

September 26, 2017

Minutes
ICH Management Committee Meeting
Montreal, Canada
May 29 - June 1, 2017

List of Management Committee Participants

ICH Management Committee Members/Observers

Ms. Lenita Lindström-Gommers	EC, Europe
Dr. Spiros Vamvakas	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Joan Blair	FDA, US
Dr. Theresa Mullin (Chair)	FDA, US
Ms. Pujita Vaidya	FDA, US
Dr. Celia Lourenco	Health Canada, Canada
Ms. Cathy Parker	Health Canada, Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nobumasa Nakashima	MHLW, Japan
Dr. Toshiyoshi Tominaga (Vice-chair)	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland
Ms. Cordula Landgraf	Swissmedic, Switzerland

ICH Coordinators

Mr. Georgios Balkamos	EC, Europe
Mr. Pär Tellner	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Mr. Mitsuo Mihara	JPMA
Mr. Fumihito Takanashi	MHLW, Japan
Ms. Camille Jackson	PhRMA

Technical Coordinators:

Dr. Milton Bonelli	EC, Europe
Dr. Michelle Limoli	FDA, US
Ms. Chieko Hirose	MHLW/PMDA, Japan

Standing Observers:

Dr. David Jefferys	IFPMA
Mr. Mike Ward	WHO

Other Participants:

Mr. Martin Harvey Allchurch	EC, Europe
Dr. Tomas Salmonson	EC, Europe
Mr. Faraz Kermani	EFPIA
Mr. Stephan Rönninger	EFPIA
Ms. Machiko Sumi	JPMA
Ms. Erina Yamada	JPMA
Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Gabriela Zenhäusern	WHO

ICH Secretariat:

Dr. Isabelle Güller
Dr. Véronique Kuntzelmann
Dr. Anne Latrive
Dr. Dawn Ronan

ICH Management Committee Meeting Minutes

Welcome & Adoption of the Agenda

Dr. Mullin (MC Chair, FDA, US) and Dr. Tominaga (MC Vice-Chair, MHLW/PMDA, Japan) welcomed MC Member Representatives and Standing Observer delegates and the agenda was adopted without modification.

A. Adoption of the Report of the Previous Teleconferences

Actions/Decisions:

- The MC adopted as final the Report of the MC teleconference held on May 16, 2017 (MC2017/06);
- The MC adopted as final the Report of the MC teleconference held on April 13, 2017 (MC2017/04R);
- The MC noted the Report of the Coordinators teleconference which was held on March 2, 2017 (Coord2017/Montreal).

B. General Operational Matters

ICH Secretariat

The ICH Secretariat provided an update on its activities and on general operational matters, including: the status of transfer of assets of the former ICH (International Conference on Harmonisation) from IFPMA to the new ICH Association; current ICH Secretariat staffing; considerations regarding increasing the efficiency of ICH operations; a proposal regarding the addition of a further ICH signatory; the status of use of the ICH Logo and New Member Logo; administration of ICH Member and Working Group websites; and recent ICH Secretariat meetings with external organisations.

Actions/Decisions:

- 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 operational ICH Association;
- The MC approved the ICH Secretariat proposal regarding the amendment of ICH signatory rules in the ICH Secretariat Staff Handbook and named Ms. Emilie Macara (ICH Secretariat) as an additional ICH signatory, alongside existing signatories Mrs. Lenita Lindström-Gommers (EC, Europe), Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan) and Dr. Dawn Ronan (ICH Secretariat);
- The MC supported the launch of the recently developed Assembly section of the ICH members-only website for roll-out to Members at the meeting in Montreal and supported the proposal of the ICH Secretariat to explore extending the use of the new section to enable Members to also share information for example on ICH related presentations/meetings/training with which they are involved;
- The MC approved the measures to increase efficiency presented in the proposal for increasing efficiency developed by the ICH Secretariat. The MC approved in particular the categorisations of situations requiring express or tacit MC approval, with the comment that email communications about matters requiring only tacit approval should explicitly state so in the subject line.

IPRF (International Pharmaceutical Regulators Forum) Cooperation

Action/Decision:

- The MC agreed with the proposal that the ICH Secretariat will provide support services to IPRF activities starting in January 2018 and supported presentation of the proposal to the Assembly in Montreal. The MC noted that support of IPRF activities will be conducted and financed separately from support of ICH activities.

Preparation for Opening-up of ICH MC to Elected Representatives

The ICH Secretariat highlighted the provision in the ICH Articles of Association that no later than January 1, 2018, the MC shall consist of up to 16 Permanent MC Representatives and 12 Elected MC Representatives with inclusion of up to 4 New Regulatory Members and 2 New Industry Members, each with 2 Elected Representatives. The MC noted the additional provision that proposals for nominees for Elected MC Representatives would need to be submitted to the ICH Secretariat in writing at least 4 months prior to the next Assembly meeting.

Actions/Decisions:

- The MC noted the procedures related to Elected MC Representatives as stated in the ICH Articles of Association and ICH MC Rules of Procedure (RoP), and supported a July 15 deadline for Regulatory and Industry Members to submit their nomination applications ahead of an election at the Assembly meeting in Geneva on November 16, 2017. The MC noted that the decision at the Assembly meeting regarding the election of the new MC Representatives would become effective immediately;
- The MC approved the Regulatory and Industry Elected Management Committee Representative nominations forms;
- The MC agreed that the ICH Secretariat be responsible for the formal check of applications received against the eligibility criteria in the RoPs prior to MC consideration and that the aim should be to circulate to the Assembly the MC's recommendations on the eligibility of applicants no later than 2 weeks prior to the next meeting in Geneva in November 2017.

C. ICH Meetings

Future ICH Meeting Organisation

Actions/Decisions:

- The MC acknowledged the different options proposed by the Financial Subcommittee for future ICH Meeting Organisation, and provided its agreement in principle to the proposal to contract a global Meeting Planner pending further investigation by the Financial Subcommittee;
- The MC supported that as part of its further investigation, the Financial Subcommittee solicits proposals from several Meeting Planners, with a view to presenting its assessment of proposals at/ahead of the Geneva meeting in November 2017, when the MC will be invited to take a final decision;
- The MC agreed that, for organisation purposes, the location of ICH meetings should be formally decided at least between 18 and 24 months in advance;
- The MC acknowledged the different options for future meeting structure and supported that the Financial Subcommittee assesses the further option of organising 1-2 interim meetings of the MC annually in conjunction with some Working Groups (WGs) and presents its proposal at/ahead of the Geneva meeting in November 2017;

- The MC agreed that three regional rotation (North America/South America, Europe/Africa, Asia) is a general rule of the meeting location, and also considered that the possibility of the ICH meeting being held in the same location several times in each region, provided the location is appropriate in terms of accessibility and security;
- The MC supported the approach to include a buffer in the ICH budget in order to mitigate the risk of currency fluctuations having a negative impact on the meeting budget;
- The MC agreed in principle to the implementation of a meeting participation fee for non-Members from 2019, pending further work on the administration aspects.

Designation of November 2018 Meeting Host

Action/Decision:

- The MC agreed that the November 2018 Meeting will be hosted in the USA by PhRMA and FDA, US, with the location and dates to be defined.

Organisation of November 2017 & June 2018 ICH Meetings

Actions/Decisions:

- The MC acknowledged the report from Swissmedic, Switzerland that the organisation of the Geneva meeting in November 2017 is on track;
- The MC acknowledged the report from JPMA that the organisation of the Kobe meeting in June 2018 is on track. The MC noted that current planning was on the basis of 300 meeting participants and that 16 meeting rooms could be allocated to WG meetings/break-out meetings;
- The MC agreed to change the “autumn” and “spring” meeting designations to avoid confusion on the part of new southern hemisphere ICH Members and Observers, and supported that the months June and November be alternatively referenced.

D. ICH Procedural Matters

The MC was updated by the Lead for the revision of the ICH Articles of Association and RoP on the status of revisions to the Assembly and MC RoP documents and the ICH Articles of Association.

Action/Decision:

- The MC agreed that the web links included in the annual report (available on the ICH public website) to the current versions of the Assembly/ICH MC/MedDRA MC RoP, Standard Operating Procedures (SOPs) for EWGs/IWGs, and Articles of Association, should be kept active by creating an archive on the ICH website to previous versions of these documents.

ICH Articles of Association & Assembly Rules of Procedure

The MC agreed that there were several amendments needed to the Assembly RoP which should be raised for consideration by the Assembly, in order to reflect the changes made to the ICH Articles of Association, as well as for clarification and consistency.

Actions/Decisions:

- The MC supported the updated version of the Assembly RoP which were revised in Montreal;
- The MC agreed to share the version of the Assembly RoP, dated May 29, 2017 with the Assembly for approval in Montreal;

- The MC agreed that the ICH Secretariat organises the printing of the ICH Articles of Association in the form of a booklet for distribution to the participants of the next ICH Assembly meeting in Geneva in November 2017.

ICH Management Committee Rules of Procedure

Actions/Decisions:

- The MC approved revisions to the ICH MC RoP including changes proposed for consistency with the revisions to the Articles of Association and the Assembly RoP;
- The MC agreed to share the version of the ICH MC RoP, dated May 29, 2017 with the Assembly for information in Montreal.

Standard Operating Procedures for EWGs / IWGs

The Lead of the Standard Operating Procedures (SOPs) for EWGs/IWGs Subcommittee reported on the last version 3.0 of the SOPs for EWGs/IWGs.

Action/Decision:

- The MC approved version 3.0 of the SOPs for EWGs / IWGs, dated May 29, 2017, including a new application form to be used by Industry Members to request appointment of experts to EWGs/IWGs;
- The MC approved the revised Industry Membership application form, dated May 29, 2017, which had been revised to request information on the types of regulated products the applicant organisation works on;
- The MC agreed to share these documents with the Assembly for information in Montreal.

E. ICH Membership and Observership Applications

The Leads 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 application to the Assembly for approval:
 - CFDA, China;
- The MC agreed to recommend the following Observership application to the Assembly for approval:
 - PIC/S;
- The MC agreed not to recommend the following Membership application to the Assembly for approval:
 - BPTF;
- The MC agreed not to recommend the following Observership applications to the Assembly for approval:
 - BPTF;
 - AAPS;

- AAHRPP;
 - HPCUS;
 - SINDUSFARMA;
- The MC approved to continue with the *status quo* in consideration of a proposal from the Membership Subcommittee to revise the process for the review of applications for Membership and Observership.

F. ICH Financial Matters

The Lead of the Financial Subcommittee provided an update on the activities of the Financial Subcommittee and sought MC views on items including: 2016 Financial Audit; 2016 costs; 2018 ICH budget; multi-year budget planning; cash flow; and development of a proposal for a participation fee for non-membership fee paying ICH meeting participants.

Actions/Decisions:

- The MC noted the documents to be presented to the Assembly in Montreal;
- The MC approved that the ICH Secretariat support to IPRF activities will begin in January 2018 and that these services will be funded separately from ICH activities.

G. ICH Communication

The Lead of the Communication Subcommittee updated the MC on the activities of the Communication Subcommittee including proposals for: Q&As on transparency to be published on the ICH public website; implementation of a Transparency Policy; and a Communication and Stakeholder Engagement Plan for 2017.

Actions/Decisions:

- The MC agreed to publish on the ICH public website the names of the Regulatory Chairs and Rapporteurs (including nominating party, name of representative and role) for all active EWGs/IWGs, effective immediately, and, following consultation, to further discuss at the Geneva meeting in November 2017 the next step to either publish the names of all active EWG/IWG experts or only the names of experts on new EWG/IWGs;¹
- The MC agreed on the Communication Subcommittee proposal regarding the ICH transparency policy, including publication of a set of Q&As on transparency, as well as photographs and biographies of MC and Assembly Member Representatives and Observer delegates along with their names (already published) on the ICH public website;
- The MC endorsed the Communication and Stakeholder engagement plan.

¹ Post-meeting note: Following the Montreal meeting, the MC agreed to the publication on the ICH website of the names of all experts of ongoing EWGs/IWGs along with a disclaimer to clarify that Expert Working Groups members are appointed by their nominating ICH Member or Observer party and are responsible for representing the views of that party, which may not necessarily reflect their personal views.

H. Training

The Lead of the Training Subcommittee updated the MC on the activities of the Training Subcommittee, including the progress of the pilot supported in Osaka, in November 2016, for the Training Subcommittee to partner with a small group of training providers.

Actions/Decisions:

- The MC noted the status of the pilot which had been supported by the MC in Osaka for the Training Subcommittee to partner with a small group of training providers;
- The MC supported the use of a new logo “ICH Recognised Training Programme” to be made available to training providers following signature of a disclaimer provided by the ICH Secretariat;
- The MC noted that all training providers involved in the pilot were required to sign their agreement with the Terms of Reference (previously endorsed by the MC) and that the Training Subcommittee was responsible for monitoring adherence with these terms;
- As agreed in the Terms of Reference, the MC supported that the ICH Secretariat communicates on the training programmes via the ICH website, as well as through the Assembly Member and Observer email distribution list. The Training Subcommittee agreed to assist the ICH Secretariat with the development of language for the ICH website and use in email communications.

I. New Topic Proposals and Strategic Discussions

The Lead of the New Topic Subcommittee provided the MC with an update on the activities of the New Topic Subcommittee, including collection of new topic proposals, as well as considerations related to the refinement of the process and framework for the selection of new ICH technical topics and development of a process regarding work on strategic topics. The MC noted the new topic proposals which had been submitted by several of the Members prior to the Montreal meeting. All topics were ranked by each Member according to priority and the MC agreed to recommend to the Assembly for approval those with the highest priority rankings.

New Topic Proposals

Actions/Decisions:

- The MC agreed to recommend two new Efficacy Topics to the Assembly for endorsement as new ICH topics: Paediatric Extrapolation and E8 revision;
- The MC was in principle supportive of the new Quality topic proposals: Quality Overall Summary and Continuous Manufacturing, however agreed that further consideration was needed regarding the scope and sequencing of new Quality topics and agreed that the Quality Reflection Paper be further amended to support these considerations (see below for more on the Quality Reflection Paper);
- The MC agreed to the annual organisation of an interim face-to-face meeting of the New Topic Subcommittee in the mid-March/mid-April timeframe (with support from the ICH Secretariat) exclusively dedicated to: make recommendations to the Assembly on new topics to adopt (and proposed starting times); advance discussions on ongoing Strategic Reflections Papers; and present/brainstorm on new potential areas for development of Strategic Reflections Papers. The MC agreed that the location for the next interim meeting should be determined in the June meeting and that the first interim face-to-face meeting should be held in the first quarter of 2018;

- The MC agreed on the general principles of an amended new topic process, and supported the development of a visual flow-chart with timeframes and a revision of the corresponding part of the SOP and/or RoP. The New Topic Subcommittee will work by teleconference to finalise the documentation of the adjustments supported by the MC. Adjustments agreed in principle included: moving the initial submission of New Topic proposals to end of December;; scheduling earlier the dates for the mid-February teleconferences with experts; the inclusion of a formal deadline for submission of revised proposals, submission of evaluation forms ahead of the interim Subcommittee meeting, producing the shortlist of topics recommended to the Assembly as outcome of the interim Subcommittee meeting (including recommended starting time), and inviting non-MC Assembly parties who have submitted proposals to participate in teleconferences where their proposals are discussed;
- The MC agreed that the interim meeting of the New Topic Subcommittee would also be helpful in allowing the preparation of timely communication with the Assembly on New Topic proposals and agreed that the Assembly should be sent all proposals submitted, along with the MC's considerations forming the background to the prioritisation of each topic.

Strategic Discussions: Path Forward for Integrating Strategic Discussion Approach with Individual New Topic Proposal Approach

Actions/Decisions:

- The MC agreed to more clearly define the process related to discussion of strategic areas for harmonisation, including development of a template for Strategic Reflection Papers and confirming timelines for: submission of papers (4 months ahead of ICH meeting); comments by the MC on papers (3 months before ICH meeting); and sending revised final paper to Assembly (1 month before ICH meeting). It was also agreed that these timelines would have to be adapted for the first cycle in order to enable submission of Strategic Reflection Papers, ahead of the next Geneva meeting in November 2017;
- The MC supported the development of a visual flow-chart with timeframes and a revision of the corresponding part of the SOP and/or the RoP document, including linkage with New Topic Proposal process. The MC noted that the output of Strategic Reflection Papers endorsed by the Assembly would be for individual New Topic proposals to be entered into the New Topic process;
- The MC supported further discussion in Geneva on strategic themes and noted that in addition to the Quality Reflection Paper (see below), other parties were also working on Strategic Reflection Papers to be shared with the MC ahead of the Geneva meeting: on vaccines and on generic medicines.

Strategic Discussions: Compliance of Reliability for Electronic Data

Actions/Decisions:

- The MC noted the proposal to put on hold work regarding the *Compliance of Reliability for Electronic Data* and supported disbanding the Feasibility Group by Industry;
- The MC also supported tasking the M2 EWG to watch this potential issue as part of its remit to review the external environment, and to seek the view of the M2 EWG on the best operating model to achieve this goal.

Strategic Discussions: Quality Reflection Paper

Actions/Decisions:

- The MC supported further revision of the draft Quality Reflection Paper with a view to circulating to the MC no later than September 2017 to allow time to prepare for discussion at the Geneva meeting in November 2017.

J. MC Subcommittee Mandates

Action/Decision:

- The MC reconfirmed the mandates for the following MC Subcommittees: Communication Subcommittee, Financial Subcommittee; Membership Subcommittee; New Topic Subcommittee; SOP Subcommittee; and Training Subcommittee, and agreed that those participating in the Subcommittees participate as individuals and Subcommittee Leads should request when participants should consult their Member organisations in instances where it would be helpful that they provide the Member view.

K. Implementation of ICH Guidelines

The ICH Secretariat presented to the MC the functionalities of the newly developed ICH Guideline implementation table. The MC noted that in addition to the collection of information from all Regulatory Members, a couple of Regulatory Observers had also shared information.

Actions/Decisions:

- The MC noted the table developed by the ICH Secretariat to monitor the progress of ICH Guideline Implementation and supported further discussions at the Geneva meeting in November 2017 on ICH Guideline implementation, as well as on the presentation of implementation information within the table;
- The MC agreed to present an overview of the ICH Guideline implementation table to the Assembly for its views;
- The MC noted that the ICH Secretariat would explore options to allow Regulatory Members and Observers to update the table themselves and to consider tools to enable the population of the table and the corresponding sections of the website under Q, S, E, M topics in a more automated way.

L. Oversight of Expert Working Groups and Implementation Working Groups

Participation of Observers in EWGs/IWGs

Actions/Decisions:

▪ ***IFPMA Participation***

- The MC noted IFPMA's proposal regarding its engagement in ICH and a process to facilitate the participation of IFPMA National Association experts in EWGs/IWGs;
- The MC was supportive of IFPMA presenting its proposal to the Assembly and piloting the approach and tasked IFPMA to develop a short 1-page document on the process to enable the MC and the ICH Secretariat to communicate in a consistent manner if approached on the process.

- **Other Observers**

- The MC approved the request from COFEPRIS, Mexico to appoint experts in the E17 EWG and M9 EWG.
- The MC approved the request from the National Center, Kazakhstan to appoint experts in E9(R1) EWG following the adoption of the Guideline at *Step 2a/b*.

Groups Meeting in Montreal

Actions/Decisions:

- **M2 EWG Electronic Standards for the Transfer of Regulatory Information**

- Regarding the Project Opportunity proposal on electronic Clinical Trial Application (eCTA), the MC charged M2 to engage further with subject matter experts to determine interest and further clarify or refine the project scope, in order to present a preliminary draft Concept Paper for the Geneva meeting in November 2017;
- Regarding the Project Opportunity proposal on Common Protocol Template (CPT), the MC charged M2 to engage further with subject matter experts to clarify or refine the project scope, in order to present a preliminary draft Concept Paper for the Geneva meeting in November 2017;
- Regarding the proposed M2 Work Plan, the MC approved the document and congratulated the group on its work.

- **E19 informal Working Group**

- The E19 informal Working Group will undertake further work on the E19 Concept Paper and Business Plan based on the direction provided by the MC;
- Once the Concept Paper and Business Plan are approved by the MC, an E19 EWG will be established.

- **Other Groups**

- **E9(R1) EWG**

- The MC endorsed the new Regulatory Chair from MHLW/PMDA, Japan;
- The MC supported the group to reinforce the communication package for the E9(R1) Addendum with a communication video;
- The MC agreed to allocate a budget to develop this video, on the basis of an estimate provided by E9(R1) experts based on previous projects of the same size, as well as contacts with potential providers, and agreed that the ICH Secretariat proceed to engage the provider proposed by the EWG.

- **Q12 EWG**

- The MC supported the Q12 EWG proposal to develop two documents that would go for Assembly endorsement under *Step 2a/b*: the Q12 Technical Document and a Q12 Annex that would include detailed example scenarios on how to implement the future Q12 Guideline;
- The MC supported that both documents would undergo public consultation under *Step 3*, after further clarity is obtained following EC legal review;
- The MC supported that the Q12 Annex could be updated with additional examples after public consultation and proceed to be directly signed-off under *Step 3* and

adopted under *Step 4* by the Assembly without going through another public consultation;

- The MC supported that in the long term, this Annex would be periodically updated without undergoing extensive consultation;
- The MC agreed that the SOP for EWGs/IWGs be revised to reflect this new approach;
- The MC endorsed the new Regulatory Chair from EC, Europe after endorsement of *Steps 2a/b* by the Assembly. EC, Europe will advise the MC when it has completed the EC, Europe legal review, at which time Q12 will proceed from its current *Step 1* to *Step 2a* and *Step 2b* as per the intention of the Q12 EWG as presented to, and discussed by the Assembly.

Groups Not Meeting in Montreal

Actions/Decisions:

- **Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents**
 - The MC supported the recommendation of the Q3C(R7) Maintenance EWG to develop PDEs of the following compounds: 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol;
 - The MC will be recommending the Assembly on these 3 proposals during the Assembly meeting in Montreal;
 - The MC supported that the EWG liaise with the ICH Secretariat to inform the stakeholders who submitted the two other proposals on isopentane and trichloroethylene about the reasons why they were not recommended by the group.
- **Other Groups**
 - The MC noted that Rapporteurship of the following groups was for Assembly approval in Montreal: Q3D(R1) EWG, Q12 EWG, E14/S7B DG, E18 EWG and M1 PtC.

M. EWGs/IWGs Meeting in Geneva, Switzerland

The MC discussed the requests made by EWGs/IWGs to meet face-to-face at the next ICH meeting in Geneva, Switzerland, on November 11 to 16, 2017 and made provisional planning.

Actions/Decisions:

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

List of 23 Current ICH Working Groups (as of June 1, 2017)		Meeting in Geneva	Not meeting in Geneva	For decision at MC TC
e-Groups	M2 EWG	X		
	M8 EWG/IWG			X
	E2B(R3) IWG			X
Safety Groups	S1(R1) EWG		X	
	S3A IWG		X	
	S5(R3) EWG		X	
	S9 IWG			X
	S11 EWG	X		
	M7(R1) Maintenance EWG			X
Quality Groups	Q3C(R7) Maintenance EWG		X	
	Q3D(R1) Maintenance EWG			X
	Q11 IWG		X	
	Q12 EWG			X
	M4Q(R1) IWG		X	
Efficacy Groups	E8(R1) EWG (<i>once established</i>)	X		
	Paediatric Extrapolation EWG (<i>once established</i>)	X		
	E9(R1) EWG			X
	E11(R1) EWG		X	
	E14/S7B DG		X	
	E17 EWG	X (5-6 days)		
	E18 EWG		X	
	E19 EWG	X		
Other Groups	M1 PtC WG	X		
	M9 EWG	X		
	M10 EWG	X (<i>start Saturday – to be confirmed</i>)		

N. Press Release

Action/Decision:

- The MC noted the points proposed for communication in the press release, and that in line with the Assembly RoP, the press release should undergo MC consultation and approval by the Assembly Chair.

O. DATES of NEXT MEETINGS

Teleconferences

Action/Decision:

➤ The MC noted the dates of the next teleconferences & face-to-face meetings:

- ICH Coordinators call - Thursday, August 31, 2017
- MC Technical call - Monday, September 25, 2017
- MC Policy call - Tuesday, October 3, 2017
- MC Policy call - Wednesday, October 11, 2017 (*tentative*)
- MC Policy call - Tuesday, October 17, 2017 (*tentative*)

Face-to-face Meetings

- | | |
|--------------------------|---|
| • November 11 – 16, 2017 | Geneva, Switzerland |
| • June 2 – 7, 2018 | Kobe, Japan |
| • November 2018 | USA (<i>dates & location to be confirmed</i>) |