

3 June 2019

**SUMMARY REPORT
ICH MC TELECONFERENCE
8 May 2019**

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lila Feisee	BIO
Ms. Lenita Lindström	EC, Europe
Dr. Milton Bonelli	EC, Europe
Dr. Sabine Luik	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, United States
Ms. Joan Blair	FDA, United States
Mr. Leo Bouthilier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Young-Ok Kim	MFDS, Republic of Korea
Dr. Nobumasa Nakashima (<i>MC Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Junko Sato	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Xiaoling Qin	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Dr. Peter Honig	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Ms. Lila Feisee	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Dr. Yang Wang	NMPA, China
Ms. Camille Jackson	PhRMA

ICH MC Technical Coordinators

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, United States
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

ICH MC Standing Observers

Mr. David Jefferys	IFPMA
Ms. Sharon Olmstead	IFPMA

Other Participants

Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Dr. Gabriela Zenhäuser	WHO
Mr. Jerry Stewart	PhRMA

ICH Secretariat

Dr. Anne Latrive
Ms. Nikoleta Luludi
Ms. Nadia Myers Biggs
Dr. Dawn Ronan

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin - FDA, United States

MC Vice Chair: Dr. Nobumasa Nakashima - MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair - FDA, United States) welcomed all participants. The ICH Secretariat proposed to raise two items under Any Other Business to request MC feedback on matters related to Working Groups (WGs) in view of the proposed new rules to manage the size of Working Groups. The agenda was adopted without any modification.

2. ORGANISATION OF THE AMSTERDAM MEETING

The ICH Secretariat provided an update on Secretariat's work with the Professional Conference Organiser (PCO) on the organisation of the upcoming meeting to be held in Amsterdam, the Netherlands on 1-6 June 2019.

ICH MC Actions/Decisions:

- The MC noted that in view of the exceptionally large size of the meeting (16 WGs and approximately 500 participants), it will not be possible for all WG meeting rooms to be set up in square-shape;
- The MC noted as the host region EC, Europe proposed the invitation of two senior colleagues who would join the reception and address participants.

3. 2018 ANNUAL REPORT

The ICH Secretariat informed the MC on the 2018 Annual Report of the Association and that only a couple of minor comments had been received from MC/MedDRA MC Members which the ICH Secretariat had addressed.

ICH MC Action/Decision:

- The MC approved the provision to the ICH Assembly Members and Observers of the 2018 Annual Report of the Association as part of the Assembly Agenda Papers package.

4. GENERAL OPERATIONAL MATTERS

▪ *IPRP*

The ICH Secretariat informed the MC on the Annual Report the ICH Secretariat had developed regarding the support services provided in 2018 to the International Pharmaceutical Regulators Programme (IPRP), further to the Memorandum of Understanding (MoU) between ICH and IPRP.

ICH MC Action/Decision:

- The MC approved the provision to the IPRP MC of the 2018 Annual Report on support services provided by the ICH Secretariat to the IPRP.

▪ *Admin email box questions*

The ICH Secretariat informed the MC on the ongoing work regarding the review of the process to address technical questions about ICH Guidelines received from stakeholders through the ICH Admin email box.

ICH MC Action/Decision:

- The ICH MC noted that a proposal for a new process was under development with a view to a draft being shared with the MC ahead of the meeting in Amsterdam.

5. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

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

6. PROCEDURAL MATTERS

▪ *Revisions to ICH Procedural Documents*

The ICH Secretariat provided an update regarding revisions proposed to the ICH procedures: the ICH Articles of Association (AoA); ICH Assembly Rules of Procedure (RoP); ICH Management Committee RoP; and Standard Operating Procedure (SOP) for WGs, in view of items including: the new definitions and degrees of implementation; MC decisions regarding managing the size of WGs (further to discussion at the interim MC meeting on 1-2 April 2019); and clarification of rules regarding ICH cooperation with other organisations, which also impacts the MedDRA MC RoP.

ICH MC Actions/Decisions:

- The MC noted that the revisions proposed to the ICH procedures would be circulated to the MC for consideration and feedback within a one-week timeframe, with a view to providing revised documents as part of the Assembly Agenda Papers package;
- The MC supported that in consultation of the Chairs, the ICH Secretariat prepare a few slides to present an overview of the proposed revisions to the Assembly in Amsterdam.

▪ *Process for Reflection Papers*

The MC was updated by the Coordinator for the FDA, United States on the feedback received from MC Members on the process for development of Reflection Papers and ICH strategic framework.

ICH MC Action/Decision:

- The MC noted that FDA, United States would revise the proposal in view of the feedback received and would provide an updated draft to the MC ahead of the meeting in Amsterdam.

▪ *General Principles for Discussion Groups*

The MC was updated by the Coordinator for the FDA, United States on the development of a proposal for general principles regarding procedures for ICH Discussion Groups and on next steps ahead of the Amsterdam meeting.

ICH MC Action/Decision:

- The MC noted that the proposal was still undergoing MC consultation and that the FDA, United States would provide a revised proposal to the MC ahead of the meeting in Amsterdam if any comments were received.

7. NEW TOPICS AND REFLECTION PAPERS

▪ *New Topic Proposals*

The MC was updated by the Lead and Co-Lead of the New Topics Subcommittee on the provision to ICH Assembly Members and Observers of the New Topics Assessment Summary Table and Compilation of MC Member Evaluations for comments by 17 May 2019.

- ***Reflection Papers***

MHLW/PMDA, Japan Revised Draft Reflection Paper: Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data

The MC was updated by the Technical Coordinator for MHLW/PMDA, Japan on the revisions made to its Reflection Paper.

ICH MC Action/Decision:

- The MC supported the revised draft Reflection Paper on Pharmacoepidemiology and its provision as an ICH Reflection Paper to the Assembly ahead of Amsterdam.

PhRMA Revised Draft Reflection Paper: Model Informed Drug Development (MIDD):

The MC was updated by the Coordinator of PhRMA on revisions made to its Reflection Paper.

ICH MC Action/Decision:

- The MC agreed to review the Reflection Paper on MIDD and further discuss at its meeting in Amsterdam.

8. IMPLEMENTATION

The MC was updated by the Lead and Co-Lead of the Implementation Subcommittee on the ongoing work further to the completion of the Implementation Survey and on preparations for the Amsterdam meeting.

ICH MC Action/Decision:

- The MC noted that in view of the stepping down of the Implementation Subcommittee Lead after the meeting in Amsterdam, a new Implementation Subcommittee Lead would need to be appointed in Amsterdam.

9. TRAINING

- ***Call for Expression of Interest from Training Associates***

The MC was updated by the Lead and Co-Lead of the Training Subcommittee on the conduct of the Call for Expression of Interest from Training Associates.

ICH MC Actions/Decisions:

- The MC noted that further to questions received from third-parties, a Questions and Answers on the Call for Expression of Interest from Training Associates had been posted on the ICH public website for transparency;
- The MC noted that further to the deadline for the Call for Expression of Interest from Training Associates on 3 May, the Review Subcommittee will review all expressions of interests and present the outcome of the review at the ICH meeting in Amsterdam.

10. FINANCIAL MATTERS

- ***Strategic plan regarding surplus funds***

The MC Chair updated the MC on work done in collaboration with the ICH Secretariat to prepare MC discussions in Amsterdam regarding the use of surplus funds.

▪ **2020 Provisional ICH Budget & 5-Year Budget Plan**

The ICH Secretariat informed the MC on the current versions of the 2020 Provisional ICH Budget and 5-Year Budget Plan.

ICH MC Action/Decision:

- The MC supported the provision to the Assembly Members and Observers in the Agenda Papers package ahead of the Amsterdam meeting of: the 2019 Approved ICH budget, current versions of the 2020 Provisional ICH Budget and the Provisional 5-Year Budget Plan , along with a cover note to explain that pending MC discussion in Amsterdam, revisions may be proposed to these documents in line with the considerations of the strategic proposal on the use of surplus funds.

▪ **2018 Financial audit and Financial Statements**

Further to the 2018 Financial Audit, the ICH Secretariat informed the MC on updates made to the 2018 Financial Statements of the ICH Association and that the Auditor's report would be issued upon ICH's signature of the management representation letter and final 2018 Statements. The MC furthermore noted the development by the ICH Secretariat of 2018 ICH expense reports to provide a view on actual versus budgeted costs, including for one-time costs incurred in 2018.

ICH MC Actions/Decisions:

- The MC approved the final 2018 Financial Statements of the ICH Association and the management representation letter for signature by the Assembly Chair and the ICH Secretariat Director and subsequent provision to the Assembly Members ahead of the Amsterdam meeting;
- The MC supported the provision of the 2018 ICH expense reports to the Assembly Members and Observers ahead of the Amsterdam meeting.

11. OVERSIGHT OF WORKING GROUPS

Informal Quality Discussion Group (IQDG) (Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Ms. Kruse – EC, Europe)

The MC noted the work plan of the IQDG and was updated by the Coordinator of PhRMA on the activities of the group.

ICH MC Action/Decision:

- The MC approved the provision of the IQDG Work Plan to the Assembly Members and Observers in the Agenda Papers package ahead of the Amsterdam meeting.

S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe; Regulatory Chair: N/A)

The MC was updated by the Coordinator for EC, Europe on the revision made by the group to the proposed maintenance procedure, further to MC comments made at the MC Technical TC on 25 March.

ICH MC Action/Decision:

- The MC supported the revised S5 maintenance procedure and its provision to the Assembly Members and Observers in the Agenda Papers package ahead of the Amsterdam meeting, for approval by the Assembly in Amsterdam.

12. MEETINGS

ICH meeting in November 2020 in Europe

The ICH Secretariat informed the MC on the Site Selection Report with proposed options for the November 2020 meeting (15-19 November) in Europe developed by the PCO contracted by ICH to organise meetings from 2019.

ICH MC Action/Decision:

- The MC agreed the venue of the November 2020 meeting pending successful conclusion of a contract with the selected venue and confirmation of the booking cancellation conditions.

13. ORGANISATION OF THE AMSTERDAM MEETING

The MC was updated by the ICH Secretariat on the documents to be included in the Assembly Agenda Papers and MC Agenda Papers.

▪ *Assembly Agenda Papers*

ICH MC Actions/Decisions:

- The MC approved the draft agenda of the Assembly meeting and its provision to the Assembly 4 weeks ahead of the meeting;
- The MC confirmed its support for the documents to be included in the Assembly Agenda Papers package to be circulated by 22 May 2019;

▪ *MC Agenda Papers*

ICH MC Actions/Decisions:

- The MC confirmed its support for the Draft Agenda and Timetable for the MC meeting in Amsterdam;
- The MC confirmed its support for the documents to be included in the MC Agenda Papers package to be circulated by 20 May 2019.

14. NEXT TELECONFERENCES & MEETINGS

ICH MC Action/Decision:

- The MC noted the ongoing poll for the identification of the dates of the teleconferences of the next meeting cycle, as well as the ongoing poll for the identification of suitable date(s) for the November 2021 meeting and placeholder dates for a March/April 2020 MC interim meeting and that the final dates will be confirmed at the Amsterdam meeting.

▪ *Face-to-Face Meetings*

1-6 June 2019	Amsterdam, The Netherlands
17-21 November 2019*	Singapore
24-28 May 2020*	Vancouver, Canada
15-19 November 2020*	Europe (location to be confirmed)
30 May - 3 June 2021*	Asia (location to be confirmed)

**Note: The new meeting schedule is implemented for meetings from November 2019 onwards, with the ICH meeting week starting on Sunday.*

15. ANY OTHER BUSINESS

- *Considerations on establishment of E20 and M12 informal WGs*

ICH MC Action/Decision:

- The MC supported that although the E20 and M12 informal Working Groups will not start work until June/July 2019, they should be established on the basis of the rules in effect prior to the Amsterdam meeting given that the ICH Secretariat had already completed the call for the nomination of experts. The MC furthermore agreed that the MC would review the nomination requests received at the Amsterdam meeting.

- *Additional WG expert requests*

ICH MC Action/Decision:

- The MC supported that the expert nomination requests received prior to Amsterdam on the basis of current rules would be assessed by the MC at the meeting in Amsterdam, rather than being held until the next Technical MC teleconference in September, in order to support a smooth transition to new rules following the meeting, if approved by the Assembly in Amsterdam.