scientific requirements which is the remit of ICH and to refrain from entering into policy and regulatory issues. In this context, the ICH Q12 is a particular guideline which was recognised as a challenging topic and the reason why the Business Plan states that the guideline "[…] is not intended to introduce new requirements necessitating changes to the regulations in the regions." Therefore, its implementation will be a challenging and time-consuming exercise for most ICH Regulatory Members as many of them have indicated their intention to introduce legislative changes.

The MC Members expressed their appreciation of the efforts made by EC, Europe in putting forward a new amendment with a view to finding an outcome that would allow for the adoption of the Q12 guideline by the ICH Regulatory Members at the Assembly. The EC, Europe took note of the concerns expressed by several MC Members that the previous 'disclaimer' (4th paragraph in the Introduction of the draft Q12 guideline) could become a precedent for future ICH guidelines which would undermine the ICH goal of harmonisation. The EC, Europe stated that its preference was nevertheless to maintain the previous disclaimer and that the new amendment was presented solely as an ultimate compromise.

MC Action/Decision:

- The MC supported the amendment proposed by EC, Europe and shared with the Q12 EWG to the draft Q12 Technical Document clarifying that the extent of the operational and regulatory flexibility outlined in the Q12 guideline as well as the adequate implementation of this flexibility will be subject to the regulatory frameworks in place. Moreover, it is stated in the Q12 guideline that Regulatory Members of ICH are encouraged to provide publicly available information, preferably on their website, about the implementation of ICH Q12 in their region, especially with regard to regulatory considerations.

- ***Q5A(R2) EWG: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Rapporteur: Dr. Welch - FDA, United States)***

MC Actions/Decisions:

- The MC approved the Q5A(R2) Concept Paper and Business Plan and the subsequent establishment of the Q5A(R2) EWG;
- The MC noted that the membership of the Q5A(R2) informal WG would be transferred to the EWG.

- ***S12 EWG: Non-Clinical Biodistribution Considerations for Gene Therapy Products (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Serabian – FDA, United States)***

MC Actions/Decisions:

- The MC approved the S12 Concept Paper and Business Plan and the subsequent establishment of the S12 EWG;
- The MC noted that the membership of the S12 informal WG would be transferred to the EWG.

Groups Not Meeting in Singapore

The MC was informed by the ICH Secretariat and MC Coordinators of items regarding WGs not meeting in Singapore requiring MC input.

- ***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-Rapporteur on the M2 White Paper titled "HL7 Fast Healthcare Interoperability Resources (FHIR) Considerations for ICH" and on the progress made by the group on recommendations on how ICH should address rapid technology advancement of electronic standards impacting harmonisation activities.

MC Action/Decision:

- The MC noted the progress made on the development of recommendations on addressing rapid technology advancements requested by the MC, and that recommendations would be provided in early 2020.

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

MC Action/Decision:

- The MC supported presentation to the ICH Assembly of the recommendation from the M8 EWG/IWG and M2 EWG to move forward with the eCTD v4.0 implementation.

- ***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)***

MC Actions/Decisions:

- The MC approved the request for an interim meeting (hosted by EC, Europe at the EMA premises in Amsterdam), ahead of the ICH meeting in Vancouver, Canada in May 2020, of the S1(R1) Regulatory experts who have access to the Carcinogenicity Assessment Documents (CADs) via confidentiality arrangements;
- The MC further noted that the S1(R1) EWG would submit a request to meet at the ICH meeting in Vancouver, Canada.

Plenary Working Parties

The ICH Secretariat informed the MC of considerations to establish Plenary Working Parties (PWP) further to the implementation of this new concept approved at the ICH meeting in Amsterdam, the Netherlands in June 2019 as part of the new process to manage the size of WGs.

MC Actions/Decisions:

- The MC noted the interest expressed so far to join PWPs, as well as ongoing discussions with Members and Observers who expressed potential interest;
- The MC supported that the Secretariat send a reminder to the Assembly on the possibility to join PWPs of the new EWGs established further to approval of Concept Papers and Business Plans approved at the ICH meeting in Singapore, and that the Secretariat subsequently begin the establishment of PWPs based on the interest expressed so far in line with the ICH procedures.

Appointment of experts to WGs

The ICH Secretariat informed the MC of a procedural question received regarding the possibility for Observers to request to nominate experts from outside their organisations to join an EWG as an Observer expert. The MC noted the Secretariat's understanding that this question was raised in view of interest expressed by the E11A EWG for an external liaison expert to become an Observer expert to enable them to join face-to-face meetings.

MC Actions/Decisions:

- The MC supported to consider requests for Observers to nominate experts from outside their organisations on a case-by-case basis and not to implement any rule in the SOPs at this time until further experience gained with the circumstances under which such request might be made
- The MC acknowledged the valuable expertise of the E11A external liaison and supported that this liaison would also be able join face-to-face meetings as considered necessary by the E11A EWG.

O. Welcome to MC Elected Representatives

MC Action/Decision:

- The MC welcomed the newly elected MC Representatives from ANVISA, Brazil.

P. Working Groups meeting in Vancouver

MC Actions/Decisions:

- The MC agreed on 17 WGs which will meet in Vancouver in May 2020, pending confirmation of logistical feasibility on the number of meeting rooms available;
- The MC supported that once finalised the list will be made available to the Assembly and also on the ICH website and noted that the ICH Secretariat will send shortly (January 2020) registration information for Vancouver to support the making of travel arrangements by participants to the meeting;
- The MC supported that the S1(R1) EWG (Regulatory Members who have access to the CADs only) and the QDG would both hold interim meetings in the March/April 2020 timeframe. The MC noted that it had already supported that the E8(R1) EWG would hold an interim meeting in March 2020;
- The following table summarises MC decisions regarding the WGs to meet.

List of ICH WGs		Meeting	Not Meeting
E-WGs	Standing Paediatric EWG		x
	E2B(R3) EWG/IWG		x
	E2D(R1) EWG	4 days (Sunday - Wednesday)	
	E6(R3) EWG	5 days (Saturday - Wednesday)	
	E8(R1) EWG	4 days (Sunday - Wednesday)	
	E9(R1) EWG		x
	E11A EWG	5 days (Saturday - Wednesday)	
	E14/S7B IWG		x
	E19 EWG	4 days (Saturday - Tuesday)	
	E20 EWG	4 days (Sunday - Wednesday)	
M-WGs	M1 PtC WG	2 days (Tuesday - Wednesday)	
	M2 EWG		x
	M4Q(R1) IWG		x
	M7(R2) Maint. EWG/IWG		x
	M8 EWG/IWG		x
	M9 EWG		x
	M10 EWG	5 days (Saturday - Wednesday)	
	M11 EWG	4 days (Sunday - Wednesday)	
	M12 EWG	4 days (Saturday - Tuesday)	
	M13 informal WG	4 days (Sunday - Wednesday)	
Q-WGs	Q2(R2)/Q14 EWG	4 days (Sunday - Wednesday)	
	Q3C(R8) Maint. EWG		x
	Q3D(R2) Maint. EWG		x
	Q3E informal WG	4 days (Sunday - Wednesday)	
	Q5A(R2) EWG	4 days (Sunday - Wednesday)	
	Q12 EWG		x
	Q13 EWG	5 days (Saturday - Wednesday)	
S-WGs	S1(R1) EWG	4 days (Sunday - Wednesday)	
	S5(R3) EWG		x
	S11 EWG		x
	S12 EWG	4 days (Sunday - Wednesday)	
DGs	GDG		x
	QDG		x
	PEpiDG		x

Q. Next meetings

Teleconferences

MC Actions/Decisions:

- The MC noted the below dates of the next teleconferences:
  - Policy 1: 4 March 2020;
  - Technical: 9 March 2020;
  - Policy 2: 2 April 2020;
  - Policy 3: 22 April 2020;
  - Coordinators (for information): 20 February 2020;
- The MC noted that the Secretariat would shortly circulate the timeline for the next cycle including deadlines for background documents to the provided to the Secretariat, which is 10 days ahead of each TC to ensure that the MC has sufficient time to review the documents and can operate efficiently.

2020 ICH MC Interim Meeting

MC Actions/Decisions:

- The MC agreed to hold its next interim meeting on Thursday 19 and Friday 20 March 2020, with the holding of a Thursday morning session to be confirmed depending on the programme of the DIA Europe meeting on this day and any impact for ICH MC participants.

Face-to-face Meetings

MC Actions/Decisions:

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

• 19-20 March 2020 (MC Interim)	Brussels, Belgium
• 23-27 May 2020	Vancouver, Canada
• 14-18 November 2020	Athens, Greece
• 29 May - 2 June 2021	Incheon, Republic of Korea (confirmation pending)
• 13-17 November 2021	The Americas (location to be confirmed)
• 21-25 May 2022 OR 11-15 June 2022	Europe (location & dates to be confirmed)

R. Press release

MC Action/Decision:

- 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.