

# Initiatives to promote global regulatory convergence.... ...how to build trust...

**Tomas Salmonson, PhD**  
Former chair, CHMP, EMA

# Trust

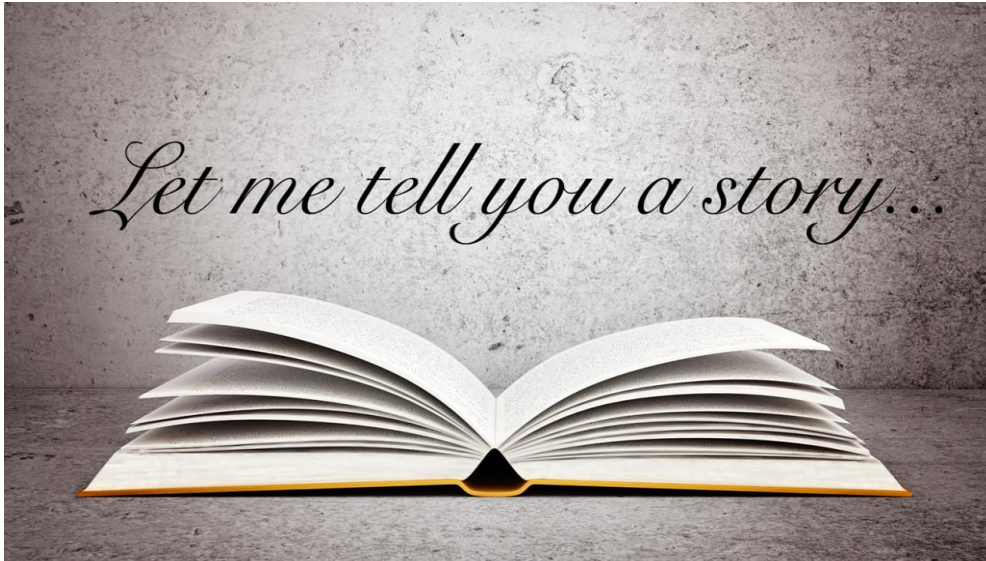
**Webster:** Reliance on the [character](#), [ability](#), [strength](#), or [truth](#) of someone or something

**Collins:** If you **trust** someone, you believe that they are [honest](#) and [sincere](#) and will not deliberately do anything to harm you.

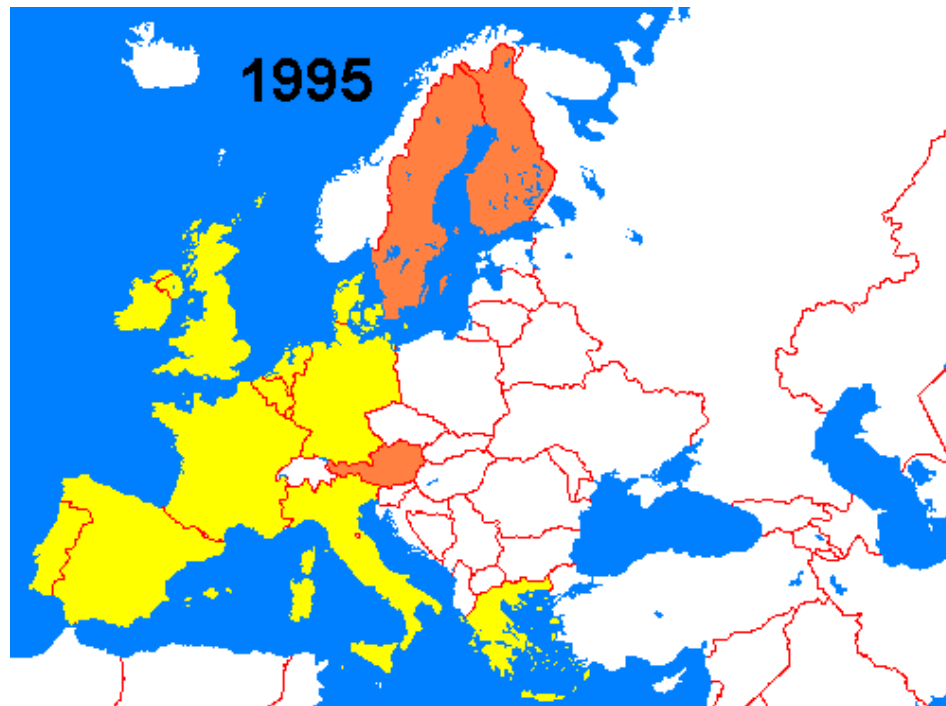
# My starting points:

- Regulators cannot and should not work in isolation
  - Working together is the way to obtain maximum public health impact at a national level
- Trust and leadership are the key to the success of any reliance models....
- Several ways to collaborate:
  - ADR reporting
  - Regulatory and scientific standards; eg ICH
  - Inspections
  - **Reliance/recognition of assessments**
- The EU model is a specific example of reliance and recognition

*Let me tell you a story...*

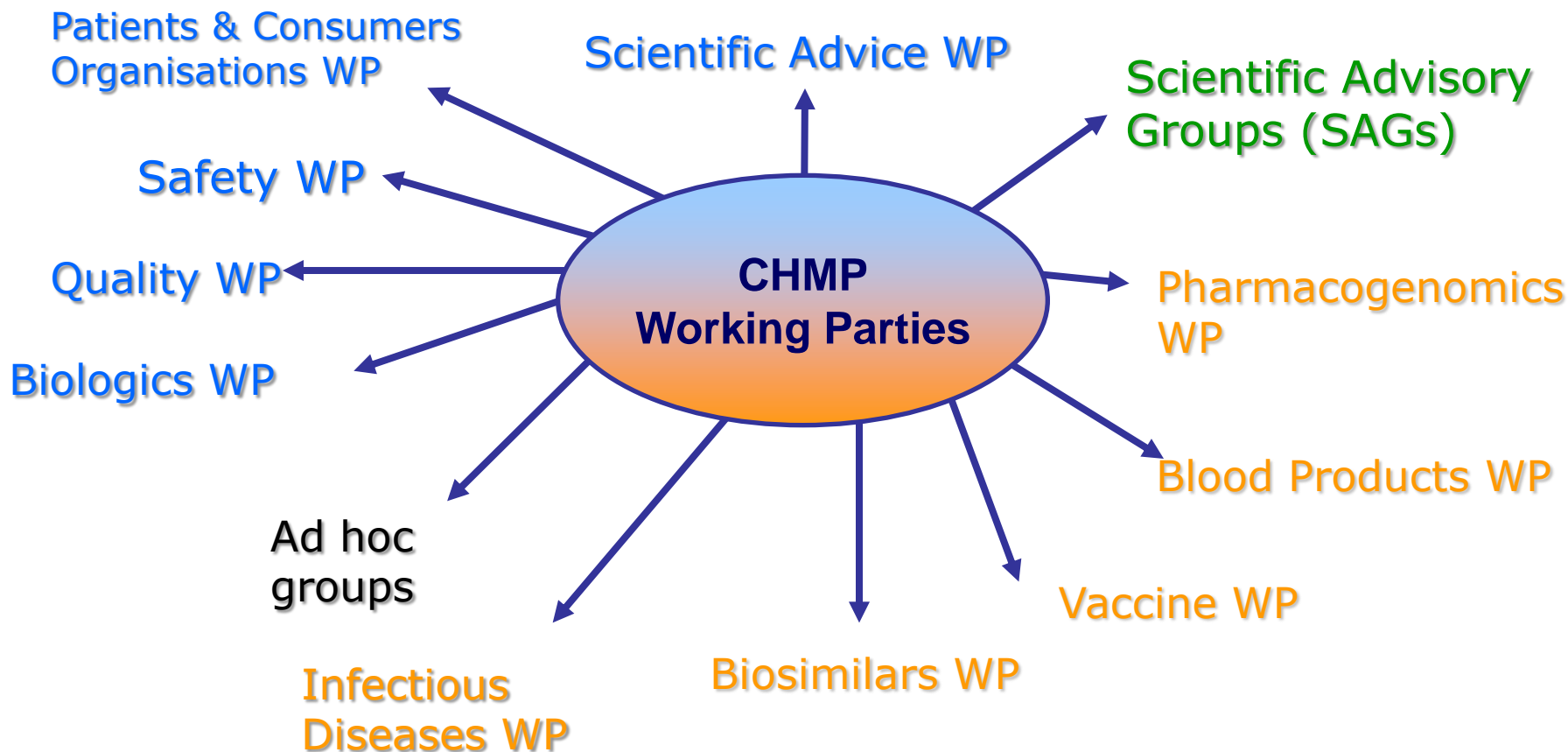


Once upon a time, in a specific area of the world ...





# CHMP Working Parties and Expert Groups



# All involved have responsibility for building trust

- ❖ The regulatory agency delivering the assessment report
- ❖ The applicant
- ❖ The regulatory agency relying on the AR

So how can involved stakeholder build trust



# The Agency initially reviewing the application:

- ❖ Legislation and procedures. Public health role and responsibilities.
- ❖ General scientific standards
  - (ICH) guidelines
  - CHMP Working Parties
  - Earlier decision
  - Scientific Advice
- ❖ Assessment teams and quality assurance. EU: two assessment teams.
- ❖ Decision making process.



# The Agency initially reviewing (continue):

- ❖ B/R structure, policies e.g. wording of the indication
- ❖ Transparency:
  - Comprehensive assessment report
  - Subjective judgments
  - Webinar? Possibilities to ask questions for clarification
  - Possibilities to follow an individual application

# How can a non-EU regulator gain trust in the EU system (examples....)

- Followed an review cycle, including the Scientific Advisory Group meeting
- Followed the CHMP meetings including the Oral Explanation
- etc

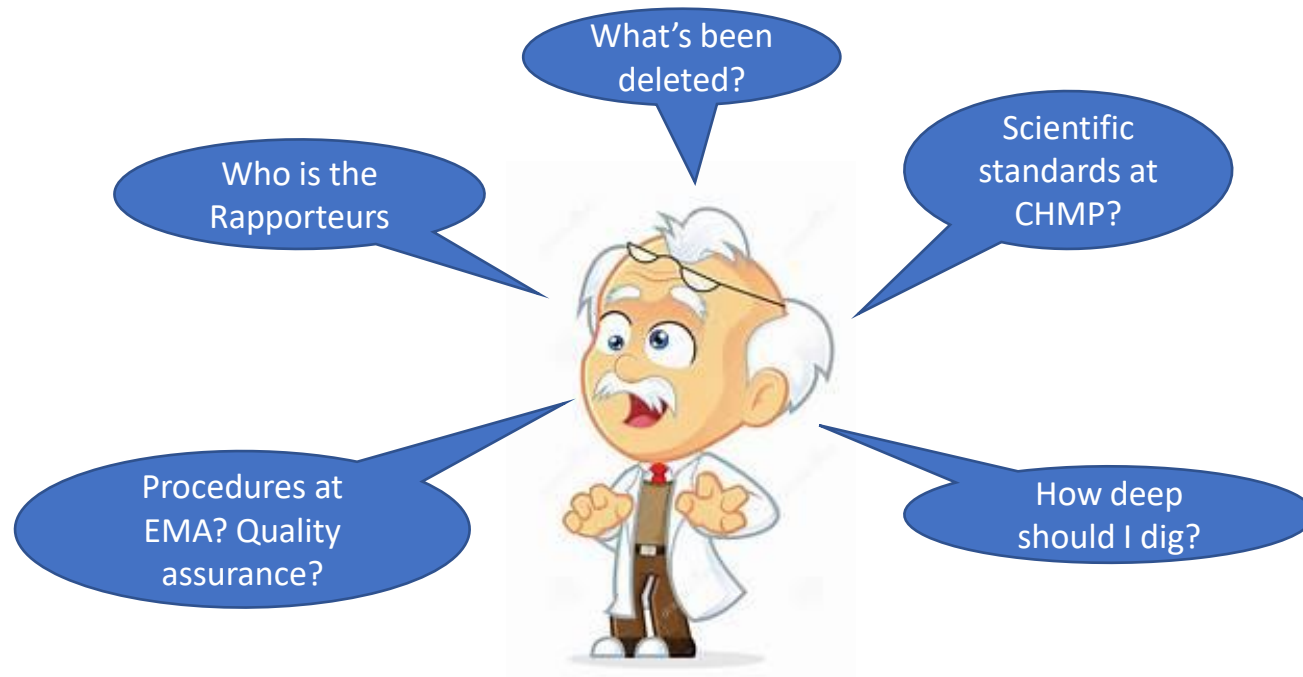
# Applicant

- ❖ Support the collaboration between regulators by using the system and support adequate funding
- ❖ Allow a “prospective” approach (eg follow initial review of a selected application)
- ❖ The entire final assessment report plus earlier versions made available; including Scientific Advice, Paediatric development plans, orphan status, Conditional Marketing Authorisation justifications etc
- ❖ Updates made to the application

# Receiving agency

- ❖ Invest in the reliance model – expect internal resistance. Leadership!
- ❖ Training, including why we rely on the work of other agencies?
- ❖ Scientific support to the assessors
- ❖ Frequent use of the reliance model
- ❖ Maintenance of trust

The reasons why he is uncertain how to conduct the review may include....



# GLOBAL COLLABORATION

- Global collaboration – global public health perspective.
- EU is a good example of how national agencies by working together better can serve the public health.
- But it requires the guts to give up some independence.....
- Support from WHO Good regulatory reliance models (and Bill & Melinda Gates Foundation etc)
- “Bilateral” collaborations – eg HSA - Swiss Medic - Health Canada – TGA
- Regional Harmonization initiatives; eg the Eurasian Union...



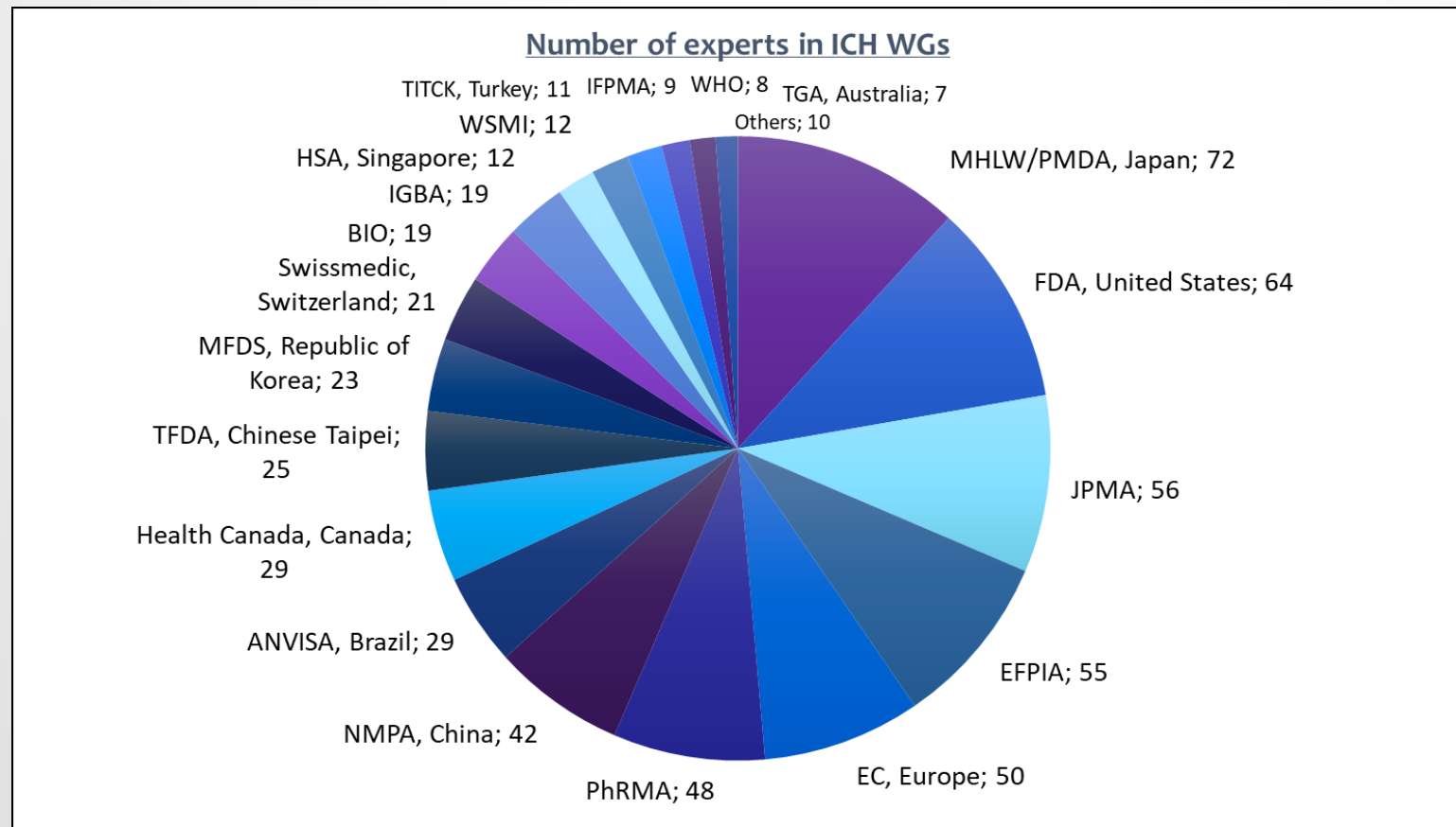
# Overview of ICH

# ICH SUCCESSES INCLUDE:

- CTD / eCTD
- GCP
- MedDRA
- **Over 60 Guidelines on technical requirements on:**
  - Safety-14 Guidelines
  - Quality-23 Guidelines
  - Efficacy-21 Guidelines
  - Multidisciplinary-6 Guidelines
- But it is not a reliance model...



# COMPOSITION OF ICH WGS -646 EXPERTS IN 26 WGS



## In conclusion.....

- ❖ Trust is essential for a reliance model to work
- ❖ Recognise the challenges
  - Complex scientific assessments
  - Subjective conclusions
  - Expect resistance
- ❖ All stakeholders have responsibilities in creating trust
- ❖ When trust is established it must be maintained
- ❖ A common legislation is very helpful....

# Questions?