

13 May 2019

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

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lila Feisee	BIO
Ms. Lenita Lindström	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. Dorothy Toh	HSA, Singapore
Ms. Siew Wei Chua	HSA, Singapore
Dr. Nick Cappuccino	IGBA
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
Dr. Naoyuki Yasuda	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

Ms. Lila Feisee	BIO
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
Ms. Siew Wei Chua	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
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

Ms. Sharon Olmstead	IFPMA
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Other Participants

Mr. Martin Harvey	EC, Europe
Ms. Agnes Saint Raymond	EC, Europe
Dr. Sarah Adam	IFPMA
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Dr. Gabriela Zenhäuser	WHO

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. Mullin (ICH MC Chair - FDA, United States) welcomed all participants. The agenda was adopted without modification.

2. ORGANISATION OF THE AMSTERDAM MEETING ON 1-6 JUNE 2019

▪ *2018 Annual Report*

The MC was updated on the drafting of the 2018 Annual Report of the ICH Association which should be submitted to the Assembly ahead of the Amsterdam meeting where it will be invited to approve the report and by doing so, discharge the ICH MC, MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2018 on behalf of the ICH Association.

The MC noted that a draft had been developed by the ICH Secretariat and was currently under review by the MC Chair and Vice Chair, further to which the draft will be shared with the ICH MC, with the MedDRA related sections shared with the MedDRA MC.

ICH MC Action/Decision:

- *The MC noted that it will be invited to approve the draft 2018 Annual Report at its next teleconference on 8 May 2018 for inclusion in the package of background documents to be sent to the Assembly ahead of Amsterdam.*

▪ *Amsterdam Meeting Logistics*

The MC was updated on logistical aspects related to the organisation of the Amsterdam meeting. The MC noted that in view of the 16 Working Groups approved to meet, the Amsterdam meeting was expected to be one of the largest ICH meetings to-date with 450-500 participants currently expected. The ICH Secretariat informed the MC that it had just received news that the room block at the Hotel was now sold out, and furthermore there were no more available rooms at the hotel covering all meeting nights. The MC noted that a similar block of rooms had been booked for recent ICH meetings, with the block being based on historical information/experience, and consideration of the level of risk given that ICH would need to take in relation to any unsold rooms in the block booking.

ICH MC Actions/Decisions:

- *The MC supported that the ICH Secretariat inform the Assembly that rooms are no longer available at the Hotel and provide information on alternative hotels in the vicinity;*
- *The MC supported that the ICH Secretariat explore the feasibility of offering breakfast at the Hotel for meeting participants staying at other hotels;*
- *The MC acknowledged the inconvenience for ICH Members and Observers presented by the unavailability of further rooms at Hotel and agreed the need for discussion in Amsterdam on how to improve the situation for future ICH meetings;*
- *The MC agreed the need to approve as early as possible Working Groups to meet at ICH meetings to help facilitate the smoother organisation of the meeting, and noted a suggestion that in Amsterdam the MC already see if possible to take a decision on some of the Working Groups to meet in Singapore in November 2019.*

▪ **Key Dates**

The MC noted the following key dates in preparation of the Amsterdam meeting:

- By **30 April**: The draft MC Agenda is circulated to the MC for comments.
- By **1 May**: All background documents for the Assembly meeting are to be provided to the Secretariat for MC review prior to inclusion in the Assembly Agenda papers.
- By **8 May**: The draft Assembly Agenda is circulated to the Assembly for comments.
- By **13 May**: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers.
- By **22 May**: The Assembly Agenda papers are circulated to the Assembly.

3. NEW TOPICS AND REFLECTION PAPERS

▪ **New Topic Proposals**

The MC was updated by the Lead of the New Topic Subcommittee on next steps further to the decisions taken at the interim ICH MC meeting on 1-2 April 2019.

ICH MC Actions/Decisions:

- *The MC agreed as final the version of the New Topics Assessment Summary Table for provision to ICH Assembly Members and Observers, and supported that the Compilation of MC Member Evaluations also be provided subject to any changes made by Members to their respective evaluations which should be submitted to the ICH Secretariat by 19 April 2019;*
- *The MC agreed that the New Topics Assessment Summary Table and Compilation of MC Member Evaluations be provided to ICH Assembly Members and Observers the week of 22 April 2019 with comments invited by 17 May 2019 which would allow the New Topics Subcommittee/MC two weeks ahead of the meeting to consider any comments received;*

▪ **Reflection Papers**

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

ICH MC Action/Decision:

- *PhRMA will circulate its revised draft Reflection Paper to the MC by 19 April for discussion at the next MC teleconference on 8 May 2019 with a view to the MC taking a decision at its call on whether to include the revised draft Reflection Paper in the package of background documents to be submitted to the Assembly ahead of Amsterdam.*

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

ICH MC Action/Decision:

- *MHLW/PMDA, Japan will circulate its revised draft Reflection Paper to the MC but given the scheduling of a teleconference on 25 April to discuss their input, the MC acknowledged that its circulation to the MC may be later than the 1 May deadline for background documents for the Assembly meeting.*

4. PROCEDURAL MATTERS

▪ *Revisions to ICH Procedural Documents*

The MC was updated by the ICH Secretariat on work being undertaken ahead of the Amsterdam meeting to revise: the ICH Articles of Association; ICH Assembly Rules of Procedure (RoP); ICH Management Committee RoP; MedDRA Management Committee RoP; and Standard Operating Procedure (SOP) for WGs, in view of items including: the new definitions of degrees of implementation; MC decisions regarding managing the size of WGs (further to discussion at the interim MC meeting on 1-2 April 2019); clarification of rules regarding ICH cooperation with other organisations; and other changes for clarity/consistency. The MC noted that the Lead of the Implementation Subcommittee had been consulted regarding the changes related to the new definitions of degrees of implementation.

ICH MC Action/Decision:

- The ICH Secretariat will solicit the input of the MC Chair and Vice Chair, as well as that of the former Lead of the RoP Subcommittee, on the first drafts of the revisions by 19 April prior to circulation to the MC for its consideration at its next teleconference on 8 May 2019 with a view to sending to the Assembly ahead of Amsterdam revisions supported by the MC.

▪ *Process for Reflection Papers*

At the interim MC meeting on 1-2 April 2019 the MC discussed the need to refine the process for development of Reflection Papers as part of a more structured multi-year strategic plan of near and long-term planning for Q, S, E and M ICH topics, to reflect more linkage to the new topic selection process, and inclusion of a pre-Reflection Paper discussion step to ensure MC input prior to initiation of Reflection Paper development.

The MC supported working in Amsterdam to structure this process, in preparation of which the paper discussed at the interim meeting will be further worked on based on the views already expressed by the MC, with the MC to provide further input ahead of the meeting on the updated paper and open questions. A visual framework schematic previously proposed to the MC at the Geneva meeting in November 2017 will also be recirculated with a view to also taking this into consideration.

ICH MC Actions/Decisions:

- An updated paper, including open questions will be circulated to the MC by 19 April 2019 for MC input ahead of the Amsterdam meeting;
- The previously presented visual framework schematic will be circulated to the MC in parallel of the updated paper.

▪ *General Principles for Discussion Groups*

Further to discussion at the interim MC meeting on 1-2 April 2019, the MC was updated on the development of general principles regarding procedures for ICH Discussion Groups.

ICH MC Actions/Decisions:

- Draft general principles for ICH Discussion Groups will be circulated to the MC by 22 April, with the MC to provide input by 6 May 2019 with a view to allowing time for the proposal to be revised by 13 May 2019 for inclusion in the package of background documents for the MC meeting in Amsterdam.

5. TRAINING

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

The MC was updated by the Lead of the Training Subcommittee on the launch of the Call for Expression of Interest from Training Associates on 5 April 2019. The MC noted that the Call had been communicated via the plan approved at the MC interim meeting on 1-2 April 2019 and that the deadline for applications had been announced as 3 May 2019.

Noting that some questions regarding the Call had been received, the MC supported an approach where all questions are addressed publicly via a Q&A section on the ICH website, with a deadline to be set ahead of the application deadline after which time further questions would not be addressed.

ICH MC Action/Decision:

- The ICH Secretariat will follow-up with the Review Committee regarding communication and implementation of the approach regarding the addressing of Q&As.

6. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

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

7. FINANCIAL MATTERS

▪ *Strategic plan regarding surplus funds*

Further to discussion at the interim MC meeting on 1-2 April 2019, the MC noted that the MC and Assembly Chairs had followed-up with the ICH Secretariat in preparation of discussion in Amsterdam regarding the use of surplus funds. The MC noted that the strategic proposal would be refined with a view to its inclusion in the package of background documents to be circulated to the Assembly ahead of Amsterdam. The MC also noted that the ICH Secretariat had worked on a spreadsheet cash flow tool to provide a high-level multi-year view of income and expenditure which could be used to run simulations of the impact of different budget plans. The MC noted that the Secretariat would continue to work with the Chairs to prepare the MC's further discussion in Amsterdam where the tool would be used to assist the MC with the finalisation of the budget plan to be proposed to the Assembly for approval.

ICH MC Action/Decision:

- *The MC and Assembly Chairs will work with the ICH Secretariat to prepare MC and Assembly discussions in Amsterdam regarding the strategic use of surplus funds.*
- ***2020 Provisional ICH Budget & 5-Year Budget Plan***

The MC noted the current versions of the 2020 Provisional ICH Budget and 5-Year (2020-2024) ICH Budget Plan which included minor adjustments by the ICH Secretariat in view of current ICH operations. The MC discussed the current yearly budget placeholders for training and implementation activities in the 5-Year ICH Budget Plan and supported that these items could be merged into a single line entry given the relation of these activities. The MC also noted that the outcome of the current implementation survey would be useful to consider in the planning of future surveys.

ICH MC Actions/Decisions:

- *The MC agreed to the inclusion in the package of background documents to be circulated to the Assembly ahead of Amsterdam of: the approved 2019 ICH Budget; the current version of the 2020 Provisional ICH Budget; and current version of the 5-Year (2020-2024) ICH Budget Plan, along with a cover note to explain that pending MC discussion in Amsterdam, revisions would be proposed to these documents in line with the considerations of the strategic proposal on the use of surplus funds;*
- *The ICH Secretariat will implement in the budget plans the change suggested by the MC regarding the merging of line entries for training and implementation activities.*

▪ **2018 Financial audit**

The MC noted that the ICH Secretariat had provided the 2018 Financial Statements along with all supporting documents to the Auditor and that the Auditor was due to come to the ICH Secretariat office on 15 April 2019 to perform the audit work.

ICH MC Action/Decision:

- *Once the audit is complete, the MC will be invited to provide support for sign-off of a Management Representation Letter which will allow the Auditor to issue its report for provision to Assembly Members in the package of background documents for the Amsterdam meeting where the Assembly will be invited to approve the 2018 Audited Accounts and Financial Statements.*

8. Q4B ANNEX MAINTENANCE

The MC was updated by the ICH Secretariat on correspondence it had recently with PDG regarding the updating by PDG of the ICH Q4B Guideline to reflect the new maintenance process of the Q4B Annexes approved by the Assembly in Charlotte in November 2018.

ICH MC Action/Decision:

- *The MC noted that PDG would provide a proposed work plan for this activity after the Amsterdam meeting.*

9. OVERSIGHT OF WORKING GROUPS

Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)

The MC noted Members' views regarding the timeframe for the Q12 EWG to complete its work on the Q12 Core Guideline and accompanying Annex and for *Step 4* to be reached. Although the EWG had initially aimed for *Step 3/Step 4* of the Q12 Core Guideline to be reached at the Amsterdam meeting and to continue work on the Annex with examples, the MC noted a proposal that the Core Guideline and Annex be finalised at the same time. This would ensure that any changes considered necessary to the Core Guideline arising from work on the Annex could be made easily, and would also allow sufficient time for Members to conduct the appropriate legal reviews of the Core Guideline, as well as to conduct outreach activities. Dr. Mullin (MC Chair, FDA, United States) commented that extra time would allow follow-up to help both assessor and inspectors understand the new ICH Guideline.

ICH MC Action/Decision:

- *The MC supported that the timeframe for the Q12 Core Guideline to reach Step 3/Step 4 be moved until November 2019 to allow the Core Guideline and Annex be finalised at the same time leaving more time for legal reviews and outreach activities.*

10. NEXT TELECONFERENCES & MEETINGS

ICH MC Actions/Decisions:

- *Ahead of the next MC teleconference on 8 May 2019, the MC will receive the Site Selection Report (SSR) developed by the PCO proposing three options for the meeting to be held in Europe on 15-19 November 2020;*
- *The ICH Secretariat will shortly launch a poll to identify dates for MC teleconferences ahead of the Singapore meeting and dates for the November 2021 meeting and to also identify dates which can be saved as a placeholder for an interim MC meeting in the March 2020 timeframe.*

▪ **Teleconferences**

8 May 2019 ICH MC Policy 4

▪ **Face-to-Face Meetings**

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)
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.*