

10 November 2018

**SUMMARY REPORT**  
**ICH MC TELECONFERENCE**  
**10 October 2018**

## LIST OF PARTICIPANTS

### ICH MC Members

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
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
Ms. Beata Stepniewska	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

Ms. Lila Feisee	BIO
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
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, US
Ms. Chieko Hirose	MHLW/PMDA, Japan

### ICH MC Standing Observers:

Dr. David Jefferys	IFPMA
Dr. Mike Ward	WHO

**Other Participants:**

Mr. Tomas Salmonson

Ms. Ashley Baron

Ms. Sayaka Kurihara

EC, Europe

Health Canada, Canada

MHLW/PMDA, Japan

**ICH Secretariat:**

Ms. Nadia Gerweck

Dr. Anne Latrive

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. Mullin (ICH MC Chair - FDA, US) welcomed all participants. The agenda was adopted without any comments.

### 2. ORGANISATION OF ICH MEETINGS

#### Organisation of the ICH Meeting in Charlotte, NC, USA, 10-15 November 2018

##### *ICH MC Actions/Decisions:*

- *The ICH MC approved the circulation to the Assembly of the draft Assembly Agenda with minor revisions;*
- *The ICH MC noted the following key dates in preparation of the Charlotte meeting:*
  - *By 12 October: All background documents for the Assembly meeting are to be provided to the Secretariat for ICH MC review prior to inclusion in the Assembly Agenda papers.*
  - *By 17 October: The draft Assembly Agenda is circulated to the Assembly for comments.*
  - *By 19 October: The draft ICH MC Agenda is circulated to the ICH MC for comments.*
  - *By 23 October: All background documents for the ICH MC meeting are to be provided to the Secretariat for inclusion in the ICH MC Agenda papers.*
  - *By 31 October: The final draft Agenda and Assembly Agenda papers are circulated to the Assembly.*

#### Organisation of 2019 & 2020 Meetings

##### ▪ *Site Selection*

The ICH MC was updated by the ICH Secretariat on the Site Selection Report with proposed options for the November 2019 meeting (16-21 November) in Asia developed by the Professional Conference Organiser (PCO) contracted by ICH to organise meetings starting in 2019.

The ICH MC noted that as part of the selection process, ICH meetings are held with a three-region rotation (The Americas; Europe/Africa; Asia) and that within a region with more than one ICH Member, the PCO is to identify the three best options (based on the agreed selection criteria) looking across ICH Member countries/regions, with one of the options to come from the country/region of a Founding or Standing ICH Member, and with the ICH MC to take the final decision.

The ICH MC noted that despite the extensive search for venues conducted in Japan, no suitable venues could be identified within the ICH meeting budget, due to a high number of international events occurring in the country in November 2019, and in view of the fact that the search for venues had been initiated late as the PCO had only been contracted by ICH in mid-2018. The ICH MC also noted that the PCO would be informed that they are required to start negotiations 1.5 – 2 years before the scheduled meeting in order to reserve rooms and that the Secretariat will ask the PCO to start their survey at the earliest possible time for the next ICH meeting in Asia in 2021.

The ICH MC further noted that with the PCO looking after the organisation of the ICH meeting, there were no meeting organisation tasks for the ICH Member of the host country, with all costs to be covered by ICH/MedDRA/IPRP budgets.

### ***ICH MC Actions/Decisions:***

- *The ICH MC agreed to hold the November 2019 meeting in Singapore, pending successful conclusion of a contract with the selected venue;*
- *The ICH MC agreed that, as a general principle and if logistically feasible, venues should be selected 24 months ahead of the meeting.*

#### **▪ *New Schedule***

The ICH MC was informed by the Vice Chair of IPRP on the IPRP MC's feedback regarding the proposed new schedule of the ICH biannual meetings.

The ICH MC was further updated by the Secretariat on the feedback to-date from the PCO regarding the timeframe for implementation of the new meeting schedule, given that it had already started work on the identification of options for the June 2020 meeting in the Americas.

### ***ICH MC Actions/Decisions:***

- *The ICH MC noted that the IPRP MC had expressed no concern on the proposed new schedule of the ICH meeting;*
- *In order to complete the instructions to the PCO on meeting room requirements according to the new schedule, the ICH MC agreed that in the new schedule, WGs would not be allowed to meet at the ICH meetings for over 5 days, and that additional WG TCs should be promoted instead;*
- *The ICH MC noted that for logistical reasons the new schedule would be implemented at the latest for meetings from 2020 onwards, and that the Secretariat would liaise with the PCO to determine whether this could be done already for the November 2019 or June 2020 meetings, considering that discussions with those venues had already started.*

## **3. PROCEDURAL MATTERS**

#### **▪ *ICH Rules of Procedure (RoP) & Standard Operating Procedures (SOPs)***

The ICH MC was updated by the ICH Secretariat on eleven proposed categories of revision to ICH procedure documents, based on the discussions of the ICH MC and the Assembly, feedback from the ICH MC and Assembly Chairs, and the need for clarity and consistency between the ICH procedure documents identified by the ICH Secretariat.

### ***ICH MC Actions/Decisions:***

- *The ICH MC approved the proposed revisions to the ICH MC RoP;*
- *The ICH MC approved the proposed revisions to the ICH SOP of WGs, with a minor revision to further clarify one of the suggested changes;*
- *The ICH MC supported seeking Assembly approval of the proposed revisions to the Assembly RoP at its meeting in Charlotte in November 2018<sup>1</sup>.*

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

In preparation of a more in-depth discussion in Charlotte in November 2018, the ICH MC was presented with proposals regarding the possible future management of the size of ICH WGs.

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<sup>1</sup> Post-TC note: When soliciting nominations for the Assembly Vice Chair election via email, the ICH Secretariat will highlight to the Assembly the proposed change to the Assembly RoP regarding the alignment of the terms of the Chair and Vice Chair in cases where one steps down mid-term, so that the Assembly is aware of the proposed Vice Chair term ahead of the election in Charlotte

#### **ICH MC Actions/Decisions:**

- *The ICH MC noted that comments on these proposals and/or alternative proposals should be provided to the ICH Secretariat by 15 October 2018;*
- *The ICH MC agreed to allocate between 60 to 90 minutes to further discuss the management of the size of ICH WGs at its meeting in Charlotte in November 2018.*

#### **4. FINANCIAL MATTERS**

##### **▪ *MedDRA Financial Matters***

The ICH MC was updated by the ICH Secretariat on the MedDRA MC's 5-year MedDRA budget plan including proposed use of surplus funds, as well as the MedDRA MC's proposal for the 2019 MedDRA budget, including MedDRA 2019 Subscription Fees.

#### **ICH MC Action/Decision:**

- *The ICH MC supported the circulation of the 2019 MedDRA budget, including 2019 MedDRA Subscription Fee proposal, and the 5-Year MedDRA budget plan to the Assembly, with a view to seeking Assembly approval of the 2019 MedDRA budget and the 2019 MedDRA Subscription Fees at the meeting in Charlotte in November 2018.*

##### **▪ *Use of ICH Funds***

In preparation of a more in-depth discussion in Charlotte, the ICH MC was updated by the co-Lead of the Implementation Subcommittee as well as the Lead of the Training Subcommittee on their considerations regarding work which could be supported by ICH surplus funds. The ICH MC further discussed possible outreach activities related in particular to training.

#### **ICH MC Action/Decision:**

- *The ICH MC agreed that possible areas of work and further outreach activities of the Implementation and Training Subcommittees which could be supported by surplus funds would be presented to the ICH MC at its meeting in Charlotte in November 2018.*

#### **5. NEW TOPIC PROPOSALS AND STRATEGIC DISCUSSIONS**

##### **▪ *2018 New Topics Follow-up Discussion***

- *2018 New Topic M11: Clinical electronic Structured Harmonized Protocol (CeSHarP)*

#### **ICH MC Action/Decision:**

- *The ICH MC noted that it had electronically approved the M11 informal WG's request to meet for 4 days (Monday-Thursday) in Charlotte, in November 2018.*

- *2018 New Topics with a Delayed Start*

#### **ICH MC Action/Decision:**

- *The ICH MC agreed to further discuss the timeframe for initiation of work on Drug Interaction Studies (M12) and Adaptive Clinical Trials (E20) at its meeting in Charlotte in November 2018.*

##### **▪ *2019 New Topics Selection Process***

The ICH MC was updated by the New Topics Subcommittee on the organisation of the 2019 New Topics Selection Process.

### **ICH MC Actions/Decisions:**

- *The ICH MC confirmed that the cut-off date for the submission of New Topic proposals to the 2019 New Topics Selection Process by the Assembly Members and Observers would be 14 December 2018<sup>2</sup>;*
- *The ICH MC supported to further discuss at its meeting in Charlotte in November 2018 the need to hold an interim meeting in the March/April 2019 timeframe in support of the New Topics Selection Process, agreeing that it would be helpful if Members could indicate in Charlotte whether they planned to submit proposals in order to have an idea of the volume of proposals expected.*

#### ▪ **Informal Quality Discussion Group (IQDG)**

Further to the Assembly's approval in Kobe of the ICH Quality Reflection Paper on *Advancing Pharmaceutical Quality Standards*, the Coordinator for PhRMA presented to the ICH MC the proposed revised IQDG remit following PhRMA's work to include the expected time-commitment for participants, as well as the expertise needed.

### **ICH MC Action/Decision:**

- *The ICH MC agreed that, further to comments expressed during the call PhRMA should liaise with the Members who raised the comments and the ICH Secretariat to would make some further amendments to the IQDG remit document and provide a revised version for the ICH MC's consideration at its Policy 3 TC on 22 October.*

#### ▪ **Revised 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 status of the revisions to be made to its Reflection Paper on *Organization of Basic Principles and Methodologies for Pharmacoepidemiological Studies* in view of comments received from the ICH MC Members.

### **ICH MC Action/Decision:**

- *The ICH MC noted that MHLW/PMDA, Japan would provide shortly to the ICH MC the revised Reflection Paper on **Organization of Basic Principles and Methodologies for Pharmacoepidemiological Studies** for consideration by the ICH MC at the MC Policy 3 TC on 22 October for provision to the ICH Assembly ahead of the Charlotte meeting in November 2018.*

#### ▪ **Draft Reflection Paper: Further Opportunities for Harmonization of Standards for Generic Drugs**

The MC was updated by the Coordinator for FDA, US on the status of the revised Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drugs*.

### **ICH MC Action/Decision:**

- *Pending minor edits to the Reflection Paper, the ICH MC approved the circulation of the revised FDA, US Reflection Paper on **Further Opportunities for Harmonization of Standards for Generic Drugs** to the Assembly Members and Observers with a view to collecting comments by 2 November 2018 ahead of the Charlotte meeting.*

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

The ICH MC was updated on the status of work by PhRMA on its the draft Reflection Paper on *Model-Informed Drug Development (MIDD)*.

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<sup>2</sup>Post-TC note: The ICH Secretariat will notify the ICH Assembly of the 14 December 2018 deadline for the submission of proposals to the New Topics Selection Process.

***ICH MC Action/Decision:***

- *The ICH MC noted that an update on the status of draft Reflection Paper on **Model-Informed Drug Development (MIDD)** would be provided to the ICH MC at its meeting in Charlotte in November 2018.*

**6. ANNUAL WORK PLAN AND MULTI-ANNUAL STRATEGIC PLAN OF THE ASSOCIATION**

The Secretariat presented to the ICH MC the draft 2019 Work Plan and Multi-Annual Strategic Plan of the Association.

The ICH MC was further informed by the Secretariat on the status of the 2019 MedDRA MC Work Plan.

***ICH MC Action/Decision:***

- *The ICH MC approved the circulation of the draft 2019 Work Plan and Multi-Annual Strategic Plan to the Assembly, pending a minor revision to the Multi-Annual Strategic Plan, 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.*

**7. TRAINING**

The ICH MC was updated by the Lead of the Training Subcommittee on the Training Subcommittee's considerations regarding the possibility of the development of scripts to accompany the remaining E9(R1) seven training modules, with a view to having a professional voiceover production.

***ICH MC Action/Decision:***

- *The ICH MC supported that the Training Subcommittee engage with the E9(R1) EWG at the Charlotte meeting to seek the further views of the group regarding possible development of scripts for the remaining seven training modules and report back to the MC on the EWG's considerations in Charlotte in November 2018.*

**8. IMPLEMENTATION**

The ICH MC was updated by the co-Lead of the Implementation Subcommittee on the finalisation of the new terminology and definitions regarding the degrees of implementation and adherence to ICH Guidelines, and of the survey to assess the level of implementation of ICH Guidelines by new ICH Regulatory Members and the level of adherence to ICH Guidelines within the Founding and Standing Regulatory Member countries/regions.

***ICH MC Action/Decision:***

- *The MC approved the final version of the definitions of the degrees of implementation and its provision to the Assembly for adoption at the Charlotte meeting in November 2018.*



## **9. NEXT TELECONFERENCES AND MEETINGS**

### ***ICH Teleconferences***

22 October 2018                      MC Policy 3

### ***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)

## **10. ANY OTHER BUSINESS**