January 25, 2016

Minutes
ICH Management Committee Meeting
Osaka, Japan
November 7-10, 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
Ms. Joan Blair	FDA	USA
Dr. Theresa Mullin	FDA	USA
Dr. Celia Lourenco	Health Canada	Canada
Ms. Cathy Parker (Vice-chair)	Health Canada	Canada
Dr. Akira Kawahara	JPMA	Japan
Dr. Hironobu Saito	JPMA	Japan
Dr. Nobumasa Nakashima	MHLW	Japan
Dr. Toshiyoshi Tominaga (Chair)	MHLW/PMDA	Japan
Mr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Peter Honig	PhRMA	USA
Mr. Jerry Stewart	PhRMA	USA
Dr. Petra Doerr	Swissmedic	Switzerland
Ms. Cordula Landgraf	Swissmedic	Switzerland

ICH Coordinators

Mr. Sébastien Goux	EC	Europe
Mr. Pär Tellner	EFPIA	Europe
Ms. Amanda Roache	FDA	USA
Mr. Nick Orphanos	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
Dr. Spiros Vamvakas	EC/EMA	Europe
Dr. Michelle Limoli	FDA	USA
Ms. Chieko Hirose	MHLW/PMDA	Japan

Standing Observers:

Dr. David Jeffreys	IFPMA	Switzerland
Dr. Samvel Azatyan	WHO	Switzerland
Mr. Mike Ward	WHO	Switzerland

Other Participants:

Mr. Martin Harvey Allchurch	EC/EMA	Europe
Ms. Agnès Saint-Raymond	EC/EMA	Europe
Ms. Machiko Sumi	JPMA	Japan
Ms. Emi Tomotake	JPMA	Japan
Mr. Toshihiko Tsunenari	JPMA	Japan
Dr. Masafumi Yokota	JPMA	Japan
Dr. Yoshihiro Katsura	MHLW/PMDA	Japan

ICH Secretariat:

Dr. Isabelle Güller
Dr. Dawn Ronan

ICH Management Committee (MC) Meeting Minutes

Welcome & Adoption of the Agenda

Dr. Tominaga (MC Chair, MHLW/PMDA) and Ms. Parker (MC Vice-Chair, Health Canada) welcomed MC Member Representatives and Standing Observer delegates and the agenda was adopted without modification.

A. Adoption of the Report of the Previous Teleconference

Actions/Decisions:

- The MC adopted as final the Report of the MC teleconference held on October 25, 2016 (MC2016/39);
- The ICH Secretariat will publish the Report on the ICH website.

B. ICH Operational Matters

The ICH Secretariat provided an update on its activities. The MC noted the next steps towards the completion of the transfer of assets from IFPMA to the ICH Association and the set-up of the fully independent ICH Secretariat. This included the seeking of a tax exemption for the ICH Association, and work to address the remaining legal/fiscal points to facilitate the transfer of assets from trustee IFPMA to ICH. The MC noted that the exact timeframe for the transfer still needed to be confirmed and that there were many practical points to be addressed prior to the transfer in preparation of the fully independent ICH Secretariat.

Actions/Decisions:

- The MC approved the request of the ICH Secretariat for an increase of 0.4 FTE from 2017;
- The MC agreed that it was important to ensure the efficiency of operations of the new ICH Association and tasked the ICH Secretariat to prepare a proposal for the Montreal meeting on ways to increase efficiency by considering changes to existing procedures;
- The MC agreed the Member Logo developed by the ICH Secretariat, along with the disclaimer developed by the ICH lawyer, and agreed to present these to the Assembly for roll-out for use by Members from the Osaka meeting;
- The MC noted the recent updates made to the ICH website, including: the publication of MC meeting minutes and summary reports, and plans to publish shortly the membership lists for the Assembly, MC and Coordinators on the ICH website.

C. ICH Strategic Discussions

The MC prepared the strategic discussions for the Assembly on the topics:

- *"GCP Renovation": Modernization of ICH E8 and Subsequent Renovation of ICH E6; and*
- *Compliance of Reliability for Electronic Records.*

"GCP Renovation": Modernization of ICH E8 and Subsequent Renovation of ICH E6

Actions/Decisions:

- The MC supported that FDA revises its Reflections Paper on *"GCP Renovation": Modernization of ICH E8 and Subsequent Renovation of ICH E6* based on comments received and transform it into an ICH Reflections Paper;
- Additional comments were invited from the MC by the end of November 2016, with a revised Reflections Paper to be circulated by FDA in early December after which, if there are no major concerns, the document will be for publication on the ICH website by January 2017;
- The MC supported proposing to the Assembly the publication of the Reflections Paper on the ICH public website by January 2017, along with some text to introduce the document, and that stakeholder input should be invited within a 2-month period via a dedicated email box managed by the ICH Secretariat;
- The MC supported that MHLW/PMDA translate the Reflections Paper into Japanese and make it available in Japan for Japanese stakeholder input;
- The MC agreed that a proposal for the revision of the ICH E8 Guideline should already be submitted by FDA into the new topic process in January 2017.

Compliance of Reliability for Electronic Records

Actions/Decisions:

- The MC agreed that it should be the Industry Members who primarily conduct the initial work;
- The MC agreed that a sub-group of the M2 EWG may support only when a technical issue will be raised, with expertise relevant to the identified technical issues be tasked to work in conjunction with Industry Members and their identified technical experts, to assess feasibility by: conducting a gap analysis; fact finding to identify the core elements/ requirements for harmonisation; alignment of definitions and determining value proposition;
- The MC agreed to inform the Assembly on the need for further assessment of this strategic topic and the outcome of this continued assessment in Montreal.

Strategic Approach

Actions/Decisions:

- The MC supported a *Strategic Portfolio Approach* presented in Osaka aimed at identifying themes for future potential areas of work and supported that the New Topics Subcommittee align this approach with the ICH Strategic Discussion General Outline developed in Lisbon in June 2016;
- The MC will further consider possible future theme areas with a view to having strategic discussions on these themes.

D. New Topics

Actions/Decisions:

- Regarding the new topic proposal Adaptive Clinical Trials from PhRMA and in order to advance it, the MC supported that PhRMA revises the proposal to encompass a more limited scope, one that is less dependent on statistical considerations given the stated capacity concerns related to some active EWGs (e.g., E9). The MC supported as well that PhRMA circulates the revised proposal to MC Members for their comments to the revision, with a

timeline of submitting the updated proposal ahead of the Montreal meeting with enough time to the MC's comments;

- Regarding the new topic proposal *Safety Data Collection* from FDA, the MC supported renaming the proposal *Optimization of Safety Data Collection* to reflect the actual focus of the guideline and noted that MHLW/PMDA would be able to sign-off at *Step 1* after positive consultation with their stakeholders;
- The MC agreed to submit the new topic proposal *Optimization of Safety Data Collection* to the Assembly for approval in Osaka;
- The New Topics Subcommittee will present the Assembly with an overview of the timeline for the new topic process to be run in 2017, including key dates, such as that for the submission of proposals in January 2017.

E. ICH Procedural Matters

ICH Articles of Association

The MC noted the revised ICH Articles of Association which were circulated to Assembly Members and Observers ahead of the ICH Assembly meeting in Osaka and included changes for clarification and consistency, and to ensure the efficiency of ICH's harmonisation activities.

Assembly Rules of Procedure

The MC noted the revised Assembly Rules of Procedure which were circulated to Assembly Members and Observers ahead of the ICH Assembly meeting in Osaka, and noted that as a reflection of the revised Articles of Association changes were included for clarification and consistency, and to ensure the efficiency of ICH's harmonisation activities.

Actions/Decisions:

- In Osaka, the MC supported two additional changes to the revised Assembly Rules of Procedure for presentation to the Assembly for approval:
    - Deletion of the requirement for Observers to provide a written proxy for their delegates – Observers will instead be asked to confirm via email any changes to their delegates;
    - Inclusion of a new procedure to make meeting participants aware that photographs may be taken at ICH meetings for use in ICH communications (e.g., ICH website and social media), unless a participant explicitly requests not to be photographed;
- The MC agreed to consider the revision of the Assembly Rules of Procedure, and if necessary the ICH Articles of Association, to adjust the Rules of Procedure related to Article 17(1)(d) *International organisations with an interest in pharmaceuticals on the basis of their contribution or benefit to ICH* to ensure ICH expands in a manageable way given the growing interest in ICH from this type of organisation.

ICH Management Committee Rules of Procedure

The MC noted changes proposed to the ICH Management Committee Rules of Procedure which included new procedures for: the organisation of ICH meetings; selection of new topics; and use of the ICH logo.

Actions/Decisions:

- The MC approved the revised ICH Management Committee Rules of Procedure for presentation to the Assembly in Osaka for its information;
- The ICH Secretariat will publish the revised ICH Management Committee Rules of Procedure on the ICH public website.

Standard Operating Procedures for EWGs / IWGs

Further to v1.0 of the Standard Operating Procedures for EWGs/IWGs which was published on the ICH website in October 2016, the MC noted the work of the Subcommittee on the Standard Operating Procedures for EWGs/IWGs to complete work on v2.0.

Actions/Decisions:

- The MC approved v2.0 of the Standard Operating Procedures for EWGs/IWGs for presentation to the Assembly in Osaka for its information;
- The ICH Secretariat will publish v2.0 of the Standard Operating Procedures for EWGs/IWGs on the ICH public website;
- The MC agreed that the Subcommittee on Standard Operating Procedures for EWGs/IWGs should continue its activities and that it would be premature to disband this Subcommittee.

F. ICH Membership and Observership Applications

The Lead of the Membership Subcommittee provided an update on the activities of the Membership Subcommittee including an overview of all applications for Membership/Observership received to-date.

The MC finalised its assessment and prepared recommendations for the Assembly for a number of applications.

The MC also agreed that it would not be appropriate to comment on or communicate the status of applications that have not yet been finalised and approved for recommendation to the Assembly.

Actions/Decisions:

- The MC agreed to recommend the following Membership applications to the Assembly for approval:
    - The Agência Nacional de Vigilância Sanitária (ANVISA, Brazil);
    - The Biotechnology Innovation Organisation (BIO);
    - The Ministry of Food and Drug Safety (MFDS, Korea);
- The MC agreed to recommend the following Observership applications to the Assembly for approval:
    - The Active Pharmaceutical Ingredients Committee (APIC);
    - The Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED, Cuba);
    - The Medicines Control Council (MCC, South Africa);
    - The National Center for the Expertise of Drugs, Medical Devices and Equipment, (National Center, Kazakhstan).

G. ICH Financial Matters

The Lead of the Financial Subcommittee provided an update on the Subcommittee's activities. The MC noted the proposal on the *Annual Fee for New Members* circulated to the Assembly ahead of the Osaka meeting and agreed on the proposal of an annual fee for Regulatory and Industry Members of CHF 20,000 for implementation in 2018. During the discussion, it was pointed out that the difference in the amounts of the annual membership fee for the new Members (Regulatory and Industry Members) and for the Founding Members do not reflect the differences in their respective rights under the Articles of Association. The MC noted that information was being added to the ICH website to highlight the rights of Regulatory and Industry Members. The proposed annual membership fee for Regulatory and Industry Members has been set at the lower end of the range (presented at the Lisbon meeting) as several regulatory authorities expressed a concern that a higher fee could be an obstacle to apply for membership. The MC, however, noted that this amount may need to be revised in the future depending on how the ICH Association develops. The MC also agreed that any changes to the annual membership fees with considering the changes in circumstances surrounding and reducing the differences between the fees for the Founding Members on the one hand and the Regulatory and Industry Members on the other is one of the ideas.

Regarding the appointment of an audit firm to audit the annual financial statements of the Association in line with the ICH articles of Association, the MC noted that based on the assessment of the Financial Subcommittee, a proposal had been circulated to the Assembly prior to Osaka recommending that the Assembly approves moving forward with Moore Stephens Refidar SA as the audit firm to be appointed for a two year period.

H. ICH Communication

The Lead of the Communication Subcommittee updated the MC on the activities of the Communication Subcommittee including: publication on the ICH website of a general slide deck providing an Overview of ICH which could be used by Members and Observers invited to present on ICH; and the development of a Transparency Policy, as well as a Communication and Stakeholder Engagement Plan.

Actions/Decisions:

- The MC agreed to provide the Communication Subcommittee further feedback on the draft Communication and Stakeholder Engagement Framework by mid-December 2016 based upon which the Communication Subcommittee will prepare the final Communication and Stakeholder Engagement Proposal for formal MC approval;
- The MC agreed to provide the Communication Subcommittee with further feedback on the draft Transparency policy by mid-December 2016. Following this the Communication Subcommittee will prepare the final Transparency policy for formal MC approval.

I. Training

The Lead of the Training Subcommittee updated the MC on the activities of the Training Subcommittee.

Actions/Decisions:

- The MC approved the following outputs of the Training Strategy Subcommittee Subteam #2:
    - List of training modalities and which methods might work best for certain topics, criteria for training approaches, and various techniques and tools;

- Slide template for ICH working groups to use when developing presentations;
- "Best Practices" document with tips for drafting ICH slide presentations;

- The MC agreed that the Training Strategy Subcommittee becomes a Standing Subcommittee – the "Training Subcommittee";
- The MC agreed that the Training Subcommittee partner with a small group of training providers – curriculum based – as a pilot to:
  - Draft roles and responsibilities of parties for MC endorsement;
  - Draft expectations of each party (for example use of ICH logo; post training available on ICH Website, etc…) for MC endorsement;
  - Draft a short agreement/ToR (Terms of Reference) for MC endorsement;
  - Pilot for 12 months;
  - Evaluate and report back to MC;
  - Report on progress periodically.

J. Implementation of ICH Guidelines

Actions/Decisions:

- The MC agreed that the ICH public website be updated with information on the implementation of ICH Guidelines by all Regulatory Members, including new Members;
- The MC noted that implementation of ICH Guidelines is a standing item on the Agenda of the Assembly under the Assembly RoP (section 1.1.3). The MC agreed that the ICH Secretariat should develop and maintain a table regarding the implementation of ICH Guidelines by all Regulatory Members to provide an overview on the status of implementation for discussion at the Assembly.

K. Oversight of Expert Working Groups and Implementation Working Groups

Groups Meeting in Osaka

E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses

Action/Decision:

- The MC agreed to a delay in the timeframe for the E9 EWG(R1) to reach *Step 1* and supported that the group focus on developing the Addendum after which they will consider how best to address impact on the core Guideline e.g., targeted revision.

Groups Not Meeting in Osaka

M2 EWG: Electronic Standards for the Transfer of Regulatory Information

Actions/Decisions:

- The MC approved the revised Operating Model for the M2 EWG, but acknowledged that the M2 EWG is the same as existing ICH WG with different governing structure, and proposed that the M2 EWG be supplemented by a small Steering Group in place of a single Rapporteur, and that this is reflected in the revised Operating Model;
- The ICH Secretariat will conduct a membership refresh for the M2 EWG and invite Members to confirm the names of the experts of the Steering Group.

Appointment of Rapporteurs & Regulatory Chairs

The MC discussed the appointment of Regulatory Chairs to several WGs.

Actions/Decisions:

- The MC supported Health Canada as the new Regulatory Chair of the M2 EWG to replace the current FDA Regulatory Chair;
- The Regulatory Members of the MC were invited to propose a candidate to replace the current FDA Regulatory Chair on the M8 EWG/IWG;
- The MC supported FDA as the Regulatory Chair of the new M9 EWG;
- The MC supported MHLW/PMDA as the Regulatory Chair of the new M10 EWG;
- The MC supported FDA as the Regulatory Chair for the E11 EWG in replacement of MHLW/PMDA since they will become the Rapporteur of this EWG.

The MC noted the need for the Assembly to appoint Rapporteurs to several WGs.

Actions/Decisions:

- The MC supported recommending to the Assembly MHLW/PMDA as the new Rapporteur of the E11 EWG;
- The MC supported recommending to the Assembly that the current Acting Rapporteur from the EC for the S5(R3) EWG continue as Rapporteur;
- The MC noted the need to confirm who would replace PhRMA as Rapportuer if the Q11 EWG.

Participation of Observers in EWGs/IWGs

Action/Decision:

- The MC approved the requests which had been received from ICH Observers in advance of the Osaka meeting to appoint experts in EWGs/IWGs.

Observer Name	EWGs/IWGs
ANVISA (subsequently appointed Member)	M8 EWG/IWG
BIO	M10 EWG
TGA	M9 EWG
HSA	M9 EWG
TFDA	M9 & M10 EWGs
ANVISA (subsequently appointed Member)	M9 EWG
ANVISA (subsequently appointed Member)	M10 EWG
GCC	M9 EWG
ASEAN	M10 EWG

L. ICH Annual Work Plan and Multi-Annual Strategic Plan

Action/Decision:

- The MC supported the presentation to the Assembly of the ICH Annual Work Plan and Multi-Annual Strategic Plan with further clarification on the key areas of work and timeframes for completion.

M. IPRF Update

Action/Decision:

- The MC noted that the mechanics of the arrangement concerning secretariat support to IPRFwould be addressed after the Osaka meeting.

N. Election of Next Management Committee Chair and Vice-Chair

Action/Decision:

- The MC agreed unanimously to appoint Dr. Theresa Mullin (FDA) as MC Chair and Dr. Toshiyoshi Tominaga (MHLW/PMDA) as Vice Chair to commence their 1-year term from the close of the MC meeting on November 10, 2016.

O. Organisation of ICH Meetings

General

Actions/Decisions:

- The MC requested to have information from the ICH Secretariat on the numbers of meeting attendees and the numbers of rooms and days of Working Groups for the past few ICH meetings in order to better understand the impact of the expansion of ICH Membership and Observership on meeting organisation;
- The MC agreed that certain aspects of the organisation of ICH meetings should be reviewed in consideration of the expansion of ICH Membership and Observership;
- The MC also agreed for consideration to be given to the reorganisation of the ICH week to avoid attendees to both the IPRF and Assembly meetings having an unused day between these meetings, for example having the IPRF meeting take place at the end of the week instead of the beginning. However it was acknowledged that there could be logistical constraints to consider – the MC supported that the ICH Secretariat work with the next meeting hosts to see what is possible and make a proposal to the MC, based on this follow-up.

EWGs/IWGs Meeting in Montreal, Canada

The MC discussed the requests made by EWGs/IWGs to meet face-to-face at the next ICH meeting in Montreal, Canada on May 27 to June 1, 2017 and made provisional planning.

Actions/Decisions:

- The MC agreed to finalise the list of EWG/IWGs which will meet in Montreal in May-June 2017 at the Spring 2017 Management Committee teleconference. This list will be made available to the Assembly and also on the ICH website following the MC teleconference;
- The following table summarises MC preliminary considerations regarding the EWGs/IWGs that are likely to meet in Montreal, however, noting that the final decision is taken at the MC TC in Spring 2017:

List of 23 Current ICH Working Groups (as of Osaka, November 2016)		Meeting in Montreal	Not meeting in Montreal	For decision at MC TC
e-Groups	M2 EWG			X
	M8 EWG/IWG			X
	E2B(R3) IWG			X
Safety Groups	S1 EWG			X
	S3A IWG		X	
	S5(R3) EWG	X		
	S9 IWG			X
	S11 EWG			X
	M7(R1) EWG		X	
Quality Groups	Q3C(R6) Maintenance EWG		X	
	Q3D EWG			X
	Q11 IWG			X
	Q12 EWG	X		
	M4Q(R1) IWG		X	
Efficacy Groups	E9(R1) EWG	X		
	E11(R1) EWG	X		
	E14/S7B DG		X	
	E17 EWG	X		
	E18 EWG			X
	E19 EWG	X		
Other Groups	M1 PtC WG		X	
	M9 EWG	X		
	M10 EWG	X		

Press Release

Action/Decision:

- The MC approved the Press Release, and agreed that after additional minor edits the ICH Secretariat should circulate to the Assembly on Monday, November 14 with a view to publishing on Tuesday, November 15, 2016.

Dates/Locations of Next Meetings for 2017/2018

May 27 – June 1, 2017	Montreal, Canada
November 11 – 17, 2017	Geneva, Switzerland
June 2 – 7, 2018	Japan (location to be confirmed)