

22 November 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
31 October 2017**

LIST OF PARTICIPANTS:

ICH Management Committee Members

Ms. Lenita Lindström-Gommers	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, US
Ms. Joan Blair	FDA, US
Ms. Pujita Vaidya	FDA, US
Ms. Catherine Parker	Health Canada, Canada
Dr. Celia Lourenco	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Toshiyoshi Tominaga (<i>Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Nobumasa Nakashima	MHLW, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Mr. 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, Japan
Ms. Camille Jackson	PhRMA

Technical Coordinators:

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

Other Participants:

Dr. Gabriela Zenhäusern	WHO
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ICH Secretariat:

Dr. Dawn Ronan
Dr. Anne Latrive
Dr. Véronique Kuntzelmann
Ms. Coralie Angulo

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

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

1. ADOPTION OF THE AGENDA

Dr. Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted without any comments.

2. APPROVAL OF THE AGENDA FOR THE MC MEETING

The MC noted the draft MC Agenda for the Geneva meeting circulated to the MC on 20 October 2017 and the comments received, and that a revised version of the draft was circulated to the MC on 30 October 2017.

MC Actions/Decisions:

- *The MC endorsed the revised draft MC Agenda for the Geneva meeting;*
- *The MC noted that the MC Agenda Papers Package will be circulated to the MC by 3 November 2017.*

3. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC was updated by the ICH Secretariat on the additional information received from applicants.

MC Actions/Decisions:

- *The MC supported that the Industry survey on ICH Guideline implementation will be presented to the Assembly at the Geneva meeting along with next steps,*
- *The MC supported to have a discussion around E2B under the Assembly Agenda item on implementation and invited Founding and Standing Regulatory Members to share their experience;*
- *The MC agreed that, as per the Article 32 of the Articles of Association, the MC would be consulted by the Assembly to provide its considerations on eligibility criteria and assessment.*

4. MEMBERSHIP AND OBSERVERSHIP

The ICH Secretariat updated the MC on outstanding Membership/Observership related items.

MC Action/Decision:

- *The MC agreed to continue with the policy of not communicating any information to the Assembly on the status of any outstanding Membership/Observership applications for which a MC recommendation has not been issued.*

5. OVERSIGHT OF THE WORKING GROUPS

• E8(R1) informal WG: General Considerations for Clinical Trials

The MC was updated on the progress made towards developing the Concept Paper and the Business Plan and that these documents would need further discussion notably on the scope and are expected to be finalised at the Geneva meeting.

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

The MC noted the comments received on the document circulated by EC, Europe aimed at addressing the findings of the EC, Europe's legal review within the *Step 1 Q12 Technical Document*.

MC Action/Decision:

- *The MC agreed that the Regulatory Members would further share their views on the proposed addition to the Step 1 Q12 Technical Document by electronic means by Friday 3 November, with the aim of taking a decision by the Geneva meeting.*

6. FINANCIAL MATTERS

The MC was updated by the Lead of the Financial Subcommittee on the process and the conclusions of the request for and assessment of proposals from Professional Conference Organisers (PCOs), and noted the "Considerations on PCOs" summary document.

MC Action/Decision:

- *The MC supported that this document would be presented to the MC at the Geneva meeting and would enable the MC to take a decision on engaging any collaboration with a PCO for future meetings organisation.*

7. GENERAL OPERATIONAL MATTERS

The MC noted the update provided by the ICH Secretariat on General Operational Matters, including the status of the asset transfer from IFPMA to the new ICH Association. The MC was also updated on considerations related to the ICH logo. The MC also noted the three documents developed by the ICH Secretariat to describe the protocols for elections that will be held during the Geneva meeting: the elections by the Assembly of the Assembly Chair and Vice-Chair and of Elected MC Representatives, and election by the MC of the MC Chair and Vice-Chair.

MC Action/Decision:

- *The MC agreed that the documents developed by the ICH Secretariat describing the protocols for the elections of the Assembly Chair and Vice-Chair and of Elected MC Representatives, and of the MC Chair and Vice-Chair would be circulated to respectively the Assembly and MC ahead of the Geneva meeting, reflecting an error revision on the process for MC Chair and Vice-Chair, if no concern is raised by the MC by Friday 3 November 2017.*

8. ORGANISATION OF GENEVA MEETING

- **Assembly Agenda Papers**

MC Actions/Decisions:

- *The MC supported the Assembly Agenda Papers package to be circulated by 1 November 2017;*
- *The MC supported the draft Quality Reflection Paper to be circulated to the Assembly with mention not yet endorsed by the MC.*

- **MC Agenda Papers**

MC Action/Decision:

- *The MC supported the MC Agenda Papers package to be circulated by 3 November 2017.*

9. DATES OF NEXT TELECONFERENCE AND MEETINGS

Face-to-Face Meetings

11-16 November 2017	Geneva, Switzerland
2-7 June 2018	Kobe, Japan
November 2018	USA

The MC noted that none of the proposed dates for the November 2018 Face-Face Meeting were ideal in view of clashes with other meetings.

MC Action/Decision:

- *The MC supported that the host explore other potential dates for the organisation of the November 2018 ICH meeting and that this topic would be further discussed at the Geneva meeting.*