

Ref.: MC2016/38

October 25, 2016

**DRAFT SUMMARY REPORT
ICH MC TELECONFERENCE
October 7, 2016**

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

| | | |
|---------------------------------|---------------|-------------|
| Dr. Tomas Salmonson | EC | Europe |
| Dr. Sabine Luik | EFPIA | Europe |
| Dr. Theresa Mullin | FDA | USA |
| Dr. Joan Blair | FDA | USA |
| 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 |
| Mr. Pär Tellner | EFPIA | 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. Spiros Vamvakas | EC/EMA | Europe |
| Dr. Michelle Limoli | FDA | USA |
| Ms. Chieko Hirose | MHLW/PMDA | Japan |

Standing Observers:

| | | |
|--------------------|-------|-------------|
| Dr. David Jefferys | IFPMA | Switzerland |
|--------------------|-------|-------------|

Other Participants:

| | | |
|-----------------------|-----------|--------|
| Ms. Emer Cook | EC/EMA | Europe |
| Mr. Martin Harvey | EC/EMA | Europe |
| 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

2. APPROVAL OF REPORTS

MC Actions/Decisions:

- *The MC approved the report (MC2016/32R) of the teleconference held on September 15, 2016 as final;*
- *The ICH Secretariat will post the report (MC2016/32R) on the ICH website;*
- *The MC noted the comments received on the draft actions/decisions for the MC Teleconference held on 30 September 2016;*
- *The ICH Secretariat will prepare the report for the teleconference held on September 30, 2016, which will be circulated by email to the MC for its final approval.*

3. ORGANISATION OF OSAKA MEETING

The MC discussed a proposal from the ICH Secretariat to no longer print the MC meeting agenda papers for distribution to the MC ahead of meetings and to only provide these electronically. The MC noted that at the ICH meeting in Osaka, the Secretariat will ask participants whether they wish to have hard copies of any new documents to be discussed onsite (e.g., documents which would not have been included in the electronic agenda papers).

MC Actions/Decisions:

- *The MC was updated by the ICH Secretariat on comments received on the draft Agenda for the Assembly meeting in Osaka;*
- *The MC provided its approval on the Assembly Agenda and supported its circulation to the Assembly on October 12, 2016;*
- *The MC supported the proposal of the ICH Secretariat to no longer print the MC agenda papers ahead of ICH meetings starting in Osaka.*

4. ICH ACTIVITIES AND NEXT STEPS

❖ ICH PROCEDURAL MATTERS

The MC was updated by the ICH Secretariat on comments received on the Assembly Rules of Procedures (RoP). The MC noted that no comments were received on the revised Articles of the Association.

MC Action/Decision:

- *At its next teleconference, the MC will be invited to approve the updated Assembly RoP and the revised Articles pending legal review for subsequent sharing with the Assembly for its consideration and approval in Osaka in November 2016.*

❖ ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The Leads of the Membership Subcommittee updated the MC on all Membership/Observership applications currently under consideration.

MC Actions/Decisions:

- *The MC supported the draft letter on “Value of Membership” prepared by the Secretariat to be sent to all Assembly Observers (with Assembly Members in copy);*
- *The ICH Secretariat will send the letter to the Assembly and prepare a new webpage on the ICH website summarizing the value of membership.*

❖ NEW TOPICS AND STRATEGIC DISCUSSIONS

New Topics: Safety Data Collection and Adaptive Clinical Trials

The MC discussed the proposal from FDA on *Safety Data Collection*, and MHLW/PMDA provided feedback to the MC regarding the Safety data collection proposal’s impact for Japan.

The MC also discussed the proposal from PhRMA on *Adaptive Clinical Trials*.

MC Action/Decision:

- *In Osaka, the MC will be invited to continue its discussions on the 2 proposals and confirm next steps.*

Strategic discussions:

The MC noted the compilation of all MC comments received on the documents prepared in preparation of the strategic discussions in Osaka on *Good Clinical Practice (GCP)* (led by FDA) and on *Compliance of Reliability for Electronic Data* (led by JPMA).

The MC discussed the organisation of the strategic discussions in Osaka.

MC Action/Decision:

- *FDA and JPMA were invited to make any necessary changes to their proposals by October 21, 2016 for provision to the MC and subsequent circulation to the Assembly ahead of the Osaka meeting.*

The Lead of the Training Subcommittee provided an update to the MC on the activities of the Training Subcommittee.

The MC noted that ahead of Osaka, the Subcommittee will continue its work on the options for an ICH training strategy.

MC Actions/Decisions:

- *The MC supported that a training survey be circulated to the ICH Assembly.*
- *In Osaka, the Subcommittee will present to the MC for its consideration a options for a proposed training strategy taking account of feedback received on the training survey.*

❖ ICH COMMUNICATION

The Lead of the Communication Subcommittee provided a presentation to the MC on the activities of the Communication Subcommittee including the finalisation of the draft Transparency Policy, and the development of the draft Communication and Stakeholder Engagement Framework.

MC Actions/Decisions:

- *The MC noted the finalisation of the general slide deck on ICH and its publication on the ICH website;*
- *In Osaka, the MC will further discuss the communication and stakeholder engagement framework and it will be invited to approve the transparency document and next steps.*

5. OVERSIGHT OF EXPERT WORKING GROUPS/IMPLEMENTATION WORKING GROUPS

5.1. M8 EWG/IWG: THE ELECTRONIC COMMON TECHNICAL DOCUMENT: eCTD (Rapporteur: Mr. Watanabe – MHLW; Regulatory Chair: Dr. Fitzmartin – FDA)

MHLW/PMDA reported on M8 consideration regarding the communication between the M8 IWG and the eCTD tools vendors.

MC Actions/Decisions:

- *The MC supported that the M8 IWG continue working with eCTD tools vendors in the Implementation Phase;*
- *The MC also supported that the M8 IWG posts a communication for the attention of all eCTD tool vendors on the ICH website.*

6. DATES OF NEXT TELECONFERENCES AND MEETINGS IN 2016/2017

Teleconference

October 25, 2016

MC/MC Observers (Policy)

Face-to-Face ICH Meetings

November 5-10, 2016

Osaka, Japan

Date to be confirmed

Montreal, Canada

7. ANY OTHER BUSINESS

7.1. ELECTION OF NEXT MC CHAIR AND VICE CHAIR

The ICH Secretariat informed the MC on the process for the nomination of the MC Chair in Osaka as per MC RoP 6 which states that the MC will be invited to elect a new Chair to be appointed by the Permanent Regulatory Members and who will take office on November 10, 2016. The MC noted that at the same time a Vice Chair may also be elected from the Permanent Regulatory Members. *The MC noted that the decisions will be adopted by a qualified majority of the votes cast in line with Article 37(4) and by secret ballot.*

7.2. FINALISATION OF M9 AND M10 CONCEPT PAPERS

The MC noted the updated versions of the M9 and M10 Concept Papers.

MC Action/Decision:

- *The ICH Secretariat will proceed with finalizing the M9 and M10 Concept Papers and Business Plans and will share the final version of both documents with the Assembly and seek the formal nomination of the experts to the EWGs which will be meeting for the first time in Osaka.*