ICH Association

2025 Annual Report

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Prepared by the ICH Secretariat with ICH Management Committee approval

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Letter from Assembly Chair and Vice-Chair

2025 was truly a milestone year for ICH. It was a year of growth, change and achievement that marked 35 years since ICH was created and 10 years since ICH became an independent, registered non-profit association.

Ms. Lenita Lindström (EC, Europe), who steered the ICH Assembly through its first 10 years as a formally independent entity, stepped down as ICH Assembly Chair in November 2025. On behalf of all Members and Observers, we offer our heartfelt thanks for her extraordinary dedication and highly effective leadership. Ms. Lindström will continue to serve as a representative of EC, Europe going forward.

Elections were held for all ICH governance bodies in November 2025. For the ICH Management Committee, this resulted in a newly elected Chair, Mr. Daisuke Koga (MHLW/PMDA, Japan) and Vice-Chair Dr. Theresa Mullin (FDA, United States). The ICH Secretariat also saw a change in leadership with the appointment in March 2025 of Ms. Géraldine Lissalde-Bonnet as Secretary-General.

ICH continues to grow, reflecting the importance of Guideline harmonisation for all regions globally. In 2025, we welcomed two new Members – NAFDAC, Nigeria and SAHPRA, South Africa – and five new Observers: DIGEMAPS, Dominican Republic; DINAVISA, Paraguay; MOH, Kuwait; Philippine FDA, Philippines and SRS, El Salvador.

During the year, the ICH Assembly adopted four finalised Guidelines for implementation covering several evolving and relevant topics: ICH Expert Working Groups concluded the first revision of ICH E2D(R1) on post-approval safety data and the third revision of ICH E6(R3) Good Clinical Practice, as well as two new Guidelines, ICH M11 on electronic harmonised standards for the format and content of clinical trial protocols and ICH M14 on the use of real-world data for safety assessment of medicines. In addition, eight draft Guidelines were approved for public consultation and four new topics were endorsed.

None of the important harmonisation work of ICH could happen without the singular engagement of ICH Members and Observers, the hundreds of technical and scientific experts named to ICH Working Groups and all those who implement ICH Guidelines.

In 2025, ICH recognised the particular efforts of five valued experts with awards for Outstanding Contributions to ICH Harmonisation for Better Health.

Looking ahead, priorities in 2026 include the development of a strategic roadmap, including revisions to ICH's new topic selection process, and the development of a strategic collaboration framework to guide organisational partnerships. As newly elected Assembly Chairs, we look forward to the work of this important global collaboration to harmonise technical and scientific Guidelines in 2026 and the years to come.

Dr Gabriela Zenhäusern (Swissmedic, Switzerland), Chair

Mr Jeffrey Skene (Health Canada, Canada), Vice-Chair

ICH Mission

ICH brings together experts from regulatory authorities and the pharmaceutical industry to harmonise scientific and technical requirements globally for all stages of the pharmaceutical lifecycle to ensure safe, effective and high-quality medicines for patients in the interests of public health.

Read more about ICH's Mission

ICH Assembly in Singapore, November 2025

New Members & Observers

In 2025, ICH gained two new Members and five new Observers, bringing ICH to a total of 25 Members and 41 Observers and demonstrating the importance of harmonised pharmaceutical Guidelines in all regions.

ICH Members and Observers may be regulatory authorities, regional harmonisation initiatives, international pharmaceutical industry organisations or international organisations, according to the eligibility criteria for each.

New Members

- NAFDAC, Nigeria
- SAHPRA, South Africa

New Observers

- DIGEMAPS, Dominican Republic
- DINAVISA, Paraguay
- MOH, Kuwait
- Philippine FDA, Philippines
- SRS, El Salvador

Leadership Changes

The ICH Assembly met in person in May 2025 (ICH 50 in Madrid) and in November 2025 (ICH 51 in Singapore). At the November meeting, elections were held for ICH governance bodies, with the following results:

ICH Assembly

Dr. Gabriela Zenhäusern (Swissmedic, Switzerland), Chair

Mr. Jeffrey Skene (Health Canada, Canada), Vice-Chair

ICH Management Committee

Mr. Daisuke Koga (MHLW/PMDA, Japan), Chair

Dr. Theresa Mullin (FDA, United States), Vice-Chair

In March 2025, Ms. Géraldine Lissalde-Bonnet was newly appointed Secretary-General of the ICH Secretariat, tasked with setting and executing the strategic direction and priorities of the ICH Secretariat, as well as driving internal and external partnerships, and ensuring Secretariat efficiency and agility.

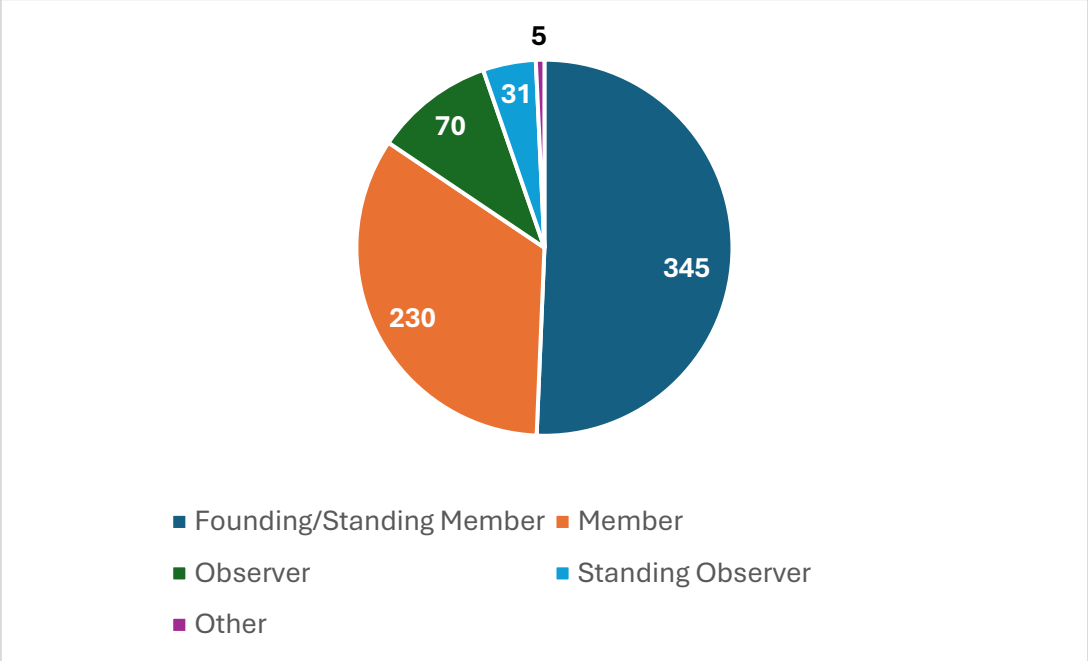
ICH Harmonisation Activities

Outstanding Contributions to ICH Harmonisation for Better Health

The work of ICH relies on the collaborative engagement of its Regulator and Industry Members and Observers. Between them, they nominate some of the world's top subject experts to lead and execute the core work of developing harmonised scientific and technical Guidelines through topic-specific Working Groups.

In 2025, ICH had 28 active Working Groups and two Subgroups involving nearly 700 experts from around the world.

Number of experts in ICH Working Groups by Nominating Party Type



At ICH 51 in Singapore, in November 2025, five experts were recognised for their significant and sustained contributions in leadership roles in ICH Working Groups with awards for Outstanding Contributions to ICH Harmonisation for Better Health presented to:

- 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)

ICH thanks all delegates and experts for their contributions throughout the year.

New Guidelines Adopted

ICH Guidelines are the core of the organisation's work and the result of bringing regulatory authorities and the pharmaceutical industry together to discuss the scientific and technical aspects of the pharmaceutical life cycle and reach a scientific consensus to produce harmonised guidance.

In 2025, four new or revised ICH Guidelines were finalised and adopted by the Assembly for implementation:

ICH E2D(R1) Guideline on Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports

This revision of a Guideline first adopted in 2003 provides guidance on definitions and standards for post-approval individual case safety reporting, as well as good case management practices.

ICH E6(R3) Revised Guideline on Good Clinical Practice

This important revision of one of ICH's Tier 1 Guidelines responds to a rapidly evolving clinical trial ecosystem with changes including additional clarity on scope, language to facilitate innovations in trial design, adoption of Quality by Design and proportionate risk-based approaches, learnings from innovative trials designs and lessons from studies in public health emergencies, with annexes for additional considerations.

ICH M11 Guideline on Clinical Electronic Structured Harmonized Protocol (CeSHarP), M11 Clinical Implementation Template and M11 Technical Specification

This Guideline provides the first internationally adopted, harmonised standard for the format and content of clinical study protocols. It will support consistency and efficiency across sponsors and the electronic exchange of protocol information.

ICH M14 Guideline, General Principles on Planning, Designing, Analysing and Reporting of Noninterventional Studies that Utilise Real-World Data for Safety Assessment of Medicines

This new Guideline addresses a gap in harmonised guidance on the development, conduct and regulatory use of non-interventional studies using real-world data. It will improve the ability of such study protocols and reports to be accepted across different regulatory authorities.

Draft Guidelines Endorsed for Regulatory and Public Consultation

Public consultation is an important step in the five-step process of ICH Guideline development. Broad regulatory and public consultation supports transparency and international collaboration, encourages input from diverse global stakeholders and ensures that Guidelines are practical, scientifically robust and globally relevant.

During the year, eight new and revised draft Guidelines were endorsed by the ICH Assembly and published on the ICH website as part of the public consultation phase:

- ICH Q1: *Stability Testing of Drug Substances and Drug Products*
- ICH Q3E: *Guideline for Extractables and Leachables* (and supporting document)
- ICH E20: *Adaptive Design for Clinical Trials*
- ICH E21: *Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials*

- ICH E22: *General Considerations for Patient Preference Studies*
- ICH M4Q(R2): *The Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use: Quality*
- ICH M11: *Clinical Electronic Structured Harmonised Protocol (CESHARP) – Revised Technical Specification*
- ICH M13B: *Bioequivalence for Immediate-Release Solid Oral Dosage Forms – Additional Strengths Biowaiver*

Working Group presentations published on draft & final ICH Guidelines

In 2025, ICH Expert Working Groups produced overview presentations on eight draft ICH Guidelines to support the public consultation process (*Step 2* of the Guideline development process) and on three finalised Guidelines following adoption *(Step 4)*.

Presentations on draft ICH Guidelines *(Step 2)*	**Presentations on final ICH Guidelines *(Step 4)***
ICH Q1: Stability Testing of Drug Substances and Drug Products	E2D(R1): Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports
ICH Q3E: Guideline for Extractables and Leachables	E6(R3): Good Clinical Practices
ICH E20: Adaptive Designs for Clinical Trials	M14: General Principles on Planning, Designing, Analysing, and Reporting of Non-interventional Studies That Utilise Real-World Data for Safety Assessment of Medicines
ICH E21: Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials	
ICH E22: General Considerations for Patient Preference Studies	
ICH M4Q(R2): The Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use: Quality	
ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)	
ICH M13B: Bioequivalence for Immediate-Release Solid Oral Dosage Forms	

New topics endorsed for harmonisation

Four new topics for harmonisation were endorsed by the ICH Assembly in May 2025:

- **ICH Q5E Annex**: Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process
- **ICH E23**: Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a Focus on Effectiveness of Medicines
    - Concept Paper endorsed by ICH Management Committee: November 2025
- **ICH E24**: Natural History Studies and Registry Data to Advance Rare Disease Drug Development
- **ICH M18**: Framework for Determining Utility of Comparative Efficacy Studies in Biosimilar Development Programs
    - Concept Paper endorsed by ICH Management Committee: November 2025

Guideline Training and Implementation

Training materials for ICH Guidelines

As part of efforts to achieve globally harmonised implementation of ICH Guidelines, materials are developed by ICH Working Groups and ICH Training Associates to ensure the availability of high-quality modules to support Guideline training.

The following Training Materials were developed and published in the **ICH Training Library** in 2025:

- **ICH Q2(R2)/Q14** – Module 1-7 – ICH Q2(R2) “Validation of Analytical Procedures” and ICH Q14 “Analytical Procedure Development”.
- **ICH Q5A(R2)** – Modules 0-3 – Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- **ICH E2B(R3)** – Module 1-2 – Electronic Transmission of Individual Case Safety Reports (ICSRs)
- **ICH E6(R3)** – Module 1 – Introduction and Foundational Concepts from Training Associates
- **ICH E11A** – Module 1 – Case Example: Development of a hypothetical TNF-alpha inhibitor "Drug X" for the treatment of polyarticular juvenile idiopathic arthritis (pJIA)

ICH-supported Training for Regulators

ICH maintains a training fund for Regulatory Members and Observers, which contributes to the cost of training regulatory staff on key ICH Guidelines. In 2025, 744 people from 14 national regulatory authorities were trained in six training sessions.

Party	Training Programme
East Africa Community	Foundations in Assessment of Quality of Biotechnological Products
EDA, Egypt	Training on Quality ICH Guidelines
Health Canada, Canada	ICH Q13 Implementation Training
NAFDAC, Nigeria	Good Clinical Practice
SFDA, Saudi Arabia	ICH Guidelines E14-E16, E18, M13A & Q12 – Educational Training Programme
JFDA, Jordan	Training on Technical and Regulatory Considerations for pharmaceutical product life cycle management/ICH Quality Guidelines*

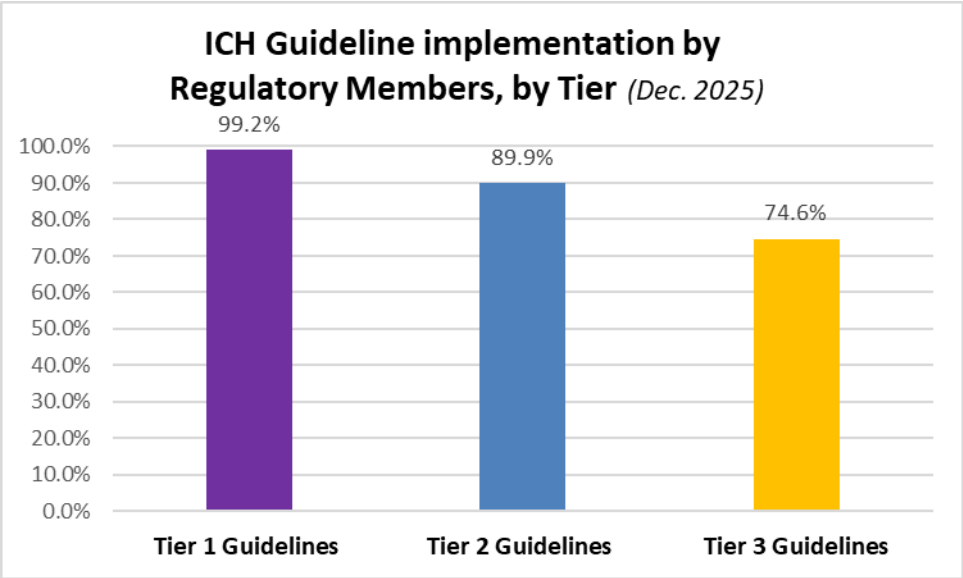
** From the 2024 training budget but postponed until 2025*

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

PIC/S supports the assessment of ICH Quality Guidelines implementation by training assessors and inspectors. In 2025, ICH contributed CHF 150,000 to the PIC/S Inspectorates' Academy, which produced new or updated online training modules for ICH Q7 (Good Manufacturing Practice) and ICH Q12 (Lifecycle Management) and conducted preparatory work for the 2026 development of new modules on ICH Q9 (Quality Risk Management) and ICH Q13 (Continuous Manufacturing of Drug Substances and Drug Products).

ICH Guideline Implementation

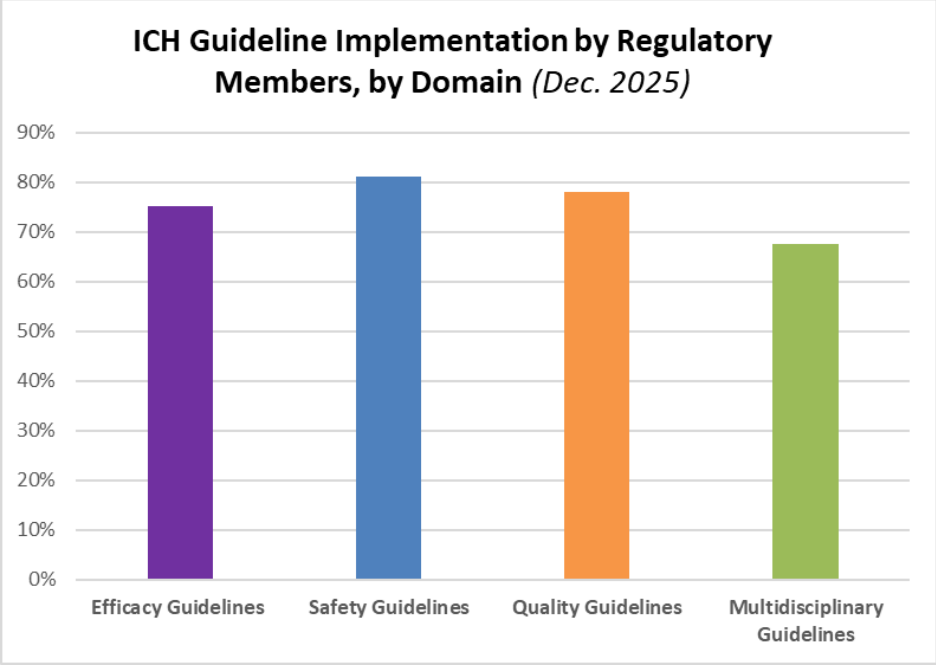
Once ICH Guidelines have been adopted as final (*Step 5* in the Guideline development process), they are ready for implementation by regulatory authorities. ICH Regulatory Members commit to implementing all ICH Guidelines. ICH maintains a searchable database that is updated twice per year on the status of Guideline implementation.



Tier 1 Guidelines are foundational ICH Guidelines and an implementation requirement for Regulatory Authorities wishing to become ICH Members: ICH Q1 series, ICH Q7 and ICH E6.

Tier 2 Guidelines represent critical operational Guidelines needed for modern regulatory systems and should be implemented within five years of becoming an ICH Member: ICH E2A, ICH E2B, ICH E2D, ICH M1 (MedDRA) and ICH M4.

Tier 3 Guidelines cover all remaining specialised ICH Guidelines across the Quality, Safety, Efficacy and Multidisciplinary domains and should be implemented by ICH Members as soon as practically possible.



MedDRA

MedDRA, the ICH Medical Dictionary for Regulatory Activities, is a mainstay of regulatory information-sharing internationally. It is used for registration, documentation and safety monitoring of pharmaceuticals, vaccines and drug-device combination products before and after they have been approved.

MedDRA was first developed by ICH in the late 1990s. It is now used by over 9,000 organisations in 144 countries and is available in 27 languages, with three newly added in 2025: Norwegian, Slovak and Slovenian.

In early 2025, a MedDRA Learning Management System was launched, offering on-demand video courses tailored to varying levels of expertise in six core languages (English, Chinese, French, Korean, Russian and Spanish). In response to the evolving needs of the global MedDRA user base, training initiatives increased with a strong focus on Latin America, the Middle East and Africa.

The MedDRA Steering Committee is responsible for the operational aspects of MedDRA. In elections held at ICH 51 in November 2025, Dr Ana Cochino (EC, Europe) was elected Chair for a two-year term and Ms. Charlotte James (MHRA, UK) was elected Vice-Chair for a one-year term. The ICH Management Committee appointed three additional ICH representatives to join the MedDRA Steering Committee in 2025: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer). The new Steering Committee members will serve a three-year term.

During the year, the agreement with MSSO, the current service provider for the maintenance of MedDRA, was extended for two years.

Looking Ahead

This report, looking back at 2025, is being published nearly halfway through 2026.

Already this year, ICH has begun to articulate a strategic vision and started a longer process of developing a strategic roadmap that includes a review of the way ICH has developed and finalised harmonised Guidelines for the last 35 years.

Collaboration is equally important in Guideline implementation. In 2026, ICH will develop a collaboration framework to guide organisational partnerships that enrich global implementation.

As technology evolves and pharmaceutical product complexity rapidly increases, ICH's scientific consensus-based processes and guidance must keep pace with and support innovation.

However, even thirty-five years after ICH was created and 10 years following its formalisation as a Swiss non-profit association, one thing remains unchanged: the importance of harmonised scientific and technical Guidelines to ensure safe, effective and high-quality medicines for everyone, everywhere.