

17 October 2018

**SUMMARY REPORT**  
**ICH MC TELECONFERENCE**  
**20 September 2018**

## LIST OF PARTICIPANTS

### ICH MC Members

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
Ms. Lenita Lindström-Gommers	EC, Europe
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
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. Siyuan Zhou	NMPA, China
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	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, US
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
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
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**Other Participants:**

Mr. Xiangyu Wang

Dr. Sarah Adam

NMPA, China

IFPMA

**ICH Secretariat:**

Dr. Dawn Ronan

Ms. Nadia Gerweck

Dr. Anne Latrive

Ms. Nikoleta Luludi

## SUMMARY REPORT

*MC Chair: Dr. Theresa Mullin, FDA, US*

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

### 1. ADOPTION OF THE AGENDA

Dr. Mullin (MC Chair, FDA, US) welcomed all participants. JPMA proposed to discuss the subject of training requests under Any Other Business and the ICH Secretariat proposed to discuss the subject of the nomination of a co-Lead for the New Topics Subcommittee under Any Other Business. The agenda was adopted without further comments.

### 2. ORGANISATION OF ICH MEETINGS

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

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

- *The 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 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 MC Agenda is circulated to the MC for comments.*
  - *By 23 October: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers.*
  - *By 31 October: The final draft Agenda and Assembly Agenda papers are circulated to the Assembly.*

#### **Organisation of 2019 & 2020 Meetings**

The MC was updated by the ICH Secretariat on the organisation of the June 2019 meeting in Amsterdam, Netherlands and noted that the selected venue had been secured and the organisation of the meeting is on track. The MC further noted that the ICH Secretariat is working with the Professional Conference Organiser (PCO) to prepare the Site Selection Report with proposed options for the November 2019 meeting to be held in Asia.

The MC was also updated on the ICH Secretariat on feedback received from MC Members regarding the future scheduling of ICH meetings (from 2020). The MC noted the alternative proposal to reduce the overall duration of the ICH week to 5 days, from Sunday to Thursday, and to re-order the sequence of the various meetings.

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

- *The MC noted that the Site Selection Report with proposed venues for the November 2019 meeting would be circulated shortly for MC decision at the Policy 2 TC to be held on 10 October 2018;*
- *The MC supported the proposal for the re-scheduling of the ICH week;*
- *The MC agreed on the need to seek the feedback of the IPRP MC on the re-scheduling of the ICH week via the Secretariat prior to making a formal decision;*
- *The MC agreed that the re-scheduling of the ICH week would be implemented at the earliest feasible opportunity, which for logistical reasons would likely be for meetings from 2020 onwards.*

### 3. ICH MEMBERSHIP AND OBSERVERSHIP

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

### 4. PROCEDURAL MATTERS

#### ▪ *ICH Articles, Rules of Procedure & SOPs*

The MC was updated by the ICH Secretariat on ongoing work on several revisions to be proposed to ICH procedural documents, including a revision to allow the Assembly to establish groups such as Discussion Groups, as well as other changes for clarity and consistency.

#### *MC Actions/Decisions:*

- *The MC noted that the proposed revisions to ICH procedural documents would be circulated shortly and supported that this topic would be discussed at the Policy 2 TC on 10 October 2018;*
- *The MC noted that a proposal for revisions to the MC's approach for managing the size of the WGs had been circulated on 20 September 2018, with an invitation for the MC to provide comments or alternative proposals by 15 October 2018 in preparation of discussion at the Charlotte meeting in November 2018.*

#### ▪ *Organisation of Elections*

The MC noted that as of the end of July 2018, Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan) stepped down from his positions as ICH Assembly and MC Vice Chair, with Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) being put forward to replace him in the interim until the next meeting when new elections will be held.

The MC was further updated by the ICH Secretariat on the procedure for the new Assembly Vice Chair *ad hoc* election and the MC Chair and Vice Chair annual election to be held at meeting in Charlotte in November 2018. The MC noted that all Regulatory Members of the Assembly are eligible for Assembly Vice-Chairmanship and that Permanent Regulatory Members of the MC are eligible for MC Chairmanship and Vice-Chairmanship.

#### *MC Actions/Decisions:*

- *The MC acknowledged that nominations for Assembly Vice-Chair and for MC Chair/Vice-Chair could be submitted until the start of the meeting in Charlotte in November 2018, but noted that, in order to help with the preparation of the meeting, eligible Members are invited to provide the names of nominees to the ICH Secretariat by Friday, 2 November 2018;*
- *The MC agreed to further discuss the duration of the term of the new Assembly Vice-Chair at the meeting in Charlotte in November 2018 including whether or not to have a non-synchronised term of office for the Chair and Vice-Chair;*
- *The MC noted that no nominations for the remaining ICH MC Elected Representative Regulatory position were received by the mid-July deadline, and that therefore no MC election would be organised at the meeting in Charlotte in November 2018.*

### 5. FINANCIAL MATTERS

The MC was updated by the ICH Secretariat on 2018 cash flow and on revisions made to the 2019 ICH Budget and the 5-Year ICH Budget Plan in view of decisions taken in Kobe and the ICH Secretariat's fully independent operation since April 2018.

The MC was further updated by the ICH Secretariat on the MedDRA MC's work on the 2019 MedDRA Budget, including 2019 Subscription Fees to be circulated to the ICH Assembly for approval at the meeting in Charlotte in November 2018.

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

- *The MC supported the revisions made to the 2019 ICH Budget and 5-Year ICH Budget Plan for provision to the ICH Assembly for approval in Charlotte in November 2018;*
- *The MC acknowledged that the MedDRA MC would provide shortly to the ICH MC the draft 2019 MedDRA Budget, including 2019 Subscription Fees, to seek ICH MC's support prior to submission to the ICH Assembly ahead of the meeting in Charlotte in November 2018; and noted that this topic would be discussed at the next Policy 2 TC on 10 October 2018.*

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

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

The MC was updated on progress made on the revision of the remit document of the IQDG, further to the ICH Assembly's approval in Kobe of the ICH Quality Reflection Paper on *Advancing Pharmaceutical Quality Standards*.

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

- *The MC noted that the revised remit document would be circulated to the MC shortly for approval at the next Policy 2 TC on 10 October 2018.*

### **▪ Draft Reflection Paper: Organization of Basic Principles and Methodologies for Pharmacoepidemiological Studies**

The MC was updated on the comments received from MC Members on the draft Reflection Paper on *Organization of Basic Principles and Methodologies for Pharmaco-epidemiological Studies* put forward by MHLW/PMDA, Japan.

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

- *The MC noted that a revised Reflection Paper would be circulated to the MC by mid-October 2018 with a view to providing to the ICH Assembly ahead of the meeting in Charlotte in November 2018.*

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

The MC was updated on progress made on the drafting by PhRMA of a Reflection Paper on *Model-Informed Drug Development (MIDD)*.

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

- *The MC noted that a draft Reflection Paper would be circulated to the MC by mid-October 2018;*
- *The MC agreed that further discussion within the MC was needed at the meeting in Charlotte in November 2018 in order to refine the paper before its provision to the Assembly at a later stage.*

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

The MC was updated on progress made on the revision of the draft FDA, US Reflection Paper on *Further Opportunities for Harmonization of Standards for Generic Drugs*.

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

- *The MC noted that a revised Reflection Paper would be circulated to the MC in early October 2018 with a view to providing to the ICH Assembly ahead of the meeting in Charlotte in November 2018, with the aim of seeking endorsement of a final ICH Reflection Paper at the meeting in June 2019.*

▪ ***New Topics Adopted with a Delayed Start Time***

The MC noted that at the Kobe meeting in June 2018 the Assembly had adopted the two New Topic Proposals on *Drug Interaction Studies* (M12) and *Adaptive Clinical Trials* (E20) with a delayed start time.

***MC Actions/Decisions:***

- *The MC acknowledged that the initiation of the work on Drug Interaction Studies (M12) and Adaptive Clinical Trials (E20) is linked to the availability of expertise which is shared in particular with the E8(R1) EWG and E9(R1) EWG;*
- *The MC agreed to discuss this topic further at the next Policy 2 TC on 10 October 2018.*

**7. IMPLEMENTATION**

The MC was updated by the co-Leads of the Implementation Subcommittee on activities including: feedback from ICH Assembly Members and Observers on the proposal for new terminology and definitions regarding the degrees of implementation and adherence to ICH Guidelines; and engagement of a third party to conduct the Phase 2a 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.

***MC Action/Decision:***

- *The MC supported that the proposed definitions regarding the degrees of implementation and adherence to ICH Guidelines and the proposed survey to assess the level of implementation of ICH Guidelines would be submitted to the MC for approval at the Policy 3 TC on 22 October 2018, with the aim of seeking Assembly approval at the meeting in Charlotte in November 2018.*

**8. TRAINING**

The MC was updated by the Lead of the Training Subcommittee on activities including: efforts to prioritise Tier 3 ICH Guidelines for training purposes; status of work with training partners; development of online training programmes; support provided to ICH WGs developing training materials (E9(R1) EWG, E17 IWG, Q11 IWG); update of the Training page on the ICH website by the ICH Secretariat; and considerations on the revision of the mission statement of the Training Subcommittee for clarity.

***MC Actions/Decisions:***

- *The MC supported that a draft prioritisation of Tier 3 ICH Guidelines for training purposes would be provided to the MC for approval at the latest at the meeting in Charlotte in November 2018;*
- *The MC acknowledged that additional considerations on funds needed for ICH training activities would be shared with the MC at the meeting in Charlotte in November 2018;*
- *The MC agreed to further discuss the potential extension of training activities of the E9(R1) EWG at an upcoming TC;*
- *The MC acknowledged the revised presentation templates to be provided to the WGs for the Step 2 informational slides and Step 4 training slides.*

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

### ***ICH Teleconferences***

10 October 2018	MC Policy 2
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	Asia (location 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**

### ***10.1 Training requests***

JPMA informed the MC on requests it was receiving for experts to provide training on ICH Guidelines and suggested a need for the MC to discuss how to manage such requests.

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

- *The MC noted that in view of requests received also by other MC Members, the Training Subcommittee planned to discuss and make suggestions for MC consideration at the meeting in Charlotte in November 2018.*

### ***10.2 Nomination of a co-Lead for the New Topics Subcommittee***

The MC noted the status of nomination of a co-Lead for the New Topics Subcommittee further to the call for expression of interest issued by the ICH Secretariat and that two candidates had been put forward.

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

- *The MC agreed to discuss further at its meeting in Charlotte in November 2018 the management of work by the New Topics Subcommittee and whether it could be of benefit to have more than one co-Lead.*