

15 April 2019

**SUMMARY REPORT
ICH MC TELECONFERENCE
12 March 2019**

LIST OF PARTICIPANTS

ICH MC Members

Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Milton Bonelli	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, United States
Ms. Joan Blair	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Mr. Leo Bouthilier	Health Canada, Canada
Dr. Nick Capuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Ms. Kyung Won Seo	MFDS, Republic of Korea
Dr. Nobumasa Nakashima (<i>MC Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Junko Sato	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Mr. Xiaoling Qin	NMPA, China
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Dr. Ingrid Markovic	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Dr. Wei Zhou	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

Ms. Sharon Olmstead	IFPMA
Mr. David Jefferys	IFPMA

Other Participants

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Harald Enzmann	EC, Europe
Dr. Yang Wang	NMPA, China

ICH Secretariat

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

SUMMARY REPORT

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

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

1. ADOPTION OF THE AGENDA

Dr. Mullin (ICH MC Chair - FDA, United States) welcomed all participants. The ICH Secretariat proposed to discuss the election of MC Representatives under Any Other Business. The agenda was adopted without further modification.

2. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

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

3. ORGANISATION OF NEXT MEETINGS

▪ *ICH MC interim meeting in April 2019 in Brussels, Belgium*

EC, Europe updated the ICH MC on the organisation of the ICH MC interim meeting to be held on 1-2 April 2019 in Brussels, Belgium hosted by EC, Europe. The ICH Secretariat further informed the ICH MC that to-date 43 participants had registered and that all MC Members and Standing Observers would be represented either in person or via a teleconference line.

ICH MC Action/Decision:

- *The ICH MC approved the revised agenda for the ICH MC interim meeting.*

4. NEW TOPICS AND STRATEGIC DISCUSSIONS

▪ *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 ICH MC was updated by the Technical Coordinator for MHLW/PMDA, Japan, on the comments received from MC Members on the revised draft Reflection Paper on Pharmacoepidemiological Studies, and on revisions made to address these comments, including on the scope and remit of a Discussion Group (DG).

ICH MC Actions/Decisions:

- *The ICH MC noted that MC Members would provide additional feedback on the revised draft Reflection Paper in the coming weeks, and that the ICH MC would discuss the new comments received at the ICH MC interim meeting in April 2019;*
- *The ICH MC noted that, following this additional feedback, MHLW/PMDA, Japan would further submit a new revised version of the draft Reflection Paper by 1 May 2019 for consideration by the ICH MC at its Policy 4 TC and, if supported by the ICH MC, for circulation to the Assembly for possible endorsement at its meeting in June 2019.*

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

The ICH MC was updated by the Coordinator for PhRMA, on the comments received from MC Members on the draft Reflection Paper on MIDD and the progress made on a revision addressing these comments.

ICH MC Action/Decision:

- *The ICH MC noted that PhRMA would submit a revised draft Reflection Paper by 22 March 2019, for ICH MC consideration at the ICH MC interim meeting in April 2019.*

5. PROCEDURAL MATTERS

▪ *Process for Reflection Papers*

The ICH MC was updated by the Coordinator for FDA, United States, on the progress made on the revision of the draft Flow Chart to clarify the process for the development and endorsement of Reflection Papers.

ICH MC Action/Decision:

- *The ICH MC noted that FDA, United States would share a revised flow chart by 18 March 2019 along with a short document regarding proposed considerations for the development of Reflection Papers, for ICH MC consideration at the ICH MC interim meeting in April 2019.*

▪ *Management of ICH Working Group Size*

The ICH MC was updated by the ICH Secretariat, on comments received from MC Members on the draft proposal on managing the size of WGs.

The ICH MC was also updated by the Coordinator for FDA, United States, on the feedback received from the internal stakeholders on the outcome of the E8(R1) Communication Pilot. As per the pilot plan, the E8(R1) EWG shared the final draft Technical Document prior to *Step 1* with interested ICH internal Member stakeholders who had expressed interest to nominate experts to the group, but had not been able to do so due to the large size of the group, and a teleconference was organised in January 2019 with the E8(R1) EWG and the interested ICH internal Member stakeholders to answer questions regarding the draft Technical Document.

ICH MC Actions/Decisions:

- *The ICH MC noted that a revised proposal on managing the size of WGs would be shared with the ICH MC shortly for further discussion at the ICH MC interim meeting in April 2019;*
- *The ICH MC noted the feedback received from the E8(R1) Communication Pilot Internal Stakeholders.*

6. FINANCIAL MATTERS

▪ *2018 Financial audit*

The ICH MC was informed by the ICH Secretariat on the closing of the 2018 Accounts for provision to the Auditor.

ICH MC Action/Decision:

- *The ICH MC approved the provision of the 2018 Financial Statements to the Auditor along with all necessary supporting documents, as well as the provision of the statements to the MedDRA MC for information.*

▪ *Strategic plan regarding surplus funds*

The ICH MC was informed on comments received from MC Members on the draft considerations document regarding the development of a plan for the use of surplus funds on strategic activities.

ICH MC Action/Decision:

- *The ICH MC supported a revision of the draft considerations according to comments received, with a view to further discussing this topic at the ICH MC interim meeting in April 2019 and at the ICH meeting in June 2019.*

7. TRAINING

▪ *Preparation of Call for Expression of Interest from Training Associates*

The ICH MC was informed by the Lead and Co-Lead of the Training Subcommittee on recent activities of the Subcommittees including on Recognised Training Programmes organised by Training Providers and recently published on the ICH website, and on the preparation, with the support of the ICH Secretariat, of the Call for Expression of Interest from Training Associates meeting the criteria of being non-profit training organisations/institutions who ICH would potentially contract with to: develop training materials for ICH ownership; deliver training; and provide consultancy services to ICH.

The ICH MC was further informed on the outcome of the ICH-funded training on ICH E6(R2) and E17 Guidelines held on 26-28 February 2019 in Ottawa, Canada which was attended by approximately 300 participants and very positively received.

ICH MC Actions/Decisions:

- *The ICH MC noted that the Training Subcommittee would further provide the MC with a list of options which would be for discussion at the ICH MC interim meeting in April 2019;*
- *The ICH MC agreed that MC Members should provide feedback in writing on the draft materials for the Call for Expression of Interest from Training Associates (including eligibility criteria, Terms of Reference and Response Form) by Tuesday, 19 March, with a view to further discussion at the ICH MC interim meeting in April 2019.*

8. GENERAL OPERATIONAL MATTERS

▪ *Trademarks*

The ICH MC was informed by the ICH Secretariat on legal follow-ups being conducted in relation to trademarks owned by the ICH Association in response to third parties seeking registration of similar trademarks, and on the approach currently being taken including consultation with the ICH MC Chairs and MedDRA MC Chair.

ICH MC Action/Decision:

- *The ICH MC supported the proposed approach to be taken going forward for legal follow-ups being conducted in relation to trademarks owned by the ICH Association.*

9. NEXT TELECONFERENCES & MEETINGS

Teleconferences

25 March 2019	ICH MC Technical
12 April 2019	ICH MC Policy 3
8 May 2019	ICH MC Policy 4

Face-to-Face Meetings

1-2 April 2019 (Interim meeting)	Brussels, Belgium
1-6 June 2019	Amsterdam, The Netherlands
17-21 November 2019*	Singapore
24-28 May 2020*	Vancouver, Canada (to be confirmed)
15-19 November 2020*	Europe (location to be confirmed)
31 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.*

10. ANY OTHER BUSINESS

Election of MC Representatives

The ICH MC was informed by the ICH Secretariat that there is currently a vacancy in the MC for up to two Elected MC Representatives from one Regulatory Member, noting that nominations would be submitted for election to the Assembly and that, in line with the procedures, nominations should be submitted at least 4 months prior to the ICH meeting.

ICH MC Action/Decision:

- *The ICH MC noted that no nomination for Elected MC Representatives had been received and that consequently no election will be held at the next meeting.*