

Ref.: MC2017/06

May 29, 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
May 16, 2017**

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

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

ICH MC Coordinators

Mr. Georgios Balkamos	EC/EMA
Ms. Amanda Roache	FDA
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW
Ms. Camille Jackson	PhRMA

Technical Coordinators

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

Standing Observers

Mr. David Jefferys	IFPMA
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Other Participants

Mr. Martin Harvey	EC/EMA
Dr. Sarah Adam	IFPMA

ICH Secretariat

Dr. Isabelle Güller	
Dr. Véronique Kuntzelmann	
Dr. Dawn Ronan	

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA

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

1. ADOPTION OF THE AGENDA

A request was made to discuss ICH Training under the AOB section. The MC adopted the agenda without any other comments.

2. ADOPTION OF THE REPORT OF THE PREVIOUS TELECONFERENCE

MC2017/04 – APRIL 13, 2017

A comment was raised on the report (MC2017/04) of the teleconference held on April 13, 2017.

MC Action/Decision:

- *The MC agreed to postpone the approval of the report (MC2017/04) to the face-to-face meeting in Montreal, Canada, in May/June 2017.*

3. NEW TOPIC PROPOSALS AND STRATEGIC DISCUSSIONS

New Topic Proposals

The MC discussed the scoring/prioritisation compilation for the shortlisted New Topic proposals.

MC Actions/Decisions:

- *The MC approved the two Efficacy topics that received the highest scores to be for recommendation to the Assembly in Montreal: Revision of ICH E8 on General Considerations for Clinical Trials and the development of a new ICH Guideline on Pediatric Extrapolation;*
- *The MC supported further discussion on the proposed Quality topics during the face-to-face meeting in Montreal;*
- *The MC also supported that the New Topics Subcommittee revisit the New Topic selection process during the summer with a view to refining based on experience gained.*

Strategic Discussions

The MC discussed the revised draft Quality Reflection Paper and noted that further comments had been received on the version sent to the MC prior to the teleconference.

MC Actions/Decisions:

- *The MC agreed to discuss a further revised version of the Quality Reflection Paper at its meeting in Montreal ;*
- *The Assembly will be informed about the status of the Quality Reflection Paper at the Montreal meeting.*

4. ICH GUIDELINE IMPLEMENTATION

The ICH Secretariat updated the MC on the status of the ICH Guideline Implementation table and that additional information still needed to be collected to reflect accurately the implementation state of all ICH Regulatory Members. The MC noted that in addition to the collection of information from all Regulatory Members, a couple of Regulatory Observers had also shared information.

MC Action/Decision:

- *The MC supported that the ICH Guideline Implementation table be presented to the Assembly at the Montreal meeting by which time the ICH Secretariat hopes to have completed the collection and clarification of the necessary information.*

5. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was updated on applications currently under consideration.

MC Action/Decision:

- *The MC agreed on the recommendation to be made to the Assembly regarding two of the applications as per the ICH Articles of Association;*
- *The MC tasked the Secretariat to send this recommendation to the ICH Assembly Members ahead of the Montreal meeting.*

6. IFPMA PROPOSAL

IFPMA presented a proposal to facilitate the participation of experts from the IFPMA National Associations in EWGs/IWGs.

MC Actions/Decisions:

- *The IFPMA will provide the Secretariat with a revised proposal ahead of the Montreal meeting;*
- *The MC supported further discussion on this proposal at the Montreal meeting;*
- *The MC agreed to add an agenda item in the Assembly Agenda and to provide the Assembly with the revised proposal at the Montreal meeting.*

7. ORGANISATION OF MONTREAL MEETING

❖ ASSEMBLY MEETING

MC Actions/Decisions:

- *The MC supported the revised Assembly Agenda and the Assembly Agenda Papers Package to be sent to the Assembly on May 17, 2017;*
- *The MC noted the publication on the ICH public website of the revised Assembly Agenda and the Assembly Agenda Papers Package without those draft documents and proposals for Assembly consideration/approval in Montreal.*

❖ **MANAGEMENT COMMITTEE MEETING**

MC Action/Decision:

- *The MC supported the revised MC Agenda and noted the MC Agenda Papers Package will be sent on May 18, 2017 including the background documents listed in the table below.*

8. DATES OF NEXT MEETINGS

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

9. ANY OTHER BUSINESS

The Lead of the Training Subcommittee clarified that the process had been endorsed by the MC in Osaka in November 2016 and that the Subcommittee was proceeding on this basis and was not intending to seek MC approval for each training event organised.