EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to the ICH guideline development process

ICH E6(R3) Good Clinical Practice workshop with PCWP and HCPWP

Presented by Lenita Lindstrom (EC DG SANTE), Milton Bonelli (EMA), Edit Szepessy (EC DG SANTE) on 3 June 2020

ICH

International Council for Harmonisation

Of Technical Requirements

For Pharmaceuticals for Human Use

http://www.ich.org

ICH Secretariat

Office in Geneva, Switzerland

Presented by Lenita Lindstrom – DG SANTE/ ICH Assembly Chair

European Commission

ICH Background

- Unique harmonisation project, involving the pharmaceutical regulators and research-based industries
- Started in 1990 (informal) and reformed in 2015 (independent, legal entity)
- Well-defined objectives:
  - **To improve efficiency of new drug development and registration process**
  - **To promote public health, prevent duplication of clinical trials in humans and minimize the use of animal testing without compromising safety and effectiveness**
- Accomplished through the development and implementation of harmonised Guidelines and standards

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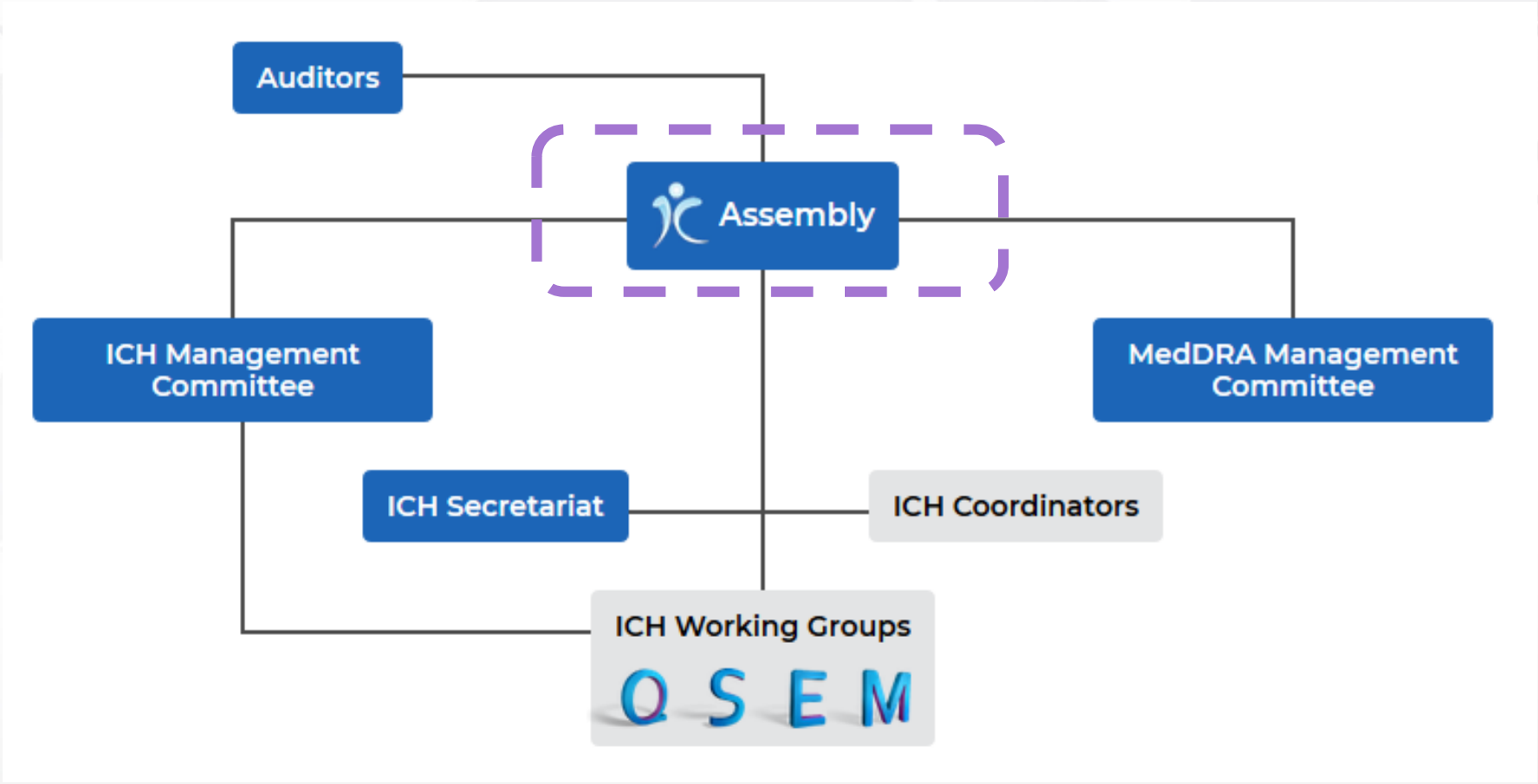
Governance of ICH Association



https://www.ich.org/page/organisation-ich

ICH Membership

- There are **17 ICH Members and 32 Observers. The Members are:**
  - **Founding Members**:
    - Founding Regulatory Members: EC, Europe; MHLW/PMDA, Japan; FDA, United States
    - Founding Industry Members: EFPIA; JPMA; PhRMA
  - **Standing Regulatory Members**: Health Canada, Canada; Swissmedic, Switzerland
  - **Regulatory Members**: ANVISA, Brazil; HSA, Singapore; MFDS, Republic of Korea; NMPA, China; TFDA, Chinese Taipei; TTICK, Turkey
  - **Industry Members**: BIO; IGBA; WSMI

European Commission

ICH Products

Over 60 Guidelines on technical requirements on:

- Safety – 14 Guidelines
- Quality - 23 Guidelines
- Efficacy – 21 Guidelines (most prominent of them: ICH E6)
- Multidisciplinary - 6 Guidelines

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

CTD/eCTD

MedDRA (standardised medical terminology)

European Commission

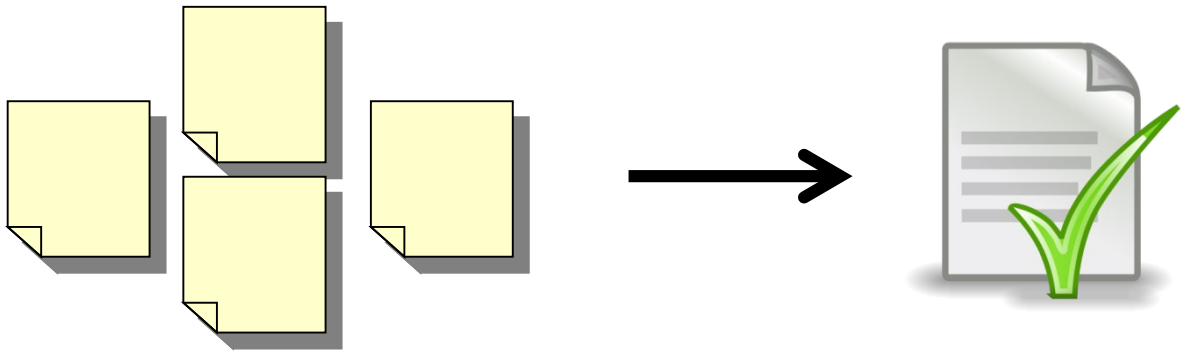
ICH Harmonization Process

ICH E6(R3) Good Clinical Practice workshop with PCWP and HCPWP

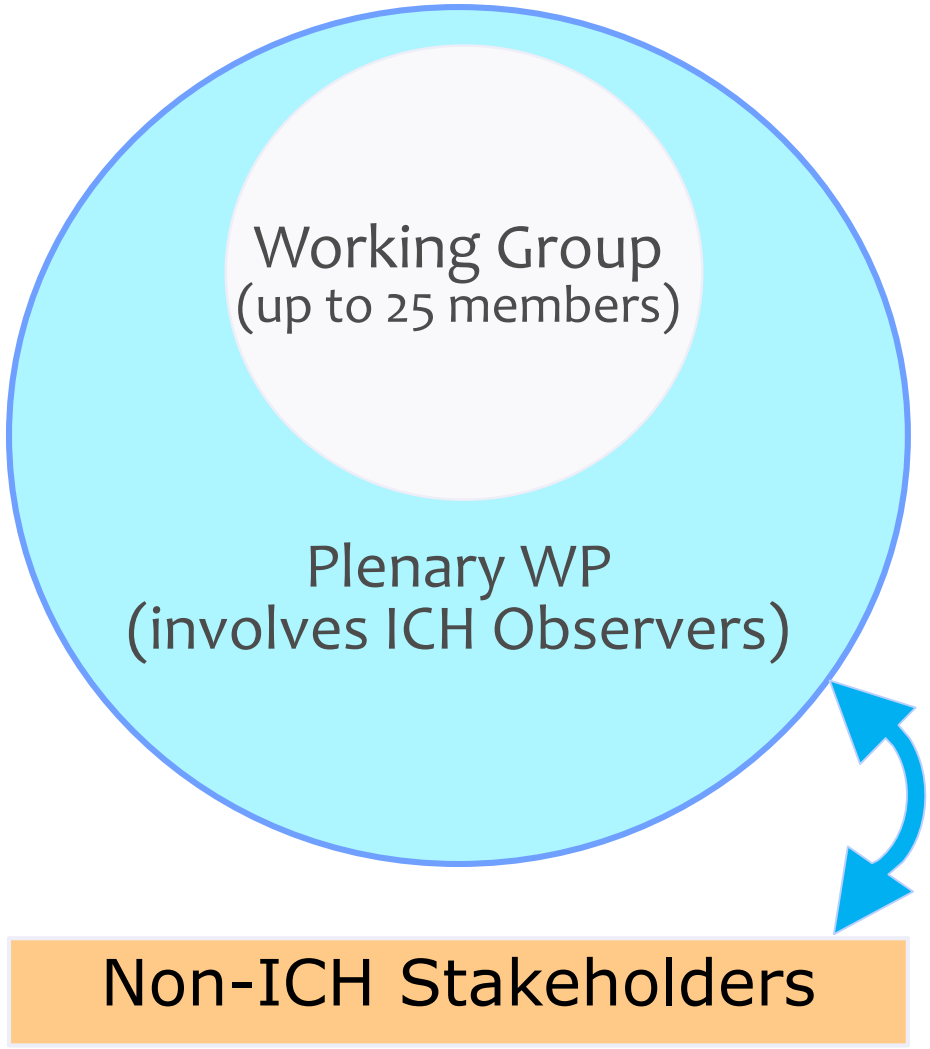
Presented by Milton Bonelli (EMA) – ICH Management Committee Member

ICH Process - Topic selection

- Any ICH Member and Observer can submit proposals for an ICH work product (New guideline, Q&A, revision of existing guideline)
- The ICH Assembly reviews topic proposals once per year and selects new topics for harmonisation during an Assembly meeting (i.e. ICH E6(R3) selected in June 2019 in Europe meeting)
- Topics can also be part of broader initiatives, such as reflection papers (i.e. “ICH GCP renovation” – includes E8, E6, E6 annexes)



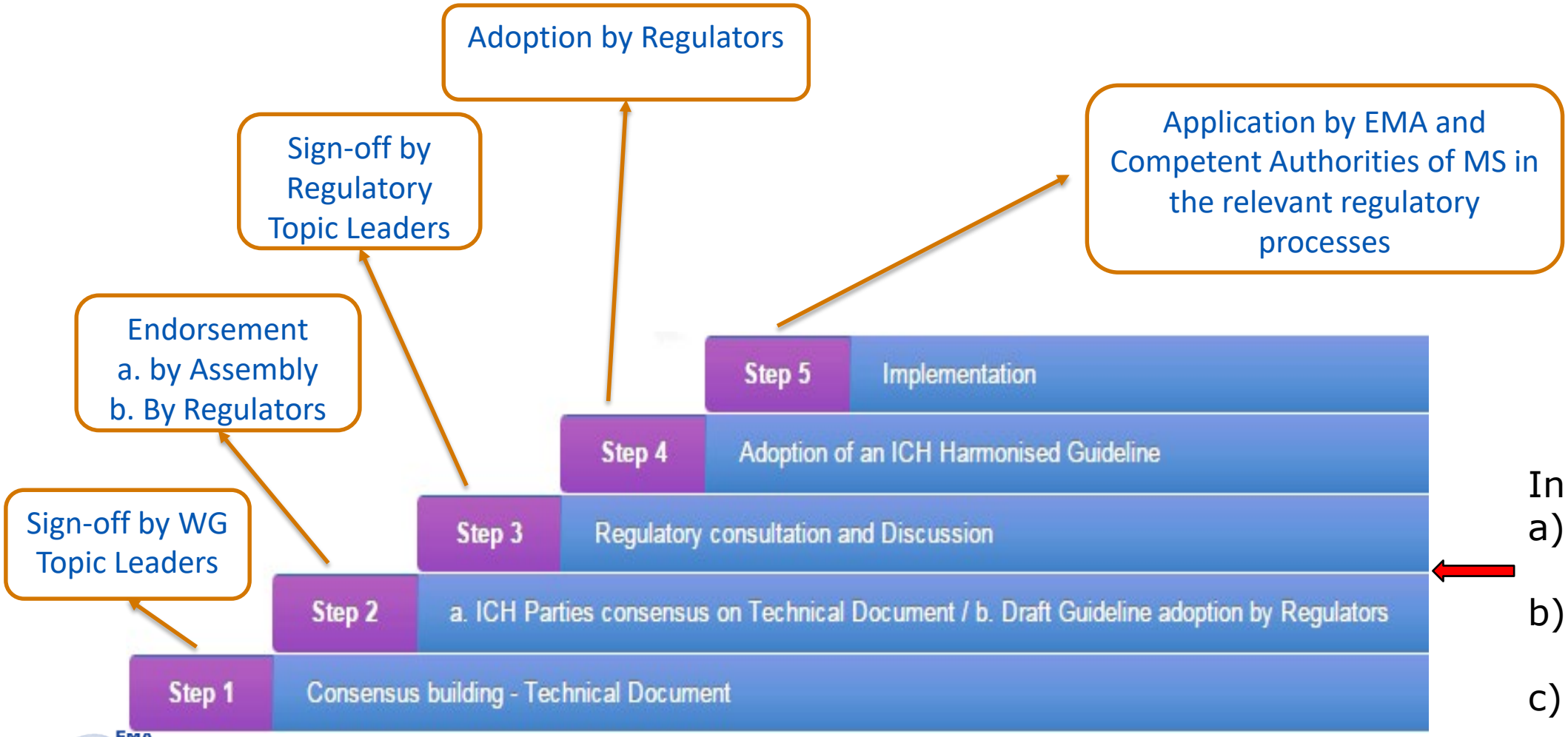
ICH Process - Working groups



For EC, Europe:

- *Usually two experts*
- *Nominated by EMA/CHMP*
- *Belonging to EU NCAs or EMA*
- *Names published (CHMP minutes/ICH website)*
- *Interact with EMA Committees/Working parties*

ICH Process – Guideline drafting



In the EU:

a) EMA/CHMP adoption
b) Publication on EMA website
c) Public consultation

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

ICH Process – Step 3 - public consultation (regional)

- Regional Regulatory Consultation – The draft Guideline proceeds to regulatory consultation in each of the Member's regions.

  Publication of draft Guideline on EMA's website under specific webpages.

- Discussion of Regional Consultation Comments – The WG resumes work and discusses the comments received in each region and revise the draft Guideline as appropriate.

  Progress/timelines can be seen on ICH website (Published WG workplans – i.e. ICH E6)

  NB - ICH Working group decisions during should be made by consensus

- Finalisation of *Step 3* Experts Draft Guideline – Once consensus is reached on the revised draft Guideline, the experts from the Regulatory Members are invited to sign-off on the *Step 3* draft Guideline.

ICH Process – Adoption and Implementation

- Step 4 - the Regulatory Members of the Assembly adopt a Harmonised Guideline
- Step 5 - The ICH Guideline is implemented by ICH Regulatory Members in their respective region.

In the EU

- Endorsement of final ICH document by EMA – Committee for Human Medicinal Product
- Publication on EMA website (usually 6-months before enforcement)
- Application of new/revised ICH guideline principles in EMA/National processes
- Training of EU NCA Assessors and EMA Staff

CTEG

Clinical trials expert group involvement

Edit Szepessy – DG SANTE

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CTEG involvement in the review of the E6 concept paper

- Clinical trials expert group (CTEG): EC (DG SANTE) expert group with 1-1 representative from the national competent authority and the national Ethics Committee from each Member State
- EMA is observer
- EMA: regular updates on the ICH GCP Renovation process since Q4/2019
- Mutual advantage: EU-wide involvement of EC/NCA representatives, coordination between CTFG/HMA, EMA and CTEG/DG SANTE, opportunity for strengthen/contribute to a harmonised European position
- Review of the E6(R3) concept paper: 2019 November
- Responses from: 5 MSs (compiled: EC and NCA)

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CTEG involvement – next steps

- Aim is to support further engagement of CTEG in the future through concrete actions:

  - 4 CTEG experts had been invited to participate at this workshop

  - EMA will present the main points from this workshop at the next CTEG meeting on 25 June

  - possibility for CTEG review of the draft guidance and for consulting the experts on specific aspects by the ICH6 WG during the development of the E6 (R3) guidance

  - CTEG involvement in the review of additional ICH documents

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Any questions?

Further information

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