

25 January 2017

**SUMMARY REPORT
ICH MC TELECONFERENCE
13 December 2017**

LIST OF PARTICIPANTS:

ICH MC Members

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

ICH MC 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, Japan
Ms. Camille Jackson	PhRMA

ICH MC Technical Coordinators:

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

ICH MC Standing Observers

Dr. David Jefferys	IFPMA
Mr. Mike Ward	WHO

Other Participants:

Dr. Tomas Salmonson	EC, Europe
Mr. Martin Harvey Allchurch	EC, Europe
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Gabriela Zenhäuser	WHO

ICH Secretariat:

Dr. Dawn Ronan
Dr. Anne Latrive

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. MHLW/PMDA, Japan proposed to discuss the subject of E17 IWG under Any Other Business. The agenda was adopted without further comments.

2. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC noted the proposed revisions to the MC Rules of Procedure (RoP) Section 2.2.1, intended to provide clarification on the interpretation of eligibility criteria with respect to the definition of a good record of implementation, as agreed at the Assembly meeting in Geneva, Switzerland on 15 November 2017.

MC Actions/Decisions:

- *The MC agreed on revisions to the MC RoP Section 2.2;*
- *The MC supported that the final revised version of the MC RoP would be circulated to the Assembly before the end of the year 2017 and published on the ICH website.*

3. ORGANISATION OF THE MC INTERIM MEETING

The MC was updated by EC, Europe on the organisation of the MC interim meeting to be hosted by the EMA/EC, Europe and held in London, UK.

MC Actions/Decisions:

- *The MC agreed on the following dates of the interim meeting: Monday, 26 March 2018 8:30am to Tuesday, 27 March 2018 6:00pm;*
- *The MC supported that the Host would further investigate the possibility of extending the meeting to Wednesday 28 March (am) but noted the logistical difficulties due to the closing of the offices on Wednesday 28 March end of afternoon for a long weekend;*
- *The MC supported the following Subcommittees to meet: New Topics 1.25 days, Implementation 0.75 day, Communication 0.5 to 1 day, Training 0.5 to 1 day;*
- *The MC noted that two meeting rooms were reserved so that the New Topics meeting would be held in parallel with the Communication meeting, and the Implementation meeting in parallel with the Training meeting, in order to minimize issues arising from overlaps of membership between Subcommittees;*
- *The MC supported that at least 2 Secretariat staff would attend the interim meeting;*
- *The MC agreed that for the next organizational steps the Host will coordinate with the ICH Secretariat, in particular on the setting up of teleconference lines during the interim meeting.*

4. DATES OF NEXT TELECONFERENCE AND MEETINGS

Teleconferences

To be confirmed

Face-to-Face Meetings

2-7 June 2018	Kobe, Japan
10-15 November 2018	USA (<i>location to be confirmed</i>)
June 2019	Europe (<i>date & location to be confirmed</i>)

5. ANY OTHER BUSINESS

The MC noted that the Concept Paper for the constitution of an E17 IWG is expected to be finalised shortly, and supported that the ICH Secretariat would circulate the final Concept Paper to the MC to enable it to reach adoption electronically.