Consilium

Salmonson & Hemmings

Initiatives to promote global regulatory convergence….

…how to build trust…

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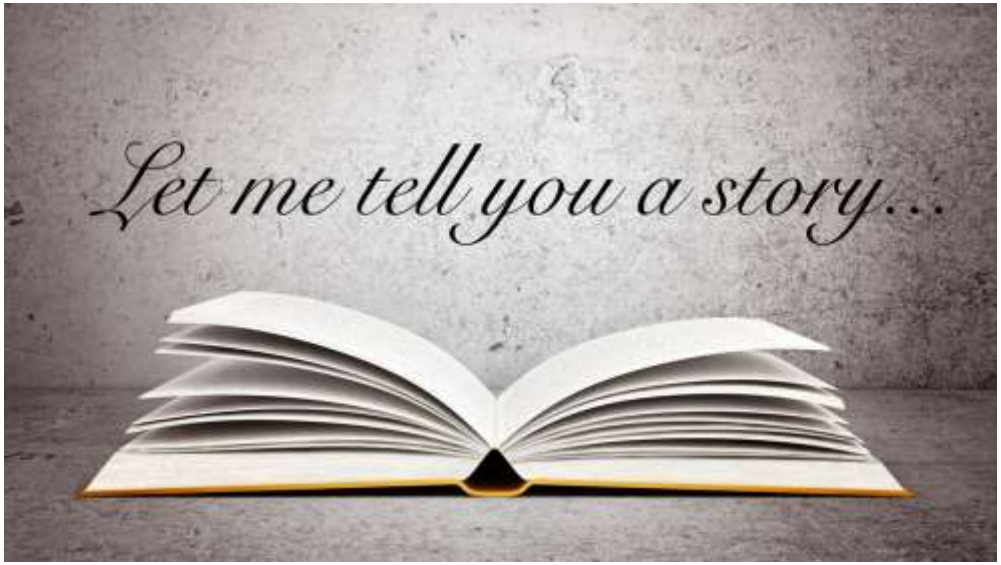
Trust

Webster: **Reliance** on the character, ability, strength, or truth of someone or something

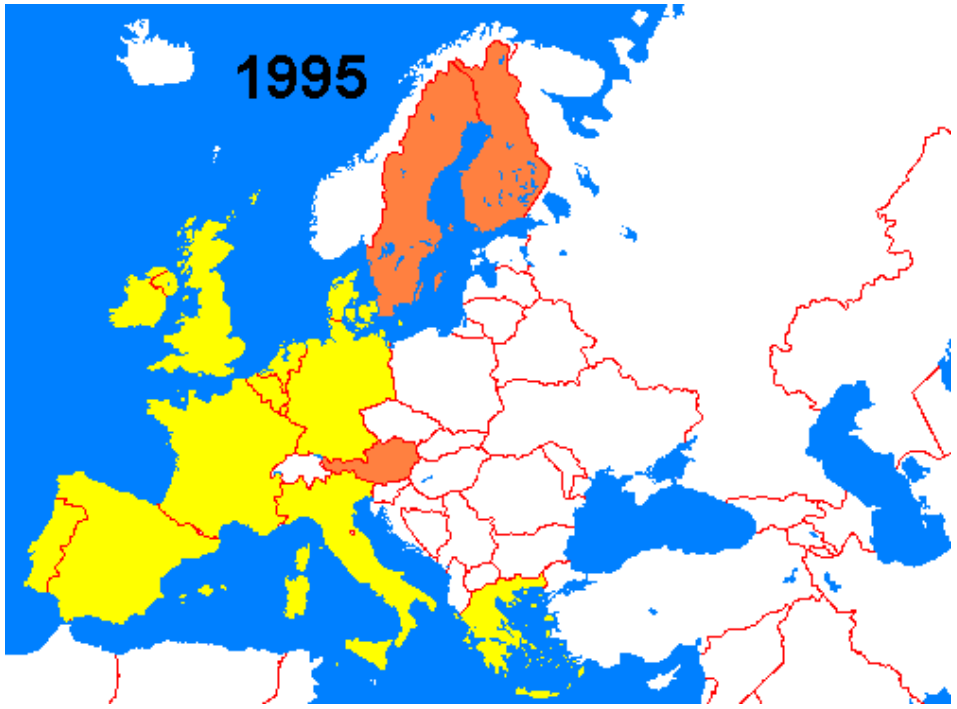
Collins: and If you **trust** someone, you believe that they are honest sincere and will not deliberately do anything to harm you.

My starting points:

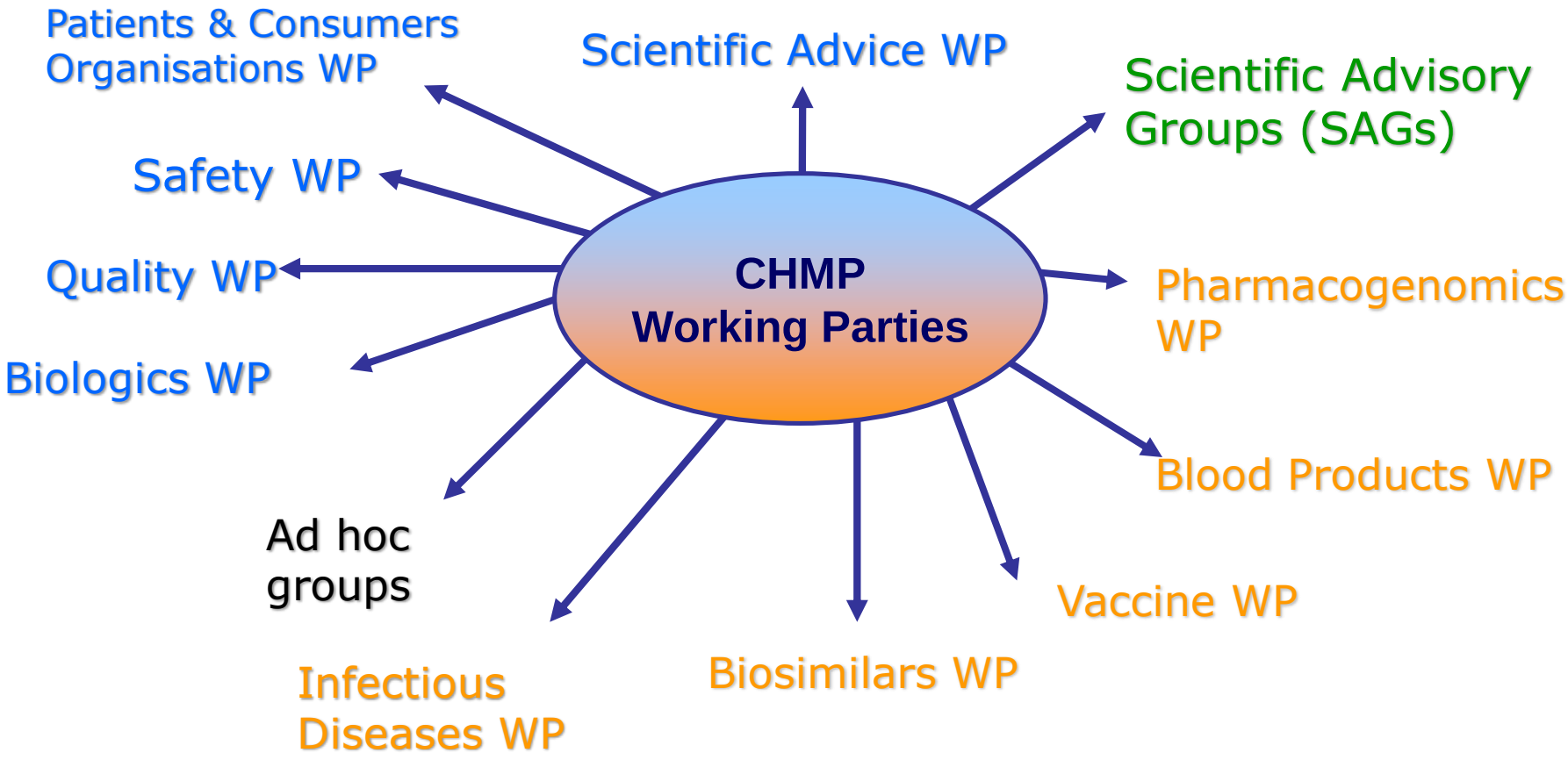
- Regulators cannot and should not work in isolation
  - Working together is the way to obtain maximum public health impact at a national level
- Trust and leadership are the key to the success of any reliance models….
- Several ways to collaborate:
  - ADR reporting
  - Regulatory and scientific standards; 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

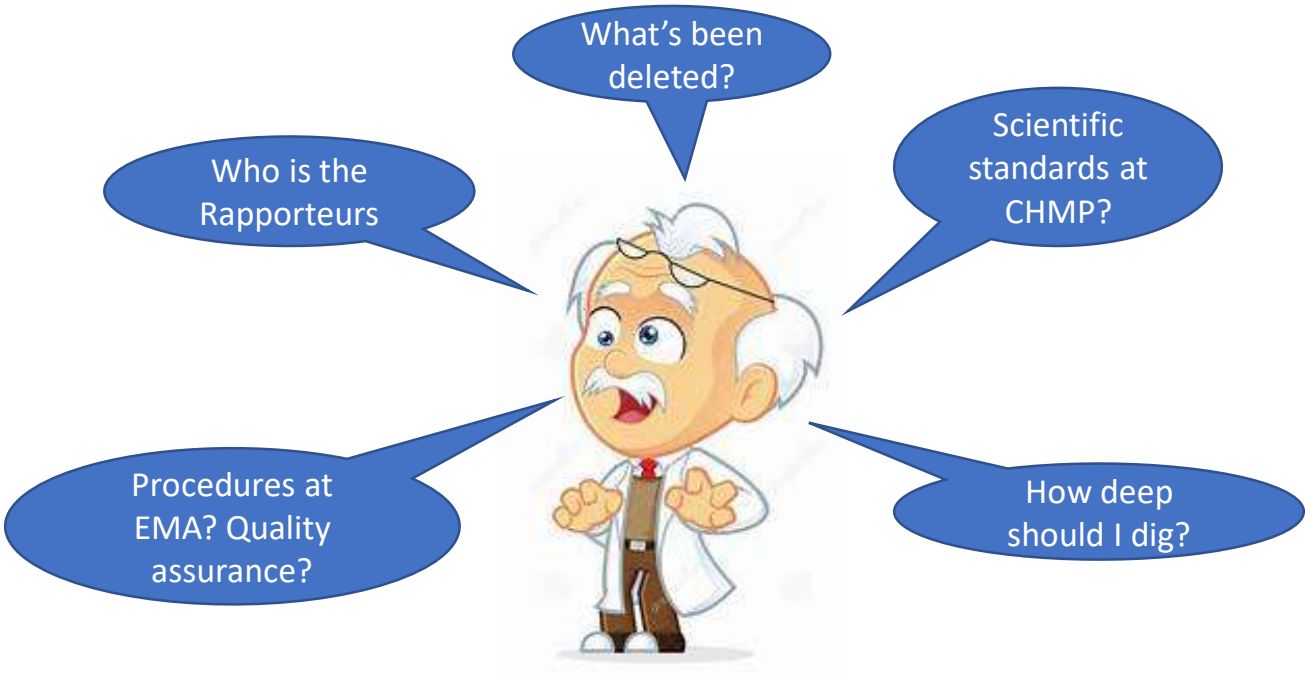
Applicant

- 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…

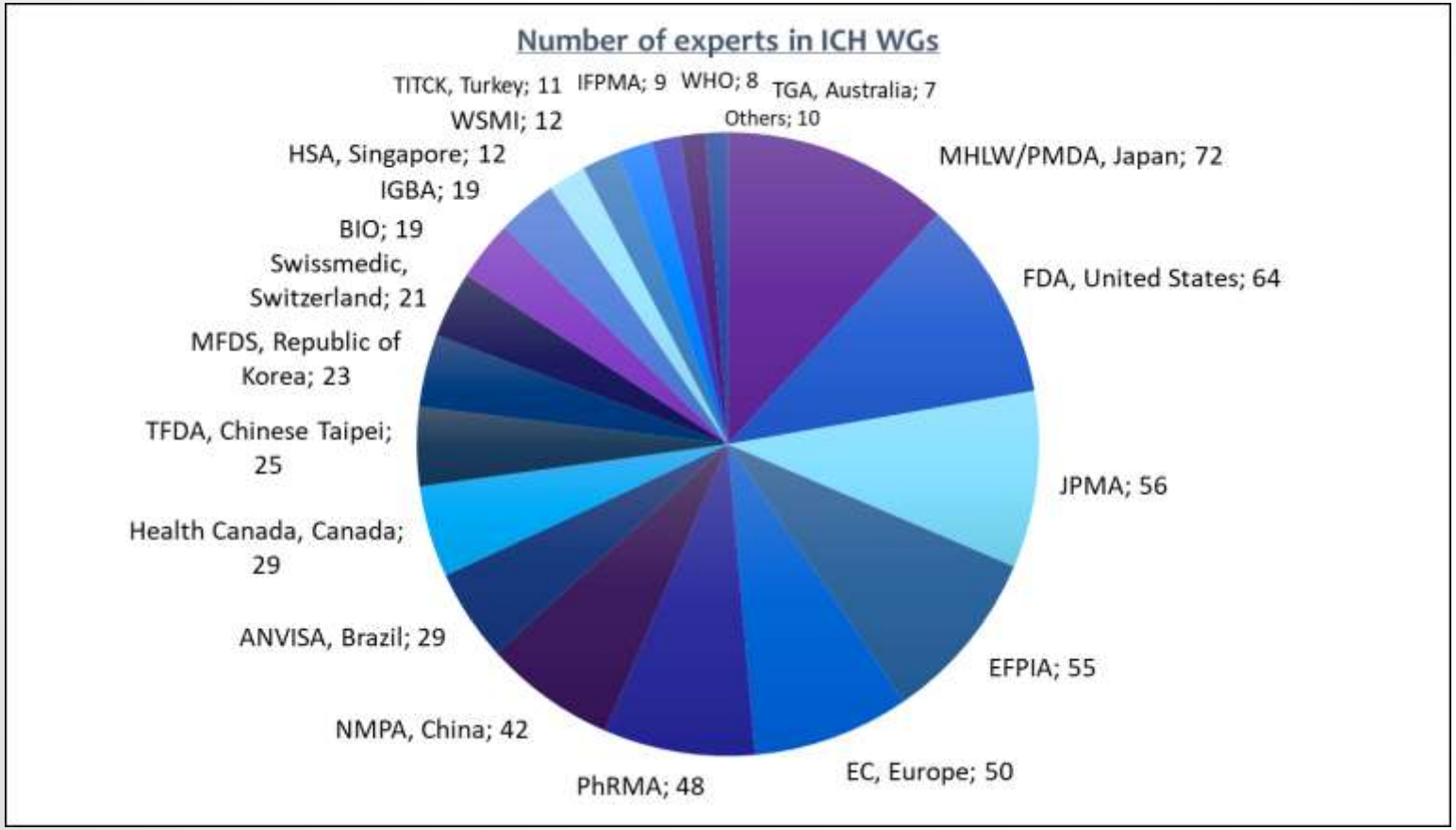
ICH
harmonisation for better health

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?