ICH Strategic Vision

Our Value Proposition

The International Council for Harmonisation (ICH), a global non-profit organisation, is unique in bringing together regulatory authorities and the pharmaceutical industry to harmonise scientific and technical requirements for the safety, efficacy and quality of medicines, for the benefit of patients everywhere.

ICH convenes the world's top experts in their fields to develop harmonised guidelines, which are seen as global standards for the safety, efficacy and quality of medicines, and are embedded in the regulatory frameworks of many jurisdictions around the world.

ICH harmonised guidelines facilitate more consistent and streamlined submissions by industry and more timely and coherent assessments by regulatory authorities, contributing to the more rapid availability of safe, effective and high-quality medicines for patients. In turn, global harmonisation and regulatory coherence support therapeutic innovation.

Our Vision

A world where all patients benefit from safe, effective and high-quality medicines and timely treatment innovations that meet harmonised, science-based requirements to protect and advance public health.

Our Mission

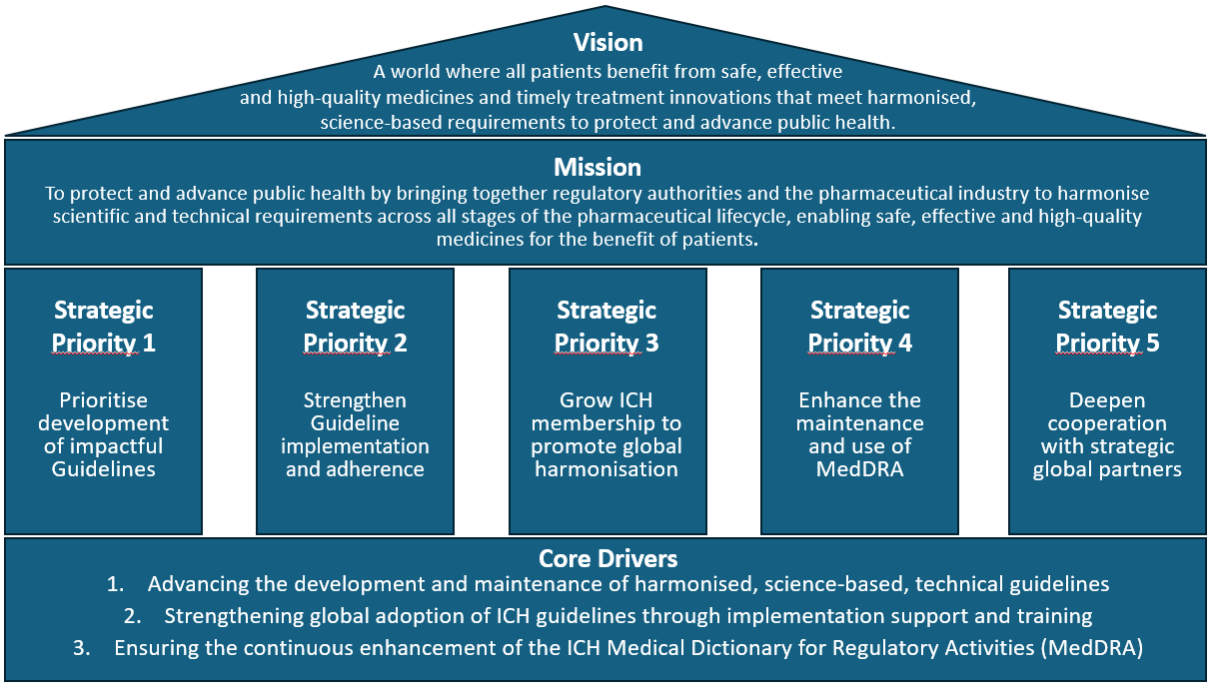
To protect and advance public health by bringing together regulatory authorities and the pharmaceutical industry to harmonise scientific and technical requirements across all stages of the pharmaceutical lifecycle, enabling safe, effective and high-quality medicines for the benefit of all patients.

Our Impact

- Trusted, globally harmonised, science-based requirements to support the safety, efficacy and quality of medicines, for the benefit of patients everywhere.
- Faster access to medicines through streamlined development, reduced duplication, fewer animal tests, more consistent regulatory submissions and more efficient regulatory processes – without compromising quality or safety.
- Increased regulatory certainty, which supports innovation and the development of advanced technologies.
- Important contributions to international regulatory convergence, supporting global equity of product quality and clinical evidence, and more aligned assessment of medicines worldwide.
- Shared, standardised medical language that makes global medicine safety monitoring and reporting possible through MedDRA (the Medical Dictionary for Regulatory Activities).

3 June 2026

ICH Strategic Plan 2026-2030



1. Operating Context

The ICH Strategic Plan covers all technical harmonisation activities related to medicinal products for human use, as defined in the **ICH Articles of Association**.

Participation is open to all ICH Members and Observers (with some limitations). Regulators make the final decisions on ICH guideline endorsement.

We are operating in a time of rapidly evolving technology and increasing product complexity, combined with global public health and supply chain challenges. In this context, ICH must prioritise the timely and targeted science-based harmonisation of guidelines that anticipate the areas of greatest need and potential for impact, including evolving scientific and technological advances.

2. Vision and Mission

ICH brings together regulatory authorities and the pharmaceutical industry to harmonise scientific and technical requirements for the development, registration and lifecycle management of safe, effective and high-quality medicines for the benefit of patients and the protection of public health.

Science-driven, global requirements:

ICH works to achieve greater harmonisation worldwide through the development of scientific and technical guidelines that are regarded as **global standards for the safety, efficacy and quality of medicines**. ICH convenes the world's top experts in subject-specific working groups to develop these guidelines, working together to achieve scientific consensus. ICH guidelines **focus on technical and scientific aspects** and complement existing national and regional legislation.

More rapid availability of safe and effective new medicines:

Harmonisation efforts aim to **streamline regulatory efficiency**, **reduce non-essential animal testing, prevent unnecessary duplication of clinical trials**, where medicines are tested in humans, and address regional differences in approaches that can delay the authorisation of new medicines. Harmonised requirements contribute to shortening the development and approval times of medicines without compromising quality or safety, resulting in faster availability of new medicines and alternatives to off-patent medicines. They enable consistent assessments against the same requirements, contributing to global equity of product quality and clinical evidence, and support pharmacovigilance, the monitoring and reporting of medicine safety.

Increased regulatory certainty and accelerated innovation:

ICH aims to **prioritise harmonisation in areas with the greatest potential for public health impact**, focusing on topics, including novel products and technologies, where differences in the requirements of different regions indicate a stronger need to harmonise these requirements. As the most innovative technologies have higher perceived risks in terms of

success, harmonised guidelines with clear scientific and technical requirements contribute to **reducing scientific and regulatory uncertainty, thus de-risking medical innovation**.

3. Core Drivers

Core Drivers

1. Advancing the development and maintenance of harmonised, science-based, technical guidelines
2. Strengthening global adoption of ICH guidelines through implementation support and training
3. Ensuring the continuous enhancement of the ICH Medical Dictionary for Regulatory Activities (MedDRA)

Three core drivers form the dynamic foundation for ICH activities:

3.1. Advancing the development and maintenance of harmonised, science-based, technical guidelines

Developing and maintaining **harmonised technical guidelines** has been the core activity of ICH since its inception in 1990. These guidelines serve as the global gold standard across all aspects of the medicine lifecycle, ranging from early developments involving laboratory studies and testing to the conduct of clinical trials, authorisation of medicines, quality manufacturing and safety monitoring of medicines on the market. Harmonised guidelines advance public health, access to medicines, scientific innovation and efficient global development of medicines. Guideline development is based on a process where regulatory and industry members work towards **scientific consensus**. Since the reform in 2015, when ICH was registered as an independent non-profit legal entity under Swiss law, major changes were introduced regarding governance, membership and funding. Since 2015, **ICH guidelines are adopted by the regulatory members, who are also responsible for their implementation**.

3.2. Strengthening global adoption of ICH guidelines through implementation support and training

ICH provides globally accessible training materials on ICH guidelines to facilitate timely uptake, better understanding, and consistent and adequate implementation across all regions. The **online ICH Training Library** is continuously updated. ICH also provides targeted support to Members and Observers for guideline implementation.

3.3. Ensuring the continuous enhancement of MedDRA

ICH is the owner of the **Medical Dictionary for Regulatory Activities**, better known as **MedDRA**, which provides a shared, standard medical vocabulary used around the world to describe and report the side effects and adverse events resulting from the use of authorised

medicines by larger populations. Patient safety depends on clear, consistent medical information, and MedDRA provides one common "language" for reporting. ICH contributes to the protection of public health by developing and maintaining MedDRA with twice yearly updates, to provide a single standardised international medical terminology that enables high-quality, interoperable safety data exchange, global pharmacovigilance coordination and a common language across different regulators, industry and systems. MedDRA also supports ICH electronic communication within the electronic Common Technical Document (eCTD) and underpins numerous other ICH guidelines.

4. Strategic Priorities

The five strategic priorities presented here provide a framework for ICH in its planning and conduct of core activities and fulfil its mission to protect and advance public health through globally harmonised technical and scientific requirements for medicines.

4.1. Prioritise development of impactful guidelines

ICH will strive to prioritise harmonisation where it most advances public health, access to medicine, scientific innovation and efficient global development of medicines. ICH guidelines should be impactful, support innovation and keep pace with scientific, technical and technological developments. In addition, ICH will improve the efficiency of the guideline development process to enhance the availability of safe, effective and high-quality medicines, including by making greater use of digital platforms and tools, and developing selective approaches for applying AI.

4.2. Strengthen ICH Guideline implementation and adherence

Full implementation of ICH guidelines is a prerequisite for achieving global harmonisation of regulatory requirements that support faster and more predictable global access to medicines, protect patient safety, improve medicine quality and data integrity, support efficient development and assessment of medicines, ensure transparent and science-based expectations from regulators, ultimately, supporting standards and public trust in medicine

safety. ICH will support coherent, consistent and adequate implementation of ICH guidelines by Regulatory Members through training, implementation monitoring and responding to implementation challenges, including those identified through surveys and input from Members.

4.3. Grow ICH membership to promote global harmonisation

ICH will work to expand membership and outreach to maximise worldwide adoption of ICH guidelines. Growing the membership is essential to increase the global reach of scientific alignment on requirements for safe, effective and high-quality medicines that benefit patients and public health. For regulatory authorities, membership in ICH brings value and shows regulatory maturity and integrity. It also increases access to the expertise required to develop and maintain harmonised guidelines.

4.4. Enhance the maintenance and use of MedDRA

ICH will ensure that MedDRA (the Medical Dictionary for Regulatory Activities) keeps pace with scientific and medical progress to meet the evolving needs of its users around the world, including through timely updates, high-integrity, multilingual access, and interoperability with other terminologies. MedDRA is a powerful tool in the registration, documentation and safety monitoring of medicines, both before and after a medicine has been authorised. MedDRA's role in global pharmacovigilance and public health is thus pivotal for the reporting, coding and analysis of adverse events associated with medicines. ICH will seek to ensure that MedDRA remains the primary terminology used for regulatory information exchange and to support the uptake of MedDRA worldwide for better protection of patient health.

4.5. Deepen cooperation with strategic global partners

ICH seeks opportunities to better enhance engagement and cooperation with relevant international organisations to expand understanding, uptake and impact of ICH guidelines. ICH will develop a strategic framework to guide the development of mutually beneficial collaborations, including those governed by memoranda of understanding. Global partners could include, for example, organisations representing patients or focusing on international standards development and training delivery.