ICH – the global platform for harmonisation

01 About ICH

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH Guidelines.

ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective and high quality medicines are developed, and registered and maintained in the most resource efficient manner whilst meeting high standards.

02 Purpose

The purpose of ICH is the promotion of public health through international harmonisation that contributes to:

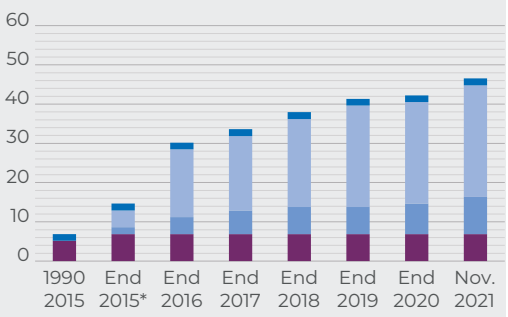
- Reduction of unnecessary animal testing without compromising safety and effectiveness accomplished through technical guidelines implemented by the regulatory authorities
- Prevention of unnecessary duplication of clinical trials and post-market clinical evaluations
- Development and manufacturing of new medicines
- Registration and supervision of new medicines
- Post-authorisation safety reporting and pharmacovigilance

03 Sphere of influence

ICH has grown over the years in terms of Members, Observers and experts as an increasing number of regulatory authorities as well as global organisations representing for example the generic industry and the over-the-counter industry have joined ICH. This reflects the global dimension, diversity and complexity of drug regulation and the importance of broad engagement to achieving its mission – considerations central to the ICH Reform in 2015. Member and Observer economies represent approximately two-thirds of the world's population, not counting Regional Harmonisation Initiatives.

Some specifics:

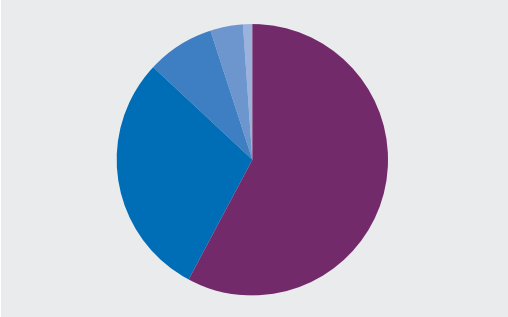
- Over 1,000 individuals are involved in ICH work
- Membership spans all six populated continents



ICH Members and Observers

- Founding/Standing Member
- Member
- Observer
- Standing Observer

*Reform of the ICH



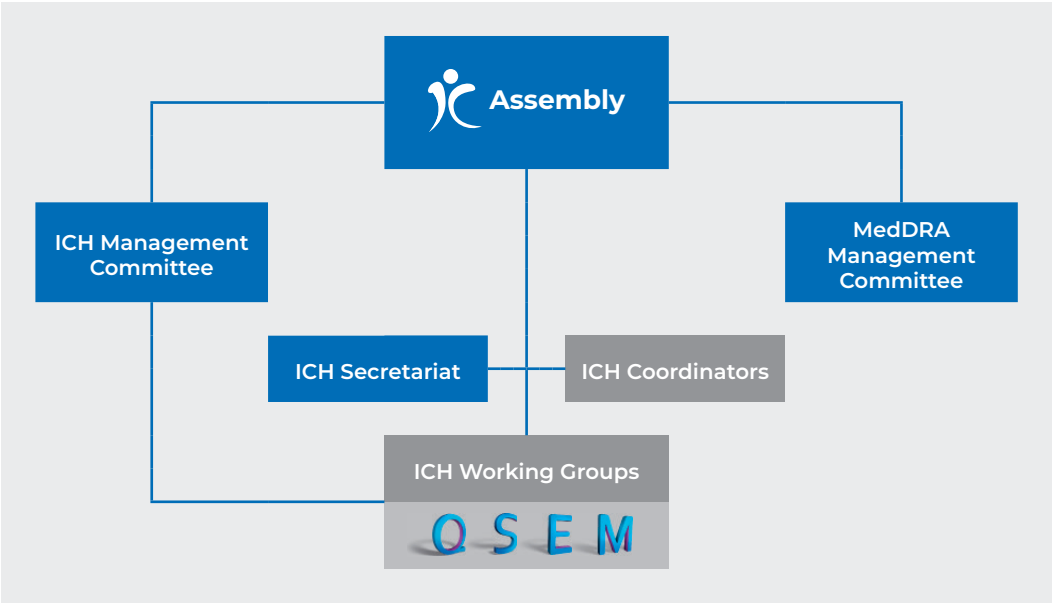
Numbers of experts in ICH WGs

- 58% 441 Founding/ Standing Member
- 29% 218 Member
- 8% 64 Observer
- 4% 31 Standing Observer
- 1% 5 Other

04
Structure

The structure of the ICH Association includes the ICH Assembly as the decision-making body composed of all ICH Members and Observers, assisted by the ICH Management Committee (ICH MC) that oversees the ICH Working Groups (ICH WGs) where the ICH Guidelines are developed, as well as the MedDRA (Medical Dictionary for Regulatory Activities) Management Committee (MedDRA MC). The ICH Assembly meets on a biannual basis in conjunction with meetings of the ICH MC, ICH MedDRA MC and ICH WGs.

ICH Assembly meeting
November 2019
Singapore



05
ICH Work

As of November 2021, 67 state-of-the-art technical ICH Guidelines and standards have been produced spanning the pharmaceutical products lifecycle, with further guidelines under development. This impressive body of work is categorised along four broad workstreams:

- Quality (Q) - Manufacture, control and stability of products and ingredients
- Efficacy (E) - Design, conduct, safety and reporting of clinical trials
- Safety (S) - Nonclinical test strategies and methods
- Multidisciplinary (M) - Diverse cross-cutting topics, including CTD/eCTD, medical dictionary and e-standards for transfer of regulatory information.

In addition, ICH has developed an extensive set of Q&A documents and training materials to further clarify concepts and principles in ICH Guidelines.

06
Impact of ICH

ICH Guidelines, once implemented by ICH Regulators, form a common backbone of technical requirements across the globe. To achieve the intended effect of promoting a greater level of harmonisation worldwide, the ICH Regulators are expected to implement the ICH Guidelines after they have been adopted by the ICH Regulatory Members.
This is also reflected in the Articles of Association as a commitment by ICH Regulatory Members to implement ICH Guidelines - a core operating principle of ICH since its inception.
ICH has adopted important measures to ensure a proper interpretation and adequate implementation of ICH Guidelines, many of which present complex scientific concepts and principles. Key among these measures is training. Authoritative ICH-endorsed training materials and courses by accredited non-profit training organisations serve to promote a better understanding and consistent application of ICH Guidelines. Training slide-decks are also now developed for each ICH Guideline.
Additional measures include webinars on specific ICH Guidelines, training by ICH Members and Observers, and participation in regional and international events.

For more information on ICH, please visit the ICH 30th Anniversary Publication available on the ICH website: www.ich.org

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ICH
harmonisation for better health