8 October 2021

FINAL REPORT
ICH MC Technical TELECONFERENCE
17 September 2021

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

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FINAL REPORT

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

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

1. WELCOMING REMARKS AND ADOPTION OF THE AGENDA

Dr. Nobumasa Nakashima (MC Vice-Chair) welcomed all participants. The agenda was adopted without modification.

2. ORGANISATION OF NEXT MEETING

***ICH MC Actions/Decisions**:*

- The MC noted the following key dates in preparation of the meeting:
  - By **8 October**: All background documents for the Assembly meeting are to be provided to the Secretariat for MC review at Policy 3 TC on 18 October prior to inclusion in the Assembly Agenda papers.
  - By **20 October**: The draft Assembly Agenda is circulated to the Assembly for comments.
  - By **29 October**: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers.
  - By **3 November**: The Assembly Agenda papers are circulated to the Assembly.

3. OVERSIGHT OF THE WORKING GROUPS (WGS)

Status of WGs

The Coordinators for the Members holding the Rapporteurship of each WG provided a status update on the WG's activities, and written status reports are included below for each WG.

ICH MC Action/Decision:

- The MC noted that at the Assembly virtual meeting there could be sufficient time for the Rapporteurs/Regulatory Chairs of a few WGs to make a brief presentation to the Assembly, and the MC supported the following WGs to be considered for reporting: E6(R3) EWG; E11A EWG; E14/S7B IWG; M4Q(R2) informal WG; Q13 EWG, and if time permits, E8(R1) EWG and M7(R2) Maintenance EWG/IWG; with DGs (QDG; GDG; MIDD DG) to be considered depending on status of MC discussion on their deliverables and next steps;
- The MC noted that to facilitate Coordinators' and MC discussion, the ICH Secretariat will include from the next ICH cycle in the multi-year overview of hamonisation activities for information a note on any delay incurred by any WG since their last work plan.

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

Written Status Report

The Standing Paediatric EWG did not receive any request for paediatric advice from WGs and the group 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.

3.2. 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, United States)

Written Status Report

Steps 3 and 4 for v1.1. of the Dose Forms and Routes of Administration for Individual Case Safety Reports in the E2B(R3) message were finalised in July 2020.

The Information Paper regarding the Use of ISO IDMP Standards in ICH E2B(R3) Messages was finalised in June 2021.

The E2B(R3) EWG/IWG continues its work, including on the development of Training Module III and the voice over for Training Module I, and on the update of the ICSR BFC (Backwards and Forwards Compatibility) Specification document (in view of an error correction and updates needed further to the revision of the EDQM User Guide).

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

Written Status Report

The E2D(R1) EWG was established at the ICH meeting in November 2019.

The E2D(R1) EWG continues its work on the development of the E2D(R1) draft Technical Document.

Steps 1 and 2a/b are expected by November 2022. The E2D(R1) draft Technical document should be shared with the E2D(R1) Plenary Working Party (PWP) ahead of Step 1 sign-off, and is expected to be shared by August 2022.

ICH MC Action/Decision:

- The MC noted that there have been challenges in the E2D(R1) EWG in incorporating both regulatory and industry perspectives in the development of the draft Technical Document, and agreed that the MC should be kept informed of the progress of the group's discussions to consider any need for discussion at the level of the MC.

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

Written Status Report

The EWG published the draft principles of Good Clinical Practice on the ICH website on 19 April 2021 and has organised a global web conference on 18 and 19 May 2021 to facilitate broad dissemination of and public engagement on the principles of Good Clinical Practice.

The E6(R3) EWG continues its work on the E6(R3) draft Technical Document, including revisions to the overarching general principles guideline, with Annex 1 on traditional interventional trials being developed in parallel, and continues engaging with stakeholder representatives and EWG members during guideline development to ensure that stakeholders' perspectives on and experiences with clinical trials, specifically with GCP guidelines, are considered in developing ICH E6(R3).

Steps 1 and 2 a/b for Principles and Annex 1 are expected by October 2022. The E6(R3) draft Technical document should be shared with the E6(R3) PWP ahead of Step 1 sign-off, and is expected by August 2022.

Endorsement of the revised E6(R3) Concept Paper updated in regards to Annex 2 is expected by September 2022. Timeline for Steps 1 and 2 a/b for Annex 2 is to be determined (work to be undertaken following reaching of Steps 1 and 2 a/b for Annex 1).

ICH MC Actions/Decisions:

- The MC supported the proposal from the Coordinator for FDA, United States that the report on the global web conference held on 18 and 19 May 2021 by the ICH E6(R3) EWG would be shared with the MC for tacit approval for publication on the ICH Public Events webpage;
- The MC supported to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting.

3.5. E8(R1) EWG: Revision on General Considerations for Clinical Studies (Rapporteur: Dr. LaVange – FDA, United States; Regulatory Chair: Dr. Kirisits – EC, Europe)

Written Status Report

The E8(R1) draft Guideline was in public regulatory consultation in the ICH Member regions until end of October 2019.

The E8(R1) EWG held a global public stakeholder meeting as per the GCP renovation plan on 31 October 2019 at the FDA, United States headquarters, and a report was published on the ICH website summarising the discussion from the global public stakeholder meeting on E8(R1).

The E8(R1) EWG has finalised the E8(R1) Guideline for *Step 3* sign-off and is working on the development of training materials.

Steps 3 and 4 are expected in September/October 2021. Training materials are expected by December 2021.

ICH MC Action/Decision:

- The MC supported to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting, if there would be enough time as priority should be given to other WGs.

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

Written Status Report

Steps 3 and 4 were reached at the ICH meeting in November 2019.

The E9(R1) EWG is working on the development of training materials and videos.

The E9(R1) training materials are expected to be finalised in 2021.

ICH MC Action/Decision:

- The MC noted that the training materials and videos are expected to be finalised by the end of 2021.

3.7. E11A EWG: Paediatric Extrapolation (Rapporteur: Dr. Yao – FDA, United States)

Written Status Report

The E11A EWG was established in October 2017.

The E11A EWG continues its work on the E11A draft Technical Document and the development of examples to be included in an Annex.

Steps 1 and 2a/b are expected by November 2021.

ICH MC Action/Decision:

- The MC supported to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting, if the E11A draft Technical Document and the Annex are finalised ahead of the meeting.

3.8. E14/S7B IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Rapporteur: Dr. Strauss – FDA, United States)

Written Status Report

Steps 1 and 2a/b of the first stage of Q&As were reached electronically in August 2020 and the document underwent public consultation until end of December 2020. The E14/S7B IWG held a virtual meeting on the draft E14/S7B Q&As on 15 and 16 October 2020.

The E14/S7B IWG continues to address the comments received during the regional public consultation period which ended in December 2020.

Step 3 and 4 of the first stage of Q&As are expected by November 2021.

ICH MC Actions/Decisions:

- The MC supported the proposal to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting, with a recommendation that the WG's update to the Assembly would focus more on the impact of its work than on very specific technical content.

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

Written Status Report

The E19 draft Guideline was in public regulatory consultation in the ICH Member regions until end of September 2019.

The E19 EWG continues to address the comments received during the regional public consultation period which ended in September 2019.

Steps 3 and 4 are expected by April 2022.

3.10. E20 EWG: Adaptive Clinical Trials (Rapporteur: Dr. Zhong - PhRMA; Regulatory Chair: Dr. Levin – FDA, United States)

Written Status Report

The E20 EWG was established at the ICH meeting in November 2019.

The E20 EWG continues its work on the E20 draft Technical Document.

Steps 1 and 2a/b are expected by June 2023. The E20 draft Technical document should be shared with the E20 PWP ahead of Step 1 sign-off, and is expected to be shared by March 2023.

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

Written Status Report

In October 2020, the MedDRA MC approved the development of an additional section of the Companion document on manufacturing quality issues.

V2.0 of the Companion document with a new section on product quality issues was released in October 2020.

Updated "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 24.0) in English, Japanese, Chinese, Korean, and Spanish translations were released in March 2021, with the next release in March 2022.

The M1 PtC WG continues its work on the revision of the Companion document and on the Points to Consider documents.

Release of v3.0 of the Companion document with a new section on manufacturing product quality issues in English and Japanese is expected in December 2021.

3.12. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) (Co-Rapporteurs: Ms. Slack – FDA, United States / Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Dr. Jaermann – Swissmedic, Switzerland)

Written Status Report

The sign-off on revised M2 Recommendation documents was completed in September 2021 and Assembly endorsement is ongoing.

The M2 EWG continues to work on: exploring/identifying technological risks or opportunities by discussing with ICH WGs at *Step 1* and reviewing *Step 3-4* documents; the development of 1-2 detailed process pilots for streamlining the ICH process for developing technical standards which would be submitted for ICH MC consideration; on the development of a technical specification document for CeSHarP with the M11 EWG; and on monitoring FHIR development and maturity progress that is relevant to ICH.

3.13. M4Q(R2) informal WG: Revision of M4Q(R1) CTD on Quality guidance (informal WG Lead: Dr. Yu - FDA, United States)

Written Status Report

At the Virtual meeting in May 2020, the Assembly endorsed the proposal "Revision of M4Q(R1) CTD on Quality guidance". The M4Q(R2) informal WG was established further to the Q13 draft Guideline reaching Step 2a/b in July 2021, and the M4Q(R1) IWG was disbanded upon establishment of the M4Q(R2) informal WG with the support of the MC.

The M4Q(R2) informal WG is working on the development of its Concept Paper and Business Plan.

Finalisation of the Concept Paper and Business Plan is expected by mid-November 2021.

ICH MC Actions/Decisions:

- The MC noted that the Concept Paper and Business Plan is expected to be finalised for MC endorsement at the MC virtual meeting in November 2021;
- The MC supported the proposal to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting.

3.14. M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (Rapporteur: Dr. Froetschl – EC, Europe)

Written Status Report

Steps 1 and 2 a/b for the M7(R2) Q&As were reached in June 2020. As part of Steps 2a/b, the Assembly Members / Regulatory Members of the Assembly pre-approved a change to be included in the future M7(R2) draft Guideline which is referenced in the Q&As, so that the change could be published alongside the M7 Q&As as a support document.

At the Virtual meeting in June 2021, the Assembly endorsed the Rapporteurship of the M7(R2) Maintenance EWG/IWG, in line with Annex 4 of the SOP on rotation of Rapporteurship of the group amongst the Founding Regulatory Members, to rotate to Dr. Aisar Atrakchi (FDA, United States), but for continuity reasons only after the M7(R2) Q&As reach Step 4, which is now expected by June 2022.

The M7(R2) Maintenance EWG/IWG finalised the M7(R2) draft Guideline, which as approved by the MC, includes as revisions: (1) the core Guideline and (2) one Addendum document with all the monographs, and with both documents being interlinked via the URLs of the documents on the ICH webpage.

The M7(R2) Maintenance EWG/IWG continues its work on the finalisation of the M7(R2) Q&As.

Step 1 of the M7(R2) draft Guideline is ongoing.

Steps 3 and 4 of the M7(R2) Q&As are expected by June 2022.

ICH MC Actions/Decisions:

- The MC supported the WG's recommendation on the publication format of the M7(R2) Guideline and Addendum for public consultation under *Step 3* which would only include a document with a list of the revisions to the M7(R1) Guideline and the new monographs for the 7 new compounds;
- The MC supported that the proposed publication format for the M7(R2) draft Guideline and Addendum under *Step 3* for public consultation would apply to all Maintenance WG's draft Guideline which would undergo public consultation under *Step 3,* for consistency;
- The MC supported to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting, if there would be enough time as priority should be given to other WGs.

3.15. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) (Rapporteur: Mr. Gray – FDA, United States; Regulatory Chair: Ms. Puusaari – EC, Europe)

Written Status Report

Step 4 of the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 was reached in June 2018.

Step 4 of the eCTD v4.0 Q&As and Specification Change Request Document v1.5, Specification for Submission Formats v1.3, as well as the eCTD v4 Implementation Package v.1.4 were reached electronically in June 2021.

The M8 EWG/IWG continues its work to monitor the status of implementation of eCTD v4.0.

If Change Requests are received, Step 4 is expected in November 2021 for the eCTD v4.0 Q&As and Specification Change Request Document v1.6.

If Change Requests are received, Step 4 is expected in November 2021 for the eCTD v3.2.2 Q&As and Specification Change Request Document v1.32.

3.16. M10 EWG: Bioanalytical Method Validation (Rapporteur: Dr. Watabe – MHLW/PMDA, Japan; Regulatory Chair: Dr. Booth – FDA, United States)

Written Status Report

The M10 draft Guideline was undergoing public regulatory consultation in the ICH Member regions until end of September 2019.

The M10 EWG continues to address the comments received during the regional public consultation period.

Steps 3 and 4 are expected by May 2022.

The M10 EWG will develop and finalise training materials shortly after completion of the M10 Guideline.

3.17. M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Ms. Combs – PhRMA; Regulatory Chair: Dr. Fitzmartin – FDA, United States)

Written Status Report

The M11 EWG continues its work on the development of the M11 draft Technical Document, the clinical protocol template and the Technical Implementation Guide; as well as on the strategic engagement with other key WGs including: E6(R3) EWG, E9(R1) EWG, E20 EWG, and M2 EWG.

Steps 1 and 2 a/b for the Guideline, Template, and Technical Implementation Guide are expected by May 2022.

Steps 3 and 4 for Guideline, Template, and Technical Implementation Guide are expected by May 2023.

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

Written Status Report

At the ICH meeting in November 2019, the MC endorsed the M12 Concept Paper and Business Plan, and the transition of the M12 informal WG to an EWG.

The M12 EWG continues its work on the development of the M12 draft Technical Document.

Steps 1 and 2a/b are expected by May 2022. The M12 draft Technical Document should be shared with the M12 PWP ahead of Step 1 sign-off, and is expected to be shared by March 2022.

3.19. M13 EWG: Bioequivalence for Immediate-Release Solid Oral Dosage Forms (Rapporteur: Dr. Zhang - FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)

Written Status Report

In July 2020, the MC approved the M13 Concept Paper and Business Plan, and the transition of the M13 informal WG to an EWG.

The M13 EWG continues its work on the development of the first M13 draft guideline in the series (M13A).

Steps 1 and 2a/b are expected by May 2022.

3.20. 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)

Written Status Report

As noted at the Assembly meeting in November 2019, the group is working on two separate draft documents (i.e. for Q2(R2) and Q14), with the group to consider at a later stage whether they should be combined into a single draft Technical Document.

The Q2(R2)/Q14 EWG continues its work on the development of the two draft Q2(R2)/Q14 Technical Documents.

Steps 1 and 2a/b are expected by December 2021.

3.21. Q3C(R9) Maintenance EWG: Maintenance of the Guideline for Residual Solvents (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

Written Status Report

Steps 3 and 4 of the Q3C(R8) Guideline including the Permitted Daily Exposure (PDE) levels for the solvents 2-2-Methyltetrahydrofuran, Cyclopentyl methyl ether and Tertiary butyl alcohol were reached in April 2021.

The Q3C(R9) Maintenance EWG remains in a dormant state until proposals for revisions are received.

3.22. Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities (Rapporteur: Dr. Hirose – MHLW/PMDA, Japan)

Written Status Report

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products were reached in September 2020, and the Q3D(R2) Guideline underwent public consultation in the ICH Member regions until June 2021.

At the Virtual meeting in June 2021, the Assembly endorsed Dr. Roland Froetschl (EC, Europe) for the Rapporteurship of the group in line with Annex 4 of the SOP on rotation of Rapporteurship of the group amongst the Founding Regulatory Members, and that this rotation would be effective for continuity reasons only after Steps 3 and 4 are reached, which is now expected by January 2022.

The Q3D(R2) Maintenance EWG continues to address the comments received during the public regulatory consultation period.

Steps 3 and 4 of the Q3D(R2) revision for the cutaneous and transdermal products are expected by January 2022.

3.23. 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)

Written Status Report

The MC approved the Q3E Concept Paper and Business Plan in July 2020, and the transition of the Q3E informal WG to an EWG.

The Q3E EWG and the Q9(R1) EWGs have identified a Q9(R1) liaison who is attending discussions of the Q3E EWG as needed to help both WGs coordinate their efforts, as the Q9(R1) work on the Quality Risk Management Framework may have an impact on the Q3E Guideline.

The Q3E EWG continues its work on the development of the Q3E draft Technical Document.

Steps 1 and 2a/b are expected by November 2022. The Q3E draft Technical Document should be shared with the Q3E PWP ahead of Step 1 sign-off and is expected to be shared by September 2022.

3.24. Q5A(R2) EWG: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (Rapporteur: Dr. Welch - FDA, United States; Regulatory Chair: Dr. Blumel – EC, Europe)

Written Status Report

At the ICH meeting in November 2019, the MC endorsed the Q5A(R2) Concept Paper and Business Plan, and the transition of the Q5A(R2) informal WG to an EWG.

The Q5A(R2) EWG continues its work on the development of the Q5A(R2) draft Technical Document.

Steps 1 and 2a/b are expected by May 2022. The Q5A(R2) draft Technical Document should be shared with the Q5A(R2) PWP ahead of Step 1 sign-off and is expected to be shared by September 2021.

3.25. Q9(R1) EWG: Quality Risk Management (Rapporteur: Mr. O'Donnell - EC, Europe; Regulatory Chair: Mr. Viehmann - FDA, United States)

Written Status Report

In October 2020, the MC endorsed the Q9(R1) Concept Paper and Business Plan and the transition of the Q9(R1) informal WG to an EWG.

The Q3E EWG and the Q9(R1) EWGs have identified a Q9(R1) liaison who is attending discussions of the Q3E EWG as needed to help both WGs coordinate their efforts, as the Q9(R1) work on the Quality Risk Management Framework may have an impact on the Q3E Guideline.

The Q9(R1) EWG continues its work on the development of the Q9(R1) draft Technical Document.

Steps 1 and 2a/b are expected by December 2021. The Q9(R1) draft Technical Document should be shared with the Q9(R1) PWP ahead of Step 1 sign-off and is expected to be shared by September 2021.

Training materials are expected by August 2022.

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

Written Status Report

At the ICH meeting in November 2019, the Assembly approved the development of training material on the Q12 Guideline, and further to the MC endorsement of the Q12 IWG Concept Paper in March 2020, the Q12 IWG was established in May 2020.

The Q12 Training Materials Modules 0-7 were finalised in June 2021.

The Q12 IWG is working on the finalisation of Training Material Module 8 and case studies as well as on a broad-audience video with the support of the FDA, United States studios.

The Q12 Training Materials are expected to be finalised by November 2021.

ICH MC Action/Decision:

- The MC noted that the broad-audience video may be finalised by end of 2021 or shortly thereafter, and that following finalisation of this last deliverable the MC may consider the disbandment of the group.

3.27. Q13 EWG: Continuous Manufacturing of Drug Substances and Drug Products (Rapporteur: Dr. Lee – FDA, United States; Regulatory Chair: Dr. Matsuda – MHLW/PMDA, Japan)

Written Status Report

Steps 1 and 2a/b on the Q13 draft Guideline were reached in July 2021, further to which the draft Guideline was published for public consultation.

The Q13 EWG continues to receive comments during the public regulatory consultation period and is working on the development of training materials.

Steps 3 and 4 are expected by November 2022.

ICH MC Action/Decision:

- The MC supported to include this WG amongst the list of those to present their progress at the Assembly November 2021 virtual meeting.

3.28. S1B(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline (Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: Dr. Van der Laan – EC, Europe)

Written Status Report

Steps 1 and 2a/b on the S1B(R1) draft Guideline were reached in May 2021, further to which the draft Guideline was published for public consultation.

The 4th Status Report from Regulatory Authorities was finalised and published in August 2021.

The S1B(R1) EWG continues to collect comments during its public consultation period.

Steps 3 and 4 on the S1B(R1) Guideline are expected by May 2022.

3.29. S5(R4) Maintenance EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals (Rapporteur: Dr. Waxenecker – EC, Europe)

Written Status Report

Steps 3 and 4 for the S5(R3) Guideline were reached electronically in February 2020, and the S5(R3) Step 4 training presentation was published on the ICH website in June 2020.

No proposals for revisions of Annex 1 or 2 have been received at this time and that therefore the group remains in a dormant state.

3.30. S12 EWG: Biodistribution Studies for Gene Therapy Products (Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Serabian – FDA, United States)

Written Status Report

Steps 1 and 2a/b on the S12 draft Guideline were reached in June 2021, further to which the draft Guideline was published for public consultation.

The S12 EWG continues to collect comments during the public consultation period.

Steps 3 and 4 on the S12 Guideline are expected by May 2023.

3.31. Generic drug Discussion Group (GDG) (Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)

ICH MC Actions/Decisions:

- The MC noted the GDG report to the MC on finalisation of its activities;
- The MC noted the proposal by the GDG not to disband the GDG further to the completion of its activities, and instead to keep the GDG in a dormant state until the MC requests them to resume work. The MC discussed the merit of keeping the GDG in a dormant state versus disbanding it in view of the anticipated delay before the start of any other New Topic and agreed to continue its discussion at an upcoming TC.

3.32. Quality Discussion Group (QDG) (Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Ms. Kruse – EC, Europe)

ICH MC Actions/Decisions:

- The MC noted the proposal of the QDG not to disband the QDG further to the completion of its activities and instead to keep a standing QDG, in case the expertise of the QDG might be needed to support the next New Topic Proposal cycle, and the MC supported to discuss further the proposal and future options at an upcoming TC;
- The MC supported the QDG recommendation and prioritization report on assessment of ICH Q and relevant M Guidelines to be shared with the Assembly for its approval to be published on the ICH website, but prior to doing so to remove the text regarding the proposal for a standing QDG as this needs further discussion;
- In support of general considerations on the work of DGs, the MC tasked the Coordinators to work on a proposal to submit to the MC for specifying high-level operating parameters and principles for engagement of DGs.

3.33. Pharmacoepidemiology Discussion Group (PEpiDG) (Rapporteur: Dr. Uyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Ball – FDA, United States)

Written Status Report

The PEpiDG developed a New Topic proposal, which has been submitted as part of the 2021 ICH New Topics cycle. At the Virtual meeting in June 2021, the Assembly supported the New Topic proposal and submission of the Concept Paper Outline.

The MC approved the PEpiDG to operate for a 2-year term. The PEpiDG is expected to have completed its work by early 2022.

ICH MC Action/Decision:

- The MC noted that the M14 informal WG on "General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine" would be established in the October/November timeframe, and that the PEpiDG will further discuss to agree on a proposal to submit to the MC on what would be the next steps for the DG in view of the overlap of expertise between the two groups.

3.34. Model-Informed Drug Development Discussion Group (MIDD DG) (Rapporteur: Dr. Marshall - PhRMA; Regulatory Chair: Dr. Karlsson – EC, Europe)

Written Status Report

The MIDD DG was established in January 2021.

The MIDD DG continues its work to make a recommendation of a "roadmap" for appropriate sequencing and format for incorporating MIDD concepts into a proposal on ICH E4 (i.e., Revision, Addendum, Q&A).

MIDD DG is expected to complete its activities by December 2021.

ICH MC Action/Decision:

- The MC noted that the MIDD DG had recently finalised its proposal for a revised scope of a Guideline on MIDD, and agreed that the MC would review and further discuss at an upcoming TC the next steps and confirm if ready to share with the Assembly.

4. MEMBER/OBSERVER REQUESTS TO NOMINATE EXPERTS TO WGS

ICH MC Action/Decision:

- The MC noted that there are no pending requests at this time.

5. PLENARY WORKING PARTIES

ICH MC Action/Decision:

- The MC noted the overview table (below) of WGs which have Plenary Working Parties (PWPs).

WG	Member(s)/Observer(s)	Timeline for next *Steps 1* or *Steps 3*	PWP next step
E20	CPED, Israel	*Step 1 by June 2023*	*To be involved prior to Step 1 sign-off*
E2D(R1)	Health Canada, Canada	*Step 1 by November 2022*	*To be involved prior to Step 1 sign-off*
E6(R3)	CPED, Israel INVIMA, Colombia SFDA, Saudi Arabia	*Step 1 by October 2022*	*To be involved prior to Step 1 sign-off*
M4Q(R2) Informal WG	Swissmedic, Switzerland	*(Concept Paper and Business Plan by November 2021)*	*PWP to be established once M4Q(R2) EWG is established*
M12	Health Canada, Canada SFDA, Saudi Arabia	*Step 1 by May 2022*	*To be involved prior to Step 1 sign-off*
Q3E	Swissmedic, Switzerland Health Canada, Canada	*Step 1 by November 2022*	*To be involved prior to Step 1 sign-off*
Q5A(R2)	CPED, Israel	*Step 1 by May 2022*	*To be involved prior to Step 1 sign-off*
Q9(R1)	Health Canada, Canada	*Step 1 by December 2021*	*To be involved prior to Step 1 sign-off*
S12	SFDA, Saudi Arabia	*Step 3 by May 2023*	*To be involved prior to Step 3 sign-off*

6. GENERAL OPERATIONAL MATTERS

The MC was informed by the Secretariat on a proposal discussed at the Coordinators TC regarding the publication on the ICH website of the names of the Rapporteur Supporters alongside the names of the Rapporteurs and Regulatory Chairs as a recognition of the Rapporteur Supporters' work.

ICH MC Action/Decision:

- The MC supported to acknowledge the contribution of the Rapporteur Supporters to help the WGs meet their objectives. The MC agreed to publish their names on the ICH website in a separate manner to

those of the Rapporteur and Regulatory Chair and to those of the experts, making clear the different roles. The ICH Secretariat will share a proposal with the MC prior to publication.

7. NEXT TELECONFERENCES & MEETINGS

Teleconferences / Virtual Meetings

30 September 2021	MC Policy 2
18 October 2021	MC Policy 3
9-15-16 November 2021	MC Meeting in virtual format

Face-to-Face Meetings

21-25 May 2022	Athens, Greece (final confirmation pending)
12-16 November 2022	Incheon, Republic of Korea (final confirmation pending)
10-13 June 2023	Vancouver, Canada (final confirmation pending)
28 October-1 November or 11-15 November 2023	Europe (dates & location do be confirmed)