

Ref.: MC2017/04

May 29, 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
April 13, 2017**

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

Ms. Lenita Lindström	EC/EMA
Dr. Spiros Vamvakas	EC/EMA
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA
Ms. Joan Blair	FDA
Ms. Pujita Vaidya	FDA
Dr. Celia Lourenco	Health Canada
Ms. Catherine Parker	Health Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Toshiyoshi Tominaga (<i>Vice Chair</i>)	MHLW/PMDA
Dr. Nobumasa Nakashima	MHLW
Mr. Naoyuki Yasuda	MHLW/PMDA
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Ms. Cordula Landgraf	Swissmedic

ICH MC Coordinators

Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA
Mr. Nick Orphanos	Health Canada
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW
Ms. Camille Jackson	PhRMA

Technical Coordinators:

Dr. Michelle Limoli	FDA
Ms. Chieko Hirose	MHLW/PMDA

Other Participants:

Dr. Tomas Salmonson	EC
Dr. Sarah Adam	IFPMA
Dr. Gabriela Zenhäusern	WHO

ICH Secretariat:

Dr. Dawn Ronan
Dr. Isabelle Güller
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 agenda was adopted without any comments.

2. ORGANISATION OF MONTREAL MEETING

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

By/at latest May 1: The draft Assembly Agenda will be circulated to the Assembly;

By/at latest May 17: The Assembly Agenda Papers Package, including background documents will be circulated to the Assembly.

MC Actions/Decisions:

- *The MC supported the draft Assembly Agenda prepared by the ICH Secretariat pending minor updates in view of the outcome of the teleconference.*
- *Following the teleconference, the ICH Secretariat will share the final draft Assembly Agenda with the Assembly Chair and Vice Chair for their support and thereafter with the MC for any final comment before sending to the Assembly Members and Observers.*

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

The MC was updated on the comments received from MC Members on the proposed revisions to the ICH Articles of Association and Assembly Rules of Procedure and the main changes made in view of these comments.

The MC noted these changes included those related to keeping the size of ICH meetings manageable. The MC confirmed support for many of the changes, but agreed further discussion was needed on some items.

The MC supported to update the proposed revisions to the Articles of Association and Assembly Rules of Procedures based on its discussion, leaving aside those items that would require further discussion. This would enable the circulation of the proposed revisions to the Assembly for its consideration ahead of the Montreal meeting.

The MC noted that some revisions to the MC Rules of Procedure would be proposed for consideration by the MC in Montreal.

MC Actions/Decisions:

- *Revised versions of the Articles of Association and Assembly Rules of Procedure will be shared with the MC for its support, following which these revisions will be proposed to the Assembly ahead of the Montreal meeting for consideration by the Assembly for approval in Montreal.*
- *In Montreal, the MC will be invited to discuss proposed revisions to the MC Rules of Procedure, in addition to items raised in discussion of the revisions to the Articles of Association and Assembly Rules of Procedure which were considered as needing further consideration.*
- *The MC supported scheduling 1 hour for this topic at both the MC and Assembly meetings in Montreal.*

4. NEW TOPIC PROPOSALS AND STRATEGIC DISCUSSIONS

MC Action/Decision:

- *The MC supported allocating 90 minutes at the MC meeting and 60 minutes at the Assembly meeting in Montreal for discussion regarding the following items.*

New Topics Subcommittee

The MC was updated on the activities of the New Topic Subcommittee in consideration of the 16 New Topic Proposals received in January. While noting that some topics still needed further discussion by the MC and the Assembly, the MC supported the following short-list of 8 topics* to be sent to the Assembly by May 1, pending prioritization by the MC ahead of Montreal, based on which a recommendation would be made to the Assembly regarding the progression of these topics:

1. Continuous Manufacturing
2. Quality Overall Summary
3. Analytical Procedure Development and Q2 Revision
4. E8 Revision
5. E2A
6. Natural History Studies
7. Outlier Investigation
8. Paediatric Extrapolation

MC Action/Decision:

- *The MC supported the short-list of 8 topics which will be: (1) sent to the Assembly by May 1; and (2) scored and prioritized by the MC by May 1, to allow a compilation to be provided to the MC ahead of the May 16 MC teleconference, when the MC should finalize its recommendation to the Assembly.**

GCP Renovation

The MC was updated on the 22 comments received on the Reflection Paper on GCP Renovation. The MC noted that the E8 revision would be progressed first.

MC Action/Decision:

- *The MC supported that the analysis of the comments will be provided to the Assembly in the Agenda Papers Package ahead of Montreal.*

Adaptive Clinical Trials

The MC was updated on the advancement of the *Adaptive Clinical Trials* topic.

MC Action/Decision:

- *The MC supported that further discussion of the Adaptive Clinical Trials topic takes place at the Geneva meeting in November 2017, with consideration of the progress of existing working groups' activities, with discussion of the proposal with the Assembly thereafter.*

Strategic Discussions

The MC discussed the organisation at the Montreal meeting of discussion on strategic topics to progress, further to the Strategic Portfolio approach presented in November 2016, and the general outline discussed in June 2016.

* **Post-Meeting Note:** For the formal record it is noted that while these 8 topics were sent to the Assembly on May 1, 2017, MHLW/PMDA subsequently raised a concern, highlighting that at the TC on April 13, there had been discussion that all 14 proposals should be sent to the Assembly and prioritised by the MC. Noting this confusion at the subsequent MC TC on May 16, the MC agreed to further discuss in Montreal next steps for these other proposals which had not been sent to the Assembly and had not been prioritised by the MC.

MC Actions/Decisions:

- *The MC noted that material will be sent to the Assembly ahead of the Montreal meeting to support presentation of the progress made on the strategic topic Compliance of Reliability for Electronic Records.*
- *The MC noted that a Quality Reflection Paper, will be shared with the MC by May 1 for comments prior to sharing with the Assembly.*
- *The MC supported further discussion in Montreal on strategic themes and the process for progressing work on new topics (i.e., progression in view of strategic themes versus individual topics).*

5. ICH MEMBERSHIP AND OBSERVERSHIP

The MC was updated on applications currently under review.

MC Action/Decision:

- *The MC supported 30 min for discussion at both the MC and Assembly meetings in Montreal.*

6. SOPs FOR EWGs/IWGs

The MC noted that prior to the Montreal meeting, the SOP Subcommittee planned to make a recommendation for MC approval on proposed revisions to the SOPs for WGs to address items including the procedures on how experts join a working group and how to manage the size of the working groups appropriately.

MC Action/Decision:

- *The MC supported that the SOPs for EWGs/IWGs will be discussed during 30 min at the MC meeting and during 15 min at the Assembly meeting in Montreal.*

7. ICH FINANCIAL MATTERS

The MC was updated on the activities of the Financial Subcommittee in preparation of the Montreal meeting, where the Assembly will be invited to approve the 2018 ICH Budget and the 2016 audited accounts of the Association, and will be updated on other items including: a multi-year budget plan; a proposal for a participation fee for Observers and cash flow.

The MC noted that the Financial Subcommittee was also working on an options paper regarding the future organisation of ICH meetings, but would propose to discuss this topic separately to financial matters in Montreal in view of the fact that it extends beyond financial considerations. The MC noted that the Financial Subcommittee would share with it the documents for discussion in Montreal following its next teleconference on April 26, 2017.

MC Actions/Decisions:

- *The MC supported that financial matters be discussed during 60 min at the MC meeting and during 30 min at the Assembly meeting in Montreal.*
- *The MC supported that the future organisation of ICH meetings be discussed during 45 min at the MC meeting and 15 min during the Assembly meeting in Montreal.*

8. ICH TRAINING STRATEGY

The MC noted that in Montreal the Training Subcommittee will provide an update on the progress of the pilot supported by the MC in Osaka in November 2016 for the Training Subcommittee to partner with a small group of training providers. The MC was informed that a more substantial discussion was planned for the next ICH meeting in Geneva in November 2017 after the completion of many of the pilot training programmes.

MC Action/Decision:

- *The MC confirmed that the status of the Training Subcommittee's activities will be presented during 10 min at both the MC and the Assembly meetings in Montreal.*

9. ICH COMMUNICATION

The MC noted that in Montreal, the Communication Subcommittee will provide an update on the activities of the ICH Communication Subcommittee and seek MC formal approval of the final *Communication and Stakeholder Engagement Plan for 2017-2018* and *Transparency Policy*.

MC Action/Decision:

- *The MC noted the need to confirm with the Communication Subcommittee the time needed for discussion at both the MC and the Assembly meetings in Montreal.*

10. ICH OPERATIONAL/SECRETARIAT MATTERS

The ICH Secretariat informed the MC on the status of the ICH Guideline Implementation table, and the MC noted other items for discussion in Montreal including: preparation for the expansion of the MC; IPRF cooperation; and general ICH meeting organisation.

MC Actions/Decisions:

- *The MC supported ICH Secretariat efforts to complete the Implementation table for provision to the Assembly with information from all ICH Regulatory Members (with Observer Members to also be invited to share information if they wish).*
- *The MC supported further discussion at its next teleconference on May 16, 2017 on the preparation of a discussion with the Assembly on Guideline Implementation in Montreal.*

11. ICH INFORMAL E19 WG

The MC noted the progress made towards developing the E19 Concept Paper and Business Plan and that further time was needed by the informal WG to finalise these items for MC approval.

MC Actions/Decisions:

- *The MC confirmed that the E19 informal WG will meet in Montreal to finalize the Concept Paper and Business Plan.*
- *Once the E19 Concept Paper and Business Plan will be endorsed by the MC at the Montreal face-to-face meeting, the E19 Expert Working Group will be established.*

12. DATES OF NEXT TELECONFERENCE AND MEETINGS

Teleconference Ahead of Montreal Meeting:

- **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