

5 March 2019

**SUMMARY REPORT**  
**ICH MC TELECONFERENCE**  
**30 January 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
Ms. Pujita Vaidya	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 Capuccino	IGBA
Ms. Beat Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nakyung Kim	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
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Ms. Cordula Landgraf	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
Ms. Siew Wei Chua	HSA, Singapore
Dr. Shinichiro Hirose	IGBA
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. Mike Ward	WHO

### Other Participants

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Agnès Saint Raymond	EC, Europe

**ICH Secretariat**

Dr. Anne Latrive

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 interim meeting of the E17 IWG under Any Other Business. The agenda was adopted without further modification.

### 2. ORGANISATION OF NEXT MEETINGS

#### ▪ *ICH meeting in May 2020 in the Americas*

The ICH MC was updated by the ICH Secretariat on the revised Site Selection Report developed by the Professional Conference Organiser (PCO) with proposed options for the May 2020 meeting (24 -28 May) in the Americas focusing on Canada (in view of its accessibility to a higher number of ICH attendees from the perspective of visa requirements).

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

- *The ICH MC agreed to hold the May 2020 meeting at the higher-scoring venue located in Vancouver, Canada, pending successful inspection and conclusion of a contract with the selected venue;*
- *The ICH MC supported that the cost of breakfast for the May 2020 meeting would be covered by the ICH budget, in order to allow for an appropriate guestroom rate to be proposed to participants.*

#### ▪ *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. The ICH Secretariat further informed the ICH MC on the circulation of the first announcement of the meeting and on the next steps for the registration.

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

- *The ICH MC noted that the organisation of the ICH MC interim meeting is on track and that the registration would be opened shortly;*
- *The ICH MC agreed that New Topics would be the main item on the agenda of the meeting to be allocated at least one full day, and noted that a draft agenda would be proposed by the ICH MC Chair and Vice Chair and would be shared shortly with the ICH MC for comments.*

### 3. TRAINING

#### ▪ *Feedback from ICH Regulatory Members regarding interest for Training Funding*

The ICH Secretariat informed the ICH MC on feedback received from ICH Regulatory Members in response to the call issued in December 2018 to ICH Regulatory Members inviting expressions of interest to receive ICH funding support for training on ICH Guidelines in 2019. The ICH MC noted that 7 requests were received from 4 Regulatory Members.

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

- *The ICH MC agreed that funding support should be provided to the requests received up to a cap based on the median amount per requester;*

- *The ICH MC supported that a recommendation for an increase to the 2019 budgeted amount for training would be made to the ICH Assembly to support such funding;*
- *The ICH MC noted that this should be considered as an ad-hoc approach and supported further discussing the strategy regarding the funding of training activities on ICH Guidelines organised by ICH Regulatory Members, with a view to submitting to the Assembly a proposal for a long-term strategy as well as an associated budget.*

▪ ***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 the status of the work of the Subcommittee, with the support of the ICH Secretariat, to prepare a Call for Expression of Interest (including finalisation of eligibility criteria, development of Terms of Reference etc...) for non-profit training organisations/institutions who ICH engage to: develop training materials for ICH ownership; deliver training; and provide consultancy services to ICH.

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

- *The ICH MC noted that the materials for the Call for Expression of Interest, including the Terms of Reference and Response Form, would be shared with the ICH MC ahead of the Policy 2 TC with a view to having further discussion on next steps at the ICH MC interim meeting.*

**4. IMPLEMENTATION**

The ICH MC was updated by the Co-Lead of the Implementation Subcommittee on the progress made by the Implementation Subcommittee, including on the finalisation of the survey and the Data Collection Tool following consideration of comments received from the Assembly in November 2018, and on the launch of the survey amongst regulatory authorities and companies.

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

- *The ICH MC supported that the Implementation Subcommittee would launch the Implementation Survey within the first to the second week of February, with a deadline for responses set by Friday 29 March, which could be extended by one to two weeks if necessary;*
- *The ICH MC noted that a tutorial video explaining the process and timeline for the survey would accompany the sending of the Survey;*
- *The ICH MC noted that, further to review by the Subcommittee Leads, the ICH Secretariat would shortly update the ICH website to include a page dedicated to the implementation of ICH Guidelines, which would include the publication of the definitions of terms to be used in the context of implementation as approved by the Assembly in November 2018, as well as, in a second step, a searchable table of information on the implementation of ICH Guidelines by ICH Regulatory Members.*

**5. NEW TOPICS AND STRATEGIC DISCUSSION**

▪ ***New Topic proposals***

The ICH MC was updated by the Lead and Co-Lead of the New Topics Subcommittee on the 16 New Topic proposals received and on the conduct of the New Topics selection process for 2019.

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

- *The ICH MC noted the following timeline for the process of selection of New Topics in 2019 and work to be conducted by the New Topics Subcommittee:*
  - *25 January, 1 February, and 12 February: Teleconferences with experts are conducted;*
  - *By 20 February: Proposing parties are invited to confirm whether they wish to revise/merge their proposal further to comments received;*

- *By 14 March: Subcommittee Members fill in the evaluation forms for non-revised proposals;*
- *By 19 March: Proposing parties submit revised/merged proposals;*
- *By 27 March: Subcommittee Members fill in the evaluation forms for revised/merged proposals and the priority scoring table.*

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

FDA, United States provided an update on comments received from ICH MC Members on the draft remit document for the Informal Generic drug Discussion Group (IGDG).

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

- *The ICH MC approved the remit document for the IGDG including a minor amendment to ensure flexibility of the proposed timeline for work of the group and agreed to proceed with the publication of the ICH Reflection Paper on Further Opportunities for Harmonization of Standards for Generic Drugs on the ICH website along with the remit document for the IGDG.*

▪ ***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***

MHLW/PMDA, Japan provided an update on comments received to-date from ICH MC Members on its revised draft Reflection Paper.

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

- *The ICH MC noted that further comments were expected to be submitted by MC Members and agreed that this topic would be further discussed at the upcoming Policy 2 TC to be held on 12 March.*

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

PhRMA provided an update on comments received to-date from ICH MC Members on its draft Reflection Paper on Model Informed Drug Development (MIDD).

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

- *The ICH MC noted that further comments were expected to be submitted by MC Members and that a revised draft Reflection Paper would subsequently be developed with a view to circulating ahead of the ICH MC interim meeting.*

**6. PROCEDURAL MATTERS**

▪ ***Management of ICH Working Group Size***

The ICH MC was informed on the development of an updated proposal on managing the size of Working Groups (WGs) in view of the ICH MC discussions at its meeting in Charlotte, USA in November 2018.

The ICH MC was also informed on the outcome of the communication pilot conducted for E8(R1). As per this pilot, the E8(R1) EWG shared the final draft Technical Document prior to *Step 1* with interested ICH internal Member stakeholders, which had expressed interest but had not been able to nominate experts 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 the ICH Secretariat would invite ICH MC Members to provide comments on the proposal on managing the size of WGs with a view to discussing the proposal further at the Policy 2 TC to be held on 12 March;*

- *The ICH MC noted the positive feedback given by the E8(R1) EWG on the conduct of the communication pilot and supported that ICH internal stakeholders also be invited to provide their feedback.*

- **Process for Reflection Papers**

**ICH MC Action/Decision:**

- *The ICH MC agreed to further discuss the process for the development and endorsement of Reflection Papers at the ICH MC interim meeting in April 2019.*

## 7. FINANCIAL MATTERS

- **2018 Financial audit**

The ICH Secretariat updated the ICH MC on the closing of the 2018 accounts of the ICH Association and the organisation of the financial audit.

**ICH MC Action/Decision:**

- *The ICH MC noted that the closing of the 2018 accounts was in progress and that in February the ICH MC would be invited to provide its express approval of the accounts for provision to the Auditor.*

- **Surplus funds**

The ICH MC noted draft considerations shared regarding the development of a plan for the use of surplus funds on strategic activities such as training, outreach and stakeholder engagement.

**ICH MC Action/Decision:**

- *The ICH MC noted that the ICH Secretariat would invite ICH MC Members to provide comments on the draft considerations, with a view to further discussing at the Policy 2 TC to be held on 12 March.*

## 8. NEXT TELECONFERENCES & MEETINGS

The MC noted the schedule of the next teleconferences and meetings.

### Teleconferences

5 March 2019	ICH Coordinators
12 March 2019	ICH MC Policy 2
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)

## **9. ANY OTHER BUSINESS**

### **▪ *Establishment of the Informal Quality Discussion Group (IQDG)***

The ICH MC noted the requests received for expert nominations in the IQDG and comments expressed by ICH MC Members on the assessment of these requests and the need for any restriction of the size of the group.

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

- *The ICH MC approved all the requests received for expert nomination in the IQDG, for a total of 31 experts;*
- *The ICH MC noted that the Secretariat would proceed with the establishment of the IQDG accordingly.*

### **▪ *Interim meeting of the E17 IWG***

The ICH MC noted the difficulties raised after the ICH Charlotte meeting by a couple of ICH MC Members regarding participation in the interim meeting of the E17 IWG, which would present an issue for the reaching of the necessary Member quorum for the meeting to proceed. The MC expected that the E17 IWG would meet in Amsterdam, subject to MC agreement at the MC Technical TC in March.

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

- *The ICH MC agreed to cancel the interim meeting of the E17 IWG in view of the difficulties raised after the ICH Charlotte meeting.*