10 April 2018

SUMMARY REPORT
ICH MC TELECONFERENCE
22 March 2018

LIST OF PARTICIPANTS

ICH MC Members

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

ICH MC Coordinators

Dr. 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/PMDA, Japan
Ms. Camille Jackson	PhRMA

ICH MC Technical Coordinators:

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

Other Participants:

Dr. Yoshihiro Katsura	MHLW/PMDA, Japan
Dr. Gabriela Zenhäusern	WHO

ICH Secretariat:

Ms. Coralie Angulo
Dr. Anne Latrive
Dr. Dawn Ronan

FINAL REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

MC Vice-Chair: Dr. Toshiyoshi Tominaga, MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair, FDA, US) welcomed all participants. The agenda was adopted with some reordering of agenda items.

2. ORGANISATION OF THE INTERIM MEETING

The MC was updated on the organisation of the Kobe meeting to be held in June 2018 and confirmed that meeting rooms would be made available for all Working Groups (WGs) based on the decisions taken by the MC at its teleconference.

MC Actions/Decisions:

- *The MC supported that requests for WG joint meetings and for caucus meetings should be submitted to the ICH Secretariat at the latest by 30 March 2018;*
- *The MC supported the organisation of a Briefing Session for ICH experts on Monday, 4 June 2018 from 8h00 to 8h45 to be provided by the ICH Secretariat;*
- *The MC supported the draft overall timetable for the meeting with the modification that the MC meeting start at 10h00 on Monday, 4 June 2018.*

3. PREPARATION OF KOBE: ORGANISATION OF WG MEETINGS

MC Action/Decision:

- *The MC supported the following requests from EWGs/IWGs to meet in Kobe in June 2018: M9, S5(R3) and S11 and noted it had previously electronically supported the meeting requests from: E2B(R3), E8(R1), E9(R1), E11A, E19, M2, M8, M10. Additional information regarding each WG is also provided in the following sections.*

Summary table of MC decisions taken electronically and at the TC:

List of 23 Current ICH Working Groups		Meeting	Not Meeting	Days and Requests
Efficacy	Standing Paediatric EWG		X	
	E2B(R3) EWG/IWG	Y		5 days, Sunday-Thursday Joint meeting M2
	E8(R1) EWG	Y		5 days, Sunday-Thursday Joint meeting E19
	E9(R1) EWG	Y		4 days, Monday-Thursday
	E11A EWG	Y		5 days, Friday-Tuesday
	E14/S7B DG		X	
	E17 IWG		X	
	E19 EWG	Y		4 days, Monday-Thursday Joint meeting E8(R1)
Multidisciplinary	M1 PtC WG		X	
	M2 EWG	Y		4 days, Monday-Thursday Joint meeting E2B(R3)
	M4Q(R1) IWG		X	
	M7(R2) Maintenance EWG		X	
	M8 EWG/IWG	Y		4 days, Monday-Thursday
	M9 EWG	Y		4 days, Monday-Thursday
	M10 EWG	Y		5 days, Sunday-Thursday
Quality	Q3C(R7) Maintenance EWG		X	
	Q3D(R1) Maintenance EWG		X	
	Q11 IWG		X	
	Q12 EWG		X	
Safety	S1 (R1) EWG		X	
	S5(R3) EWG	Y		4 days, Monday-Thursday
	S9 IWG		X	
	S11 EWG	Y		4 days, Monday-Thursday
TOTAL		**11**	**12**	

WORKING GROUPS MEETING IN KOBE

3.1. M9 EWG: Biopharmaceutics Classification System-based Biowaivers *(Rapporteur: Dr. Welink – EC, Europe; Regulatory Chair: Dr. Seo – FDA, US)*

The MC noted the work plan for the M9 EWG including the progress made towards developing the M9 Technical Document on Biopharmaceutics Classification System-based Biowaivers.

Steps 1 and 2a/b are expected at the meeting in Kobe, Japan in June 2018.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018.*

3.2. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals *(Rapporteur/Regulatory Chair: Dr. Waxenecker – EC, Europe)*

The MC noted the work plan for the S5(3) EWG and that the group had started to discuss comments received in some regions from the public regulatory consultations to be closed at end of March 2018.

Steps 3 and 4 are expected by June/November 2019.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018.*

3.3. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines *(Rapporteur: Dr. Keller – PhRMA; Regulatory Chair: Dr. van der Laan – EC, Europe)*

The MC noted the work plan for the S11 EWG including the progress made towards developing the S11 Technical Document on Nonclinical Safety Testing in Support of Development of Paediatric Medicines.

Steps 1 is expected at the meeting in Kobe, Japan in June 2018 and Step 2a/b are expected by July 2018.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018.*

3.4. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports *(Rapporteur: Dr. Misu – MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, US)*

The MC noted the work plan of the E2B(R3) EWG/IWG and the group's activities with respect to the development with the M2 EWG of a standard operation procedure (SOP) for data extraction and publication of EDQM Dose Form (DF) and Routes of Administration (RoA) terms, and the development of a mapping table for RoA between E2B(R2) and EDQM terms.

The MC further noted that the expert sign-off on the explanatory memorandum on the use of the EDQM terminology in E2B(R3) messages is ongoing.

Sign-off on the SOP for data extraction and publication of EDQM terms, as well as sign-off on the ICSR documents including Q&As are expected at the meeting in Kobe, Japan in June 2018.

MC Action/Decision:

- *The MC supported the group's request to meet for 5 days (Sunday-Thursday) in Kobe, Japan in June 2018 and hold a joint meeting with the M2 EWG.*

3.5. E8(R1) EWG: Revision on General Considerations for Clinical Trials *(Rapporteur: Dr. LaVange – FDA, US; Regulatory Chair: Dr. Sweeney – EC, Europe)*

The MC noted the work plan of the E8(R1) EWG including the progress made towards developing the E8(R1) Technical Document on General Considerations for Clinical Trials, for which a draft is expected ahead of the meeting in Kobe, Japan in June 2018; and noted that the group had been internally divided into 3 sub-groups working an overview, on trial types and data sources, and on quality principles.

The MC further noted that as per the MC's decision the group will not accommodate any further Member/Observer expert nominations at this time, but that the other interested parties will be involved in and informed of the work of the group via the communication pilot endorsed by the MC.

Steps 1 and 2a/b are expected by November 2018/early 2019.

A public stakeholder meeting following Step 2b is expected in the first half of 2019, as per the GCP renovation plan.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 5 days (Sunday-Thursday) in Kobe, Japan in June 2018 and hold a joint meeting with the E19 EWG;*
- *The MC supported that the draft E8(R1) Technical Document would be shared with the E19 EWG ahead of the meeting in Kobe, Japan in June 2018.*

3.6. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses *(Rapporteur: Mr. Hemmings – EC, Europe; Regulatory Chair: Dr. Ando – MHLW/PMDA, Japan)*

The MC noted the work plan of the E9(R1) EWG including the progress made on the development of an extensive training slide deck including examples and case studies, as well as on the development of a video explaining the Estimand concept.

The MC further noted that the draft E9(R1) Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses is undergoing public regulatory consultations until April 2018.

Steps 3 and 4 are expected by June 2019.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018.*

3.7. E11A EWG: Paediatric Extrapolation *(Rapporteur: Dr. Yao – FDA, US)*

The MC noted the work plan of the E11A EWG including the progress made towards developing the E11A Technical Document on Paediatric Extrapolation and activities with respect to reviewing literature on paediatric extrapolation and discussing comments compiled by E11(R1).

Steps 1 and 2a/b are expected by November 2020.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 5 days (Friday-Tuesday) in Kobe, Japan in June 2018 and that the Topic Leader for EC, Europe would present the report to the Assembly on Wednesday 6 June 2018;*
- *The MC agreed to further discuss at the meeting in Kobe the need to identify a Regulatory Chair and noted that the Regulatory Chair can be nominated by any ICH MC Regulatory Member.*

3.8. E19 EWG: Optimization of Safety Data Collection *(Rapporteur: Dr. Thanh Hai – FDA, US; Regulatory Chair: Dr. Mol - EC, Europe)*

The MC noted the work plan for the E19 EWG including the progress made towards developing the E19 Technical Document on Optimization of Safety Data Collection.

Steps 1 and 2a/b are expected by November 2018.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018 and to hold a joint meeting with the E8(R1) EWG;*
- *The MC noted that, further to the discussion of the ICH Assembly at the meeting in Osaka in November 2016, MHLW/PMDA, Japan confirmed it was agreeable to proceed directly to public regulatory consultation following the finalisation of the Technical Document.*

3.9. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) *(Co-Rapporteurs: Dr. Okada – MHLW/PMDA, Japan; Ms. Slack – FDA, US; Regulatory Chair: Mr. Srivastava – Health Canada, Canada)*

The MC noted the work plan for the M2 EWG and the group's current activities with respect to the project opportunity proposals including on eCCTS – electronic Common Clinical Trial Submission and on e-Trial Master File metadata harmonization (eTMF); the development of a revised ESTRI recommendation; and the development of a Service Level Agreement (SLA) with E2B(R3) EWG/IWG for terminology list management.

Finalization of the concept proposal for electronic Common Clinical Trial Submission (eCCTS) and the project opportunity proposals including e-Trial Master File metadata harmonization (eTMF) are expected by June 2018.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018 and to hold a joint meeting with the E2B(R3) EWG/IWG and a meeting with the MC on Monday PM / Tuesday AM to seek guidance on the eCCTS and any other project opportunity proposal;*
- *The MC noted that Mr. Kampmeijer the current co-Rapporteur from EC, Europe had to step down in 2018 and that the nomination of a new co-Rapporteur was pending until further clarity can be given on whether Mr. Kampmeijer would be able to assume the co-Rapporteurship again in 2019.*

3.10. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) *(Acting Rapporteur: Mr. Gray – FDA, US; Regulatory Chair: Dr. Menges – EC, Europe)*

The MC noted the work plan for the M8 EWG/IWG and the group's current activities with respect to the finalization of the eCTD v4.0 Implementation Package v1.3, addressing change requests received, and the finalisation of a recommendation to the MC to revise the following SOP templates to define the location of Submission Contents in the CTD/eCTD: the Business Plan template to include questions on the impact to the dossier; the ICH Guideline format document to add information about the placement of the dossier content in the CTD/eCTD; and the *Step 2/4* presentation template to add information about the CTD/eCTD.

Steps 3 and 4 on the eCTD v4.0 Implementation Package v1.3, Q&As and Specification Change Request Document v1.2, as well as on the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 and on the Specification for Submission Formats for CTD v1.2 are expected at the meeting in Kobe, Japan in June 2018.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Kobe, Japan in June 2018;*
- *The MC noted that in Kobe, Japan in June 2018 the Assembly will be invited to endorse the current Acting Rapporteur as Rapporteur;*
- *The MC approved the revisions to the SOP templates including the Business Plan template, the ICH Guideline Format document and the Step 2/4 presentation template, and their publication on the ICH "Groups" platform for use by the ICH WGs.*

3.11. M10 EWG: Bioanalytical Method Validation *(Rapporteur/Regulatory Chair: Dr. Ishii-Watabe – MHLW/PMDA, Japan)*

The MC noted the work plan for the M10 EWG including the progress made towards developing the M10 Technical Document on Bioanalytical Method Validation.

Steps 1 and 2a/b are expected by November 2018.

MC Action/Decision:

- *The MC supported the group's request to meet for 5 days (Sunday-Thursday) in Kobe, Japan in June 2018.*

WORKING GROUPS NOT MEETING IN KOBE

3.12. Standing Paediatric EWG *(Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, US)*

The MC noted the establishment of the Standing Paediatric EWG.

MC Action/Decision:

- *The MC noted that any request for paediatric expertise should be directed to the ICH Secretariat who will circulate to the Rapporteur and Regulatory Chair, and supported that this will be communicated at the Briefing session at the meeting in Kobe, Japan in June 2018 by MHLW/PMDA, Japan.*

3.13. E14/S7B DG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs *(Rapporteur: Dr. Leishman – PhRMA; Regulatory Chair: Dr. Prasad – EC, Europe)*

The MC noted the work plan of the E14/S7B DG including the group's activities on the CiPA (Comprehensive *in vitro* Proarrhythmia Assessment) initiative for which data will be shared at a public meeting in May 2018, as well as on issuing a preliminary recommendation to the MC on the reopening of E14 for Q&As and/or S7B for Q&As.

Finalization of the recommendation on the reopening of E14 for Q&As and/or S7B for Q&As is expected by June 2018.

3.14. E17 IWG Multi-Regional Clinical Trials *(Acting Rapporteur: Dr. Dunder – EC, Europe; Regulatory Chair: Dr. Otubo – MHLW/PMDA, Japan)*

The MC noted the establishment of the E17 IWG and the appointment of the Regulatory Chair and the Acting Rapporteur and that the group would initiate its work shortly with the development of a work plan.

MC Action/Decision:

- *The MC noted that in Kobe, Japan in June 2018 the Assembly will be invited to endorse the current Acting Rapporteur as Rapporteur.*

3.15. M1 PtC WG: MedDRA Points to Consider *(Rapporteur: Dr. Winter – EFPIA; Regulatory Chair: Dr. Brajovic – FDA, US)*

The MC noted the work plan for the M1 PtC WG and the group's current activities with respect to the updating with the MedDRA version 21.1 release on 1 September 2018 of the two PtC documents on Term Selection and Data Retrieval and Presentation; as well as the development of a Companion Document to the PtC Documents.

Sign-offs on the Companion Document to the PtC documents and endorsement by the MedDRA Management Committee are expected to be requested by the group by April 2018.

3.16. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions *(Rapporteur: Dr. Schmuff – FDA, US; Regulatory Chair: N/A)*

The MC noted that the group is in a dormant stage since the Osaka meeting, Japan in November 2016 and that no questions following the implementation of the revised M4 Granularity Document were received so far which would need to be addressed by the M4Q(R1) IWG.

3.17. M7(R2) Maintenance EWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk *(Rapporteur: Dr. Honma – MHLW/PMDA, Japan; Regulatory Chair: N/A)*

The MC noted the work plan for the M7(R2) Maintenance EWG and the group's current activities with respect to finalizing the Concept Paper with the list of the new set of compounds to be evaluated in the second Addendum, and evaluating the need for developing any additional Q&As.

Steps 1 and 2a/b are expected by June 2019.

3.18. Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents *(Rapporteur: Dr. McGovern – FDA, US; Regulatory Chair: N/A)*

The MC noted the work plan for the Q3C(R7) Maintenance EWG including the progress made on the development of Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol, as well as on the error correction for the PDE for ethyleneglycol.

Steps 1 and 2a/b are expected by June 2018.

3.19. Q3D(R1) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities *(Rapporteur: Dr. McGovern – FDA, US; Regulatory Chair: N/A)*

The MC noted the work plan for the Q3D(R1) Maintenance EWG including the progress made on the development of the Addendum to the Q3D Guideline to include PDEs for cutaneous and transdermal products, and finalisation of the procedure for error correction to remove an incorrect reference in the Module 8-1a of the Q3D Training Package.

The MC further noted that *Step 1* sign-off on the revision Q3D(R1) of the Cadmium inhalation PDE is ongoing.

Steps 1 and 2a/b on the Addendum Q3D(R2) to include PDEs for cutaneous and transdermal products are expected by November 2018.

3.20. Q11 IWG: Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances *(Rapporteur: Mr. McDonald – EC, Europe; Regulatory Chair: Dr. Condran – Health Canada, Canada)*

The MC noted the work plan for the Q11 IWG including progress made on the finalisation of training materials (slide deck) to be disseminated in the ICH regions.

Finalisation of the first phase of the training is expected by April 2018.

3.21. Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management *(Rapporteur: Ms. Boam – FDA, US; Regulatory Chair: Ms. Kruse – EC, Europe)*

The MC noted the work plan for the Q12 EWG and that the draft Q12 Guideline and Annexes are undergoing public regulatory consultations until the end of 2018.

Steps 3 and 4 are expected by June 2019.

3.22. S1(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline *(Rapporteur: Dr. Sistare – PhRMA; Regulatory Chair: Dr. van der Laan – EC, Europe)*

The MC noted the work plan for the S1(R1) EWG and the group's current activities with respect to reviewing received confidential Carcinogenicity Assessment Documents (CADs), as well as reviewing the conclusions of Drug Regulatory Authorities on all new CADs submissions since January 2016.

Steps 1 and 2a/b are expected by June/November 2019.

3.23. S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals *(Rapporteur/Regulatory Chair: Dr. Leighton – FDA, US)*

The MC noted the work plan for the S9 IWG and that the *Step 3* Regulatory Topic Leaders sign-off on the draft S9 Q&As is ongoing.

4. COMMUNICATION ABOUT ICH

The MC noted the organisation of an ICH public meeting by ANVISA, Brazil in May 2018, of a joint ICH public meeting by FDA, US and Health Canada, Canada on 6 April 2018 which will also be publicly webcasted, of ICH information days at the DIA meetings in Basel, Europe on 19 April 2018, in Beijing, China on 28 May 2018 and in Boston, US in June 2018, and a joint ICH public meeting by MHLW/PMDA, Japan and JPMA on 18 July 2018.

5. NEXT TELECONFERENCES AND MEETINGS

MC Teleconferences

10 April 2018	Policy 4
25 April 2018	Policy 5
15 May 2018	Policy 6

Interim MC Subcommittees' Face-to-Face Meeting

26-27 March 2018	London, UK

Face-to-Face ICH Meetings

2-7 June 2018	Kobe, Japan
10-15 November 2018	Charlotte, USA
1-6 June 2019	Europe
16-21 November 2019	Asia