

9 November 2018

SUMMARY REPORT
ICH MC TELECONFERENCE
22 October 2018

LIST OF PARTICIPANTS

ICH MC Members

Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Sabine Luik	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (<i>Chair</i>)	FDA, US
Ms. Joan Blair	FDA, US
Ms. Pujita Vaidya	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Catherine Parker	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nakyung Kim	MFDS, Republic Korea
Dr. Nobumasa Nakashima (<i>Vice-Chair</i>)	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Xialoing Qin	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Cordula Landgraf	Swissmedic, Switzerland
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, US
Ms. Siew Wei Chua	HSA, Singapore
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Ms. Wei Zhou	NMPA, China
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:

Dr. Tomas Salmonson	EC, Europe
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ICH Secretariat:

Ms. Nadia Gerweck

Dr. Isabelle Guller

Dr. Anne Latrive

Ms. Nikoleta Luludi

Dr. Dawn Ronan

SUMMARY REPORT

ICH MC Chair: Dr. Theresa Mullin - FDA, US

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

1. ADOPTION OF THE AGENDA

Dr. Nakashima (ICH MC Vice-Chair – MHLW/PMDA, Japan) welcomed all participants. The agenda was adopted with a reordering of the agenda items.

2. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The ICH MC was updated by the ICH Secretariat on the pending MC recommendations regarding Membership/Observership applications to be provided to the Assembly at the meeting in Charlotte, NC, USA.

3. PROCEDURAL MATTERS

▪ *Management of ICH Working Group (WG) Size*

In preparation of a more in-depth discussion in Charlotte, NC, USA, and further to discussions at the ICH MC Policy 2 TC on 10 October 2018, the ICH MC was presented with additional proposals regarding the possible future management of the size of ICH WGs.

ICH MC Actions/Decisions:

- *The ICH MC agreed to increase the time that was allocated at its meeting in Charlotte, NC, USA to the discussion of the management of the size of ICH WGs;*
- *In preparation of its discussion on the management of ICH WG size at its meeting in Charlotte, the ICH MC agreed to consider which criteria should be used to weigh the merits of the proposals.*

4. NEW TOPICS AND STRATEGIC DISCUSSIONS

▪ *Informal Quality Discussion Group (IQDG)*

The ICH MC was updated by the Coordinator of PhRMA on recent revisions made to the IQDG remit document further to comments raised at the ICH MC Policy 2 TC on 10 October 2018 related to (1) the alignment of the remit document with the current ICH procedures; (2) the IQDG scope; and (3) the activities of the IQDG in relation to the New Topics process.

ICH MC Action/Decision:

- *To provide the ICH MC Members additional time to consider the revised version of the IQDG remit document, the ICH MC agreed to postpone its decision on endorsement until the upcoming meeting in Charlotte.*
- *Revised MHLW/PMDA, Japan Reflection Paper: Organization of Basic Principles and Methodologies for Pharmacoepidemiological Studies*

The ICH MC was updated by the Technical Coordinator for MHLW/PMDA, Japan on the revisions made to its Reflection Paper on *Organization of Basic Principles and Methodologies for Pharmacoepidemiological Studies* in view of comments received from the ICH MC.

ICH MC Action/Decision:

- *The ICH MC noted that further comments may still be provided by ICH MC Members and supported that the revised Reflection Paper on Organization of Basic Principles and Methodologies for Pharmaco-epidemiological Studies would be circulated as an MHLW/PMDA, Japan Reflection Paper to the Assembly for discussion at the meeting in Charlotte.*

5. ANNUAL WORK PLAN AND MULTI-ANNUAL STRATEGIC PLAN OF THE ASSOCIATION

The ICH Secretariat presented to the ICH MC the draft 2019 ICH Association Work Plan and the revisions made to the draft 2019 Multi-Annual Strategic Plan of the Association which were made further to the discussion at the MC Policy 2 TC on 10 October 2018.

The ICH MC also noted the draft 2019 MedDRA MC Work Plan developed by the MedDRA MC for provision to the Assembly ahead of the Charlotte meeting.

ICH MC Actions/Decisions:

- *The ICH MC approved the circulation to the Assembly of the draft 2019 ICH Association Work Plan and Multi-Annual Strategic Plan, pending minor amendments (see item 7 below), with a view to seeking Assembly approval of these documents at its meeting in Charlotte in November 2018, which would subsequently be published on the ICH website.*

6. IMPLEMENTATION

The ICH MC was updated by the Lead of the Implementation Subcommittee on the progress made on the development of the Phase 2a implementation survey questionnaire and the online data collection tool; and considerations of the Implementation Subcommittee regarding the possibility of including Tier 3 Guidelines into the Phase 2a implementation survey.

ICH MC Actions/Decisions:

- *The ICH MC noted that it would be invited to approve the Phase 2a implementation survey questionnaire at its meeting in Charlotte, further to which the questionnaire would be circulated to the Assembly for comments and endorsement;*
- *The ICH MC noted that the online data collection tool is scheduled to be finalised by end of 2018;*
- *The ICH MC agreed to invite a representative from the third-party conducting the survey for the implementation discussions during the ICH MC and Assembly meetings in Charlotte, in order to present to the ICH MC and the Assembly the Phase 2a survey and demonstrate the online data collection tool;*
- *The ICH MC noted that, pending the Implementation Subcommittee reaching consensus at its next TC on 31 October, the ICH MC would be invited to approve the inclusion of additional Guidelines from Tier 3 into the Phase 2a implementation survey at its meeting in Charlotte;*
- *The ICH MC approved the provision to the Assembly of the ICH Guideline Implementation Table and the final Definitions of terms in the context of the implementation of ICH Guidelines, the latter of which had been approved by the ICH MC during the ICH MC Policy 2 TC on 10 October 2018.*

7. TRAINING

The ICH MC was updated by the Lead of the Training Subcommittee on the documents developed by the Training Subcommittee; the status of the applications received from organisations interested in developing an ICH Recognised Training Programme; the progress made by the Q11 IWG on the Q11 Narrated Training Material. The ICH MC was further updated on the ongoing discussions of the Training Subcommittee, including the revision of the Training Mission Statement; the possibility of working with Training Partners; the process for triaging ICH speaker requests; and training activities which would require further financial support.

ICH MC Actions/Decisions:

- *The ICH MC noted that the Training Subcommittee would develop a template for Expression of Interests from organisations interested in developing an ICH Recognised Training Programme, with the aim of submitting it to the ICH MC for its consideration at its meeting in Charlotte;*
- *The ICH MC noted that at its meeting in Charlotte, it would be invited to endorse the Procedure for Organisations Interested in Developing an ICH Recognised Training Programme; the ICH Training Programme Providers Eligibility Criteria; and the Prioritisation List of Tier 3 Guidelines for Training Purposes;*
- *The ICH MC supported the Training Subcommittee’s consideration to replace the term “ICH Training Partner” by the term “ICH Training Provider”, and that amendments to the ICH training webpage, the training documents provided to the MC at its meeting in Charlotte, and the draft 2019 ICH Work Plan and Multi-Annual Strategic Plan would be made accordingly;*
- *The ICH MC noted that the Training Subcommittee endorsed the Chinese Pharmaceutical Association (CPA)’s application to provide an ICH Recognised Training Programme on the ICH M4 Guideline, and Duke NUS CoRE Singapore’s request to provide an ICH Recognised Training Programme on Chemistry, Manufacturing and Control (CMC);*
- *The ICH MC agreed to extend an invitation for Ad-Hoc Observership for the Charlotte Assembly meeting to a representative of Northeastern University (NEU);*
- *The ICH MC approved the circulation to the Assembly of the Step 2 Informational Slides Template and the Step 4 Introductory Training Slides Template.*

8. Q4B ANNEXES MAINTENANCE

The ICH MC was updated by the ICH Secretariat on the receipt of a proposal for maintenance of Q4B Annexes provided by the Pharmacopoeial Discussion Group (PDG).

ICH MC Action/Decision:

- *The ICH MC agreed to discuss the PDG proposal at its meeting in Charlotte.*

9. ORGANISATION OF THE CHARLOTTE MEETING

The ICH 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 Action/Decision:

- *The ICH MC confirmed its support for the documents to be included in the Assembly Agenda Papers package to be circulated by 31 October 2018.*

▪ **MC Agenda Papers**

ICH MC Action/Decision:

- *The ICH MC confirmed its support for the documents to be included in the MC Agenda Papers package to be circulated by 29 October 2018.*

10. NEXT TELECONFERENCES AND MEETINGS

ICH MC Actions/Decisions:

- *The ICH MC noted the ongoing poll for the identification of the dates of the teleconferences for the next ICH meeting cycle, as well as the ongoing poll for the identification of suitable date(s) for the June 2021 meeting, circulated with a deadline of 26 October 2018 and 2 November 2018 respectively;*
- *The ICH MC noted that the final dates will be confirmed at its meeting in Charlotte.*

Face-to-Face ICH Meetings

10-15 November 2018	Charlotte, NC, USA
1-6 June 2019	Amsterdam, the Netherlands
16-21 November 2019*	Singapore (to be confirmed)
23-28 May 2020*	The Americas (location to be confirmed)
14-19 November 2020*	Europe (location to be confirmed)

**Note: Final dates may differ slightly if the new schedule for the ICH week is implemented for these meetings.*