ICH Press Release

ICH Assembly Meeting, Singapore, November 2025

Geneva, 26 November 2025

The Assembly of the International Council for Harmonisation (ICH) met in person on 18-19 November 2025 in Singapore, in parallel with meetings of 12 Working Groups and preceded by meetings of the ICH Management Committee (MC) and the MedDRA Steering Committee (SC).

ICH is delighted to welcome NAFDAC, Nigeria and SAHPRA, South Africa as new ICH Members, in addition to two new Observers: DIGEMAPS, Dominican Republic and Philippine FDA, Philippines, bringing ICH to a total of 25 Members and 41 Observers.

Elections

The Assembly, Management Committee and MedDRA Steering Committee Chair and Vice-Chair elections were held during the meeting, which saw the following appointments:

- Dr. Gabriela Zenhäusern (Swissmedic, Switzerland) and Mr. Jeffrey Skene (Health Canada, Canada) were elected as Assembly Chair and Vice-Chair respectively to serve a two-year term;
- Mr. Daisuke Koga (MHLW/PMDA, Japan) and Dr. Theresa Mullin (FDA, United States) were elected as Management Committee Chair and Vice Chair respectively to serve a two-year term;
- Dr. Ana Cochino (EC, Europe) and Ms. Charlotte James (MHRA, UK) were elected as MedDRA Steering Committee Chair and Vice-Chair to serve respectively for a two-year and one-year term.

Progress on ICH Guideline Development and Important Revisions

The Assembly was updated on the MC approvals of the Concept Papers for the new ICH Guidelines E23 on *Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a focus on Effectiveness of Medicines* and M18 on *Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs.* In addition to receiving reports on progress made at ICH Working Group meetings in Singapore, the Assembly also noted significant milestones reached by several Working Groups since the last ICH meeting, which included important updates to both new ICH Guidelines and ICH Guidelines currently under revision.

Final Guidelines adopted by the Assembly *(Step 4 of the ICH process)*

- The M11 Guideline on *Clinical Electronic Structured Harmonized Protocol (CeSHarP), M11 Clinical Implementation Template and M11 Technical Specification* was adopted and has now entered the implementation phase. The Guideline describes general protocol design principles and approach used to develop the separate associated documents, the ICH M11 Clinical Electronic Structured Harmonised Protocol Template and the Technical Specification that are acceptable to all regulatory authorities of the ICH regions. The Template presents the format and structure of the protocol, including table of contents, common headers, and instructions for content. The Technical Specification presents the data elements and technical attributes (e.g., definition, conformance, cardinality) that enable the interoperable electronic exchange of protocol content.

- The ICH E2D(R1) Guideline on *Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports* was adopted and has now entered the implementation phase. The guideline provides recommendations that are harmonised to the extent possible given differences in post-market safety reporting requirements among ICH regions.

- The ICH M14 Guideline, *General Principles on Plan, Design and Analysis of Pharmacoepidemiological Studies that Utilise Real-World Data for Safety Assessment of Medicines*, was adopted and has now entered the implementation phase. The Guideline provides internationally harmonised recommendations to plan, design, analyse and report non-interventional pharmacoepidemiological studies that generate real-world evidence for post-marketing safety submissions.

Draft Guidelines endorsed by the Assembly *(Step 2b of the ICH process)*

- The ICH E22 draft Guideline *General Considerations for Patient Preference Studies was adopted* and entered the public consultation period. This draft guideline outlines general considerations about the use, design, conduct, analysis, and submission of Patient Preference Studies aimed at informing drug development, regulatory submission and evaluation, drug approvals and maintenance of such approvals.
- The ICH Q3E draft *Guideline for Extractables and Leachables* and supporting document was adopted and entered the public consultation period. The draft guideline presents a framework and process for the assessment and control of leachable impurities to further expand the existing ICH guidelines on impurities, including impurities in new drug substances (ICH Q3A) and new drug products (ICH Q3B), residual solvents (ICH Q3C), and elemental impurities (ICH Q3D), as well as DNA reactive (mutagenic) impurities (ICH M7).
- The ICH E20 draft Guideline on *Adaptive Design for Clinical Trials* was adopted and entered the public consultation period. The draft Guideline provides guidance on confirmatory clinical trials with an adaptive design intended to evaluate a treatment for a given medical condition within the context of its overall development program.

MedDRA

MedDRA is now available in 27 languages, including the newly added Norwegian, Slovak, and Slovenian. The MedDRA Learning Management System (LMS), launched in early 2025, had already attracted approximately 1,500 users by the end of September and the LMS now supports six languages (Chinese, French, Korean, Russian and Spanish). Reflecting MedDRA's commitment to meeting the evolving needs of its global user base, training initiatives have increased with a strong focus on Latin America, the Middle East, and Africa.

Training

The Assembly was also updated on ICH training-related activities, including the publication of the training module *Interpretation and Application of ICH E6(R3): Good Clinical Practice Guideline - Module 1: Introduction and Foundational Concepts*, released in October 2025.

In addition, the Assembly was informed of a new ICH training strategy to support ICH Working Groups in their training efforts. This strategy includes the use of AI tools to help streamline the development and delivery of training materials, while also enhancing interactivity and learner engagement.

ICH Award

During the meeting, the ICH Assembly gave the third biennial ICH Awards for Outstanding Contributions to ICH Harmonisation for Better Health, with 5 recipients of the 2025 awards recognised for their significant and sustained contributions in ICH leadership roles in ICH Working Groups.

The names of the awardees are listed below and will be published on the ICH website.

- Dr. Johannes Blümel (EC, Europe)
- Dr. Yukio Hiyama (MHLW/PMDA, Japan)
- Dr. Masayuki Mishima (JPMA)
- Dr. Lutz Mueller (EFPIA)
- Dr. Joel Welch (FDA, United States)

Communication

The Assembly took the opportunity of this meeting to launch a campaign to mark 35 years since the founding of ICH and 10 years since the establishment of ICH as an Association, with the creation of an official ICH LinkedIn account to enhance visibility and engagement.

The next ICH Assembly meeting is planned for 2-3 June 2026 in Rio de Janeiro, Brazil.

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About ICH

The **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use** (ICH) brings together regulatory authorities and the pharmaceutical industry to discuss the scientific and technical aspects of pharmaceutical development.

Through working groups of regulatory and industry experts, ICH produces harmonised technical requirements to ensure the development and registration of safe, effective and high-quality medicines for human use. Guidelines are developed through scientific consensus with public consultation. ICH also produces a standardised reference tool for medical terminology (MedDRA) and electronic standards for the transfer of regulatory information (ESTRI).

Since it was created in 1990, ICH has finalised nearly 80 Guidelines that are increasingly applied by regulatory authorities around the world. ICH has 25 members, 41 observers, and a network of more than 700 experts globally. The ICH Association was registered as a non-profit legal entity under Swiss law in 2015. **ich.org**

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