17 October 2018

SUMMARY REPORT
ICH MC TELECONFERENCE
19 September 2018

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lila Feisee	BIO
Dr. Wassim Nashabeh	BIO
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
Ms. Siew Wei Chua	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Nakyung Kim	MFDS, Republic Korea
Dr. Nobumasa Nakashima *(Vice-Chair)*	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Dr. Peter Honig	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Ms. Lila Feisee	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, US
Mr. Nick Orphanos	Health Canada, Canada
Ms. Siew Wei Chua	HSA, Singapore
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Dr. Wei Zhou	NMPA, China
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:

Ms. Ashley Baron	Health Canada, Canada
Ms. Sayaka Kurihara	MHLW/PMDA, Japan
Mr. Xiangyu Wang	NMPA, China

ICH Secretariat:

Ms. Coralie Angulo
Ms. Nadia Gerweck
Dr. Anne Latrive
Ms. Nikoleta Luludi
Dr. Dawn Ronan

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin, FDA, US

MC Vice-Chair: Dr. Nobumasa Nakashima, MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair) welcomed all participants. The agenda was adopted without modification.

2. ORGANISATION OF THE MEETING IN CHARLOTTE

The MC was updated on the organisation of the Charlotte, NC, USA meeting to be held in November 2018 and confirmed that conference rooms would be made available to all Working Groups (WGs) meeting in Charlotte based on the decisions taken by the MC at its teleconference. The MC was furthermore informed on the possible organisation of an informal social event for the newly expanded MC, still to be confirmed.

The MC was updated by the Secretariat on the status of requests received for WG joint meetings[1] and caucus meetings, and noted that 14 Members had requested to hold caucus meetings.

MC Actions/Decisions:

- *The MC supported the organisation of a Briefing Session for ICH experts on Monday, 12 November 2018 from 8h00 to 8h45 to be provided by the ICH Secretariat;*
- *The MC supported the draft overall timetable for the meeting;*
- *The MC noted the following key dates in preparation of the Charlotte, NC, USA meeting:*
  - *By **12 October**: All background documents for the Assembly meeting are to be provided to the Secretariat for MC review prior to inclusion in the Assembly Agenda papers;*
  - *By **17 October**: The draft Assembly Agenda is circulated to the Assembly for comments.*
  - *By **19 October**: The draft MC Agenda is circulated to the MC for comments;*
  - *By **23 October**: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers;*
  - *By **31 October**: The final draft Agenda and Assembly Agenda papers are circulated to the Assembly.*

3. WG PROCEDURAL MATTERS

The MC was updated by the Secretariat on the composition of the three new informal WGs, Q2(R2)/Q14, Q13 and M11, further to the size restrictions discussed by the MC on the numbers of experts to be appointed by ICH Regulatory and Industry Members.

MC Actions/Decisions:

- *The MC agreed on the necessity to continue developing the strategy to manage the size of WGs in view of the steady expansion of the ICH Association, and which would include respecting the requirements for the consistent participation of experts to their WGs as per the ICH procedures;*
- *The MC agreed to dedicate at least an hour at the meeting in Charlotte, NC, USA to further develop the strategy to manage the size of WGs going forward, noting that one proposal would be shared shortly in preparation of the meeting and that comments on this proposal, as well as alternative proposals were invited.*

[1] Post-TC note: no joint meeting of a WG is requested.

4. PREPARATION OF CHARLOTTE: ORGANISATION OF WG MEETINGS

MC Actions/Decisions:

- *The MC supported the following requests from EWGs/IWGs to meet in Charlotte, NC, USA in November 2018: E14/S7B; E17; M7(R2); Q2(R2)/Q14; Q13 and S1(R1).*
- *The MC deferred its decision regarding the request from the M11 informal WG to meet in Charlotte, NC, USA at the latest by the MC Policy 2 TC on 10 October 2018.*
- *The MC noted that it had previously electronically supported the meeting requests from the E8(R1); E9(R1); E11A; E19; M10; S5(R3) EWGs.*

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 25 Current ICH Working Groups		Meeting	Not Meeting	Days and Requests
Efficacy	Standing Paediatric EWG		X	
	E2B(R3) EWG/IWG		X	
	E8(R1) EWG	Y		5 days, Sunday-Thursday
	E9(R1) EWG	Y		4 days, Saturday-Tuesday
	E11A EWG	Y		4 days, Monday-Thursday
	E14/S7B DG	Y		4 days, Monday-Thursday
	E17 IWG	Y		3.5 days, Monday-Thursday AM
	E19 EWG	Y		4 days, Monday-Thursday
Multidisciplinary	M1 PtC WG		X	
	M2 EWG		X	
	M4Q(R1) IWG		X	
	M7(R2) Maintenance EWG	Y		4 days, Monday-Thursday
	M8 EWG/IWG		X	
	M9 EWG		X	
	M10 EWG	Y		5 days, Sunday-Thursday
	M11 informal WG	TBD at the MC Policy 2 TC on 10 October.		4 days, Monday-Thursday
Quality	Q2(R2)/Q14 informal WG	Y		4 days, Monday-Thursday
	Q3C(R7) Maintenance EWG		X	
	Q3D(R1) Maintenance EWG		X	
	Q11 IWG		X	
	Q12 EWG		X	Note: Interim meeting from 11 to 15 February
	Q13 informal WG	Y		4 days, Monday-Thursday
Safety	S1 (R1) EWG	Y		4 days, Monday-Thursday
	S5(R3) EWG	Y		5 days, Sunday-Thursday
	S11 EWG		X	
TOTAL		**12**	**12**	Note: M11 is not included in the count as the decision was deferred.

WORKING GROUPS REQUESTING TO MEET IN CHARLOTTE

4.1. 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 and was updated by the Coordinator for PhRMA on the progress made on the analysis of the CiPA (Comprehensive in vitro Proarrhythmia Assessment) initiative validation data set.

The MC further noted the revised Concept Paper regarding the development of Q&As for S7B / E14.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Charlotte, NC, USA in November 2018;*
- *The MC supported that the group continue the revision of the Concept Paper at its meeting in Charlotte, NC, USA in November 2018 in particular regarding the availability of data to support the development of Q&As for E14.*

4.2. E17 IWG: Multi-Regional Clinical Trials (Rapporteur: Dr. Dunder – EC, Europe; Regulatory Chair: Mr. Otsubo – MHLW/PMDA, Japan)

The MC noted the work plan of the E17 IWG and was updated by the Coordinator for EC, Europe, on the progress made on the development of training materials.

MC Action/Decision:

- *The MC supported the group's request to meet for 3.5 days (Monday-Thursday morning) in Charlotte, NC, USA in November 2018.*

The publication of initial training materials on the ICH public website is expected by March 2019.

4.3. 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 of the M7(R2) Maintenance EWG and was updated by the Coordinator for MHLW/PMDA, Japan on the progress made towards developing a list of compounds to be evaluated in the second Addendum. The MC further noted the group's proposed Concept Paper which was revised in particular to reflect the development of Q&As. The MC noted that some Members were interested in having an additional expert in order to be able to support both Safety and Quality discussions in view of the new focus of the Q&As.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Charlotte, NC, USA in November 2018;*
- *The MC endorsed the revised Concept Paper and noted that the Assembly would subsequently be invited to approve electronically preliminary work on Q&As, further to which the Assembly will be invited to endorse formally the group's new area of work including the development of Q&As at its meeting in Charlotte, NC, USA in November 2018;*
- *The MC acknowledged that additional expertise especially on Quality topics may be needed in view of the group's new area of work to be undertaken and that further discussion was needed on how best to address the discussion on Safety and Quality topics within the group also in the context of the MC discussion planned for the Charlotte meeting on the management of WGs size.*

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

4.4. M11 informal WG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (informal WG Leader: Ms. Vanderslice, PhRMA; Regulatory Chair: Dr. Fitzmartin, FDA, US)

The MC was updated by the Secretariat on the establishment of the M11 informal WG on 13 September 2018, and by the Coordinator for PhRMA on the planning of the group's first WG teleconference in October.

MC Action/Decision:

- *The MC deferred its decision regarding the request from the M11 informal WG to meet in Charlotte, NC, USA for 4 days (Monday-Thursday) to be taken at the latest at the MC Policy 2 TC on 10 October 2018.*

4.5. Q2(R2)/Q14 informal WG: Analytical Procedure Development and Revision of Q2(R1) Validation of Analytical Procedures *(informal WG Leader: Dr. Hiyama, MHLW/PMDA Japan; Regulatory Chair: Dr. Keire, FDA, US)*

The MC was updated by the Secretariat on the establishment of the Q2(R2)/Q14 informal WG on 13 September 2018, and by the Coordinator for MHLW/PMDA, Japan on the initiation of work on the development of a draft Concept Paper and Business Plan.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Charlotte, NC, USA in November 2018.*

The Concept Paper and Business Plan are expected at the meeting in Charlotte, NC, USA, in November 2018.

4.6. Q13 informal WG: Continuous Manufacturing *(informal WG Leader: Dr. Lee, FDA, US; Regulatory Chair: Dr. Matsuda, MHLW/PMDA Japan)*

The MC was updated by the Secretariat on the establishment of the Q2(R2)/Q14 informal WG on 13 September, and by the Coordinator for FDA, US on the initiation of work by the group, including the planning of its first WG teleconference early October.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Charlotte, NC, USA in November 2018.*

The Concept Paper and Business Plan are expected at the meeting in Charlotte, NC, USA, in November 2018.

4.7. 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 of the S1(R1) EWG and was updated by the Coordinator for PhRMA on the progress made on the review of confidential Carcinogenicity Assessment Documents (CADs) and final Study Reports (FSRs); and on the drafting of the revisions to the S1B Guideline.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Charlotte, NC, USA in November 2018.*

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

4.8. 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 and was updated by the Coordinator for FDA, US on the progress made by the group on the E8(R1) draft Technical Document, which had internally divided into 3 sub-groups working on framework; trial types and data sources; and quality principles.

MC Actions/Decisions:

- *The MC noted that as part of the E8(R1) communication pilot, the E8(R1) draft Technical Document, expected to be finalised by January 2019, would be subsequently shared with interested ICH Members that had not been permitted to appoint experts to the E8(R1) EWG due to the large size of the EWG;*
- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 5 days (Sunday-Thursday).*

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

A public stakeholder meeting following Step 2b is expected in Q3/Q4 of 2019, as per the GCP renovation plan.

4.9. 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 and was updated by the Coordinator for EC, Europe on the activities of the group, including the publication on the ICH website in August 2018 of the Training Materials on the draft E9(R1) Guideline, consisting of an extensive slide deck including case studies, and on the progress made on the draft Addendum.

MC Action/Decision:

- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 4 days (Saturday-Tuesday), and that the Rapporteur would be available to make the presentation to the ICH Assembly on Wednesday, 14 November 2018.*

Steps 3 and 4 are expected by June 2019.

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

The MC noted the work plan of the E11A EWG and was updated by the Coordinator for FDA, US on the progress made on the E11A draft Technical Document by the group, which had internally divided into 3 sub-groups to work on disease similarity; modelling and simulation; and statistics.

MC Actions/Decisions:

- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 4 days (Monday-Thursday);*
- *The MC noted that additional experts would be nominated by ICH Members to participate in the group's work on topic specific issues, under the supervision of the Rapporteur, in line with section 1.5.1.4 of the Standard Operating Procedures (SOP) for ICH WGs;*
- *The MC noted that the Secretariat is following-up with the Members whose experts have not been participating consistently in the E11A EWG as per Annex 2 of the SOP of the ICH WGs.*

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

4.11. 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 of the E19 EWG and was updated by the Coordinator for FDA, US on the progress made on the E19 draft Technical Document.

MC Action/Decision:

- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 4 days (Monday-Thursday).*

Steps 1 and 2a/b are expected at the meeting in Charlotte, NC, USA in November 2018.

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

The MC noted the work plan of the M10 EWG and was updated by the Coordinator for MHLW/PMDA, Japan on the progress made on the M10 draft Technical Document.

MC Action/Decision:

- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 5 days (Sunday-Thursday).*

Steps 1 and 2a/b are expected in November 2018 at the meeting in Charlotte, NC, USA.

4.13. 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 of the S5(R3) EWG and the proposal for a Maintenance Procedure for the proposed Annexes to the ICH S5(R3) Guideline. The MC was further updated by the Coordinator for EC, Europe on the progress made on the review of the comments received during the regional public consultation period which ended in March 2018.

MC Actions/Decisions:

- *The MC noted that as agreed electronically on 27 August 2018, the group will meet in Charlotte, NC, USA for 5 days (Sunday-Thursday);*
- *The MC supported the principle of a Maintenance Procedure for the S5(R3) Guideline and that a Concept Paper defining the Maintenance Procedure would be drafted and further submitted to the MC for support and to the Assembly for endorsement of a new area of work.*

Steps 3 and 4 are expected by November 2019.

WORKING GROUPS NOT MEETING IN CHARLOTTE

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

The MC was informed by the Coordinator for MHLW/PMDA, Japan that the Standing Paediatric EWG did not receive any requests for paediatric advice.

The group will not meet in Charlotte, NC, USA in November 2018, but remains available for expert consultation and guidance to WGs charged with developing new or revised guidance which may be of relevance to paediatric drug development.

4.15. 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 was updated by the Coordinator for MHLW/PMDA, Japan on the progress made on the Route of Administration (RoA) term mapping between E2B(R2) and EDQM; the Service Level Understanding (SLU) regarding the SOP to extract and post the EDQM Dose Form (DF) and RoA terminology list for E2B(R3) use; and plans for developing training materials for E2B(R3) adopters.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

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

The MC noted the work plan of the M1 PtC WG and was updated by the Coordinator for EFPIA on the progress made on the PtC documents MedDRA Term Selection and Data Retrieval and Presentation, which were updated with the MedDRA version 21.1 release on 1 September 2018, and the group's considerations on the potential need for changes to the recently released Companion Document.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

Release of Condensed Versions of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" into all MedDRA languages (except English and Japanese) are expected by December 2018.

Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 22.0) are expected in March 2019.

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

The MC noted the work plan of the M2 EWG and was updated by the Coordinator for MHLW/PMDA, Japan on the progress made on the White Paper on the potential of the HL7 Fast Healthcare Interoperability Resources (FIHR) standard for ICH initiatives; the consultation of subject matter experts to confirm interest and concerns with Common Clinical Trial submission (eCCTS); and the finalization of the terminology list maintenance process.

MC Actions/Decisions:

- *The MC noted that Mr. Srivastava, the current Regulatory Chair from Health Canada, Canada had to step down in September 2018 and that Health Canada would not nominate a new Regulatory Chair;*
- *The MC acknowledged that the Secretariat would follow-up according to the procedures to identify a candidate(s) for the role of M2 EWG Regulatory Chair to be endorsed by the Regulatory Members of the MC.*

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

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

The MC was informed by the Coordinator for FDA, US that no questions were so far received following the implementation of the revised M4 Granularity Document which would need to be addressed by the M4Q(R1) IWG.

MC Action/Decision:

- *The MC noted that the group is in a dormant stage since the meeting in Osaka, Japan, in November 2016.*

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

The MC noted the work plan of the M8 EWG/IWG and was informed by the Coordinator for FDA, US that no Change Requests were received since the eCTD v4.0 Q&As and Specification Change Request Document v1.2, as well as the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 reached *Steps 3* and *4* at the meeting in Kobe, Japan, in June 2018.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

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

The MC noted the work plan of the M9 EWG and was informed by the Coordinator for EC, Europe that further to Assembly endorsement of *Step 2b* at the meeting in Kobe, Japan in June 2018, the M9 Draft Guideline is currently undergoing public regulatory consultation in the ICH Member regions.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

Steps 3 and 4 are expected by June 2019.

4.21. 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 of the Q3C(R7) EWG and was updated by the Coordinator for FDA, US on the development of Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol, and on the finalisation of the error correction for the PDE for ethyleneglycol.

MC Actions/Decisions:

- *The MC approved the error correction for the PDE for ethyleneglycol;*
- *The MC noted that the Secretariat will shortly invite the MC to approve the publication on the ICH website of the Supporting Documents to the error correction for the PDE for ethyleneglycol, which contain the summaries of the toxicity data from which the PDEs were derived for the original ICH Q3C Guideline.*

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

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

4.22. 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 of the Q3D(R1) EWG/IWG and was informed by the Coordinator for FDA, US that further to Assembly endorsement of *Step 2b* in May 2018, the Q3D(R1) Draft Guideline is undergoing public regulatory consultation in the ICH Member regions. The MC was further updated on the progress made to the revision to the Q3D(R2) draft Technical Document for cutaneous and transdermal RoA PDEs. Furthermore, the MC noted that experts from PhRMA and EFPIA are discontinuing their participation on the Q3D(R1) EWG, and that MC Representatives are invited to consider whether these experts could continue participation in any way, given their valuable experience.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

Steps 3 and 4 on the Q3D(R1) revision to the Cadmium inhalation PDE are expected by November 2018.

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

4.23. 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 of the Q11 IWG and was updated by the Coordinator for EC, Europe on the progress made on the development of the script for the narrated slide deck, which would be the last activity of the group.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference.

The finalisation of the Training Material in the form of a video with the narrated slide deck is expected in November 2018.

4.24. 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 of the Q12 EWG and that the Q12 draft Guideline is undergoing public regulatory consultations in the ICH Member regions until December 2018. The MC was further updated by the Coordinator for FDA, US on the organization of the interim meeting the group will hold in February 2019.

The group will not meet in Charlotte, NC, USA in November 2018, but will continue working by email and teleconference, and will hold an interim meeting from 11 to 15 February 2019 in Tokyo, Japan.

Steps 3 and 4 are expected by November 2019.

4.25. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines *(Rapporteur: Dr. Keller – PhRMA[2]; Regulatory Chair: Dr. van der Laan – EC, Europe)*

The MC noted that the Regulatory Members of the Assembly had endorsed *Step 2b* of the S11 draft Guideline on 18 September 2018, and that this would now be submitted to public regulatory consultation in the ICH Member regions.

Steps 3 and 4 are expected by November 2019.

[2] Post-TC note: Further to *Step 2b*, and as agreed by the MC at the meeting in Kobe, Japan, the Rapporteurship role will rotate to FDA, US with Dr. Paul Brown as Acting Rapporteur, pending Assembly endorsement as Rapporteur at its next face-to-face meeting in Charlotte, in November 2018.

5. COMMUNICATION ABOUT ICH

The MC noted the organisation on 17 October 2018 of an ICH public meeting by ANVISA, Brazil and by MHLW/PMDA, Japan; as well as a joint public ICH meeting by Health Canada, Canada and FDA, US.

MHLW/PMDA, Japan and JPMA will hold a public meeting on 14 December 2018 in Tokyo, Japan as well as MFDS, Republic of Korea on 24 October 2018.

6. DATES OF TELECONFERENCES AND NEXT MEETINGS IN 2018 / 2019 / 2020

ICH Teleconferences

20 September 2018	MC Policy 1
10 October 2018	MC Policy 2
22 October 2018	MC Policy 3

Face-to-Face ICH Meetings

10-15 November 2018	Charlotte, NC, USA
1-6 June 2019	Amsterdam, the Netherlands
16-21 November 2019	Asia (location to be confirmed)
23-28 May 2020	The Americas (location to be confirmed)
14-19 November 2020	Europe (location to be confirmed)

7. ANY OTHER BUSINESS

7.1. Maintenance of Q4B Annexes

The MC noted that the Pharmacopeial Discussion Group (PDG) would shortly submit a recommendation to the MC regarding maintenance of Q4B Annexes in view of revisions to PDG General Chapters and the involvement in ICH of more countries/regions.