Overview of ICH

June 2024

International Council for Harmonisation of Technical Requirements
for Pharmaceuticals for Human Use

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ICH

INTERNATIONAL COUNCIL FOR HARMONISATION
of
Technical Requirements
for Pharmaceuticals for Human Use

- Unique harmonisation initiative for regulators and pharmaceutical industry
- Originally founded in 1990
- Reformed as a non-profit legal entity under Swiss Law on 23 October 2015

Purpose of ICH

Promotion of public health through **international harmonisation** that contributes to:

- Prevention of unnecessary duplication of clinical trials and post market clinical evaluations

- Development and manufacturing of new medicines

- Registration and supervision of new medicines

- Reduction of unnecessary animal testing without compromising safety and effectiveness

Accomplished through **Technical Guidelines** that are implemented by the regulatory authorities.

23 Members:

- Founding Regulatory:
  - EC, Europe; MHLW/PMDA, Japan; FDA, United States
- Founding Industry:
  - EFPIA; JPMA; PhRMA
- Standing Regulatory:
  - Swissmedic, Switzerland; Health Canada, Canada
- Regulatory:
  - ANMAT, Argentina; ANVISA, Brazil; COFEPRIS, Mexico; EDA, Egypt; HSA, Singapore; JFDA, Jordan; MFDS, Republic of Korea; MHRA, UK; NMPA, China; SFDA, Saudi Arabia; TFDA, Chinese Taipei; TITCK, Turkey
- Industry:
  - BIO; Global Self-Care Federation; IGBA

See *https://www.ich.org/page/members-observers* *for details*

ICH Observers
(as of June 2024)

2 Standing Observers:

- WHO; IFPMA

35 Observers:

- Regulatory authorities; Regional Harmonisation Initiatives; international industry pharmaceutical organisations; international organisations regulated or affected by ICH Guidelines
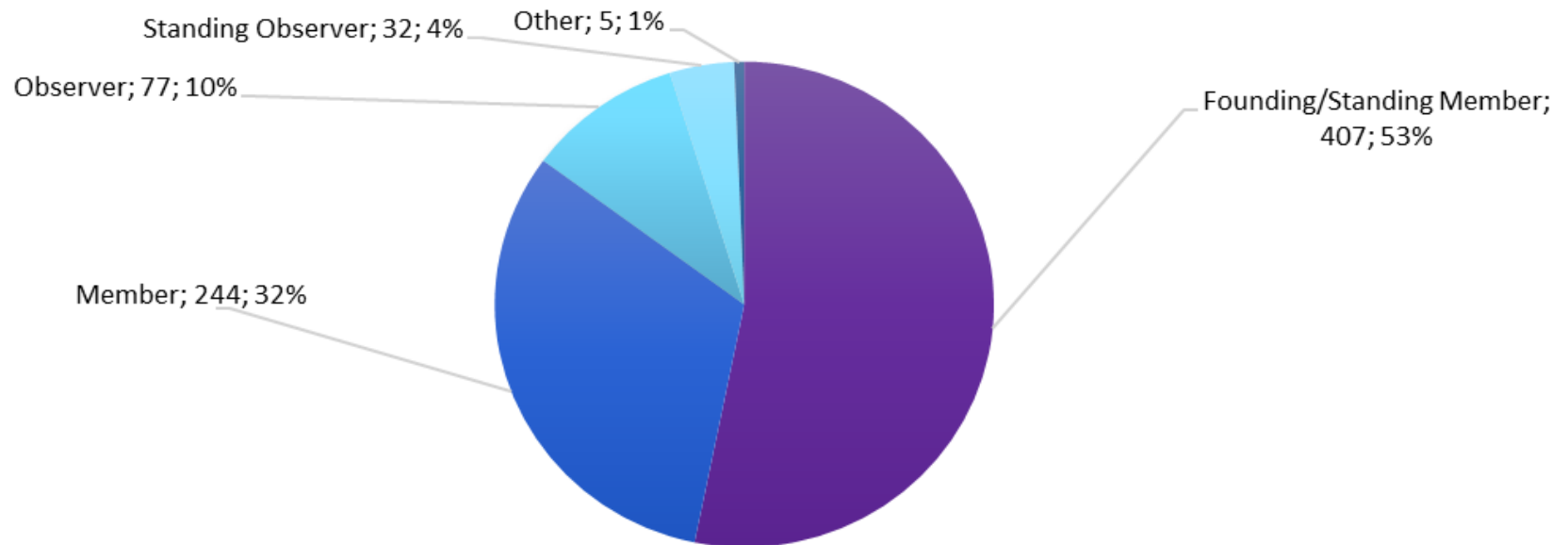
See https://www.ich.org/page/members-observers for details

Composition of ICH WGs

With over 765 technical experts in over 33 WGs – as of June 2024

Number of experts in ICH WGs

Standing Observer; 32; 4%
Other; 5; 1%
Observer; 77; 10%
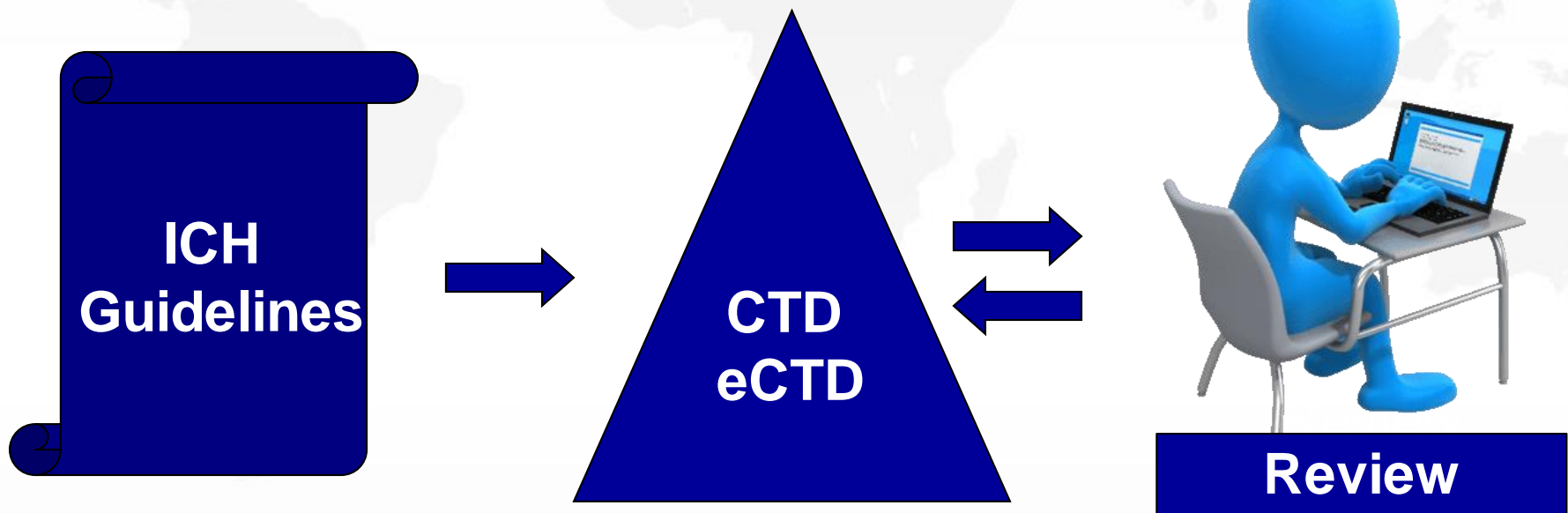Founding/Standing Member; 407; 53%
Member; 244; 32%

GCP (Good Clinical Practice)

Clinical trials <u>conducted in one ICH region can be used in other ICH regions</u> by setting the common standards on science and ethics.

CTD/eCTD *(Common Technical Document)*

CTD brings together all Quality, Safety and Efficacy information in a common, harmonised format, accepted by regulators in all ICH regions. It has revolutionised regulatory review processes for regulators and industry.

MedDRA (Medical Dictionary for Regulatory Activities)

- Highly specific, standardised <u>medical terminology</u> developed by ICH to facilitate sharing of regulatory information

- It is used for registration, documentation and safety monitoring of medical products both before and after marketing authorisation

ICH Products (as of June 2024)

75 Guidelines on technical requirements on:

- Safety – 16 Guidelines

- Quality - 26 Guidelines

- Efficacy – 22 Guidelines

- Multidisciplinary - 11 Guidelines

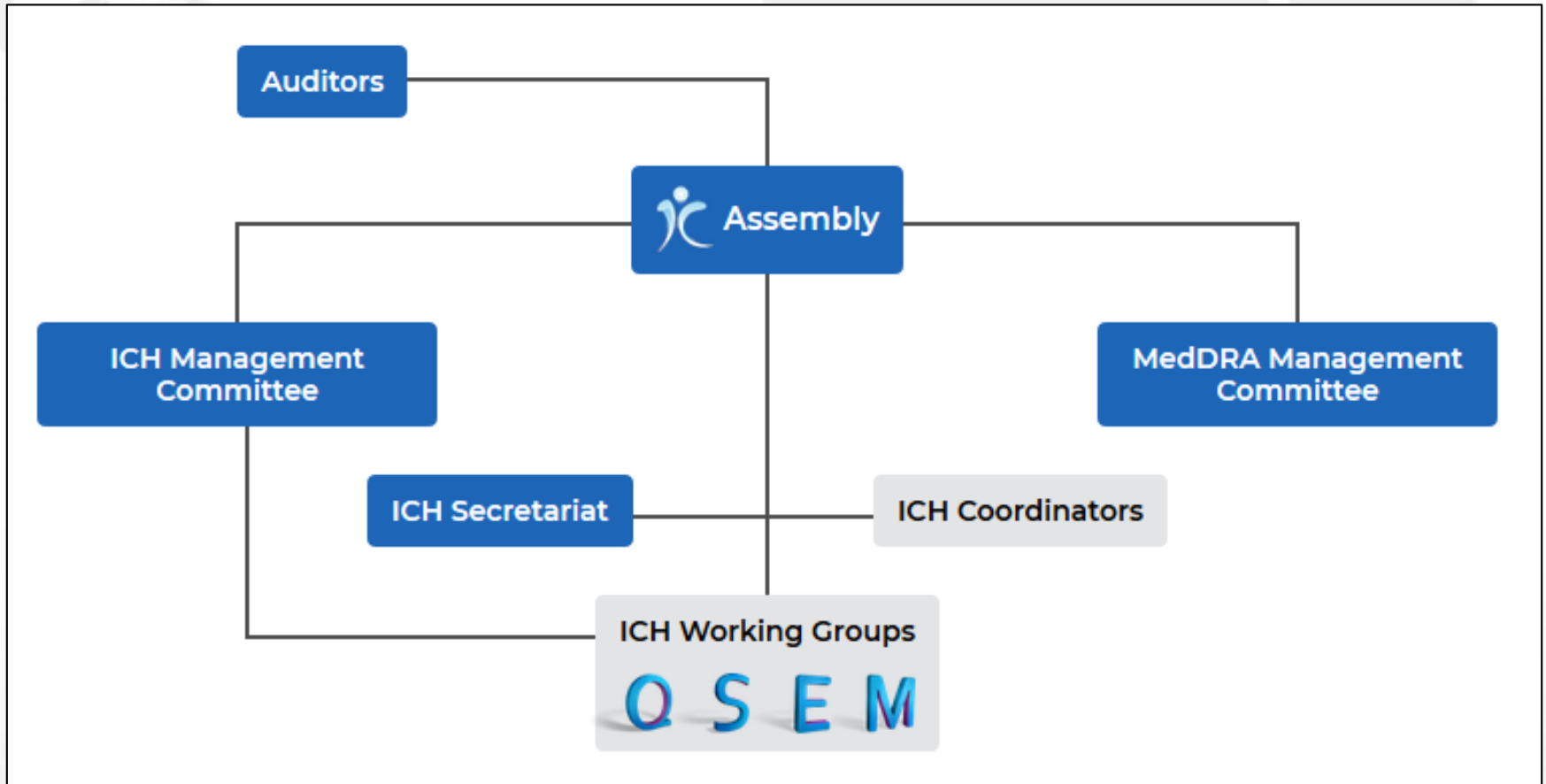**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**

CTD/eCTD

MedDRA (standardised medical terminology)

See https://www.ich.org/page/ich-guidelines for details

Remit of the Assembly and the Management Committee

Assembly is:

- The <u>overarching body</u> of the Association, composed of all Members that take decisions, regarding Articles of Association, Rules of Procedures, admission of new Members, Adoption of ICH Guidelines, etc.

Management Committee is:

- The <u>body that oversees operational aspects</u> of the Association on behalf of all Members, including administrative and financial matters and oversight of the WGs.

- The **Management Committee** provides:
  - Recommendations on the selection of new topics for harmonisation as well as on the adoption, withdrawal or amendments of ICH Guidelines

- The **Assembly** takes decisions:
  - By consensus
  - In the absence of consensus: vote in accordance with the Articles of Association, where only regulatory members have the right to vote

Membership in the Assembly—Eligibility Criteria for <u>Regulators</u>

Engagement in the ICH Process

- Past regular attendance in ICH meetings

- Past appointment of experts in WGs

Application of ICH Guidelines

- Have implemented at least the following ICH Guidelines ("Tier 1"):

    - Q1: Stability Testing Guidelines

    - Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

    - E6: Good Clinical Practice Guideline

See [*https://www.ich.org/page/application-process*](https://www.ich.org/page/application-process) *for details*

Membership in the Assembly— Eligibility Criteria for Industry

Type of Organisation

- International pharmaceutical industry organisation

Engagement in the ICH Process

- Past regular attendance in ICH meetings
- Past appointment of experts in WGs

Impact of ICH Guidelines

- The organisation and/or its members must be regulated or affected by ICH guidelines
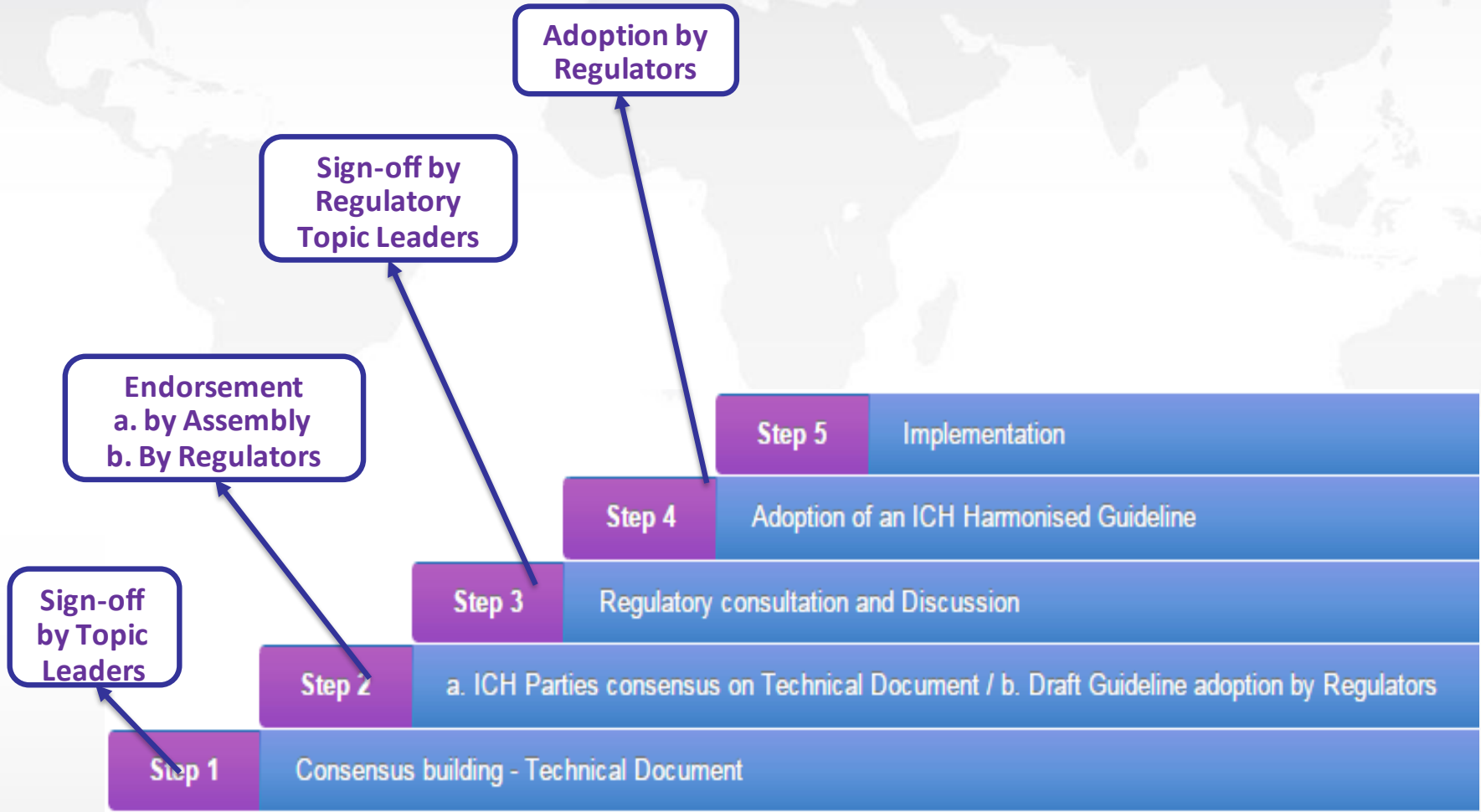
See https://www.ich.org/page/application-process for details

ICH Observers

- Limited eligibility criteria for new Observers

- Rights of Observers:

  - To attend ICH Assembly meetings, but no right to vote or automatically appoint experts in WGs

  - Standing Observers (WHO and IFPMA) maintain their right to appoint experts in WGs

- No duties are imposed on Observers

See https://www.ich.org/page/application-process for details

Steps in the ICH Process for Guideline Development

Adoption by Regulators

Sign-off by Regulatory Topic Leaders

Endorsement a. by Assembly b. By Regulators

Sign-off by Topic Leaders

Step 5 — Implementation

Step 4 — Adoption of an ICH Harmonised Guideline

Step 3 — Regulatory consultation and Discussion

Step 2 — a. ICH Parties consensus on Technical Document / b. Draft Guideline adoption by Regulators

Step 1 — Consensus building - Technical Document

https://www.ich.org/page/formal-ich-procedure

The ICH Step Process (1)

- ***Step 1:***
  - o ___The WG___ *works to prepare a consensus draft of the technical document.*

- ***Step2:***

  - ✓ ***Step 2a:***
  - o ___The Members of the ICH Assembly___ *are invited to endorse the technical document.*

  - ✓ ***Step 2b:***
  - o ___The Regulatory Members of the ICH Assembly___ *are invited to endorse the draft Guideline.*

- *Step 3:*
  - o *Public consultation by the ICH Regulatory Members and ICH Secretariat. All comments are considered by the WG.*
  - o *Step 3 is finalised once consensus is reached by the regulatory experts of the WG.*

- *Step 4:*
  - o *The Regulatory Members of the ICH Assembly adopt the final ICH harmonised Guideline.*

- *Step 5:*
  - o *Implementation by the ICH Regulatory Members.*

Keys to ICH Success

- Involves expertise from both regulatory authorities and regulated industry

- Science-based, consensus driven

- Clear and effectively managed process

- Close collaboration of parties with comparable regulatory and technical capability

- Commitment of regulators to implement products of harmonisation

- Common global platform and tools

- Revised processes and governance

Summary

- ICH has achieved international harmonisation of technical guidelines, with engagement of regulators and industry.

- ICH has clear governance and increasingly global membership following ICH reform.

- Five transparent steps in the ICH process for Guideline development.