11 June 2023

FINAL REPORT
ICH MC TELECONFERENCE – POLICY 3
12 May 2023

LIST OF PARTICIPANTS

ICH MC Members

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Ms. Nancy Schwalje Travis	BIO
Dr. Milton Bonelli	EC, Europe
Ms. Lenita Lindström	EC, Europe
Mr. Raun Kupiec	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin *(MC Chair)*	FDA, United States
Dr. Léo Bouthillier	Health Canada, Canada
Mr. Bruce Randall	Health Canada, Canada
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Manabu Yanagisawa	JPMA
Dr. Masafumi Yokota	JPMA
Dr. Younjoo Park	MFDS, Republic of Korea
Dr. Junko Sato *(MC Vice-Chair)*	MHLW/PMDA, Japan
Dr. Shinichi Okudaira	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Sheng Yang	NMPA, China
Mr. Siyuan Zhou	NMPA, China
Dr. Michelle Rohrer	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Andreas Pfenninger	Swissmedic, Switzerland
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ICH MC Coordinators

Ms. Casey Rosner	BIO
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Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichiro Hirose	IGBA
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Ms. Sarah Koechlin	Swissmedic, Switzerland

ICH MC Technical Coordinators

Mr. Kevin Cunningham	EC, Europe
Dr. Takashi Misu	MHLW/PMDA, Japan

ICH MC Standing Observers

Ms. Judith MacDonald	IFPMA
Dr. Samvel Azatyan	WHO

Additional Participants

Dr. Varley Dias Sousa	ANVISA, Brazil
Dr. Peter Bachmann	EC, Europe
Dr. Bruno Sepodes	EC, Europe
Ms. Brooke Dal Santo	FDA, United States
Ms. Olivia Suarez-Milan	Health Canada, Canada
Ms. Lidija Samardzic	IFPMA
Dr. Risa Ishitani	MHLW/PMDA, Japan
Ms. Kaori Ogawa	MHLW/PMDA, Japan
Mr. Felipe Dolz	PhRMA
Mr. Jerry Stewart	PhRMA
Ms. Marie Valentin	WHO

Invited Participants

Dr. Peter Arlett	EC, Europe
Ms. Catherine Cohet	EC, Europe
Ms. Kelly Plueschke	EC, Europe
Dr. Dorina Bischof	EFPIA
Dr. John Concato	FDA, United States
Dr. Leyla Sahin	FDA, United States
Dr. Lawrence Yu	FDA, United States
Dr. David Keire	FDA, United States
Ms. Yukiko Watabe	JPMA
Dr. Akihiro Ishiguro	MHLW/PMDA, Japan
Dr. Yukio Hiyama	MHLW/PMDA, Japan

ICH Secretariat

Mr. Sivashen Cunden	ICH Secretariat
Ms. Olga Frei	ICH Secretariat
Ms. Nahimeh Jaffar	ICH Secretariat
Ms. Nikoleta Luludi	ICH Secretariat
Ms. Anca Matei	ICH Secretariat
Dr. Dawn Ronan	ICH Secretariat

FINAL REPORT

MC Chair: Dr. Theresa Mullin, FDA, United States

MC Vice Chair: Dr. Junko Sato, MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Junko Sato (Vice MC Chair – MHLW/PMDA, Japan) welcomed all participants. The agenda was adopted with a request from the ICH Secretariat to confirm final updates to the ICH Assembly Draft Agenda which was to be sent to the Assembly immediately after the teleconference.

2. OVERSIGHT OF WORKING GROUPS

2.1. *M4Q(R2) EWG: Revision of M4Q(R1) CTD on Quality guidance (Rapporteur: Dr. Yu – FDA, United States; Regulatory Chair: Mr. van der Stappen – EC, Europe*

The MC was updated by the M4Q(R2) EWG Rapporteur, Dr. Lawrence Yu, (FDA, United States) on work achieved during the M4Q(R2) EWG interim meeting, in Switzerland in March 2023. Based on the progression of work on Module 2 and the impact on product life cycle, the M4Q(R2) EWG will hold a joint teleconference with Q12 IWG Experts to evaluate current terminology being considered, such as Key Registration Elements and/or Established Conditions, and define where in the CTD mandatory elements should be submitted. The MC acknowledged that new terminology should not be introduced by the EWG unless necessary.

The Rapporteur also informed the MC that high level structure and guiding principles for Module 3 had been agreed but crucially Module 3 is informed by Module 2.

MC Action/Decision:

- The MC noted the work progressed during the M4Q(R2) EWG interim meeting and the current status of M4Q(R2) EWG discussions

2.2. *M12 EWG: Drug Interaction Studies (Rapporteur: Dr. Madabushi – FDA, United States; Regulatory Chair: Dr. Ishiguro – MHLW/PMDA, Japan)*

The MC was updated by the M12 EWG Regulatory Chair, Dr. Akihiro Ishiguro, (MHLW/PMDA, Japan) on work achieved during the M12 EWG interim meeting, in Switzerland in March 2023, focusing on actions plans to address important comments, and consideration of the development of training materials or Questions & Answers (Q&As) to address several points raised by the comments. The EWG was invited to consider the need for the development of Q&As, noting that the intent of Q&As should not be to address all items not covered by the Guideline.

MC Actions/Decisions:

- The MC noted the work progressed during the M12 EWG interim meeting and the current status of M12 EWG discussions;
- The MC supported that the EWG carefully consider the need to develop Q&As.

2.3. *Q2(R2)/Q14 EWG: Analytical Procedure Development and Revision of Q2(R1) Validation of Analytical Procedures (Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)*

The MC was updated by the Q2(R2)/Q14 EWG Rapporteur, Dr. Yukio Hiyama, (MHLW/PMDA, Japan), on work achieved during the Q2(R2)/Q14 EWG interim meeting, in Japan in February 2023, focusing on addressing comments received for Q2(R2) and Q14 draft guidelines. During the meeting it was

determined the Q2(R2) and Q14 guidelines will not be merged and will remain as two documents and an alternative title for Q14 is to be considered. The MC noted Q2(R2)/Q14 EWG interest to transition into an IWG in November 2023, after reaching *Step 4* to develop training materials to provide explanations of the new concepts in Q2(R2) and Q14.

MC Actions/Decisions:

- The MC noted the work progressed during the Q2(R2)/Q14 EWG interim meeting and the status of Q2(R2)/Q14 discussions;
- The MC agreed deferring further discussion of Q2(R2)/Q14 EWG interest to transition to an IWG to the MC meeting in Vancouver, considering also available resources given pending work on other Quality topics.

2.4. *E21 informal WG: Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials (informal WG Leader: Dr. Bischof – EFPIA; Regulatory Chair: TBC)*

The MC was updated by the E21 informal WG Leader, Dr. Dorina Bischof (EFPIA) on the development of the E21 Concept Paper and proposed Work Plan for the E21 guideline, noting the scientific and regulatory principles to ensure appropriate inclusion of pregnant and breastfeeding individuals in clinical trials. The MC noted the comments received on the draft E21 Concept Paper and the proposed approach to addressing all comments in the Concept Paper, with the exception of those which would be saved for the guideline. It was also acknowledged that work regarding the evaluation of the impact of the guideline should be discussed at a future point and not included in the Concept Paper.

MC Action/Decision:

- The MC endorsed the E21 informal WG Concept Paper, conditional on the addressing of comments provided by the MC Members, and the transition of the E21 informal WG to an E21 EWG, with Dr. Dorina Bischof (EFPIA) becoming the E21 EWG Rapporteur.

3. REFLECTION PAPERS

3.1. *EC, Europe, FDA, United States and Health Canada, Canada Reflection Paper on Harmonisation of real-world evidence terminology, and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines*

The MC was updated by EC, Europe, FDA, United States and Health Canada, Canada on the draft Reflection Paper on *Harmonisation of real-world evidence terminology, and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines* for ICH MC endorsement to be shared with ICH Assembly for approval during the Vancouver meeting for public consultation. Furthermore, the MC was provided with a high-level overview of how the comments received from MC Members in March were addressed and incorporated or not incorporated into the Reflection Paper. The MC noted comments regarding concerns with the inclusion of transparency aspects surrounding study reports and the definition of RWE data and evidence with observational or non-interventional study designs in mind, with a request for further revisions be made to the Reflection Paper before circulation to the Assembly to address these comments.

MC Actions/Decisions:

- The MC endorsed the Reflection Paper for sharing with the ICH Assembly Members and Observers as an "MC endorsed Reflection Paper" for approval in Vancouver as an ICH Reflection Paper, conditional on further revisions being made to address the comments raised[1];

[1] Post-Meeting Note: Following the MC TC, and the sending of the Reflection Paper to the ICH Assembly, a MC Member commented that the Reflection Paper had not been revised in line with its comments. An Erratum was therefore sent to the ICH Assembly to indicate that the Reflection Paper was "not yet endorsed by the MC", pending further discussion at the Vancouver meeting.

- In view of the requirement in the ICH MC Rules of Procedure for a Reflection Paper to be shared one-month in advance of the ICH Assembly meeting, the MC supported the revised Reflection Paper be shared with the ICH Assembly without further ICH MC review, immediately after the close of the Policy 3 teleconference;
- The MC agreed to defer discussion regarding the approach to stakeholder engagement and the proposal for public meeting/webinar(s), as well as public consultation to the Vancouver MC meeting.

3.2. *BIO Reflection Paper on Strategic Approach to International Harmonization of Cell and Gene Therapy (CGT) Product Regulation*

The MC was updated on the remit document developed for the ICH Cell and Gene Therapies Discussion Group (CGTDG), further to the BIO Reflection Paper on a *Strategic Approach to International Harmonization of Cell and Gene Therapy (CGT) Product Regulation*. The MC noted remit document had been revised ahead of the teleconference in view of comments received from MC Members.

MC Actions/Decisions:

- The MC endorsed the remit document for the CGTDG, and supported that both the remit document and Reflection Paper be shared with ICH Assembly Members and Observers as background documents for the Vancouver meeting;
- The MC agreed that the call for nominations to the CGTDG, will be launched after the remit and Reflection Paper have been presented to the ICH Assembly in June 2023.

4. NEW TOPICS

The MC was informed by the Co-Leads of the New Topic Subcommittee on the package of New Topics documents for provision to the Assembly directly after the MC Policy 3 teleconference, as well as on the finalisation of Concept Paper Outlines for the three new topics proposals recommended by the MC for approval by the Assembly.

MC Actions/Decisions:

- The MC approved the revised compilation of individual MC Members' evaluations;
- The MC supported the provision to ICH Assembly Members and Observers directly after the MC Policy 3 teleconference of the package of New Topics documents, including: final New Topic proposals, summary of MC assessment, and compilation of individual MC Members' evaluations;
- The MC noted the updated Multi-Year Overview of Harmonisation Activities and also supported its provision to the Assembly;
- The MC noted Concept Paper Outlines for the three new topics proposals recommended by the MC for approval by the Assembly, and supported their provision to the Assembly after the teleconference for approval at Vancouver's meeting.

5. ICH MEMBERSHIP AND OBSERVERSHIP APPLICATIONS

The MC was informed by the ICH Secretariat on the status of ICH Membership and Observership applications.

6. PROCEDURAL MATIERS

The ICH Secretariat informed the MC on proposed amendments to the Assembly Rules of Procedure (RoP), MC RoP and Standard Operating Procedure (SOP) of the ICH Working Groups (WGs), which included updates made in view of MC decisions at its meetings in Lausanne in March 2023 and in Incheon in November 2022. The MC noted that this included: allowing Standing Observers to have a Coordinator position to support their work in relation to the ICH Assembly, MC and WGs; addition of new templates

for Concept Paper, Concept Paper Outline and New Topic Proposal; inclusion of a new minor revision procedure; addition and clarification of rules regarding Interim WGs Meetings; and clarification of rules regarding virtual participation to WGs in-person meetings.

ICH MC Actions/Decisions:

- The MC approved the proposed amendments to the SOP of the WGs, as well as the amendment of the MC RoP pending ICH Assembly approval of a similar amendment in the Assembly RoP;
- The MC supported recommending to the ICH Assembly the proposed amendments to the Assembly RoP;
- The MC supported provision to the ICH Assembly Members and Observers of the MC recommended amendments to the Assembly RoP for approval, and MC approved amendments to the MC RoP and SOP of the WGs for information.

7. 2022 ANNUAL REPORT

The ICH Secretariat informed the MC on suggested revisions received from one Member on the draft 2022 ICH Annual Report and the ongoing review and approval of the MedDRA related sections by the MedDRA MC.

MC Action/Decision:

- The MC approved the draft 2022 ICH Annual Report including the suggested revisions and its provision to ICH Assembly Members and Observers, pending MedDRA MC approval of MedDRA related sections, which the Assembly will be invited to approve at its meeting in Vancouver and discharge the ICH MC, MedDRA MC and the ICH Secretariat for the activities undertaken by these bodies in 2022 on behalf of the ICH Association.

8. ICH/PIC/S COLLABORATION

The MC Chair provided an update on follow-up with PIC/S regarding the draft Memorandum of Understanding (MoU) and ICH funding of training, further to the MC discussion from the Interim Meeting in Lausanne in March 2023.

MC Action/Decision:

- The MC noted the update and the ongoing review of the draft MoU by PIC/S.

9. ORGANISATION OF JUNE 2023 VANCOUVER MEETING

The ICH Secretariat informed the MC on the preparation of the Assembly meeting on 12-13 June and on the agenda and package of background documents for the Assembly.

MC Actions/Decisions:

- The MC noted the following key dates in preparation of the meeting:
  - By 23 May: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC agenda papers;
  - By 26 May: The Assembly agenda papers are circulated to the Assembly;
- The MC supported revisions proposed by the ICH Secretariat to the Assembly Draft Agenda based on the latest status for WGs as of that day and decisions taken by the MC at the MC Policy 3 teleconference and supported the provision of the revised Assembly Draft Agenda to the Assembly Members and Observers directly after the teleconference;

- The MC reviewed the list of documents to be shared with Assembly Members and Observers for the meeting and supported their inclusion in the package of background documents for circulation on 26 May;
- The MC noted that in line with the usual procedure, the Final Agenda for the Assembly meeting and the final list of Working Groups to meet in Vancouver, in addition to the Work Plans for each WG, will be published on the ICH website ahead of the Vancouver meeting;
- The MC supported the organisation of a Briefing Session at the Vancouver meeting on Saturday, 10 June 2023, in the usual format, and with participation from the ICH Assembly Vice Chair and MC Chair;
- The MC noted 4 new Work Plans provided by the Q3D(R3) EWG, QDG, M12 EWG and E14/S7B DG further to the MC Technical / Policy 2 TC, and supported that as usual the Work Plans be provided to the Assembly and published on the ICH website.

10. Q4B MAINTENANCE

MC Action/Decision:

- The MC noted that that at the Assembly meeting in Vancouver, representatives from the Pharmacopeial Discussion Group (PDG) will be invited to provide an update on the status of discussions further to the meeting in Incheon in November 2022 regarding PDG's recommendation for additional pharmacopoeias to harmonise with test methods agreed among ICH Q4B EWG members, and accept all the test methods in pharmacopoeias which are harmonised with PDG texts under the conditions described in Q4B Annexes.

11. NEXT TELECONFERENCES & MEETINGS

MC Action/Decision:

- The MC noted the following dates of next scheduled face-to-face meetings:

Face-to-Face Meetings

9 - 14 June 2023 in Vancouver, Canada

28 October - 1 November in Prague, Czech Republic

1 - 5 June or 18 - 22 May 2024 in Asia (dates & location to be confirmed)

2 - 6 November or 16 - 20 November 2024 in the Americas (dates & location to be confirmed)

10 - 14 May 2025 in Europe (location to be confirmed)