

Ref.: MC2016/26

September 26, 2016

**SUMMARY REPORT
ICH MC TELECONFERENCE
July 7, 2016**

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

Mrs. Lenita Lindström-Gommers	EC
Dr. Tomas Salmonson	EC
Mr. Richard Bergström	EFPIA
Dr. Theresa Mullin	FDA
Ms. Joan Blair	FDA
Ms. Cathy Parker	Health Canada
Dr. Celia Lourenco	Health Canada
Dr. Hironobu Saito	JPMA
Mr. Takuya Saiki	JPMA
Dr. Peter Honig	PhRMA
Dr. Toshiyoshi Tominaga	MHLW/PMDA
Mr. Naoyuki Yasuda	MHLW/PMDA
Ms. Cordula Landgraf	Swissmedic

ICH Coordinators

Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA
Dr. Celia Lourenco	Health Canada
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW
Ms. Camille Jackson	PhRMA

Technical Coordinators:

Ms. Chieko Hirose	MHLW (PMDA)
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Other Participants:

Mr. Martin Harvey	EC
Dr. Michelle Limoli	FDA

ICH Secretariat:

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

SUMMARY REPORT

Teleconference Chair: Dr. Toshiyoshi Tominaga – MHLW/PMDA

1. ADOPTION OF THE AGENDA

The MC Chair welcomed all participants and the agenda was adopted with an addition to Any Other Business – confirmation of next steps for the M2 EWG.

2. ICH SUBCOMMITTEE ACTIVITIES AND NEXT STEPS

❖ RULES OF PROCEDURE

The Lead of the Rules of Procedure (RoP) Subcommittee informed the MC that the MC RoP document and the updated Assembly RoP document which were approved as final in Lisbon, would be published shortly on the ICH website.

Actions/Decisions:

- *The MC agreed that the Subcommittee could be disbanded as it had completed its work to draft the Assembly and MC RoP documents;*
- *The MC supported that the ICH Secretariat could work directly with the Lead to make any necessary proposals for new procedures or revisions to existing procedures;*
- *The MC agreed that proposals for new procedures already be drafted by the Lead/ICH Secretariat for: the organisation of future meetings; the selection of new ICH topics; and the provision of Assembly endorsement via written procedure for specific items (see also below). The MC supported that these draft procedures be shared with the MC by September 1, 2016 for approval at its teleconference (operational/policy/procedural) in September.*

❖ SOP FOR EWGs/IWGs SUBCOMMITTEE

The Lead of the Standard Operating Procedures (SOPs) for EWGs/IWGs Subcommittee reported on work to finalise version 1.0 of the SOPs for EWGs/IWGs in view of the comments received from MC Members prior to and at the Lisbon meeting. The MC also noted a new proposal for specific items for which Assembly and MC endorsement could be sought via written procedure versus at the biannual face-to-face meetings.

In addition, and in response to the issue raised by the E9(R1) EWG in Lisbon, the Lead agreed to propose language which would allow the option of a “targeted” revision in the ICH procedures.

Actions/Decisions:

- *The Lead of the Subcommittee agreed to circulate by July 8, 2016 the updated version 1.0 SOPs for EWGs/IWGs for MC approval or any comments by July 15, 2016;*
- *The SOPs for EWGs/IWGs will be shared with EWGs/IWGs within each party during the confirmation by each MC before being published on the ICH website;*
- *The MC agreed that time should be allocated for an update at the Assembly meeting in Osaka in November 2016 to highlight the key points of the SOPs.*

❖ ICH FINANCIAL MATTERS

The Lead of the Financial Subcommittee highlighted the need for the MC to finalise a proposal for the Assembly in Osaka in November 2016 regarding the fees for new Members. The Lead informed the MC that the Financial Subcommittee would have a teleconference to discuss the solicitation of input from new and potential new Members to help inform the proposal on the fees for new Members.

The MC noted other items requiring further MC discussion: the 2017 ICH Secretariat budget; a proposal on a meeting participation fee for non-membership fee paying parties (i.e., Observers); and an ICH donation policy.

Action/Decision:

- *The Financial Subcommittee will share with the MC by September 1, 2016 for approval at the MC (operational/policy/procedural) teleconference a proposal for the fees for new Members and the draft 2017 ICH Secretariat budget, both of which should be submitted for Assembly approval in Osaka in November 2016.*

❖ MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The Leads of the Membership Subcommittee updated the MC on the status of activities.

The MC also noted the development of a document to outline the benefits ICH Membership compared to Observership. The MC noted that this was in response to questions raised by some Observers regarding Membership.

Actions/Decisions:

- *The Membership Subcommittee will provide an update at the September MC (operational/policy/procedural) teleconference;*
- *A document outlining the benefits of ICH Membership compared to Observership will be shared with the MC by September 1, 2016 for approval at the September MC (operational/policy/procedural) teleconference.*

❖ ICH COMMUNICATION

The Lead of the Communication Subcommittee provided the MC with an update on the development of the general slide deck on ICH, the Transparency Policy, and the Communication and Stakeholder Engagement Plan.

Actions/Decisions:

- *The Communication Subcommittee will shortly finalise the general slide deck on ICH and will share with the MC for its endorsement via written procedure;*
- *The Communication Subcommittee will provide a report at the September MC (operational/policy/procedural) teleconference on the status of the drafts of the Transparency Policy and the Communication and Stakeholder Engagement Plan with the aim of finalising these documents for MC approval at the MC (operational/policy/procedural) teleconference in October 2016.*

❖ NEW TOPICS

Informal M9 and M10 Working Groups

Regarding the nomination of the two informal Working Groups on *Biowaivers (M9)* and *Bioanalytical Method Validation (M10)*, the ICH Secretariat informed the MC that this process would be launched later in the day amongst the ICH Members and the Standing Observers.

Actions/Decisions:

- *The MC agreed that the Final M9 and M10 Concept Papers and Business Plans should be submitted by the M9 and M10 informal Working Groups (led by EC and MHLW/PMDA respectively) by September 1, 2016 to facilitate MC approval at its September (technical topics) teleconference;*
- *The ICH Secretariat will launch the nomination process for the M9 and M10 informal Working Groups on July 7, inviting nominations within a one week period.*

New Topic Proposals

The MC discussed next steps regarding the two additional new topic proposals considered by the MC in Lisbon which it had proposed to provide feedback on to the Assembly at the Osaka meeting: Safety Data Collection (proposed by FDA) and Adaptive Clinical Trials (proposed by PhRMA). The MC noted that if there would be agreement to proceed with these two new topic proposals, Concept Paper outlines would need to be approved by the Assembly in Osaka in order to have new EWGs meet at the spring 2017 meeting in Montreal.

Action/Decision:

- *The MC agreed that draft outlines of the two new topic proposals should be further discussed at the MC (technical topics) teleconference in September with draft Concept Paper outlines shared by September 1.*

Strategic Discussions

The MC discussed next steps towards the organisation of Strategic discussions in Osaka on *Good Clinical Practice (GCP)* (to be led by FDA) and on *Compliance of Reliability for Electronic Data* (to be led by JPMA).

Actions/Decisions:

- *In preparation of the Strategic Discussions in Osaka, FDA will work on a proposed approach for the structure and organisation of the discussions and provide a report at the MC (technical topics) teleconference in September;*
- *Also at the MC (technical topics) teleconference in September, FDA and JPMA will report on the development of background material for the Strategic Discussions;*
- *The Lead of the New Topics Subcommittee will work with to apply the timetable presented for Strategic Discussions in Lisbon to the period up to the Osaka meeting and will provide this to the MC by September 1, 2016.*

❖ TRAINING

The Lead of the Training Subcommittee noted that the presentation in Lisbon was cut short due to time constraints. The MC was informed that the Subcommittee is in need of MC level input before it can proceed further. Although several options and two potential models were presented, the Subcommittee is requesting general feedback and preferences on a path forward.

Actions/Decisions:

- *The MC will receive a separate email requesting input on the various issues and model options;*
- *A report on the feedback received to the email request will be provided at the MC (operational/policy/procedural) teleconference in September and next steps confirmed for the development of the ICH Training Strategy.*

3. ICH OPERATIONAL/PROCEDURAL MATTERS

The ICH Secretariat updated the MC on several operational/procedural items including the invitation to new Members to nominate ICH Coordinators, the updating of the ICH website to include a new organigram reflecting the new governance structure of ICH.

4. OVERSIGHT OF EXPERT WORKING GROUPS/IMPLEMENTATION WORKING GROUPS

❖ ***Q3D IWG: Guideline for Elemental Impurities***

Actions/Decisions:

- *The MC supported that the Q3D Working Group revise its Concept Paper to reflect the inclusion of information related to the dermal route of administration (RoA) and agreed that the revised Concept Paper be submitted to the MC for approval and a report made to the Assembly on this revision;*
- *The MC supported that the Q3D IWG provide a recommendation on the Working Group status and whether the current IWG can be maintained to conduct the additional activities related to the dermal ROA or if the IWG should be disbanded and an EWG formed to conduct these activities;*
- *The MC supported that the ICH Secretariat confirm with all Q3D IWG Topic Leaders their support for the proposed editorial changes to training module #8 and that the Assembly would be informed of the changes once the training module is finalised for publication on the ICH website.*

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

❖ ***Teleconferences***

Action/Decision:

- *The MC supported the organisation of four MC teleconferences in preparation of the Osaka meeting: one dedicated to discussion of technical topics, and the others dedicated to operational/policy/procedural items.*

❖ ***Face-to-Face ICH Meetings***

November 5-10, 2016

Osaka, Japan

Spring 2017

Montreal, Canada

6. ANY OTHER BUSINESS

❖ *M2 EWG: Electronic Standards for the Transfer of Regulatory Information*

Actions/Decisions:

- *The MC discussed and agreed to support M2's proposal related to the review of EWG materials at or before Step 1 and again at or around Step 3 or 4. Additionally, the MC expressed that M2 should use its judgment when determining when these reviews are necessary;*
- *The MC agreed that each Member should provide feedback to their M2 experts as soon as possible regarding the MC's considerations in Lisbon on the proposed new M2 operating model;*
- *The MC agreed that the M2 EWG should submit by September 1 a revised operating model and a work plan for approval at the MC (technical topics) teleconference in September.*