

2 January 2026

FINAL MINUTES
ICH Management Committee Meeting in Singapore
16, 17 and 19 November 2025

LIST OF PARTICIPANTS

ICH MC Member Representatives:

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Dr. Derek Scholes	BIO
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Ms. Lenita Lindström	EC, Europe
Mr. Stefan Herdinius	EFPIA
Mr. Pär Tellner	EFPIA
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Dr. Theresa Mullin (<i>MC Chair</i>)	FDA, United States
Dr. Manuel Osorio	FDA, United States
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Mr. Jeffrey Skene	Health Canada, Canada
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Mr. Takayuki Okubo	MHLW/PMDA, Japan
Dr. Shinichi Okudaira	MHLW/PMDA, Japan
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Ms. Janet Vessotskie	PhRMA
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ICH MC Coordinators:

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Additional Participants:

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ICH Secretariat:

Ms. Géraldine Lissalde-Bonnet
Ms. Miray Aizouki
Mr. Sivashen Cunden
Ms. Magda Dubert
Ms. Petra Grand
Ms. Nikoleta Luludi
Mr. Francis Panlilio

ICH Secretariat, Secretary General

** Virtual attendance

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ICH MANAGEMENT COMMITTEE MEETING

FINAL MINUTES

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

MC Vice Chair: Mr. Daisuke Koga, MHLW/PMDA, Japan

Adoption of the Agenda

MC Actions/Decisions:

- The MC adopted the agenda with modifications.

A. ICH Secretariat

The Secretary General of the Secretariat updated the MC on the current structure and staffing levels of the Secretariat. A new Communications Manager started just prior to the meeting in Singapore, and recruitment for the Working Groups Coordinator position with education in Public Health or Health Sciences - currently vacant - will be launched shortly after the meeting.

MC Actions/Decision:

- The MC noted the update on the Secretariat's staffing and that an organisational chart of the Secretariat and detailed descriptions of the responsibilities for the current cycle of each staff member will be presented to the MC in the near future so that the MC is fully informed of their respective functions.

B. Communication

MC Action/Decision:

- The MC noted the launch of the ICH anniversary campaign, beginning with the creation of an official LinkedIn page, and the following objectives of the campaign:
 - Publicly mark 35 years since ICH's founding and 10 years as an Association;
 - Share ICH activities and achievements with key stakeholders and new audiences;
 - Develop new communications tools for outreach and information, including a video, plain-language explainers, and additional materials.

C. General Operational Matters

ICH Secretariat Report on General Operational Matters

MC Actions/Decisions:

- The MC noted the written report of the ICH Secretariat including: level of participation of Members and Observers in ICH, as well as status of trademarks;
- The MC noted the publication of statistical information on the ICH website.

D. New Topics and Strategic Discussions

New Topics Cycle 2025 and 2026

The ICH New Topic Subcommittee Co-Chair presented an overview of recently established working groups, including ICH E23 and ICH M18, for which activities have begun, and Concept Papers have been submitted

to the ICH MC for approval. An update was also provided on the ongoing Call for Nominations for M16 (Structured Product Quality Submissions) which was to be established following M4Q(R2) reaching *Step 2a/b*. Furthermore, a reminder was provided for other Delayed Start Topics whose Calls for Nominations will be issued following the Singapore meeting or once the agreed criteria are met.

The New Topic Subcommittee Co-Chair further reminded the MC that the 2026 New Topic process remains paused due to the high number of active and delayed working groups and the associated resource constraints. This pause has already been communicated to the ICH Assembly. As agreed at the 2025 Madrid meeting, ICH Members and Observers should contact the New Topic Co-Chairs ahead of the Singapore meeting should urgent harmonization needs arise; however, no such requests were submitted. Given the ongoing pause, the formal New Topic process for the 2027 cycle will be discussed at the 2026 meeting in Rio de Janeiro. In context, the Secretariat will implement an active “one-in/one-out” portfolio management approach so new WGs are established when current WGs close out activities. This update to the MC will be informed by the updated multi-year overview, which now indicates when each working group is expected to complete its work and will inform New Topic discussion.

MC Actions/Decisions:

- The MC noted the Call for Nominations for M16 Product Quality Safety Submissions is ongoing;
- The MC approved the request to delay the Call for Nominations for the E24 “Natural History Studies and Registry Data to Advance Rare Disease Drug Development” EWG to April 2026;
- The MC noted the Call for Nominations for the Q5E Annex “Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process” EWG will be launched after the disbandment of the CGTDG;
- The MC noted the ongoing pause to the 2026 New Topic process due to current large number of active and delayed working groups, as well as constraints in regulatory authorities’ staffing capacity;
- The MC noted that no urgent harmonisation needs from ICH Members/Observers were communicated to the ICH New Topic Co-Leads in advance of the Singapore November 2025 meeting;
- The MC noted that the formal New Topic Cycle for 2027 will be discussed for recommencement, including its format and scope, at the June 2026 meeting in Rio de Janeiro.

ICH Reflection Papers

The ICH New Topics Subcommittee Co-Chair presented the minor changes to the Reflection Paper process and outlined its formal decoupling from the New Topic Process.

PhRMA presented the PhRMA Reflection Paper Proposal on “*New Approach Methodologies (NAMs)*” for MC consideration. PhRMA highlighted the regional efforts already in place to facilitate regulatory acceptance of NAMs and outlined that the bottleneck to the use of NAMs to nonclinical safety evaluation of pharmaceuticals is the lack of harmonised global regulatory acceptance. The aim for the Reflection Paper is to outline a roadmap for future ICH harmonisation related to NAMs, considering opportunities for international harmonisation, recommended timing and sequencing of proposed topics.

FDA, United States presented a high-level summary towards the revised Reflection Paper on “*Manufacturing Process Models in Pharmaceutical Manufacturing*” for MC consideration. The FDA, United States revised the ICH Reflection Paper based on feedback from the ICH MC. The paper proposes a framework for harmonised global guidelines to support advanced manufacturing technologies, focusing on process modelling, continuous process verification, and decentralized manufacturing. Key updates include clarifying that the guideline will encompass broad principles that could be applicable to AI models, improving clarity throughout, and reinforcing a phased approach to guideline development based on regulatory expertise and scientific knowledge. These revisions aim to ensure regulatory flexibility, promote global harmonisation, and maintain product quality and patient safety.

MC Actions/Decisions:

- The MC recognised the need to look at current Reflection Papers and Discussion Group outcomes published to inform a Strategic Roadmap;
- The MC approved the Reflection Paper process changes including addition of optional public consultation, decoupling from new topics process and leveraging electronic comments/approvals where possible;
- The MC approved a revised working definition for Reflection Papers to be embedded into the relevant procedures and updated on the ICH website;
- The MC approved the embedding of a slightly revised Reflection Paper Process flowchart into the Coordinators' handbook;
- The MC supported that going forward Reflection Papers should not be a pivot product for rejected New Topic Proposals, unless under exceptional and justified circumstances;
- The MC supported the development of a Reflection Paper Template as well as a Reflection Paper Evaluation Form to gather feedback on the Reflection Papers from MC/Assembly Members as part of the Efficiency group discussions;
- The MC noted subsequent SOP and RoP changes will be made when Secretariat resources allow for SOP revision activities to recommence;
- The MC supported the Reflection Paper proposal on “*New Approach Methodologies*” put forward by PhRMA as an ICH Reflection Paper to be submitted by June 2026;
 - The MC supported the general principles around NAMs and brought forward the consideration of how the development of guidelines and revisions to the guidelines is going to be included.
 - The MC highlighted the importance of practical use cases for guideline development of NAMs.
- The MC supported PhRMA's proposal on creating the Reflection Paper Drafting Team by inviting all MC Coordinators to nominate one representative and one alternate per interested MC Member, with the drafting team to be finalized in January.
- The MC approved the revised FDA, United States Reflection Paper on “*Manufacturing Process Models in Pharmaceutical Manufacturing*”;
- The MC noted that the endorsed FDA, United States Reflection Paper on “*Manufacturing Process Models in Pharmaceutical Manufacturing*” will be submitted to the Assembly for approval for a period of one month.

E. ICH Operational Efficiency

ICH Standard Operating Procedure (SOP) of the ICH Working Groups (WGs) Revision

The Secretariat provided an update that the development of the Operational Guidebook, Coordinators Handbook and Secretariat Handbook has been paused due to resource constraints and efforts will recommence by the ICH Communications Manager in 2026.

MC Actions/Decisions:

- The MC noted the update, that activities on the SOP revisions will be resumed as a priority by the ICH Communications Manager after the onboarding within the ICH;
- The ICH Communications Manager would also work on other internal documents such as the Articles of Association and the RoPs.

ICH WG Expert Nominations Processes Update

The ICH Secretariat proposed updates to the processes for Expert Nominations to Established WGs and Ad-hoc Expert Nominations. The updates to the Ad-hoc Expert Nomination Process were put forward to introduce a biannual update at MC Technical TC 2 on the number and composition of ad-hoc experts, and reinforce regular review to ensure participation remains within scope. Updates to the Expert Nomination process for Established WGs aim to provide greater flexibility for WGs to access needed expertise, noting that WGs not meeting at an ICH Assembly may submit nominations at any time except during the freeze period prior to and including the Assembly meeting.

MC Actions/Decisions:

- The MC supported shifting from annual to bi-annual MC reporting by the Secretariat of the Ad-hoc Expert numbers to provide the MC with better oversight of the expert type that is not formally included in the EWG size;
- The MC noted the update on the Expert Nominations to Established WGs and the changes introduced to provide greater flexibility in accessing needed expertise by the EWG;
- The MC approved the updates proposed to the Expert Nominations to Established WGs, including allowing rolling nominations for WGs that are not meeting in person at the ICH Assembly.

ICH Technical Writers

The ICH Efficiency Team Members provided an update on the feedback received for the Technical/Regulatory Writing Services currently assigned to the E21 EWG, S13 EWG and Q6(R1) EWG. The EWGs provided consistently positive feedback on the Technical Writers, noting their role in maintaining document quality, meeting timelines, and supporting efficient drafting. There is strong consensus to continue their involvement in future harmonisation stages, including post-public consultation work. All groups expressed a clear need for continued Technical Writer involvement across subsequent harmonisation stages, including post-public consultation work.

MC Actions/Decisions:

- The MC noted the update and the positive feedback on technical writers for the E21 EWG, S13 EWG and Q6(R1) EWG with the overall feedback emphasizing the value of having a Technical Writer, noting that their respective contributions are very valuable for producing a well-written, coherent, and timely guideline;
- The MC supported the continued engagement of the Technical Writers for the aforementioned groups, noting that the involvement of a Technical Writer in WG activities, providing independent, unbiased, and professional input, allows experts to focus on consensus building and technical content rather than drafting logistics.

ICH Sustainability and Pipeline Management

The ICH Efficiency Team Members presented the results and recommendations coming out of the ICH MC WG Pipeline and Sustainability Survey run between the Madrid meeting and Singapore meeting. The Survey results in general captured concerns on the current WG overall timelines and the need for measures to address delays. Based on the survey results 7 high-level recommendations, focusing on actionable items were developed for piloting before portfolio wide application with the aim to promote efficiency in the WG guideline development.

MC Actions/Decisions:

- The MC noted robust survey responses were received from all MC Members;
- The MC supported high-level recommendations for further development by the Efficiency Team to be discussed further at the Interim meeting in March 2026:

- The MC requested during the development of the recommendations that the Efficiency Team look at prioritizing the recommendations and providing further details of the risks per recommendation;
- The MC approved the revised Concept Paper Template, Work Plan template and Assembly/MC Reporting Template for use from 2026.

F. Training

ICH Training Associates

The ICH Secretariat provided an update on ongoing work with the current Training Associates covering progress on training deliverables and future strategy.

MC Actions/Decisions:

- The MC noted the update from the Training Co-Lead and the ICH Secretariat on training activities, including progress on Training Associates' deliverables, development of e-learning modules, and considerations for the future ICH training strategy;
- The MC noted the status of the development of training materials by ICH Training Associates on the ICH Q3 series, ICH Q5 series, ICH E6(R3), ICH E8(R1), ICH Q8-12 Guidelines, with Secretariat foreseeing majority of the work to be finalised in Q1 2026. The MC noted that no new portion of work will be included once the current deliverables are completed;
- The MC noted that recent *Step 2* presentations (Q3E, E20, E21, M4Q(R2)) and *Step 4* presentations (M14) and training materials (E11A, Q2(R2), Q14, E2B(R3)) developed by ICH Working Groups have been published on the ICH website.

ICH Training Strategy

The Training Co-Leads presented the updated ICH Training Vision and Strategy, outlining plans for timely, globally harmonised guideline implementation. The ICH Secretariat provided an update on the AI tool pilot, confirming the proposed platform to support Working Groups in developing training materials, and introduced the Master Template as the standard framework for training content creation.

MC Actions/Decisions:

- The MC supported the proposed Training Vision and Strategy with the understanding that the performance metrics are provisional and will be tested for feasibility before being finalised. The strategy aims for timely, globally harmonised implementation of guidelines by the mid-2030s, including:
 - Transitioning to a lean, sustainable model leveraging AI tools and internal resources;
 - Standardising templates and initiating front-loaded training development from *Step 2*;
- The MC endorsed the implementation plan for the AI tool to support training material development, including:
 - A one-year pilot phase starting by December 2025/January 2026;
 - Development of onboarding materials (Quick Start Guide, FAQs, short videos);
 - Phased rollout to Working Groups and evaluation checkpoints (midpoint survey and final review);
- The MC approved the Working Group Master Template as the standardised framework for developing training materials, which can also be utilised for course creation;
- The MC noted feedback from WGs (M11, Q2(R2), Q14, M14) on AI-generated content, recognising its value as a starting point but requiring expert review for accuracy;

- The MC supported continued exploration of interactive formats and multilingual functionality for broader accessibility.

ICH Funding for Regulatory Training

The ICH Secretariat updated the MC on the status of regulatory trainings postponed to 2025 and presented new funding requests from ICH Regulatory Members and Observers for trainings planned in late 2025 and early 2026. The MC reviewed these applications as part of the third decision point.

MC Actions/Decisions:

- The MC approved two applications submitted under the 2025 programme for ICH funding at the third decision point;
- Pending approval of the 2026 Budget, the MC endorsed the applications submitted under the 2026 programme for ICH funding.

G. ICH-PIC/S Collaborations

The MC Chair and Secretariat provided an update on ICH-funded training previously approved for PIC/S under the multi-year training plan and shared outcomes of recent discussions regarding future funding arrangements. The update highlighted ongoing collaboration efforts and considerations for sustaining training support within the agreed budget framework.

MC Actions/Decisions:

- The MC noted recent discussions between the ICH Secretariat and PIC/S, with some exchanges also involving ICH Chairs, focusing on two key areas:
 - a) Training – an update provided on collaboration efforts with PIC/S, particularly regarding ICH funding to support the development of training modules for the PIC/S Pharmaceutical Inspectorate Academy learning management system. This includes developing and refining modules on both well-established guidelines (e.g., Q7, Q9, Q10) and newer ones (e.g., Q12, Q13);
 - b) Best Practices Sharing – identifying mechanisms to exchange experiences on governance, cybersecurity, AI integration, and IT tools to enhance operational efficiency, as well as approaches for compliance monitoring and implementation support.;
- The MC endorsed the continuation of collaboration on training and approved the funding for 2025. The MC agreed that all PIC/S related training requests for 2026 and subsequent years under the PIC/S Multiannual Training Proposal will be reviewed and decided annually.

H. Oversight of ICH Working Groups

Q9(R1) Training Group: Training on Quality Risk Management (Rapporteur: Dr. O'Donnell – EC, Europe; Regulatory Chair: Mr. Viehmann – FDA, United States)

The Q9(R1) Training Group Rapporteur and Regulatory Chair provided a report on the positive and efficient experience working as the first pilot Training Group, developing training material fully by consensus without quorum rules. Early agreement on simple ground rules and a clear assignment plan with lead, co-lead and support roles provided clarity and accountability. Flexibility was key for continuous progress, after initial monthly meetings proved too slow, the group shifted to consecutive half-day teleconference workshops and small twice-weekly informal working sessions (consisting of 3–5 members), which enabled steady progress on revising extensive legacy training materials while keeping all members informed and engaged.

The group noted that its small size, consensus-based agile approach was more effective for developing training content than previous work under larger EWGs/IWGs. Having most Training Group members come from the

earlier EWG/IWG was also essential, as experts understood the rationale for the Q9(R1) revisions and were already invested in the quality of the training materials.

The group highlighted broader reflections: Training Groups, given their thorough knowledge of both the guideline and the training materials, could add value by advising on training strategies, stakeholder learning needs, delivery methods (including possible use of AI) and approaches to encourage uptake of ICH training resources. The group also observed that early and ongoing collaboration with third-party Training Associates would help identify content needs and support development of high-quality training materials.

MC Actions/Decisions:

- The MC noted the feedback provided by the Q9(R1) Training Group (TG);
- The MC requested the Q9(R1) TG draft a Points to Consider Document including positive and challenging experiences and share the ground rules developed by the TG, including the criteria by which membership of the TG was decided.
- The MC recognized the importance of having a broader training strategy, including when and where trainings could be delivered and how to ensure wide stakeholder outreach using a design thinking approach.

M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) (Rapporteur: Dr. Pei – FDA, United States; Regulatory Chair: Dr. Manent– EC, Europe)

The M11 EWG Rapporteur and Regulatory Chair provided the MC with an update on the status and development of the M11 Training Materials. Planning began during the Prague meeting in 2023 due to the expected challenges in implementing the M11 Guideline, Technical Specification, and Template.

Following the loss of Training Associate support in 2024, the subgroup shifted direction and explored industry-based training resources, identifying the use of a training tool as a suitable tool for developing 8 interactive training modules.

Before arriving in Singapore, the training subgroup completed the draft storyboards for the 8 M11 Training Material Modules. During the Singapore meeting, the EWG plans to review and address all comments on these storyboards.

The objective of the training package is to provide clear and comprehensive guidance on implementing M11. The intended audience is broad and includes anyone involved in clinical trials including medical writers, clinical operations staff, non-commercial sponsors, regulators, ethics committees, data scientists, and others.

MC Actions/Decisions:

- The MC approved the development of the 8 M11 EWG interactive training modules to provide comprehensive training on ICH M11 implementation and requirements;
 - Step 4 Presentation
 - Template conventions, amendments, and Trial Oversight
 - Statistical considerations (e.g., objectives, estimands)
 - Risk benefit assessment
 - Trial design (e.g., schema, schedule of activities)
 - Trial intervention
 - Safety (e.g., adverse events, serious adverse events)
 - Technical specification & Terminology module
- The MC noted the M11 EWG training materials are expected to be completed on schedule by May 2026.
- The MC noted that the M11 EWG leveraged and found benefit in using an industry training specialist to help develop the training materials given the lack of expertise within the EWG.

- The MC supported that the Training Leads further consider use of an industry training specialist and resources noting there may be challenges linked to tool licenses and maintenance of the materials developed with industry resources.

M15 EWG: General Principles for Model-Informed Drug Development (Rapporteur: Dr. Karlsson – EC, Europe; Regulatory Chair: Dr. Zhu – FDA, United States)

The EC, Europe Technical Coordinator, clarified the scope of the proposed M15 training materials, provided an update on progress toward a detailed training plan targeting completion in November 2026, and raised the question of whether a smaller footprint training group could be used or whether the full M15 EWG would be needed.

The EC, Europe Technical Coordinator outlined that the EWG will prioritize finalization of the draft Guideline during the meeting in Singapore, with *Step 3/4* sign-off expected in the weeks following the meeting. It was also clarified that the training plan will be discussed and finalized in Singapore and shared with the MC in due course.

The EC, Europe Technical Coordinator further noted the MC’s earlier consideration of a smaller Training Group, similar to Q9(R1), was shared with the M15 Rapporteur for consideration to advise on the feasible size, taking into account the minimum number of experts needed to effectively deliver the training materials within the agreed timeline.

MC Actions/Decisions:

- The MC noted the update on the M15 EWG activities and their prioritization of finalizing the guideline for *Step 3*.
- The MC noted the update on the M15 EWG training material including the need to develop case studies.
- The MC noted that the M15 EWG will submit a detailed training plan after its finalization.

Cell and Gene Therapies Discussion Group (CGTDG) (Rapporteur: Dr. Francissen – BIO; Regulatory Chair: Dr. Eacho – FDA, United States)

The CGTDG Rapporteur presented the activities of the CGTDG in the development of the final recommendation paper. The group was established to advance ICH harmonization efforts for ATMPs, with an emphasis on mature modalities such as in vivo viral vector–based gene therapies (e.g., AAV products) and ex vivo genetically modified cell therapies (e.g., CAR T-cell products). The CGTDG’s mandate included aligning on high-level principles for ATMP-specific considerations, developing a strategic framework for future harmonization work, and identifying recommendations across clinical, non-clinical, and quality disciplines.

To support this work, the CGTDG reviewed existing ATMP regulatory frameworks across all represented regions to assess the global landscape and collaborated with the Q1 and Q6(R1) EWGs. This process resulted in seven recommendations for future ICH guideline development or revision:

1. Annex to ICH Q5E on comparability of ATMPs following manufacturing changes
2. New ICH E guideline on long-term follow-up (LTFU)
3. Annex to ICH Q11 on development and manufacture of ATMPs
4. New ICH S guideline on nonclinical evaluation of ATMPs
5. Annex to ICH E8 on considerations for early-phase/exploratory clinical trials for ATMPs
6. Annex to ICH Q5A(R2) addressing viral safety for cell-based ATMPs
7. Inclusion of ATMP case studies in training materials for ICH Q2 and Q14 on unconventional analytical method development and validation

Given resource considerations, dependencies with ongoing guideline work, and the rapidly evolving ATMP field, the sequencing and initiation of work on these recommendations will require careful planning.

MC Actions/Decisions:

- The MC endorsed in principle the high-level principles document and the strategic roadmap of 7 ATMP topic recommendations with a focus on mature modalities, such as *in vivo* viral vector-based gene therapies with the first recommendation commencing with the Q5E Annex new topic adopted by the Assembly in 2025.
- The MC requested, noting that the ICH portfolio is currently at bandwidth, that the CGTDG develop a visual sequencing roadmap which captures content and expert dependencies, linked to the ICH New Topic Process.
- The MC approved retaining the ATMP guidelines captured in Annex 2 noting the explanatory note indicates “*There is no expectation for ICH to maintain or update this list in the future.*”
- The MC noted the high-level principles captured in the CGTDG Recommendations Paper principles are not to be understood as scientific guidance but provide underlying rationale for the need of new guidelines or revisions.
- The MC noted that the recommended new guidelines were put forward after review of all the ICH guidelines across QESM and interaction with the Q1 and Q6(R1) EWGs;
- The MC noted that CGTDG will be disbanded following the finalisation of all pending deliverables.

M18 EWG: Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs (Rapporteur: Dr. Yim – FDA, United States; Regulatory Chair: Mr. Neto – ANVISA, Brazil)

The M18 EWG Rapporteur and Regulatory Chair provided the MC with an update on the context of the M18 guideline and the status of work. Comparative Efficacy Studies (CES) are conducted by default in biosimilar development, but they are expensive, take multiple years, and place a resource burden on development. Given modern analytical technology and negligible differences in efficacy, CES are increasingly viewed as no longer scientifically necessary in most cases. Several regulatory authorities have issued statements suggesting CES may not be needed, but the lack of clarity and convergence on when CES may still influence biosimilar programs shows the need for harmonized guidance.

After EWG establishment and before the Singapore meeting, the co-author group progressed the Concept Paper which was shared with the EWG in early September. Consensus towards the Concept Paper was not reached before Singapore due to differing comments of M18 Scope. During the meeting, the EWG aligned, reached consensus, submitted the Concept Paper to the MC, and began work on the Workplan, guideline content, and strategy.

MC Actions/Decisions:

- The MC noted the report out from the M18 Rapporteur and Regulatory Chair.
- The MC noted that the M18 EWG resolved remaining issues of scope of the Concept Paper and have reached consensus.
- The MC will review the submitted and if no further comments have been received approve the Concept Paper¹

¹ Post Meeting Note: No MC comments were received and therefore the M18 Concept Paper was accepted as endorsed by the ICH MC on the 19 of November 2025

I. ICH Technology Task Force

The MC Chair provided an update on the work of the recently established ICH Technology TF, whose remit was approved by the ICH MC in September 2025. The MC Chair stressed that to ensure ICH Mission Readiness, ICH requires a secure platform to support efficient and effective harmonisation work that may require confidential data sharing, and discussions and collaboration amongst regulators, addressing emerging technical harmonisation challenges including harmonised implementation of guidelines, and modernising guideline development processes. This platform will future-proof ICH operations and ensure consistent application of guidelines across regions.

As per the remit, the Technology TF will analyse platform capabilities based on use cases, identifying technical, IT, and security requirements, legal considerations, and estimated costs:

The primary focus of the technology platform is to support ICH work to advance harmonization of scientific and technical standards including, for example, support for the development of ICH guidelines and ensuring harmonisation in their application via the implementation of guidelines across regions.

Once established, the platform may also enable regulatory collaborative assessment, work-sharing, and reliance activities that are conducted and governed outside of ICH.

The MC was informed that the platform governance, operational oversight, and establishment are out of scope of the remit of the Task Force. In addition, the proposed solution should be already commercially available with minimal customization, enabling secure collaboration and compliance with legal and security requirements.

MC Actions/Decisions:

- The MC noted the update and that use cases were endorsed and would be further developed into more detailed descriptions to identify requirements for platform capabilities.
- The MC also acknowledged the need to keep all ICH Members informed about these developments via updates to the Assembly;
- The MC supported that the platform must respect proprietary data, confidentiality, and legal/security requirements across regions;
- The MC supported that as a next steps, the TF will refine use cases and analyse platform capabilities to fully support ICH mission readiness and harmonisation goals with interim status update on progress to be provided at first MC Policy I TC, with a final Report on the document-sharing process, technical, ethical, legal and security requirements implied by the use cases, anticipated value to ICH community and estimated costs to be delivered for March 2026 Interim Meeting.

J. MedDRA Matters

The MC was joined by the MedDRA Steering Committee (SC) for a joint session, with the MedDRA SC Vice-Chair, acting as MedDRA SC Chair sharing an update on MedDRA matters and recent discussions of the MedDRA SC at the Singapore meeting.

MC Actions/Decisions:

- The MC was informed of the election of the MedDRA SC Chairs: Dr. Ana Cochino (EC, Europe), as MedDRA SC Chair and Ms. Charlotte James (MHRA, UK), as MedDRA SC Vice-Chair;
- The MC noted progress on collaboration with the Uppsala Monitoring Center to develop an AI-based MedDRA coding engine;
- The MC noted that the Business Continuity Plan, developed to outline the MSSO's (Maintenance and Support Services Organisation) processes and procedures for managing potential disruptions - such as cyber security incidents, ransomware, phishing attacks, leaks of sensitive information, technical

failures, natural disasters, pandemics, war, sanctions impact, lawsuits, significant changes in MedDRA subscriptions, and major scientific quality issues in a MedDRA release - continues to be regularly updated as new scenarios are identified;

- The MC approved the SC recommendation to extend the current MedDRA Service Agreement, subject to ICH Assembly approval.

K. Finance

The MC was updated by ICH Finance and Procurement Director, on the work of the Finance Committee (FC), which included a report-out from the FC meeting held in Singapore on 15 November. Based on preparatory work of the zero-based 2026 Budget and the Plan 2026-2030 and the discussions within the FC, the update of the scenarios agreed in Madrid were presented to the MC.

MC Actions/Decisions:

- The MC confirmed the legality of financing ICH core activities from MedDRA fund surplus. Further alignment of respective ICH AoA and MedDRA RoPs will be needed;
- The MC endorsed the financial contribution to PIC/S for 2025. Further financial support to PIC/S for 2026 and 2027 will be subject to MC and Assembly approval in respective years;
- The MC noted that the ICH membership fees for 2027 and the MedDRA subscription fee for 2026 remain unchanged;
- The MC was informed about planned optimisation of Secretariat costs following the review of contractual commitments, revised training strategies, and updated assumptions;
- The MC approved the 2026 Budget and the 2026–2030 Plan. Overall, the 2026 ICH Association Budget and the 2026–2030 Plan support a sound and balanced financial position for the organisation;
- The FC will hold TCs and a meeting in preparation for proposals to be presented to the MC in Rio de Janeiro, Brazil.

ICH Modernisation Activities

The MC was updated by ICH Finance and Procurement Director on recent activities related to the IT modernisation of the ICH Secretariat, initiated in 2024, leveraging on the use of modern IT tools and solutions for improved process efficiency, data security and cost optimisation.

MC Action/Decision:

- The MC noted the recent migration of the Secretariat data and emails to the cloud, use of website analytics and AI enhanced translation tools. The MC also took note of the plans to upgrade the global ICH platform and the ICH website redesign.

L. Organisation of Meetings

The ICH Secretariat provided an update on the organisation of the next meetings.

MC Actions/Decisions:

- The MC noted the ICH Secretariat report on the organisation of next ICH meetings, including on the level of participation in the November 2025 meeting in Singapore;
- The MC approved the proposed process for Ad-hoc Expert late meeting requests, extending the window from 30 to 60 days after meeting registration opens to provide more flexibility, with a MC Policy 2 TC being the latest point at which the MC may approve an ad-hoc expert to attend the meeting in person;

- The MC approved the proposed Working Groups Meeting Cancellations Policy, with a Working Group wishing to withdraw their participation at the Biannual Meeting or Interim Meeting must submit a written request to the ICH Secretariat within one (1) month after registration opens at the latest, which would allow approximately ninety (90) days before the scheduled meeting date — sufficient to cancel associated arrangements without incurring fees and to nominate replacement WGs if required. The request should include a written justification detailing the reasons for withdrawal for MC’s review and approval. In addition, during the selection process of WGs to meet at the Biannual Meeting and Interim Meeting, the MC should discuss and define any potential back-up WG in case there is a WG meeting cancellation, noting this should be based on WGs work status and justified need to meet;
- The MC noted the following dates for the TCs ahead of the Rio de Janeiro 2026 meetings:
 - TC 1: 12 February 2026
 - TC 2: 9 April 2026
 - TC 3: 28 April 2026
- The MC agreed that a post-meeting TC is not required; therefore, the placeholder for 8 December 2025 will be removed.

M. ICH External Collaboration

MC Actions/Decisions:

- The MC noted a draft standardised MoU intended as a template for collaboration with different organisations on efforts for global harmonisation, outreach activities, training, and other programs supporting the harmonised implementation of ICH guidelines. The MC supported further revisions to the template to allow tailoring to better match the objectives and scope of different collaborations, with a revised version to be shared with the MC for comments after the meeting;
- The MC supported ensuring that copyright for presentation materials used in these events is properly addressed in the MoU, allowing materials to be included in the training library after the events. Standardizing the presentation template with a copyright notice is recommended, and discussions on copyright wording will be brought to the MC soon, with input from the Communication Manager to ensure best practice.

N. Elections of MC Chairs and Vice-Chair

MC Action/Decision:

- Mr. Diasuke Koga (MHLW/PMDA, Japan) and Dr. Theresa Mullin (FDA, United States) were elected as MC Chair and Vice Chair respectively, to serve for a 2-year term from the end of the Singapore meeting.

O. Q4B Maintenance

Representatives from the Pharmacopeial Discussion Group (PDG) provided an update to the MC on the implementation of the Q4B pilot phase, including key observations and challenges identified during the evaluation and maintenance of the Q4B Annexes. The PDG highlighted challenges with maintaining the Q4B annexes due to the increased number of ICH Regulatory Members and pharmacopeia for harmonization. The pilot showed that the current maintenance process is no longer sustainable, given the extensive effort required to compare local pharmacopeial texts with the PDG harmonized text and to assess regulatory interchangeability.

MC Actions/Decisions:

- The MC noted the Representatives from the Pharmacopeial Discussion Group (PDG) update on the implementation of the Q4B pilot phase, including key observations and challenges identified during the evaluation and maintenance of the Q4B Annexes;
- The MC confirmed ICH implementation of Q4B Annexes may be identified either through full adoption of the Q4B texts (Standard approach) or through a parallel approach when local texts are used accompanied by a statement acknowledging that the Q4B text is also acceptable;
- The MC noted that PDG will propose a modified approach to the evaluation of PDG harmonisation based on feedback received from the MC.

P. WGs Meeting in Rio de Janeiro, Brazil

List of Current ICH Working Groups		MC Decision		Interim Meeting March 2026
		Approved	No. Days	Approved
Efficacy (3)	E2B(R3) EWG/IWG	<input type="checkbox"/>		
	E6(R3) EWG	<input type="checkbox"/>		
	E6(R3) EWG + Annex 2 Sub-group	<input type="checkbox"/>		
	E6(R3) Annex 2 Sub-group	<input type="checkbox"/>		
	E14/S7B IWG	<input type="checkbox"/>		
	E20 EWG	<input type="checkbox"/>		
	E21 EWG	●	4	
	E22 EWG	●	4	
	E23 EWG	●	4	
	E24 EWG	<input type="checkbox"/>		
Multidisciplinary (4)	M1 PtC WG	<input type="checkbox"/>		
	M2 EWG	<input type="checkbox"/>		●
	M4Q(R2) EWG	●	5	
	M7(R3) Maint. EWG/IWG	<input type="checkbox"/>		
	M7 Sub-Group	●	4	

List of Current ICH Working Groups		MC Decision		Interim Meeting March 2026
		Approved	No. Days	Approved
	M8 EWG/IWG	<input type="checkbox"/>		
	M11 EWG	<input type="checkbox"/>		
	M13 EWG	•	5	
	M15 EWG	<input type="checkbox"/>		
	M16 EWG	<input type="checkbox"/>		
	M18 EWG	•	4	
Quality (4)	Q1 EWG	•	5	
	Q3C(R10) Maint. EWG	<input type="checkbox"/>		
	Q3E EWG	•	4	
	Q5E Annex EWG	•	4	
	Q6(R1) EWG	•	5	
Safety (1)	S1B(R1) IWG	<input type="checkbox"/>		
	S13 EWG	•	5	
Total WGs approved to meet		12		1 <small>(5 approved in Madrid, Spain 2025 see summary below)</small>

MC Decisions/Actions:

- The MC approved the following 12 WGs to meet face-to-face at Rio de Janeiro, Brazil June 2026 meeting:
1. E21 EWG
 2. E22 EWG
 3. E23 EWG
 4. M4Q(R2) EWG
 5. M7 Sub-Group
 6. M13 EWG
 7. M18 EWG
 8. Q1 EWG
 9. Q3E EWG
 10. Q5E Annex EWG
 11. Q6(R1) EWG
 12. S13 EWG

- The MC approved the following EWGs to hold a 5-day meeting: M4Q(R2) EWG; M13 EWG; Q1 EWG; Q6(R1) EWG; and S13 EWG;
- The MC approved the M2 EWG to meet at an interim meeting in March 2026 for 4 days noting synergy and potential need for collaboration with other WGs meeting on site;
- Therefore, the following 6 WGs to meet at an interim meeting in 2026 for 4 days:
 1. E20 EWG
 2. M4Q(R2) EWG
 3. M8 EWG/IWG
 4. M16 EWG
 5. Q3E EWG
 6. M2 EWG

Q. AOB

M13 EWG and M17 EWG: Bioequivalence for Immediate-Release Solid Oral Dosage Forms and Bioequivalence for Modified-Release Products

The MC discussed that noting the overlap of the expertise on the M13 A-C Guideline Series and the upcoming M17 Guideline which is to be formed when the M13C draft Guideline reaches *Step 2a/b* it would be beneficial if the M17 work could be integrated into the M13 EWG without the expansion of the M13 Guideline Series Scope.

MC Actions/Decisions:

- The MC agreed that the M13 EWG have demonstrated an excellent capacity to manage their workload and strategically move from one guideline to the next utilizing the public consultation periods to progress on guideline development in parallel.
- The MC noted a similar modality which was used for Q2(R2)/Q14 EWG may be suitable for M13 and M17 EWG noting the natural continuity of subject matter resulting in a potential M13/M17 EWG which is to be confirmed with M13 EWG.

ICH E21 EWG Use of AI for comment processing and current ICH position on use of AI

In the context of the E21 EWG activities and the potential use of an internal Technical Writer AI tool for processing comments received during public consultation, a request to authorize the use of the AI tool was put forward to the ICH Secretariat prior to the Singapore meeting. As the ICH does not currently endorse a specific AI tool (noting the Secretariat is developing a AI Public consultation methodology, based on the pilot exercise conducted by M2 EWG, to be put forward in 2026 for MC approval) and no strict guidance has been provided to the EWGs regarding how the AI tools and what data should or should not be uploaded, the E21 EWG were not provided a sufficient response to explicitly authorize to use the internal AI tool. Additionally, as many EWGs have already begun incorporating AI methods into their workflow to aid the development of the guidelines particularly in the processing of the comments the need for MC guidance is requested.

MC Actions/Decisions:

- The MC approved authorization of the use of the Technical Writer internal AI to aid processing of E21 comments to not delay the EWG while the Secretariat develop the internal ICH AI Public Consultation methodology;
- The MC approved for the Secretariat to develop a “Best Practices”/guardrails document to be provided to all WGs to ensure that EWGs follow good data protection practices;

- The MC noted a suggestion put forward by Health Canada, Canada for EWGs who are already using AI to informally share information regarding prompt writing etc. to strengthen the overall AI use. A platform for experience sharing is to be determined by the ICH Secretariat.

R. Press Release

MC Actions/Decisions:

- The MC noted the process for the development and approval of the ICH Press release in line with the Assembly RoP requiring publication within one week of the ICH meeting.

S. Next Teleconferences & Meetings

MC Action/Decision:

- The MC noted the scheduling of teleconferences in preparation of its next meeting in June 2026 with the following dates:

12 February 2026	MC Policy 1 TC
9 April 2026	MC Policy 2 & Technical TC
28 April 2026	MC Policy 3

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

26 – 29 March 2026 Interim Meeting in Amsterdam, Netherlands
30 May - 3 June 2026 in Rio de Janeiro, Brazil
14 – 18 November 2026 in Prague, Czech Republic
12 - 16 June 2027 in Seoul, South Korea
13 – 17 November 2027 in Americas (location to be confirmed)