

**Ref.: MC2016/39**

October 27, 2016

**SUMMARY REPORT  
ICH MC TELECONFERENCE  
October 25, 2016**

## LIST OF PARTICIPANTS:

### ICH Management Committee Members/Observers

Ms. Lenita Lindström-Gommers	EC	Europe
Dr. Tomas Salmonson	EC	Europe
Mr. Richard Bergström	EFPIA	Europe
Dr. Sabine Luik	EFPIA	Europe
Dr. Theresa Mullin	FDA	USA
Ms. Joan Blair	FDA	USA
Ms. Cathy Parker (Vice-chair)	Health Canada	Canada
Dr. Celia Lourenco	Health Canada	Canada
Dr. Hironobu Saito	JPMA	Japan
Dr. Toshiyoshi Tominaga (Chair)	MHLW/PMDA	Japan
Mr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Nobumasa Nakashima	MHLW	Japan
Dr. Peter Honig	PhRMA	USA
Mr. Jerry Stewart	PhRMA	USA
Dr. Petra Doerr	Swissmedic	Switzerland

### ICH Coordinators

Mr. Sébastien Goux	EC	Europe
Ms. Amanda Roache	FDA	USA
Dr. Celia Lourenco	Health Canada	Canada
Mr. Mitsuo Mihara	JPMA	Japan
Mr. Fumihito Takanashi	MHLW	Japan
Ms. Camille Jackson	PhRMA	USA

### Technical Coordinators:

Dr. Milton Bonelli	EC/EMA	Europe
Ms. Chieko Hirose	MHLW/PMDA	Japan

### Standing Observers:

Mr. Mike Ward	WHO	Switzerland
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### Other Participants:

Mr. Nick Orphanos	Health Canada	Canada
Dr. Yoshihiro Katsura	MHLW/PMDA	Japan

### ICH Secretariat:

Dr. Dawn Ronan  
Dr. Sarah Adam  
Dr. Isabelle Güller  
Ms. Coralie Angulo

## SUMMARY REPORT

*MC Chair: Dr. Toshiyoshi Tominaga, MHLW/PMDA*

*MC Vice-Chair: Ms. Cathy Parker, Health Canada*

### 1. ADOPTION OF THE AGENDA

The MC Chair welcomed participants and the agenda was adopted without any comments.

### 2. APPROVAL OF REPORTS

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

- *The MC approved the reports (MC2016/37 and MC2016/38R) of the teleconferences held on September 30, 2016 and on October 7, 2016 as final;*
- *The ICH Secretariat will post the reports (MC2016/37 and MC2016/38R) on the ICH website.*

### 3. ORGANISATION OF OSAKA MEETING

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

- *The MC provided its support for the Assembly Agenda Papers Package which will be circulated to the Assembly on October 26, 2016;*
- *The MC agreed on the timetable for the MC and Assembly meetings in Osaka;*
- *The MC noted the current list of confirmed participants to the MC and Assembly meetings in Osaka.*

### 4. ICH ACTIVITIES AND NEXT STEPS

#### ❖ **ICH PROCEDURAL MATTERS**

The ICH Secretariat updated the MC on the recent changes made to the revised Assembly Rules of Procedures (RoP) and the Articles of Association in view of comments received.

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

- *The MC supported that the updated versions of the Assembly RoP and the Articles of the Association be included in the in the Assembly Agenda Papers Package to be sent on October 26 and which will be for Assembly approval in Osaka in November 2016.*

#### ❖ **STRATEGIC DISCUSSIONS**

The Lead of the New Topics Subcommittee updated the MC on preparations for the strategic discussions in Osaka.

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

- *The MC supported the inclusion of the strategic discussion background documents on Good Clinical Practice (GCP) (led by FDA) and on Compliance of Reliability for Electronic Data (led by JPMA) in the Assembly Agenda Papers package to be sent on October 26, 2016.*

#### ❖ **ICH FINANCIALS**

Ms. Parker (Health Canada) provided the MC the Financial Subcommittee's recommendations following its review of the proposals received from potential auditors.

Ms. Parker also updated the MC on the Financial Subcommittee's recent discussion regarding the Membership Fee Proposal to be presented to the Assembly.

The MC also noted the letters received from Assembly Members regarding the Membership Fee Proposal made in Lisbon. The MC noted that the letters would be shared with the Assembly.

**MC Actions/Decisions:**

- *The MC supported the presentation of the current Membership Fee Proposal to the Assembly indicating that future membership fees may need to be increased, or decreased based on the budget situation of the association or a revision of the relative contributions of the different types of members;*
- *The MC agreed to further discuss the Meeting Participation Fee Proposal in Osaka.*

**5. DATES OF NEXT MEETINGS IN 2016/2017**

***Face-to-Face ICH Meetings***

November 5-10, 2016

Osaka, Japan

Date to be confirmed

Montreal, Canada

**6. ANY OTHER BUSINESS**

**6.1. ICH Public Meeting**

The MC was updated on the outcome of the Health Canada and the U.S. Food and Drug Administration (FDA) joint public meeting held on October 24, 2016 on ICH Guidelines currently under development, in order to seek input on areas of current regulatory disharmony and where harmonised ICH Guidelines would be beneficial.