

19 February 2018

**SUMMARY REPORT
ICH MC TELECONFERENCE
24 January 2018**

LIST OF PARTICIPANTS:

ICH MC Members

Ms. Lenita Lindström-Gommers	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Sabine Luik	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, US
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/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH MC Coordinators

Dr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW/PMDA, 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

Other Participants:

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Gabriela Zenhäusern	WHO
Dr. Sophie Sommerer (<i>MedDRA MC Chair</i>)	Health Canada, Canada

ICH Secretariat:

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

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 with some reordering of agenda items.

2. MEDDRA RELATED FINANCIAL MATTERS

The MC was joined by the MedDRA MC Chair Ms. Sommerer and noted the documents prepared by the MedDRA MC further to its teleconference in December 2017 to discuss multi-year budget planning. The MC noted that a revised 2018 MedDRA budget had been developed by the MedDRA MC for approval by the ICH Assembly ahead of the Kobe meeting in June 2018.

The MC also discussed the procedure related to MedDRA financial matters, including use of the MedDRA subscription fee surplus. The MC noted that the ICH Articles of Association and Rules of Procedure gave the MC overall financial responsibility within ICH, including approving yearly closing accounts and making financial proposals to the ICH Assembly. However, further clarity was needed within the procedures on the role of the MC and MedDRA MC regarding MedDRA financial matters, including coordination together, as well as the process for use of surplus which requires ICH Assembly approval.

MC Actions/Decisions:

- *The MC supported that the ICH Secretariat seek ICH Assembly approval of the revised 2018 MedDRA budget via written procedure;*
- *The MC agreed that in parallel of this, work be initiated to provide clarity within the Rules of Procedure for MC consideration regarding the roles of the MC, MedDRA MC and ICH Assembly with respect to MedDRA financial matters, and supported that this activity be lead by Mrs. Lindström-Gommers (ICH Assembly Chair, EC, Europe) in coordination with the MC Chair and Vice-Chair, the MedDRA MC Chair and the ICH Secretariat;*
- *The MC also agreed that there should be further interaction between the MC and MedDRA MC Chairs ahead of the Kobe meeting in June 2018 and in preparation of the report to the ICH Assembly, and also more transparency on MedDRA activities with more MedDRA MC interaction considered, including at the level of ICH Assembly meetings.*

3. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was updated on the status of Membership/Observership applications.

4. APPOINTMENT OF ELECTED MC REPRESENTATIVES

The MC noted that the deadline for the submission of nominations for elected MC Representatives for consideration in Kobe was 6 February 2018, which was consistent with the 4-month requirement in the MC Rules of Procedure. The MC noted that the ICH Secretariat had sent the Assembly Members a reminder of this deadline, also inviting Members who had already submitted applications to also submit any updated information by this date.

5. OVERSIGHT OF THE WORKING GROUPS

The MC noted a comment received by the Secretariat which, in view of the need to manage the size of ICH WGs, suggested limiting nominations for Members joining existing WGs to 1 expert.

MC Action/Decision:

- *The MC supported not to revise the Standard Operating Procedures for ICH WGs to make it a general rule to limit to 1 expert, but to monitor WG sizes and nomination requests and treat on a case-by-case basis.*

6. ORGANISATION OF THE INTERIM MEETING

The MC noted preparations for the interim meeting of MC Subcommittees on 26-27 March 2018 where the following meetings were scheduled: New Topics Subcommittee; Implementation Subcommittee; Communication Subcommittee; and Training Subcommittee. The MC noted the finalisation of the participants list and that information on the meeting logistics would be made available shortly.

MC Action/Decision:

- *The MC supported that work on the agendas would be progressed by each Subcommittee for sharing with the MC ahead of its next teleconference on 20 March 2018.*

7. COMMUNICATION

The MC was updated by MHLW/PMDA, Japan and JPMA on their work to publish a book in Japanese which would summarize ICH activities and ICH Guidelines.

MC Action/Decision:

- *The MC congratulated MHLW/PMDA, Japan and JPMA on this activity promoting ICH Guidelines.*

8. NEXT TELECONFERENCES AND MEETINGS

The MC noted that the location of the November 2018 meeting in the USA was confirmed as the Sheraton Le Méridien Charlotte, North Carolina.

The ICH Secretariat also presented the MC with the outcome of its poll regarding dates for the June and November 2019 meetings.

MC Actions/Decisions:

- *The MC supported blocking the following dates as options for the 2019 ICH meetings: 18-23 May (pending WHO feedback regarding the dates of the WHA) or 1-6 June, and 16-21 November.*

MC Teleconferences

20 March 2018	Policy 3
22 March 2018	Technical
10 April 2018	Policy 4
25 April 2018	Policy 5
15 May 2018	Policy 6

Interim MC Subcommittee Face-to-Face Meeting

26-27 March 2018

London, UK

Face-to-Face ICH Meetings

2-7 June 2018

Kobe, Japan

10-15 November 2018

Charlotte, USA

18-23 May or 1-6 June 2019

Europe (date and location to be confirmed)

16-21 November 2019

(location to be confirmed)

9. ANY OTHER BUSINESS

9.1. S1 STATUS REPORT

The MC noted the development of a second Status Report by the Founding and Standing Regulatory Members of the S1 EWG. The MC noted that this was intended for publication on the ICH public website to inform stakeholders about the closing in December 2017 of the period for the submission of CADs.

MC Action/Decision:

- *The MC supported the publication of the S1 Status Report on the ICH public website following review and support for the report by all S1 EWG Members, and the collection by the Secretariat of signatures from the Founding and Standing Regulatory Member experts in line with procedure.*