21 April 2023

FINAL MINUTES
ICH Management Committee Interim Meeting
27-28 March 2023

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICH, Route de Pré-Bois 20, P.O. Box 1894, 1215 Geneva, Switzerland

Telephone: +41 (22) 710 7480 - admin@ich.org, http://www.ich.org

LIST OF PARTICIPANTS

ICH MC Member Representatives:

Mr. Nélio Cézar De Aquino	ANVISA, Brazil
Ms. Bianca Zimon	ANVISA, Brazil
Dr. Wassim Nashabeh	BIO
Ms. Nancy Schwalje Travis	BIO
Dr. Milton Bonelli	EC, Europe
Ms. Lenita Lindström	EC, Europe
Mr. Raun Kupiec	EFPIA
Mr. Pär Tellner	EFPIA
Dr. Michelle Limoli	FDA, United States
Dr. Theresa Mullin *(Chair)*	FDA, United States
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. Nobumasa Nakashima *(Vice-Chair)*	MHLW/PMDA, Japan
Mr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Shinichi Okudaira	MHLW/PMDA, Japan
Dr. Sheng Yang	NMPA, China
Dr. Michelle Rohrer	PhRMA
Ms. Janet Vessotskie	PhRMA
Dr. Andreas Pfenninger	Swissmedic, Switzerland
Dr. Gabriela Zenhäusern	Swissmedic, Switzerland

ICH Assembly Member Representative:

Dr. Bruno Sepodes*	EC, Europe

ICH MC Coordinators:

Ms. Ana Carolina Moreira Marino Araujo	ANVISA, Brazil
Ms. Casey Rosner	BIO
Dr. Georgios Balkamos	EC, Europe
Dr. Jyothsna Krishnan	EFPIA
Ms. Jill Adleberg	FDA, United States
Mr. Nick Orphanos	Health Canada, Canada
Dr. Shinichiro Hirose*	IGBA
Ms. Mariko Kato	JPMA
Dr. Hyun Song	MFDS, Republic of Korea
Ms. Mao Yanagisawa	MHLW/PMDA, Japan
Mr. Baoshu Wen	NMPA, China

* Virtual attendance

Ms. Amanda Roache	PhRMA
Ms. Sarah Koechlin	Swissmedic, Switzerland

ICH MC Technical Coordinators:

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

ICH MC Standing Observers Delegates:

Ms. Angelika Joos	IFPMA
Ms. Judith Macdonald	IFPMA
Dr. Samvel Azatyan	WHO
Mr. Hiiti B. Sillo*	WHO

Additional Participants:

Dr. Varley Sousa	ANVISA, Brazil
Mr. Martin Harvey Allchurch	EC, Europe
Ms. Olivia Suarez-Milan*	Health Canada, Canada
Ms. Lidija Samardzic	IFPMA
Ms. Minyoung Lim	MFDS, Republic of Korea
Ms. Kaori Ogawa	MHLW/PMDA, Japan
Dr. Risa Ishitani	MHLW/PMDA, Japan
Ms. Nannan Li	NMPA, China
Mr. Felipe Dolz*	PhRMA
Mr. Jerry Stewart*	PhRMA
Ms. Marie Valentin	WHO

Invited Participants:

Mr. Peter Twomey (for item #E)	EC, Europe
Ms. Vicki Edwards (for item #E)*	EFPIA
Dr. Stephan Roenninger (for item #G)*	EFPIA
Dr. M. Khair ElZarrad (for item #E)	FDA, United States
Dr. Jason Rodriguez (for item #E)*	FDA, United States
Ms. Isabelle Colmagne-Poulard (for item #G)*	IFPMA
Dr. Kim Li (for item #E)*	PhRMA

ICH Secretariat:

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

---

* Virtual attendance

ICH MANAGEMENT COMMITTEE INTERIM MEETING

FINAL MINUTES

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

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

ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair – FDA, United States) welcomed all participants. The agenda was adopted with the addition of two items under Any Other Business: ICMRA PQ KMS WG and Appointment of Interim MC Vice-Chair.

In addition, it was supported that the following items from the draft MC Policy 2 Teleconference (TC) Agenda scheduled for 4 April 2023 would already be discussed at the Interim Meeting: organisation of next meetings and approaches for Patient Stakeholder Engagement in ICH. And that further to this the MC Policy 2 TC is then merged with the MC Technical TC that was previously scheduled for 6 April 2023, with the merged TC to take place on 4 April 2023.

A. NEW TOPIC PROPOSALS

The MC was informed by the Co-Leads of the New Topic Subcommittee on the process for MC assessment of New Topic proposals and on the evaluations and priority ranking scoring provided by the MC Members ahead of the Interim Meeting.

ICH MC Action/Decision:

- The MC agreed on the assessment of New Topic proposals for sharing with the ICH Assembly prior to the Assembly meeting in June 2023.

B. REFLECTION PAPERS

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

The MC was updated on the revision of the Reflection Paper on a "Strategic Approach to International Harmonization of Cell and Gene Therapy (CGT) Product Regulation" based on the comments received from the MC Members prior to the Interim Meeting.

MC Actions/Decisions:

- The MC supported in principle the establishment of a Discussion Group (DG) with a two-year remit and which would focus on a narrow scope of work limited to high maturity modalities linked to broader global clinical development plans and existing approved products, with the DG to identify and recommend topics for potential harmonisation as part of a roadmap development including prioritisation, and with the DG to include experts with broad background in CGT;
- The MC supported the development of a remit document for its approval which would clarify the scope of work and expertise;
- The MC noted that the overview of the DG's work should be open to the public for transparency, considering that many emerging industries are involved in development of CGT products.

EC, Europe, FDA, United States and Health Canada, Canada Reflection Paper on International harmonisation of real-world evidence (RWE) 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 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". The MC was provided with a high-level overview of the comments received from MC Members ahead of the Interim Meeting. The MC noted that all comments were under review by the co-authors at the time of the Interim Meeting, precluding the presentation of a revised Reflection Paper. The MC noted the proposal for the paper to be revised to address the MC comments received, and then presented to the MC, potentially at the 12 May MC TC, to enable the MC to reach agreement on the Reflection Paper.

ICH MC Action/Decision:

- The MC supported that the co-authors of the Reflection Paper further discuss the comments received and revise the paper to address the comments and identified issues, with the target to present an updated version at the 12 May MC TC.

C. PROCEDURAL MATTERS

The MC was informed on the proposal to provide for a Coordinator position for Standing Observers to both the ICH Assembly and MC, including a proposal for revisions to the ICH Assembly Rules of Procedure (RoP), ICH MC RoP, and Standard Operating Procedures (SOPs) of the ICH Working Groups.

ICH MC Actions/Decisions:

- The MC noted the interest expressed by both ICH Standing Observers (IFPMA and WHO) for the Coordinator position, and supported the proposal;
- The MC approved the revisions to the ICH MC RoP and the SOPs, noting that the implementation of the revisions would be pending ICH Assembly approval of the associated changes in the Assembly RoP which the MC agreed to put forward for Assembly for decision at June 2023 meeting in Vancouver;
- The MC supported that in the interim, the ICH Standing Observers be allowed to have a third participant attend the Vancouver ICH Assembly and MC meetings to support their delegations ahead of an Assembly decision on a formal Coordinator role.

D. ICH OPERATIONAL EFFICIENCY

The MC was updated on the status of activities related to progressing with efficiency proposals, including on the following items: proposed revisions to the SOPs of the ICH Working Groups (WGs) to address: (i) virtual participation in face-to-face meetings; (ii) structure around Interim WG meetings; and (iii) Minor Revision Procedure for ICH Guideline, as well as on the ICH Efficiency Tracker.

ICH MC Actions/Decisions:

- The MC supported the revision to the SOPs of the WGs to accommodate requests for remote participation to in-person WG meetings in exceptional circumstances (i.e., illness, travel restrictions) for both biannual and interim meetings;
- The MC supported that all WG meeting rooms for both biannual and interim meetings should be equipped to allow for a virtual component and supported that the budget be adjusted accordingly;
- The MC supported the revision to the SOPs of the WGs to provide for up to 6 interim WG meetings starting from 2025, noting that the number of WGs meeting at the biannual meetings would be limited to up to 12 starting with the second meeting of 2024, and that the request for an interim

meeting should be made at least 4 months in advance of the interim meeting. In view of planning already underway for 15 WG meetings at the June 2024 biannual meeting, the number of interim WG meetings would be limited to up to 4 in 2024;

- In view of the need for Members and Observers to have predictable travel budgets, the MC supported that the maximum number of interim WG meetings should be limited to the numbers of interim meetings agreed (i.e., up to 6 per year from 2025, and up to 4 in 2024), with WGs to be encouraged as far as possible to convene interim meetings in conjunction with the MC Interim Meeting in March, but noting that a meeting could be exceptionally held at a different time if a Member was willing to host and support the associated costs;
- The MC supported the addition of the Minor Revision Procedure for ICH Guideline to the SOPs of the WGs, to be used for pre-defined revisions that are limited in scope / extent of text to be changed;
- The MC noted the update on efficacy proposals, including on the development of an efficiency tracker tool to track all initiatives since the outset including: use of the revised New Topic Proposal and Concept Paper templates; use of MS SharePoint based Excel form to make nominations including the expertise; Rapporteur and Regulatory Chair onboarding sessions with a revised slide deck; as well as the pilot use of technical writers to support the work of ICH M14 and M15 EWGs, with further considerations on the benefits of this pilot to be given at a later stage in writing.

E. OVERSIGHT OF WGS

E2D(R1) EWG: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting (Rapporteur: Ms. Edwards – EFPIA)

The MC was updated by the Rapporteur on progress of work and the addressing of MC comments made in Incheon in November 2022. The MC noted the proposed revisions to the ICH E2D Guideline for which no revision to the E2D(R1) Concept Paper is required, the revised Work Plan and request to meet in Vancouver in June 2023 and appointment of Regulatory Chair.

ICH MC Actions/Decisions:

- The MC supported the proposed revisions without the need to revise the E2D(R1) Concept Paper and revised Work Plan and the aim to reach *Step 2* by October 2023 and *Step 4* by October 2024;
- The MC supported the E2D(R1) EWG to meet in Vancouver on 10-13 June 2023 for a 4-day face-to-face meeting;
- The MC supported the appointment of a Regulatory Chair, noting that FDA, United States will put forward a nomination to the role and noted that upon reaching *Step 2,* the Rapporteurship would transition to a Regulatory Member, with EC, Europe indicating that it would most likely assume the role.

E6(R3) EWG: Good Clinical Practice (Rapporteur: Dr. M. El Zarrad – FDA, United States; Regulatory Chair: Mr. Twomey – EC, Europe)

The MC was updated by the Rapporteur on progress of work, since the meeting in Incheon in November 2022 and work to be completed during the E6(R3) interim meeting in Lausanne, which was taking place in parallel of the MC meeting on 27-30 March 2023. The MC noted the remaining comments on the draft Annex 2 Concept Paper and noted E6(R3) EWG considerations on these. The MC also noted comments on the need to limit the scope of Annex 2 and minimize the need for additional expertise to perform the Annex 2 work. The MC noted the plan to progress work on the E6(R3) Annex 2 at the Vancouver meeting.

ICH MC Actions/Decisions:

- The MC supported the endorsement of the Annex 2 Concept Paper, with a minor revision of the scope;

- The MC supported that FDA, United States provide an update on the outcome of the E6(R3) EWG interim meeting at the MC Policy 2 TC on 4 April 2023.

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

ICH MC Action/Decision:

- The MC noted the written report of the M12 EWG interim meeting and supported that FDA, United States provide an update on the activities of the M12 EWG and the outcome of the interim meeting at the MC Policy 2 TC on 4 April 2023.

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)

ICH MC Action/Decision:

- The MC noted the written report of the M4Q(R2) EWG interim meeting and supported that FDA, United States provide an update on the activities of the M4Q(R2) EWG and the outcome of the M4Q(R2) interim meeting at the MC Policy 2 TC on 4 April 2023.

Q3E EWG: Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics (Rapporteur: Dr. Li – PhRMA; Regulatory Chair: Dr. Rodriguez – FDA, United States)

The MC was updated by the Rapporteur on the Q3E EWG proposal to develop toxicological information on potential leachables to inform a robust threshold analysis and to support this proposed a 3-prong approach, engaging with a proposed provider, leveraging trade organisations, and using EWG internal resources.

ICH MC Actions/Decisions:

- The MC requested further follow-up by the Q3E regarding its proposal for a database analysis;
- PhRMA was invited to share MC feedback with the Rapporteur, and to provide any update available at the time of the next MC TC on 4 April 2023;
- If the Work Plan for a meeting in Vancouver is available, the MC will be invited to take a decision at the 4 April TC on whether the Q3E EWG can meet in Vancouver.

Q12 IWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)

ICH MC Action/Decision:

- The MC supported the Q12 IWG remain as a dormant IWG to be activated via the ICH Secretariat in case of need, and otherwise only meet virtually via 1-2 teleconferences a year to discuss Q12 implementation efforts.

Member and Observer Requests to Nominate Experts to WGs

The MC was updated by the ICH Secretariat on the Member and Observer expert nomination requests received, and in line with the procedures, the ICH Secretariat informed the MC of the considerations of the Rapporteurs in case of already large WGs (i.e. with a number of experts equal to or over 25).

ICH MC Actions/Decisions:

- The MC approved MFDS, Republic of Korea's request to nominate one expert to the M8 Subgroup of M2 EWG;

- The MC approved MHRA, UK's request to nominate one expert to each of the following WGs: E20 EWG; Q3E EWG; Q5A(R2) EWG; Q13 IWG; M13 EWG; and M15 EWG;
- The MC approved Swissmedic, Switzerland's request to nominate one expert to the M14 EWG;
- The MC approved EDA, Egypt's request to nominate one expert to the M15 EWG and Q3E EWG;
- The MC approved SECMOH, Ukraine's request to nominate one expert to the M8 Subgroup of M2 EWG;
- Further to additional expressions of interest received for the E2D(R1) EWG and E6(R3) EWG, the MC supported that these requests are revisited after the EWGs would reach *Step 2* due to the advanced stage of these WGs' activities, noting that while there may be the possibility to join the E2D(R1) EWG in view of the currently smaller size of the EWG, given that the E6(R3) EWG is already larger in size, further consideration would be needed at a later stage;
- Further to additional expressions of interest received from other Members and Observers to also appoint experts to the Q2(R2)/Q14 EWG, M13 EWG and M14 EWG, the MC did not support the requests, in view of the consultation with the respective Rapporteurs on their group's perspective on the added value of the expertise proposed as well as concerns around the efficiency of WG operations due to the size of the WGs and the stage of the work.

F. ICH/PIC/S COLLABORATION

The MC was updated on the draft Memorandum of Understanding (MoU) with PIC/S and funding application submitted by PIC/S as a part of the ICH Funding of Regulatory Training process (see also item G below).

ICH MC Action/Decision:

- The MC supported the draft MoU be shared with PIC/S for comments / approval, and subsequently be shared with the ICH Assembly for approval at the meeting in Vancouver in June 2023.

G. TRAINING

Funding of Regulatory Training

The MC was informed by the ICH Secretariat on the requests received by the deadline of 15 February 2023 from ICH Regulatory Members and Observers for the 2023 programme for ICH funding.

ICH MC Actions/Decisions:

- The ICH MC noted the 2023 applications received from EDA, Egypt; Health Canada, Canada; MHLW/PMDA, Japan; NMPA, China; SFDA, Saudi Arabia and the feedback provided by some of the Training Subcommittee Members. The MC agreed to provide support to each application;
- The MC noted one application including multiple ICH Guideline training requests, and supported that all applicant's requests are exceptionally funded pending budget availability;
- The MC noted, in addition to the aforementioned applications, one additional expression of interest which at the moment of submission did not include sufficient information for funding consideration, and supported to come back to the request at a later time if a more complete application can be provided. The MC further supported that as a next step, the Secretariat liaises with the applicant to clarify the rules on scope for training;
- The MC supported that criteria for ICH Regulatory Training Funding are further elaborated by the Training Subcommittee, with potential input from the Finance Committee, to clarify expectations regarding what Guidelines should be considered for training in submitted requests for funding and the possible use of existing training materials;

- The MC agreed to revisit any pending training funding applications postponed from 2020, 2021 and 2022 at its meeting in November 2023, at which moment the proposed way forward would be confirmed.

Training Subcommittee

The MC was updated on the outcome of the face-to-face Training Subcommittee meeting which took place on 26 March 2023 in Lausanne, preceding the MC Interim Meeting, including an update on the activities of 3 Training Subcommittee Sub-groups focusing their work on the following key areas since their formation in December 2022: renovation and organisation of the ICH Training Website; development of a training evaluation process; and assessment of needs / benefits of the ICH Training Subcommittee outputs:

- The MC noted the update provided by the Sub-group 1 Lead and the recent activities focused on three main deliverables: enhancing ICH Training website layout; developing an infographic about ICH and the ICH Training Subcommittee; and developing concept to allow targeted education;
- The MC noted the update provided by the Sub-group 2 Lead and the recent activities focused on two main deliverables: developing evaluation measures and tools for training materials developed by Training Associates, training funded by ICH, and key training partners; and developing a process to manage the developed evaluation measures and tools by reviewing and revising, if necessary, at regular intervals (e.g. annually);
- The MC noted the update provided by the Sub-group 3 Lead and the recent activities focused on three main deliverables: developing criteria and prioritising training needs related to content and / or implementation of ICH Guidelines with a more targeted approach; enhancing feedback from constituents; and providing supplementary information to the implementation survey to enhance effectiveness of feedback for training purpose, with the outcome of Sub-group 3 to inform next waves of guidelines training,

ICH MC Actions/Decisions:

- The MC supported for Sub-group 1 to explore costs and services that could be provided for the proposed design of the training webpage and development of the infographic;
- The MC noted that a further update on Training Subcommittee activities will be given at the MC meeting in Vancouver in June 2023.

ICH Training Associates

ICH MC Action/Decision:

- The MC noted the status of the development of training materials by ICH Training Associates on: ICH Q1, ICH Q3 series, ICH Q5 series, ICH M4, ICH E2, ICH E6(R3), ICH E8(R1), E17 and ICH Q8-12 Guidelines.

H. ICH ALUMNI

The MC was informed on the draft proposal for the establishment of an ICH Alumni Association.

ICH MC Action/Decision:

- The MC noted the proposal and supported further refinement of the proposal after the meeting.

I. MEETINGS

ICH MC Actions/Decisions:

- The MC took a decision on two additional WGs to meeting in Vancouver in June 2023, agreeing on a 4-day meeting for both the E2D(R3) EWG and the Q2(R2)/Q14 EWG;
- The MC deferred a final decision on whether it could support a meeting of the Q3E EWG in Vancouver, pending feedback invited for the next MC TC on 4 April 2023 regarding what would be the work plan for a meeting in view of a delay in the start of the data analysis work;
- The MC supported an interim meeting to be held shortly after the Vancouver meeting for the E2B(R3), M2 and M11 EWGs which would be hosted by EFPIA in Europe and would enable the EWGs to meet both jointly and individually to progress their work, with a hybrid meeting to also be organised with the M8 sub-group of the M2 EWG as part of this interim meeting.

J. NEXT TELECONFERENCES & MEETINGS

MC Action/Decision:

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

Teleconferences / Virtual Meetings

4 April 2023	MC Policy 2 / MC Technical combined
12 May 2023	MC Policy 3

Face-to-Face Meetings

9 - 14 June 2023	Vancouver, Canada
28 October - 1 November 2023	Prague, Czech Republic
1 - 5 June 2024	Asia (location to be confirmed)
2 - 6 November *or* 16 - 20 November 2024	the Americas (dates & location do be confirmed)
10 - 14 May 2025	Europe (location to be confirmed)

K. ANY OTHER BUSINESS

ICMRA PQ KMS WG

The MC was updated on the status of work with the ICMRA Pharmaceutical Quality Knowledge Management System (PQ KMS) WG, including on the ongoing projects.

MC Action/Decision:

- The MC supported that the Assembly Vice-Chair continues to represent ICH in the ICMRA PQ KMS WG, noting that the MC Vice-Chair is stepping down as of 1 April 2023 and would be unable to participate (see also item below).

Appointment of an Interim MC Vice-Chair

The MC noted the need for the current MC Vice-Chair Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) to step down as of 1 April 2023 and extended their sincere and warm appreciation to Dr. Nakashima for his dedicated chairpersonship since August 2018.

ICH MC Action/Decision:

- The MC supported MHLW/PMDA, Japan's proposal to nominate Dr. Junko Sato (MHLW/PMDA, Japan) as interim MC Vice-Chair until the election of the new MC Vice-Chair at the subsequent MC meeting in Vancouver in June 2023, in line with the applicable procedures.

Organisation of Next Meetings

ICH MC Action/Decision:

- The MC noted the key dates in preparation of the next meeting:
    - By **4 May**: 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 **12 May**: The draft Assembly Agenda is circulated to the Assembly for comments;
    - By **23 May**: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers.

Approaches for Patient Stakeholder Engagement in ICH

The MC was updated on the status of activities regarding ICH Patient Engagement, including organisation of an ICH session at the Annual DIA Meeting in June 2023.

ICH MC Actions/Decisions:

- The MC noted the update and the session on ICH to be held at the Annual DIA Meeting in June 2023 in Boston, with the presentation on ICH to be shared with the MC prior to the DIA meeting;
- The MC supported that communication on the forthcoming ICH session at the DIA Meeting could be done via the ICH website and the ICH Vancouver meeting press release.