3 August 2018

SUMMARY
of
MC SESSION ACTIONS AND DECISIONS

ICH Management Committee Meeting
4-7 June 2018, Kobe, Japan

List of MC Participants

ICH Management Committee Members Representatives

Ms. Lenita Lindström-Gommers	EC, Europe
Prof. Spiros Vamvakas	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Ms. Joan Blair	FDA, US
Dr. Theresa Mullin (Chair)	FDA, US
Ms. Pujita Vaidya	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Catherine Parker	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nobumasa Nakashima	MHLW/PMDA, Japan
Dr. Toshiyoshi Tominaga (Vice-Chair)	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter K. Honig	PhRMA
Mr. Rich Moscicki	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
Mr. Mike Ward	WHO

ICH Management Committee Coordinators:

Dr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Ms. Camille Jackson	PhRMA
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH Management Committee Technical Coordinators:

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

ICH Management Committee Additional Participants:

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Lei Zhang	FDA, US
Dr. Hideharu Yamamoto	JPMA
Ms. Machiko Sumi	JPMA
Ms. Sayaka Kurihara	MHLW/PMDA, Japan

ICH Secretariat:

Ms. Nadia Gerweck	ICH Secretariat
Dr. Anne Latrive	ICH Secretariat

Ms. Nikoleta Luludi	ICH Secretariat
Dr. Dawn Ronan	ICH Secretariat

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ICH MANAGEMENT COMMITTEE MEETING
REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

MC Vice-Chair: Dr. Toshiyoshi Tominaga, MHLW/PMDA, Japan

Welcome & Adoption of the Agenda

Dr. Mullin (MC Chair, FDA, US) and Dr. Tominaga (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 Geneva meeting held in November 2017, dated 31 January 2018;
- The MC noted the Report of the Coordinators teleconference which was held on 7 March 2018, dated 18 April 2018;
- The MC noted the Report of the MC Technical teleconference held on 22 March 2018, dated 29 March 2018;
- The MC noted the Report of the MC Policy 1 teleconference held on 13 December 2017, dated 25 January 2018;
- The MC noted the Report of the MC Policy 2 teleconference held on 24 January 2018, dated 19 February 2018;
- The MC noted the Report of the MC Policy 3 teleconference held on 20 March, dated 10 April 2018;
- The MC noted the Report of the MC Policy 4 teleconference held on 10 April 2018, dated 4 May 2018;
- The MC adopted as final the Report of the MC Policy 5 teleconference held on 25 April 2018, dated 25 May 2018.
- The MC adopted as final the Report of the MC Policy 6 teleconference held on 15 May 2018, dated 24 May 2018.

B. ICH Membership and Observership Applications

The Leads of the Membership Subcommittee provided an update on the activities of the Membership Subcommittee including an overview of all applications for Membership/Observership received to-date.

MC Decisions/Actions:

- The MC agreed to recommend the following Membership application to the Assembly for approval:
  - TFDA, Chinese Taipei.
- The MC agreed to recommend the following Observership applications to the Assembly for approval :

- TITCK, Turkey;
- NPRA, Malaysia;
- SCDMTE, Armenia;
- MMDA, Moldova.

- The MC agreed not to recommend the following Observership application to the Assembly for approval:
  - EEC (Eurasian Economic Commission).

C. Financial Matters

The Lead of the Financial Subcommittee provided an update on the activities of the Financial Subcommittee and sought MC views on items including: the 2017 Audited Financial Statements for Assembly approval in Kobe; the MC's recommendation to the Assembly regarding the engagement of the same auditor for the 2018 audit; the 2017 ICH Closing Report pre and post asset transfer; the update on the 2018 membership fee payments and current cash flow situation; the 2019 ICH Budget; the 5-Year ICH Budget Plan; the possibility of having ICH representatives attending certain international events and the potential funding of such participation by ICH; considerations related to Regional Harmonisation Initiatives (RHI) funding; and the future activities of the Financial Subcommittee.

MC Decisions/Actions:

- The MC agreed to recommend the same auditor Moore Stephens to be engaged for the 2018 audit which will be performed in Q1 2019[1];
- The MC agreed to maintain the status quo for the funding of RHI participation in ICH meetings;
- The MC agreed to increase the ICH meeting budget and to add a provision as a buffer to mitigate against currency fluctuations;
- The MC acknowledged that the Kobe meeting would come in over budget due to the weakening of the Yen against the CHF, as well as additional costs for the earlier meeting start on Friday, 1 June;
- The MC supported that the total USD Reserve Fund be divided into CHF and USD to split the currency fluctuation risk;
- The MC agreed to disband the Financial Subcommittee, with activities continued by the ICH Secretariat, with the possibility to reconvene an ad hoc Financial Subcommittee in the future if needed;

D. Meetings

- ***Designation of 2019 Meeting Locations and 2020 Meeting Dates***

The ICH Secretariat provided an update on the organisation of upcoming ICH meetings and sought MC views on items including: timeline for selection of meeting dates and locations; the June 2019 meeting location; the 2020 meeting dates; and additional considerations on the organisation of meetings and collaboration with the Professional Conference Organiser (PCO).

MC Decisions/Actions:

- The MC agreed on the following dates for the 2020 meetings:
  - From Saturday, 23 May to Thursday, 28 May 2020;

[1] At the Assembly meeting on 6 June, the Assembly supported the MC's recommendation and furthermore supported the engagement be extended for a second year also.

- From Saturday, 14 November to Thursday, 19 November 2020.

- 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 PCO is to identify 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 supported that the Secretariat instruct the PCO to engage in contract negotiations with the most suitable venue identified for the June 2019 meeting with the other two option to be kept as fall-back options should there be any unexpected issue with the contract negotiation;
- The MC agreed to revise the budget for the ICH meetings from 2019 onwards and to add a provision for currency fluctuation (see also item C above);
- The MC supported that the Secretariat (1-2 staff) would travel with the PCO for the inspection of the European venue for June 2019 and participate in contract negotiations to ensure the understanding/addressing of all ICH meeting requirements, and that the Project Manager of the PCO would attend part of the November 2018 ICH meeting in Charlotte to observe organisation/logistics;
- The MC confirmed the level of details to be included in the Site Selection Report provided by the PCO with proposals on meeting venues.

- ***Organisation of November 2018 Meeting***

PhRMA provided an update on the organisation of the meeting in Charlotte, North Carolina, USA in November 2018.

MC Decision/Action

- The MC noted that the organisation of the November 2018 meeting in Charlotte, North Carolina, USA is on track and that 16 meeting rooms are available.

E. General Operational Matters

- ***ICH Secretariat***

The ICH Secretariat provided a report to the MC on: legal and administrative aspects of the full operationalisation of the ICH Secretariat following the asset transfer in November 2017; Secretariat staffing; updates to ICH Employee Handbook; the status of the Trademark (TM) registration of the ICH logo; an overview of the participation of current Members and Observers in ICH Assembly and Working Groups; the ICH Secretariat's support of MC decisions and growth of ICH; and considerations for improving the efficiency of ICH record maintenance.

MC Decisions/Actions:

- The MC noted the current status of the Secretariat staffing;
- The MC supported the proposed updates to the ICH Employee Handbook by written procedure prior to the Kobe meeting;
- The MC approved Dr. Anne Latrive as a third signatory from the ICH Secretariat with joint (by two) signatory powers for ICH;
- The MC noted the status of the registration of the ICH device (logo) TM in ICH Members and Observers countries and supported that the Secretariat proceed with any necessary actions on the advice of the ICH legal advisors to address such issues;
- The MC agreed to set-up a watch service on the ICH device TM;

- The MC supported the implementation of a project for increasing the efficiency of the Secretariat and quality of ICH records involving the setting-up of an SQL database interfaced with the ICH websites;
- The MC supported that as a general principle the Secretariat does not need to seek its approval to use funds already approved within the overall operational/administrative budget and supported implementing any necessary changes to the rules within the ICH Employee Handbook in support of this principle;
- The MC supported the ICH Secretariat identifying further opportunities within its procedures to increase efficiency and reduce unnecessary MC / MC Chair & Vice Chair consultation;
- The MC noted the ICH expert participation statistics presented by the ICH Secretariat and requested further clarification from the Secretariat on the high rate of turn-over to the expert lists and to what such changes are attributed.

- ***Management Committee***

The MC discussed MC general operational matters related to: the efficiency of the operations of the MC; the MC Subcommittee's mandates; and the scheduling of the various meetings during the ICH week.

MC Decisions/Actions:

- The MC agreed to reduce the number of Policy TCs between meetings with the aim of having 3 Policy TCs and 1 Technical TC ahead of the Charlotte meeting in November 2018;
- The MC agreed to maintain only 3 Subcommittees: New Topics; Implementation; and Training, and noted that the mandate of the Training subcommittee should be reviewed to find alternative ways to provide training for ICH Members instead of merely relying on current ICH experts giving training to outsiders at various events; the MC supported that the Communication, Financial and Membership Subcommittees be disbanded with activities continued by the ICH Secretariat and Leads for each topic at the ICH MC level;
- The MC supported that each of the remaining Subcommittees should have both a Lead and Co-Lead;
- The MC agreed to further work ahead of the next meeting to revise the timetable and the scheduling of the various meetings during the ICH week. Regarding the timetable, the aim would be not to exceed a total number of 5 meeting days including the IPRP meeting that most ICH regulators attend. Concerning the sequencing of the various meetings, efforts will be made to optimise the schedule for participants needing to attend several meetings. Depending on the stage of advancement of the meeting planning, the MC will need to agree on when a revised schedule can be implemented, but the MC agreed it would not be possible to implement a revised schedule before the 2020 meetings.

- ***IPRP***

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

MC Decision/Action:

- The MC approved the renewal for the period 1 January – 31 December 2019 of the Memorandum of Understanding (MoU) between ICH and IPRP for the provision of Secretariat support services and its subsequent signature by the ICH Assembly Chair and Vice-Chair.

F. Opening-up of MC to Elected Representatives

The MC was informed that in line with the ICH Articles of Association, up to eight Elected MC Representatives representing up to four Regulatory Members could be elected as MC Elected Representatives, and up to four Elected MC Representatives representing up to two Industry Members

could be elected as MC Elected Representatives. Furthermore, it was noted that as per Article 26 (9) of the ICH AoA the election should be conducted by secret ballot. The MC noted that the following ICH Members had submitted an application: CFDA, China; HSA, Singapore; MFDS, Republic of Korea; BIO; IGBA; WSMI.

The MC further noted the assessment summaries developed by the ICH Secretariat based on the information provided by the applicants, and the organisation of the election for MC Representatives during the Assembly session.

MC Decision/Action:

- The MC supported the organisation of the election for MC Representatives during the Assembly session and the general preparations undertaken by the ICH Secretariat for an expanded MC from Thursday, 7 June afternoon.

G. Implementation

The Leads of the Implementation Subcommittee provided an update on the Subcommittee's activities including on: the development of a draft document on the terminology to be used with respect to the degrees of implementation; case studies on the implementation of the ICH E2D and M4/M8 Guidelines to be presented to the Assembly in Kobe; as well as next steps for Phase 2a of the implementation survey including tool, scope, budget, publication and contractor.

MC Decisions/Actions:

- The MC agreed on the proposed definitions for the degrees of implementation with minor amendments including on "confirmed adequate implementation";
- The MC supported that as a next step the Assembly be invited to provide comments on the proposed definitions for the degrees of implementation, with the aim of being invited to approve the final definitions at the November 2018 meeting;
- The MC supported the generic process describing the process of implementation of ICH Guidelines, with a minor amendment regarding industry stakeholder communication;
- The MC agreed to conduct the Phase 2a Study with the Centre for Innovation in Regulatory Science (CIRS), in view of their involvement with the previous phase of the project;
- The MC supported the outline for the Phase 2a Study and that as next steps, a more complete proposal be developed ahead of the Charlotte meeting and presented to the MC and the Assembly;
- The MC supported that the Implementation Subcommittee Co-Leads continue to act as primary contact points with CIRS, with the support of the ICH Secretariat;
- The MC approved the Work Plan of the ICH Implementation Subcommittee.

H. Training

The Lead of the Training Subcommittee provided an update on the Subcommittee's activities including: progress made on the creation of a general guidance for ICH training partners for the development of online training materials; considerations related to prioritisation of Tier 3 ICH Guidelines for training; support provided to WGs developing training materials in 2018; establishment of control mechanisms to review and assess existing and new training; and status of work with ICH training partners.

MC Decisions/Actions:

- The MC agreed to provide the Training Subcommittee with an initial top 5 prioritisation of Tier 3 ICH Guidelines;

- With respect to the process of having control mechanisms in place to review/assess existing and new training materials, the MC agreed that the Training Subcommittee should take a mixed approach of leveraging both existing Discussion Groups and ICH Coordinators to triage review with experts;
- The MC endorsed the ICH WG templates developed by the Training Subcommittee for *Step 2* informational materials and *Step 4* online slide presentations.

I. Oversight of Working Groups

- ***M2 EWG Electronic Standards for the Transfer of Regulatory Information (ESTRI)***

The M2 EWG co-Rapporteurs updated the MC on the progress made by the group on strategic project opportunities, in particular the completion of the proposal for the electronic Common Clinical Trial Submission (eCCTS); the progress made on the proposal for the Trial Master File (TMF); as well as the group's activities on project support for Terminology List Management and on ESTRI recommendation revision.

MC Decisions/Actions:

- The MC noted that the M2 EWG had completed its work on the project opportunity related to eCCTS, and that this topic would be submitted as an ICH New Topic proposal by WSMI in the 2019 New Topic cycle;
- The MC noted the progress made on the TMF and supported that the M2 EWG further engage with subject matter experts to clarify or refine the project scope;
- The MC noted that the M2 EWG was finalising an ESTRI recommendation to be signed-off by the M2 EWG and endorsed by the Assembly in Kobe;
- The MC noted the progress made on Terminology list management and that this topic would be put forward for endorsement at the November 2018 meeting;
- The MC supported the work plan of the M2 EWG for activities to be undertaken.

- ***IFPMA Participation***

IFPMA provided an update on the participation of IFPMA National Association experts in ICH WGs. There has been involvement of 6 IFPMA National Associations, with 30 experts contributing to 6 ICH topics. Five of the experts are attending WGs meetings in Kobe. The system put in place by IFPMA also operates as a form of training. Feedback is that the process is working well.

MC Decision/Action:

- The MC noted the current level of participation by 5 IFPMA National Association experts in 6 ICH WGs.

- ***Groups Meeting in Kobe***

MC Decisions/Actions:

- ***M8 EWG/IWG: The Electronic Common Technical Document (eCTD)***

- The MC noted that the nomination as Rapporteur of the current Acting Rapporteur for the M8 EWG/IWG, Mr. Gray from FDA, US, will be for Assembly approval in Kobe.

- ***M9 EWG: Biopharmaceutics Classification System-based Biowaivers***

➢ To address concerns raised by MHLW/PMDA, Japan, the MC supported including in the M9 draft Technical Document the possibility for regional flexibility through a simple acknowledgement that in some regions, there are regulations in place that stipulate water is an appropriate dissolution media.

- ***S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals***

➢ The MC agreed that in its consideration of the comments received during the *Step 3* consultation period, the EWG should work in alignment with the approaches in the Concept Paper and then subsequent to this consider any impact for the ICH M3 Guideline.

- ***S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines***

➢ The MC agreed that, when *Step 2b* will be reached and the Rapporteurship will rotate to a Regulatory Member, and that Dr. Brown from FDA, US would be put forward as Acting Rapporteur, pending Assembly endorsement as Rapporteur.

- ***Groups Not Meeting in Kobe***

MC Decisions/Actions:

- ***E17 IWG: Multi-Regional Clinical Trials***

➢ The MC noted that the nomination as Rapporteur of the current Acting Rapporteur for E17 IWG, Dr. Dunder from EC, Europe, will be for Assembly approval in Kobe.

- ***S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals***

➢ The MC noted that *Step 4* of the S9 Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals was reached electronically in April 2018. The MC confirmed the disbandment of the S9 IWG further to the publication of the *Step 4* presentation on the ICH website.

- ***E14/S7B DG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs***

The DG proposed a draft Concept Paper on the revision of S7B Q&A, which includes the use of in silico and iPS myocyte test methods based on the examination on the CiPA data.

➢ The MC agreed to provide to the E14/S7B a list of questions from the MC in order to help move forward the Concept Paper;

➢ The MC supported that, when finalised, the revised Concept Paper be submitted to the MC directly without the need to be submitted to the New Topic process.

- ***M7(R2) Maintenance EWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk WGs***

➢ The MC agreed that the M7(R2) Maintenance EWG could revise their original Concept Paper for submission to the MC for endorsement following the Kobe meeting to reflect the development of Q&As and confirmed that this would not need to be submitted to the New Topic Process.

- ***Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents***

➢ The MC approved the nomination request from EDQM to join the Q3C(R7) Maintenance EWG.

- ***Q11 IWG: Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances***

- The MC noted that the Q11 IWG had finalised the slide deck for training materials and agreed that to avoid delay it could be published on the ICH website after expert sign-off and circulation to the MC for information;
- The MC supported that the final training material based upon the slide deck, which was in the process of being developed as a video, would be submitted for Assembly endorsement at a later stage in line with the SOPs for EWGs/IWGs.

- ***Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management***

- The MC supported that the Q12 EWG would hold an interim meeting in the February - April 2019 timeframe and noted that MHLW/PMDA, Japan had kindly agreed to host the meeting.

J. Procedural Matters

- ***General***

MC Decisions/Actions:

- The MC supported proposing to the Assembly that E8(R1) is used as a pilot to involve those ICH Members whose requests to appoint experts have not been accepted due to the size of the WG."
- The MC agreed to assess the outcome of this pilot and if agreed, to update the Standard Operating Procedures (SOP) for EWGs/IWGs to reflect the new process.
- In addition, the MC agreed also to seek the feedback from the Regulatory Chairs and Rapporteurs regarding their experience (lessons learned) in managing the work of Working Groups that have increased in size following the expansion of ICH in order to identify best practice;

- ***ICH Articles of Association & Assembly Rules of Procedure***

MC Decision/Action:

- The MC noted that in Kobe, the Assembly will be invited to adopt the proposed revisions to the ICH Articles of Association and Assembly Rules of Procedure (RoP) put forward by the MC.

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

MC Decision/Action

- The MC noted revisions may be made in the future to the ICH MC RoP in view of changes in the definitions of the degrees of implementation, but no changes to the RoP were being put forward for approval in Kobe.

- ***MedDRA Management Committee Rules of Procedure***

MC Decision/Action:

- The MC noted the revisions to the MedDRA MC RoP approved recently by the MedDRA MC, including those related to clarifying the roles of the ICH MC, MedDRA MC and ICH Assembly with respect to MedDRA financial matters, and that in Kobe, the MedDRA MC approved a further procedure regarding use of the MedDRA logo.

- ***Standard Operating Procedures for EWGs/IWGs***

MC Decision/Action:

- The MC approved the revisions to SOP including changes proposed for consistency with the revisions to the Articles of Association and the Assembly RoP as well as minor edits proposed by the ICH Secretariat.

K. New Topic Proposals and Strategic Discussions

- ***New Topic proposals***

MC Decision/Action:

- The MC acknowledged the comments received from the Assembly Members on the New Topic proposals and the MC considerations document and that the following 3 New Topics would be recommended for endorsement by the Assembly: CeSHarP; Continuous Manufacturing; and Revision of Q2(R1) and Analytical Procedure Development, and that the following 2 New Topics would be recommended for endorsement with a further consideration on timing: Adaptive Clinical Trials and Drug Interactions Studies.
- The MC also noted that when setting up new WGs, there is a need to take into account the number of WGs that are in the process of reaching *Step 4* which is also linked to the availability of expertise, in view of keeping the total number of active WGs manageable for the MC.

- ***Strategic Reflection Papers***

MC Decisions/Actions:

- The MC endorsed the submission of the revised Quality Reflection Paper to the Assembly for endorsement in Kobe;
- The MC endorsed the establishment of the Informal Quality Discussion Group (IQDG) under the oversight of the MC with a 2-year mandate during which it would work on a survey of the existing Q-guidelines and on those Q-topics that were not endorsed by the MC as they needed further discussion ;
- The MC agreed that the remit document of the IQDG should be further revised to provide a more complete description including on the expected time-commitment for participants, as well as the type of expertise needed, and that the revised remit document should be submitted to the MC for electronic approval within a 2-week timeframe;
- The MC supported that the Assembly RoP should be further revised ahead of the meeting in Charlotte to allow the Assembly to establish groups such as Discussion Groups and agreed that in the meantime the IQDG reflect only the Membership of the ICH MC;
- The MC supported that as a next step FDA, US would progress its Reflection Paper on Generics on topics that could be pursued within ICH with the aim of circulating the revision to the MC by the end of 2018;
- The MC noted that EC, Europe would not pursue any further work on its Reflection Paper on Vaccines at this time.

- ***Future strategic priorities***

MC Decisions/Actions:

- The MC supported the following next steps for the PhRMA proposed topic Model-Informed Drug Development (MIDD):

- A draft Reflection Paper will be shared by PhRMA with the MC in July 2018 for a 2-month commenting period;

- A revised draft Reflection Paper will be shared by PhRMA with the MC by October 2018 with the aim of potentially achieving MC support and subsequent circulation to the Assembly ahead of the November 2018 meeting where it would be put forward for Assembly endorsement.

- The MC noted the status of the PhRMA proposed topic Patient-Focused Drug Development (PFDD) topic;
- The MC acknowledged mixed views expressed by MC Members on the topic on "Improving biopharmaceutical global pharmacovigilance" proposed by PhRMA in Kobe and some concerns from a regulatory point of view; the MC noted that PhRMA will bring a revised proposal forward for continued discussion by the MC.
- The MC acknowledged the need to establish a process for the adoption of reflection papers that should be further discussed by the MC.

L. Communication

The Lead of the Communication Subcommittee provided an update on the activities of the Communication Subcommittee including: the implementation of the ICH Transparency Policy; the development of the Communication and Stakeholder Engagement Plan for 2018-2019; considerations on recording Assembly meetings and alternative proposals to inform stakeholders; and considerations on recording the history of ICH; as well as on the development of the GCP Stakeholder engagement plan in coordination with the E8(R1) EWG.

MC Decisions/Actions:

- The MC agreed to disband the Communication Subcommittee and for activities to be continued by the ICH Secretariat, including further development of the "alternatives to broadcasting" and "ICH history" proposals;
- The MC agreed that the E8(R1) EWG lead the E8(R1) Stakeholder Communication Plan with any necessary support from the ICH Secretariat.

M. Welcome to MC Elected Representatives

MC Decision/Action:

- The MC noted that the ICH Secretariat will shortly issue a call for expressions of interest from newly elected MC Representatives to participate in MC Subcommittees on Training, Implementation and New Topic.

N. Any Other Business

The subsequent Agenda items O and P were dealt with on 7 June 2018 after the Assembly had taken a decision on the appointment as MC Elected Representatives of: Mr. Xiaoling Qin and Mr. Siyuan Zhou from CFDA, China; Dr. Nakyung Kim and Dr. Won Sik Lee from MFDS, Republic of Korea; Ms. Siew Wei Chua and Dr. Dorothy Toh from HSA, Singapore; Ms. Lila Feisee and Dr. Wassim Nashabeh from BIO; Dr. Nick Cappuccino and Ms. Beata Stepniewska from IGBA; many of who thus attended this part of the MC meeting.

O. Working Groups meeting in Charlotte, North Carolina, USA

The MC discussed the requests made by EWGs/IWGs to meet face-to-face at the next ICH meeting in Charlotte, North Carolina, USA, on 10 to 15 November 2018 and made provisional planning.

MC Decisions/Actions:

- The MC agreed to finalise the list of EWGs/IWGs which will meet in Charlotte, North Carolina, USA in November 2018 at the latest at the MC Technical 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 EWGs/IWGs already approved in Kobe by the MC to meet in Charlotte in November 2018 could obtain the final approval to meet shortly after the Coordinators TC;
- The following table summarises MC preliminary considerations regarding the EWGs/IWGs meeting.

List of 25 Current ICH Working Groups (as of 6 June 2018)		Meeting in Charlotte	Not meeting in Charlotte	For decision at MC TC
Efficacy Groups	Ad-Hoc Paediatric EWG		x	
	E2B(R3) EWG/IWG			?
	E8(R1) EWG	√		
	E9(R1) EWG	√		
	E11A EWG	√		
	E14/S7B DG			?
	E17 IWG			?
	E19 EWG	√		
Multidisciplinary Groups	M1 PtC WG		x	
	M2 EWG			?
	M4Q(R1) IWG		x	
	M7(R2) EWG			?
	M8 EWG/IWG		x	
	M9 EWG		x	
	M10 EWG	√ (5 days)		
	M11 informal WG (CeSHarP)			?
Quality Groups	Q3C(R7) Maintenance EWG		x	
	Q3D (R1) Maintenance EWG		x	
	Q11 IWG		x	
	Q12 EWG		x	

List of 25 Current ICH Working Groups (as of 6 June 2018)		Meeting in Charlotte	Not meeting in Charlotte	For decision at MC TC
	Q13 informal WG (Continuous Manufacturing)			?
	Q2(R2)/Q14 informal WG			?
Safety Groups	S1(R1) EWG			?
	S5(R3) EWG	√ (5 days)		
	S11 EWG		x	

P. Dates of Next meetings

Teleconferences

MC Decisions/Actions:

- The MC noted that a poll to define the dates of the next MC teleconferences will be sent at the end of the meeting.

Face-to-face Meetings

MC Decisions/Actions:

- The MC noted the dates of the next face-to-face meetings:
  - 10-15 November 2018 Charlotte, North Carolina, USA
  - 1-6 June 2019 Europe (location to be confirmed)
  - 16-21 November 2019 Asia (location to be confirmed)
  - 23-28 May 2020 America (location to be confirmed)
  - 14-19 November 2020 Europe (location to be confirmed)