ICH
harmonisation for better health

Overview of ICH

November 2019

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

Legal Notice

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.

ICH Members
(as of November 2019)

16 Members:

- Founding Regulatory:
  - EC, Europe; MHLW/PMDA, Japan; FDA, United States
- Founding Industry:
  - EFPIA; JPMA; PhRMA
- Standing Regulatory:
  - Swissmedic, Switzerland; Health Canada, Canada
- Regulatory:
  - ANVISA, Brazil; NMPA, China; HSA, Singapore; MFDS, Republic of Korea; TFDA, Chinese Taipei
- Industry:
  - BIO; Global Self-Care Federation; IGBA

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

ICH Observers
(as of November 2019)

2 Standing Observers:

- WHO; IFPMA

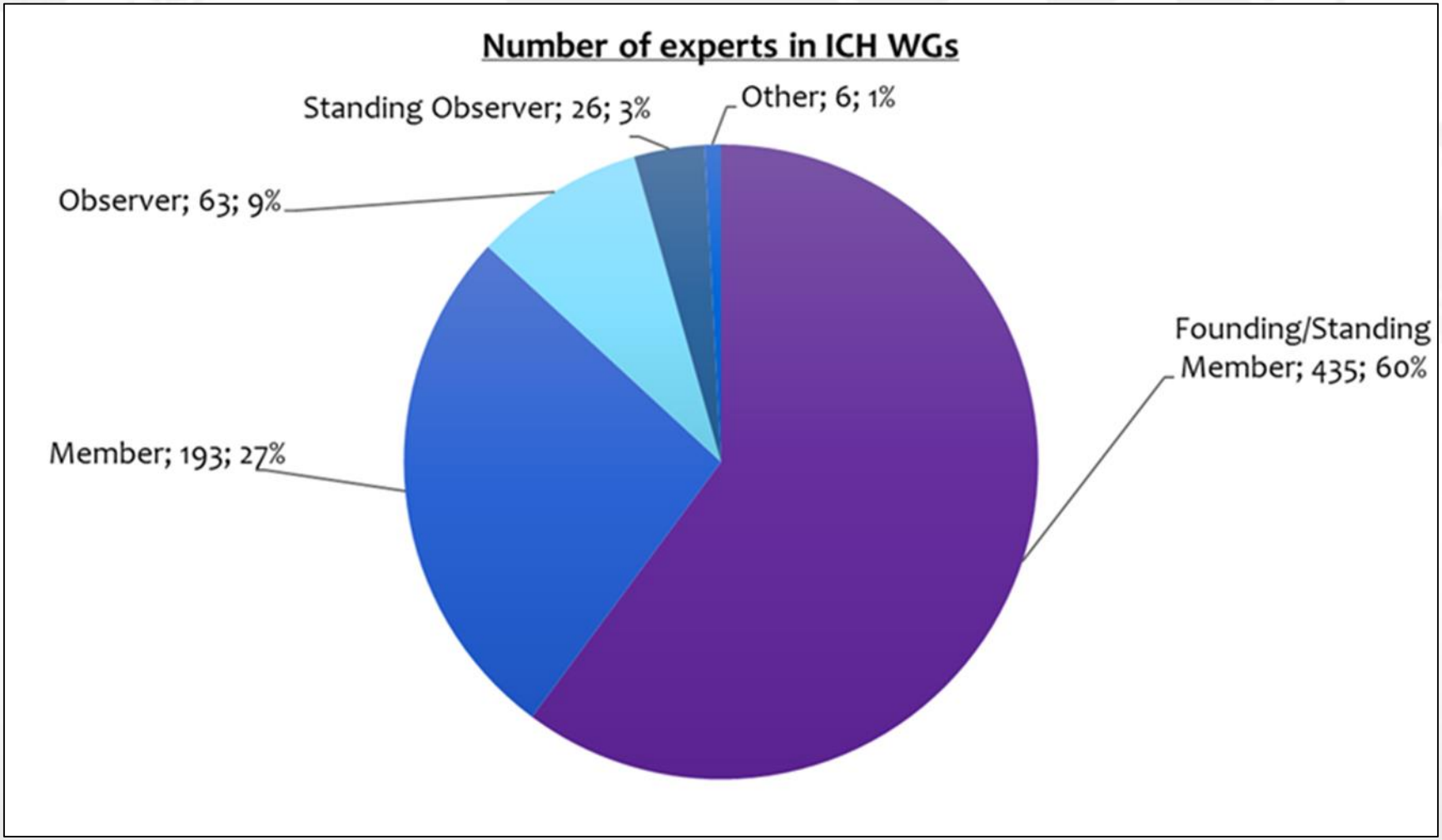
30 Observers:

- 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

723 experts in 32 WGs – as of 14 Oct. 2019



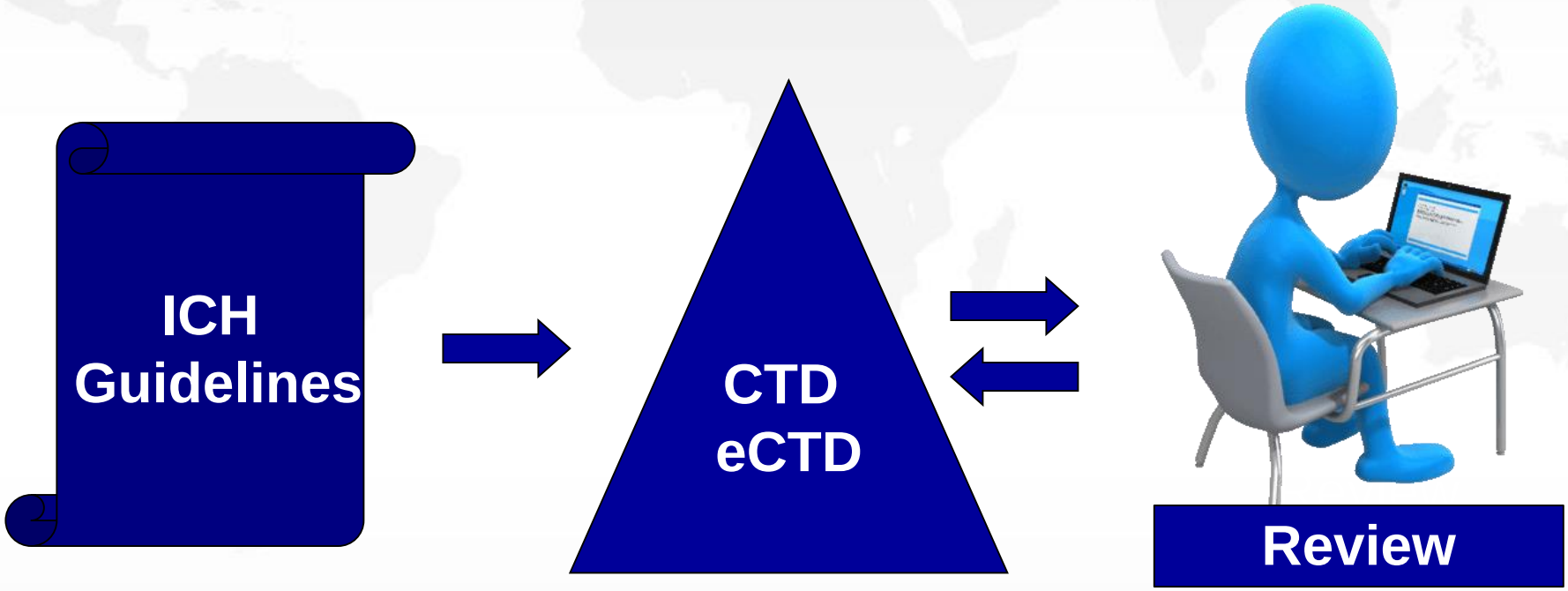
ICH Successes (1)

GCP (Good Clinical Practice)

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

ICH Successes (2)

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.

ICH Successes (3)

MedDRA (Medical Dictionary for Regulatory Activities)

- Highly specific, standardised medical terminology 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 November 2019)

Over 60 Guidelines on technical requirements on:

- Safety – 14 Guidelines
- Quality - 24 Guidelines
- Efficacy – 21 Guidelines
- Multidisciplinary - 7 Guidelines

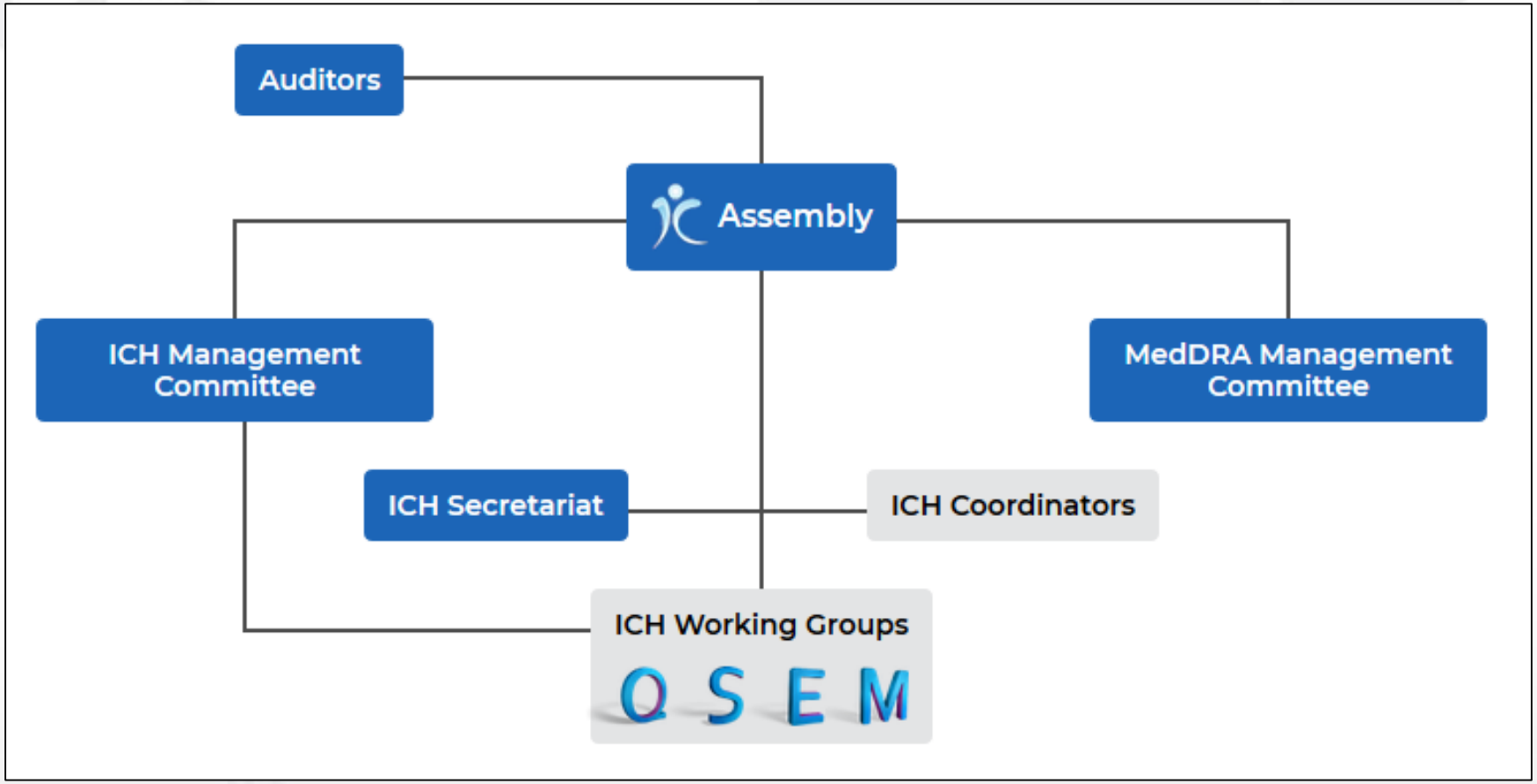
Electronic Standards for the Transfer of Regulatory Information (ESTRI)

CTD/eCTD

MedDRA (standardised medical terminology)

See http://www.ich.org/products/guidelines.html for details

Structure of the ICH Association



Remit of the Assembly and the Management Committee

Assembly is:

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

Decision-making for ICH Guidelines

- 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 Regulators

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 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

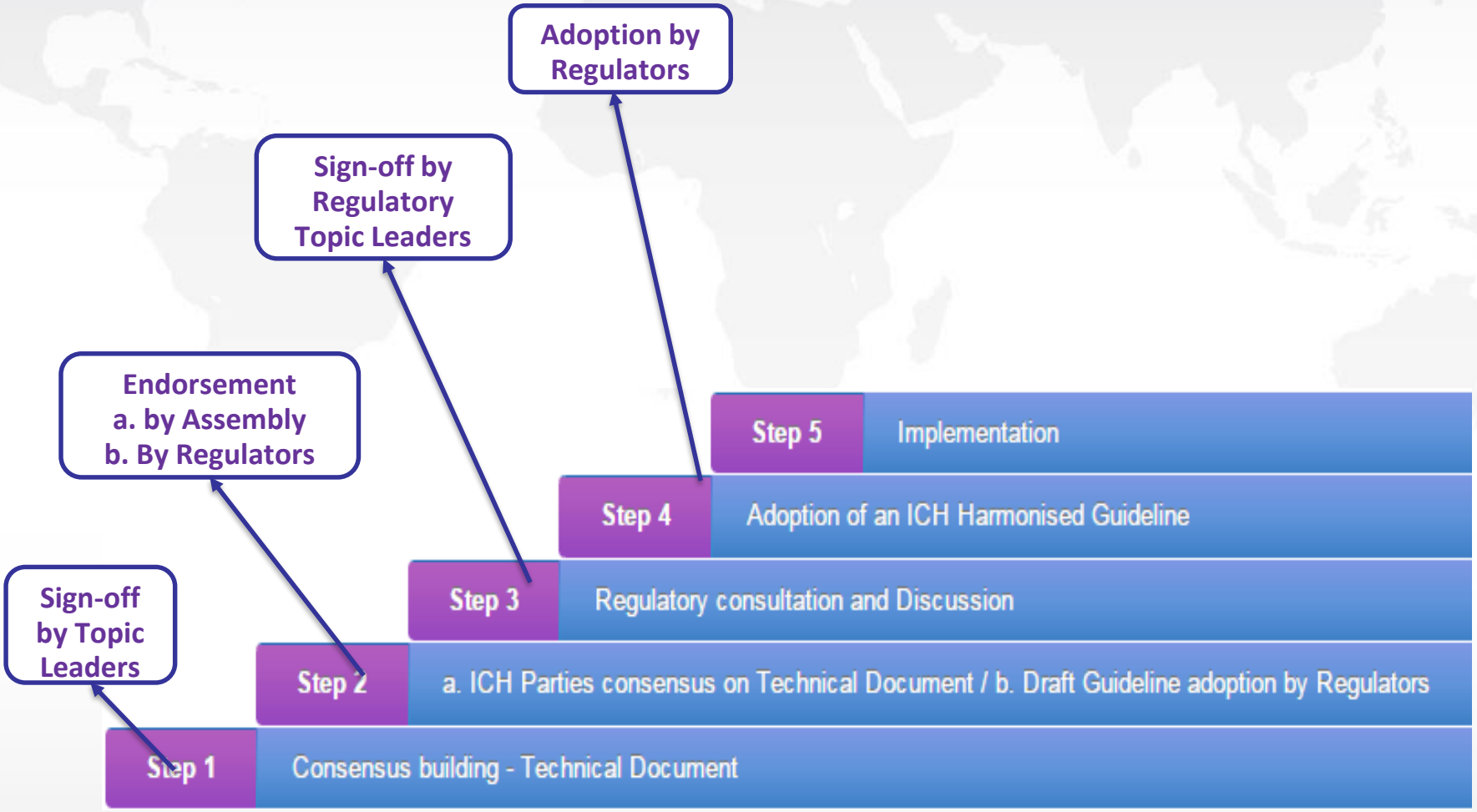
See https://www.ich.org/page/application-process for details

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



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

The ICH Step Process (1)

- ***Step 1:***
  - *The WG works to prepare a consensus draft of the technical document.*
- ***Step2:***
  - ✓ ***Step 2a:***
    - *The Members of the ICH Assembly are invited to endorse the technical document.*
  - ✓ ***Step 2b*:**
    - *The Regulatory Members of the ICH Assembly are invited to endorse the draft Guideline.*

The ICH Step Process (2)

- ***Step 3:***
  - *Public consultation by the ICH Regulatory Members and ICH Secretariat. All comments are considered by the WG.*
  - *Step 3 is finalised once consensus is reached by the regulatory experts of the WG.*
- ***Step 4:***
  - *The Regulatory Members of the ICH Assembly adopt the final ICH harmonised Guideline.*
- ***Step 5:***
  - *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.

ICH
harmonisation for better health

Thank you for your attention

Visit our websites for more information on the work of ICH:

www.ich.org

www.meddra.org

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