

Ref.: MC2017/02

April 19, 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
March 9, 2017**

LIST OF PARTICIPANTS:

ICH Management Committee Members

Ms. Lenita Lindström-Gommers	EC	Europe
Dr. Spiros Vamvakas	EC/EMA	Europe
Mr. Pär Tellner	EFPIA	Europe
Dr. Theresa Mullin (<i>Chair</i>)	FDA	USA
Dr. Celia Lourenco	Health Canada	Canada
Dr. Hironobu Hiyoshi	JPMA	Japan
Dr. Masafumi Yokota	JPMA	Japan
Dr. Nobumasa Nakashima	MHLW	Japan
Dr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Toshiyoshi Tominaga (<i>Vice-Chair</i>)	MHLW/PMDA	Japan
Mr. Jerry Stewart	PhRMA	USA
Ms. Cordula Landgraf	Swissmedic	Switzerland

ICH Standing Observer Delegates

Dr. David Jefferys	IFPMA	Switzerland
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ICH Coordinators

Mr. Georgios Balkamos	EC	Europe
Mr. Pär Tellner	EFPIA	Europe
Ms. Amanda Roache	FDA	USA
Mr. Nick Orphanos	Health Canada	Canada
Mr. Mitsuo Mihara	JPMA	Japan
Mr. Fumihito Takanashi	MHLW	Japan
Ms. Camille Jackson	PhRMA	USA

ICH Technical Coordinators

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

Other Participants:

Dr. Tomas Salmonson	EC/EMA	Europe
Mr. Martin Harvey Allchurch	EC/EMA	Europe
Mr. Stephan Rönninger	EFPIA	Europe
Dr. Sarah Adam	IFPMA	Switzerland
Dr. Yoshihiro Katsura	MHLW/PMDA	Japan

ICH Secretariat

Dr. Dawn Ronan
Dr. Véronique Kuntzelmann

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA

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

1. ADOPTION OF THE AGENDA

The MC adopted the agenda for the teleconference with agreement to discuss under Any Other Business the Working Groups which could already be agreed to meet in Montreal. A change to the ordering of agenda items was also agreed.

2. APPROVAL OF THE MC TC REPORT

MC2017/01 – FEBRUARY 13, 2017

MC Action/Decision:

- *The MC approved as final the MC report (MC2017/01) of the teleconference held on February 13, 2017 and publication on the ICH website.*

3. REVISION OF ICH ARTICLES OF ASSOCIATION & ASSEMBLY RULES OF PROCEDURE

The MC noted the revisions proposed to the ICH Articles of Association and Assembly Rules of Procedure (RoP). Once supported by the MC, these changes would be proposed to the Assembly for consideration and approval. The MC noted that the aim was to propose these changes for consideration at the Montreal meeting in May/June 2017.

The MC noted that the changes proposed could be categorised as follows: those aimed at ensuring ICH expands in a manageable way; those which prepare for the enlargement of the MC (to take place no later than January 1, 2018); and changes to the provisions related to funding in the transition period which ends with the introduction of fees for all Members.

MC Actions/Decisions:

- *The MC supported the proposal for the term in office for Elected MC Representatives to be reduced from 4 to 3 years;*
- *The MC agreed to provide any comments in writing to the ICH Secretariat by March 17, 2017 and then to determine the need for further MC discussion on any points.*

4. NEW TOPIC PROPOSALS – SUBCOMMITTEE ASSESSMENT

The MC was updated on the activities of the New Topic Subcommittee to consider 16 New Topic Proposals which had been submitted in January 2017. The MC noted that further to 2 teleconferences held with ICH experts, the following topics had received support from the Subcommittee – the MC noted that further work was needed on some proposals along with further discussion on format and timing for others:

1. *Continuous manufacturing*
2. *Quality overall summary*
3. *Analytical procedures*
4. *Extrapolation*
5. *E8 Revision*
6. *E2A Revision*

The MC noted that for each topic the Subcommittee Members had been invited to complete the Evaluation Form ahead of the next Subcommittee teleconference on March 30, but scoring and prioritization would be left to the MC to complete ahead of the Montreal meeting.

The MC noted that there were two additional topics proposed on *Natural History Studies* and *Outlier Investigation* which had not received initial support from the Subcommittee, but these would be revised for further consideration by the Subcommittee.

MC Action/Decision:

- *Once the New Topics Subcommittee has completed its evaluation of the new topic proposals, MC Members will be invited to provide their scoring and prioritization to the ICH Secretariat by May 12.*

5. NEW TOPICS AND STRATEGIC DISCUSSIONS

Adaptive Clinical Trials Proposal

The MC noted that MC Members had been invited to provide their comments on the revised *Adaptive Clinical Trials* proposal.

MC Action/Decision:

- *Further to the comments received, a recommendation will be made on how to advance the topic in view of timing/sequencing considerations linked with other Efficacy topics including current work on E9 and E17, as well as the newly proposed E8 revision.*

ICH Reflection Paper on GCP Renovation

The MC noted that a number of comments had been received to-date on the ICH Reflection Paper on *GCP Renovation* and that the deadline for comments would be March 11, 2017.

Strategic Topic: Compliance of Reliability for Electronic Records

The MC noted the status of MC Industry Members' work-to-date on a feasibility analysis for the strategic topic *Compliance of Reliability for Electronic Records*.

MC Actions/Decisions:

- *The MC agreed that the Feasibility Group working on this topic was under the governance of the MC and that the role of the M2 EWG was an advisory role;*
- *The MC agreed that regulatory input to the Feasibility Group would be provided through regulatory experts nominated by the each MC Regulatory Member.*

6. ICH OPERATIONAL/SECRETARIAT MATTERS

The ICH Secretariat updated the MC on the following items:

- ***The status of preparations for the asset transfer from IFPMA to ICH***

The MC noted that the timeframe for the transfer of assets from IFPMA to the new ICH Association still needed to be finalized.

- ***The timeframe for the closing of 2016 accounts***

The MC noted that the ICH Secretariat was currently working on the closing of the 2016 ICH and MedDRA accounts, and would provide closing reports ahead of the Montreal meeting.

- ***The organisation of first financial audit of the ICH Association***

The MC noted the engagement of auditing firm Moore Stephens Refidar SA to perform the first audit of the accounts of new ICH Association. The MC noted the process and that the aim would be to provide the Audit Report to the Assembly in Montreal.

- ***The development of the draft 2016 Annual Report***

The MC noted that in Montreal, the Assembly would be asked to approve the 2016 Annual Report for the ICH Association. The MC noted that the first draft was currently under development by the ICH Secretariat and would be shared shortly with the MC for its input.

The MC noted that the aim would be to provide the report to the Assembly in their agenda papers package to be sent by mid-May.

▪ ***The development of a table to collect information on ICH Guideline Implementation in preparation of Assembly discussion in Montreal***

The MC noted that at the Osaka meeting, it had been agreed that to facilitate Assembly discussion in Montreal, the ICH Secretariat should develop a table regarding the implementation of all ICH Guidelines by all Regulatory Members. The MC noted that the ICH Secretariat had developed the table in view of Section 1.1.3 of the Assembly RoP to capture information on Member implementation of Tier 1, Tier 2 and Tier 3 ICH Guidelines, along with other information on planned implementation timeframe, and any deviation in the implementation of a Guideline. The MC noted that the ICH Secretariat would share the table with it shortly prior to circulation to new Regulatory Members.

▪ ***The outcome of a recent meeting between the ICH Secretariat and the PIC/S Executive Bureau***

The MC noted that the ICH Secretariat (Dr. Ronan & Dr. Güller) had met with the PIC/S Executive Bureau on February 9, 2017 and had also been invited to attend the PIC/S Committee meeting as special guest.

MC Action/Decision:

➤ *The MC supported the activities undertaken by the ICH Secretariat.*

7. ICH MEMBERSHIP AND OBSERVERSHIP

Membership & Observership Applications

The MC was updated on the Membership/Observership applications currently under consideration. The MC noted that the Membership Subcommittee was undertaking follow-up with some applicants.

8. SOPs FOR EWGs/IWGs

The MC was updated on the need for some further clarification to be introduced into the SOPs for EWGs/IWGs. The MC noted that this would be to address items including the procedures on how experts join a working group and how to manage the size of the working groups appropriately. The MC noted that teleconferences of the EWG/IWG SOP Subcommittee would be organised shortly with a view to making a recommendation to the MC on proposed changes.

9. ICH FINANCIAL MATTERS

The MC was updated on the activities of the Financial Subcommittee. These included: preparation of the 2018 budget (for Assembly approval in Montreal); work on the 2017 and 2018 cash flow documents; developing a 3-5 year budget projection; updating the funding page on the ICH website to include new items such as the Membership Fees and the 2017 MedDRA budget; progressing the proposal for an ICH participation fee; and developing a proposal on mitigating risk of cost increase of ICH meetings.

10. ICH TRAINING STRATEGY

Time did not allow for a report from the Training Subcommittee which was postponed until the next MC teleconference.

11. ICH COMMUNICATION

Time did not allow for a report from the Communication Subcommittee which was postponed until the next MC teleconference. The following written report is instead provided for MC information:

Communications Strategy

The Communication Subcommittee has not met since Osaka, but a teleconference is planned soon. No comments on the communication strategy were received following Osaka, but there are a number of ideas and reflections the Subcommittee can work on.

Transparency Policy

Some comments were received on the Transparency Policy document following the Osaka discussion. It would be important to get any other comments in order to have a final document either before or at Montreal. There have been a couple of evolutions since Osaka that need to be taken into account in this document (e.g. publication of MC teleconference meeting reports).

ICH Website

The ICH Secretariat has been working on a number of updates to the ICH website, including work on: ICH History & Vision pages; a Value of Membership page, integrating the membership lists for the Assembly, MC and Coordinators. Work on updating the Funding page is also ongoing with the Financial Subcommittee. More work is needed and the Communications Subcommittee will need to develop a deliverable plan of improvements for 2017, taking into account budget and Secretariat resources.

MC Action/Decision:

- *The MC is invited to provide any remaining comments on the transparency document as soon as possible.*

12. ORGANISATION OF MONTREAL MEETING

The MC noted the following key dates for the preparation of the Montreal meeting:

- ❖ **At the latest on May 1:** The draft Assembly Agenda will be circulated to the Assembly;
- ❖ **At the latest on May 17:** The Assembly Agenda Papers Package, including background documents, will be circulated to the Assembly.

13. DATES OF NEXT TELECONFERENCES AND MEETINGS

Teleconferences Ahead of Montreal Meeting:

March 29, 2017	MC TC (Technical WGs)
April 13, 2017	MC TC (Policy/Procedures)
May 16, 2017	MC TC (Policy/Procedures)

Face-to-Face ICH Meetings:

May 27 – June 1, 2017	Montreal, Canada
November 11-16, 2017	Geneva, Switzerland
June 2-7, 2018	Kobe, Japan

14. ANY OTHER BUSINESS

Working Groups Meeting in Montreal

The MC noted a request from one of the MC Members to explore whether the MC could already provide final approval for some Working Groups (WGs) to meet in Montreal. The MC noted that in Osaka it had already provisionally agreed 8 WGs to meet face-to-face in Montreal, and that the requests of these WGs to meet had been discussed at the teleconference of the ICH Coordinators on March 2, 2016 with no concerns raised for these WGs to meet.

The MC supported the approach, but considered it too early to approve a meeting of the E19 EWG in Montreal given that the informal Working Group was still working on the Concept Paper and Business Plan for MC approval.

MC Actions/Decisions:

- *The MC supported that the following WGs meet in Montreal in May/June 2017:*
 - *S5(R3) EWG – 5 Days (Sunday to Thursday)*
 - *Q12 EWG – 5 Days (Sunday to Thursday)*
 - *E9(R1) EWG – 4 Days (Monday to Thursday)*
 - *E11(R1) EWG – 4 Days (Monday to Thursday)*
 - *E17 EWG – 4 Days (Monday to Thursday)*
 - *M9 EWG – 4 Days (Monday to Thursday)*
 - *M10 EWG – 4 Days (Monday to Thursday)*
- *Decisions regarding other WGs requesting to meet in Montreal will be taken at the MC teleconference on March 29, 2017;*
- *The ICH Secretariat will inform the Assembly on the approval of these 7 WGs to meet.*