Ref.: MC2017/03

April 19, 2017

SUMMARY REPORT
ICH MC TELECONFERENCE
March 29, 2017

LIST OF PARTICIPANTS:

ICH Management Committee Members/Observers

Dr. Spiros Vamvakas	EC/EMA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin (Chair)	FDA
Ms. Joan Blair	FDA
Dr. Celia Lourenco	Health Canada
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Mr. Naoyuki Yasuda	MHLW/PMDA
Dr. Peter Honig	PhRMA
Mr. Jerry Stewart	PhRMA
Dr. Petra Doerr	Swissmedic
Mr. Mike Ward	WHO

ICH MC Coordinators

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

Technical Coordinators:

Dr. Milton Bonelli	EC/EMA
Dr. Michelle Limoli	FDA
Ms. Chieko Hirose	MHLW/PMDA

Other Participants:

Dr. Tomas Salmonson	EC

ICH Secretariat:

Dr. Dawn Ronan
Dr. Isabelle Güller
Dr. Véronique Kuntzelmann
Ms. Coralie Angulo
Ms Emilie Macara

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA

1. ADOPTION OF THE AGENDA

The agenda was adopted without any comments.

2. ORGANISATION OF MONTREAL MEETING

The MC was updated on the organisation of the Montreal meeting to be held in May/June 2017 and confirmed that meeting rooms would be made available for all Working Groups based on the decisions taken by the MC at its teleconference.

The MC noted the following key dates for the preparation of the Montreal meeting:

- **By/at latest May 1:** The draft Assembly Agenda will be circulated to the Assembly;
- **By/at latest May 17:** The Assembly Agenda Papers Package, including background documents will be circulated to the Assembly.

MC Actions/Decisions:

- The MC supported the overall timetable for the Montreal meeting;
- The Leads of the Subcommittees were invited to provide an indication for the next MC TC on April 13 on how much time they would request on the Assembly and MC agendas to present/discuss their respective topics;
- The MC confirmed the organisation of a Briefing session for ICH experts on Monday, May 29 from 8 to 9am.

3. ORGANISATION OF 2018 MEETINGS

The MC noted the Financial Subcommittee's work to develop an options paper for MC consideration in Montreal aimed at streamlining the ICH biannual meeting organisation including the possibility to engage a meeting organiser.

MC Actions/Decisions:

- The MC will note that in Montreal it will be invited to discuss the organisation of future ICH meetings in consideration of the expansion of ICH Membership and Observership;
- In Montreal, the MC will be invited to confirm the autumn 2018 meeting host.

4. PREPARATION OF MONTREAL MEETING: ORGANISATION OF THE FOLLOWING EWGS/IWGS/DISCUSSION GROUP

MC Action/Decision:

- The MC supported that the following EWGs/IWGs will be meeting in Montreal in May/June 2017. Additional information regarding each EWG/IWG is also provided in the following sections.

Summary table of MC decisions:

List of 23 Current ICH Working Groups (as of March 2017)		Meeting in Montreal	Not meeting in Montreal	Meeting days
e-Groups	M2 EWG	**X**		4 days Mon - Thurs
	M8 EWG/IWG		**X**	
	E2B(R3) EWG/IWG	**X**		4 days Mon - Thurs
Safety Groups	S1 (R1) EWG	**X**		4 days Mon - Thurs
	S3A IWG		**X**	
	S5(R3) EWG	**X**		5 days Sun - Thurs
	S9 IWG		**X**	
	S11 EWG	**X**		4 days Mon - Thurs
	M7(R1) EWG		**X**	
Quality Groups	Q3C(R7) Maintenance EWG		**X**	
	Q3D (R1) Maintenance EWG		**X**	
	Q11 IWG	**X**		4 days Mon - Thurs
	Q12 EWG	**X**		5 days Sun - Thurs
	M4Q(R1) IWG		**X**	
Efficacy Groups	E9(R1) EWG	**X**		4 days Mon - Thurs
	E11(R1) EWG	**X**		4 days Mon - Thurs
	E14/S7B DG		**X**	
	E17 EWG	**X**		4 days Mon - Thurs
	E18 EWG		**X**	
	E19 EWG	**X**		4 days Mon - Thurs
Other Groups	M1 PtC WG		**X**	
	M9 EWG	**X**		4 days Mon - Thurs
	M10 EWG	**X**		4 days Mon - Thurs

ICH Safety Groups

4.1. S1(R1) EWG: Revision of Rodent Carcinogenicity Studies for Human Pharmaceuticals

The MC noted the work plan of the S1 EWG, the progress made towards the collection and review of confidential Carcinogenicity Assessment Documents (CADs) including those of Category 3 and summary report submissions by sponsors to DRAs within each region since January 2016. The group is on track to reach the data collection target (50 CADs including 20 of Category 3) by the end of 2017.

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

4.2. S3A IWG: Q&As on Note for Guidance on Toxicokinetics

The MC noted the work plan of the S3A IWG and that all public regulatory consultations for the draft S3A Q&As were completed by December 2016, and that the group had started analysing comments received in order to reach *Steps 3* and *4* by November 2017, or sooner if possible.

Steps 3 and 4 are expected by the Geneva meeting, Switzerland, in November 2017.

4.3. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility

The MC noted the work plan of the S5(R3) EWG and the progress made on: the S5(R3) Technical Document; addressing the feedback received from the EWG Member constituencies on a preliminary draft; and reaching *Steps 1* and *2a/b* by May/June 2017.

Steps 1 and 2a/b are expected by the Montreal meeting, Canada, in May/June 2017 or shortly afterwards by electronic sign-off.

4.4. S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals

The MC noted the work plan of the S9 IWG and that all public regulatory consultations for the draft S9 Q&As were completed by January 2017, and that the group had started analysing and addressing comments received (about 97 comments) in order to reach *Steps 3* and *4* by November 2017.

Steps 3 and 4 are expected by the Geneva meeting, Switzerland, in November 2017.

4.5. S11 EWG: Nonclinical Safety Testing in support of Development of Paediatric Medicines

The MC noted the work plan of S11 EWG and the progress made by the S11 EWG to develop the draft Technical Document and that the data collection activities are almost complete.

MC Action/Decision:

- The MC supported a joint meeting with the S5(R3) EWG if needed in Montreal, Canada in May/June 2017.

Step 1 and Step 2a/b are expected by the Geneva meeting, Switzerland, in November 2017.

4.6. M7(R1) EWG: addendum to Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

The MC noted the work plan of the M7(R1) EWG and the progress made towards reaching *Steps 3* and *4* electronically.

MC Action/Decision:

- The MC agreed to discuss in Montreal the rotation in Rapporteurship prior to the next stage of work for discussion.

Steps 3 and 4 are expected to be reached electronically in the upcoming weeks.

ICH QUALITY GROUPS

4.7. Q3C(R7) MAINTENANCE EWG: MAINTENANCE OF THE GUIDELINE FOR RESIDUAL SOLVENTS

The MC noted the work plan of the Q3C(R7) Maintenance EWG and the progress made by the group on considerations related to five proposals received.

The MC also noted that the Q3C(R7) Maintenance EWG is assessing the new proposals and before initiating work to address any new proposals will make a recommendation to the MC ahead of the Montreal meeting, after which the MC should make a recommendation to the ICH Assembly for approval for the EWG to undertake the maintenance work at the Montreal meeting.

Steps 1 and 2a/b are expected by Q1 2018.

4.8. Q3D(R1) MAINTENANCE EWG: MAINTENANCE OF THE GUIDELINE FOR ELEMENTAL IMPURITIES

The MC noted the work plan of the Q3D(R1) Maintenance EWG, and that the group has just started its work on the development of Permitted Daily Exposure levels and permitted concentrations of elemental impurities, for products administered by the cutaneous and transdermal route of administration, for all 24 elements in the ICH Q3D Guideline.

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

4.9. Q11 IWG: Q&AS ON SELECTION AND JUSTIFICATION OF STARTING MATERIALS FOR THE MANUFACTURE OF DRUG SUBSTANCES

The MC noted the work plan of the Q11 IWG and the collection of comments in the different ICH regions during the public consultation with the last closing date being for MFDS on April 13, 2017.

Steps 3 and 4 are expected by the Geneva meeting, Switzerland, in November 2017.

4.10. Q12 EWG: TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT

The MC noted the work plan of the Q12 EWG and the agenda for the interim meeting to be held in Hyattsville, Maryland, USA on April 4-7, 2017; as well as the progress made towards developing the Q12 Technical Document.

The MC noted that the Q12 Rapporteur and Regulatory Chair would be requested to provide a report after the interim meeting (summarising the progress made, the achievements and conclusions reached, the list of actions with clear deadlines and responsible individuals) for circulation to the MC.

Steps 1 and 2a/b are expected by the Montreal meeting, Canada, in May/June 2017.

ICH EFFICACY GROUPS

4.11. E9(R1) EWG: ADDENDUM TO DEFINING THE APPROPRIATE ESTIMAND FOR A CLINICAL TRIAL/SENSITIVITY ANALYSES

The MC noted the work plan of the E9(R1) EWG and the progress made towards: developing the E9(R1) Technical Document; the internal EWG Member consultations; and reaching *Steps 1* and *2a/b* by November 2017.

The MC also noted the Regulatory Chair from FDA had to step down and the position has not been filled. The MC considered that a Regulatory Chair is not required for now.

Steps 1 and 2a/b are expected by the Geneva meeting, Switzerland, in November 2017.

4.12. E11(R1) EWG: ADDENDUM TO PAEDIATRIC DRUG DEVELOPMENT

The MC noted the work plan of the E11(R1) EWG and the collection of comments in the different ICH regions during the public consultation that will end by April 13, 2017.

Steps 3 and 4 are expected electronically before the Geneva meeting, Switzerland, in November 2017.

4.13. E14/S7B DISCUSSION GROUP: THE CLINICAL EVALUATION OF QT/QTC INTERVAL PROLONGATION AND PROARRHYTHMIC POTENTIAL FOR NON-ANTIARRHYTHMIC DRUGS

The MC noted the work plan of the E14/S7B Discussion Group (DG) and the monitoring of the CiPA (Comprehensive *in vitro* Proarrhythmia Assessment) Initiative.

E14/S7B DG recommendation on whether to reopen the E14 Guideline for a complete revision is expected by December 2017/early 2018.

4.14. E17 EWG: MULTI-REGIONAL CLINICAL TRIALS

The MC noted the work plan of the E17 EWG, that all public regulatory consultations for the draft E17 Guideline were completed by January 2017, and that the group had started analysing and addressing comments received (about 1000) in order to reach *Steps 3* and *4* by November 2017. The MC also noted that the group might need to request an interim meeting between Montreal and Geneva meetings.

Steps 3 and 4 are expected by the Geneva meeting, Switzerland, in November 2017.

4.15. E18 EWG: GENOMIC SAMPLING AND MANAGEMENT OF GENOMIC DATA

The MC noted the work plan of the E18 EWG; the progress made on the draft E18 Guideline in order to reach *Steps 3* and *4* in May/June 2017; and the nomination of the Acting Rapporteur. The nomination of the new Rapporteur will be for ICH Assembly approval at the Montreal meeting, Canada, in May/June 2017, if work has not been completed by this time.

Steps 3 and 4 are expected by the Montreal meeting, Canada, in May/June 2017.

4.16. E19 INFORMAL WORKING GROUP: OPTIMIZATION OF SAFETY DATA COLLECTION

In Osaka, Japan, in November 2016, the ICH Assembly approved a Concept Paper outline and agreed on the establishment of an informal Working Group to finalise the Concept Paper and develop a Business Plan on *Optimization of Safety Data Collection*. These documents were already circulated for discussion in the WG and will be provided by mid-April for MC approval and establishment of the EWG to meet in Montreal.

In line with the procedures, the MC noted requests received from two Industry Members to appoint experts to the E19 informal Working Group and considered how these Members would be affected or regulated by the guideline in question. The MC agreed to accept expert nominations from both Members. Further to this, the MC discussed the enhancement of this expert appointment process going forward to both preserve the focus of needed expertise and perspective and manage the size of EWGs, and agreed that a clearer process should be

put in place to enable the MC to evaluate the degree to which a guideline would be relevant for a Member interested to participate. This was considered important in view of managing the interest of all Members to participate in the relevant working groups while maintaining the manageability of the working groups which currently average at a maximum of 25-30 experts.

MC Action/Decision:

- The MC agreed to accept expert nominations from both Industry Members.
- The MC agreed that a clearer process for expert appointment should be put in place to enable the MC to evaluate the degree to which a guideline would be relevant for a Member interested to participate.

ICH E-GROUPS

4.17. M2 EWG: ELECTRONIC STANDARDS FOR THE TRANSFER OF REGULATORY INFORMATION

The MC noted the work plan of the M2 EWG and the progress made toward developing the ICH project opportunities proposals, defining the maintenance process for external terminologies and evaluating existing ICH topics for technical opportunities.

The MC also noted M2's request to meet with the MC at the start of its meeting in Montreal, to discuss the project opportunity and acquire additional guidance.

MC Action/Decision:

- The MC agreed to meet with the M2 EWG at the start of its meeting in Montreal, Canada in May/June 2017.

4.18. M8 EWG/IWG: THE ELECTRONIC COMMON TECHNICAL DOCUMENT: ECTD

The MC noted the work plan of the M8 EWG/IWG and activities including: updating the eCTD v3.2.2 and v4.0 Q&As based on change requests received.

Steps 3 and 4 of the eCTD v3.2.2 Q&As are expected by the Montreal meeting, Canada, in May/June 2017.

4.19. E2B(R3) EWG/IWG: REVISION OF THE ELECTRONIC SUBMISSION OF INDIVIDUAL CASE SAFETY REPORTS

The MC noted the work plan of the E2B(R3) EWG/IWG and its sub-group including: developing the annexes to the ICSR Implementation Guide (IG) on the use of EDQM (European Directorate for the Quality of Medicines & healthcare) and UCUM (Unified Code for Units of Measure) lists; and discussion with the M2 EWG on the maintenance process for external terminologies.

The MC also noted E2B(R3) EWG/IWG's request to have a joint meeting with the M2 EWG in Montreal, Canada, in May/June 2017.

MC Action/Decision:

- The MC agreed for a joint meeting between E2B(R3) EWG/IWG and M2 EWG in Montreal, Canada in May/June 2017.

OTHER GROUPS

4.20. M1 PTC: MEDDRA POINTS TO CONSIDER WORKING GROUP

The MC noted the work plan of the M1 PtC WG and the group's current activities with respect to: the updating with each MedDRA release 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.

The MC also noted the nomination of the new Acting Rapporteur willing to stand as a candidate when the nomination for Rapporteurship will be for ICH Assembly approval at the Montreal meeting, Canada, in May/June 2017.

4.21. M4Q(R1) (CTD-QUALITY) IWG: ADDRESSING CTD-Q RELATED QUESTIONS/CHANGE REQUESTS RAISED BY ECTD (Rapporteur: Dr. Smith – FDA; Regulatory Chair: N/A)

The MC noted the absence of questions so far following the implementation of the revised M4 Granularity Document needing to be addressed by the M4Q(R1) IWG.

MC Actions/Decisions:

- The MC agreed to keep the working group in a dormant state while the eCTD v4.0 Implementation Guide, including the Granularity document is currently being implemented in the ICH Regions and in case questions are raised;
- The M4Q(R1) IWG will not need to develop a work plan during this time.

4.22. M9 EWG: BIOPHARMACEUTICS CLASSIFICATION SYSTEM-BASED BIOWAIVERS

The MC noted the work plan of the M9 EWG and the progress made towards developing the M9 Technical Document.

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

4.23. M10 EWG: BIOANALYTICAL METHOD VALIDATION

The MC noted the work plan of the M10 EWG and the progress made towards developing the M10 Technical Document.

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

5. COMMUNICATION ABOUT ICH

The MC noted the organisation by FDA and Health Canada of an ICH Public Meeting to be held at FDA headquarters in Silver Spring, MD, US on April, 24 2017 for which a live web broadcasting would be available. Additionally, FDA will be co-chairing a session on ICH with industry colleagues at the upcoming DIA meeting in the United States June 2017 (following the Montreal meeting) in Chicago, IL, US.

The MC also noted the organisation by MHLW/PMDA and JPMA of a Regional Public Meeting to be held on June 30, 2017.

The MC noted the invitation for an ICH presentation at the DIA meeting in Shanghai, China on May 21-24, 2017.

6. **DATES OF NEXT TELECONFERENCES AND ICH FACE TO FACE MEETINGS IN 2017/2018**

Teleconferences

April 13, 2017	MC (Policy/Procedures)
May 16, 2017	MC (Policy/Procedures)

ICH face-to-face meetings

May 27 – June 1, 2017	Montreal, Canada
November 11-17, 2017	Geneva, Switzerland
June 2-7, 2018	Kobe, Japan