



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Framework for interaction between EMA and healthcare professionals

Revision principles

HCPWP plenary meeting

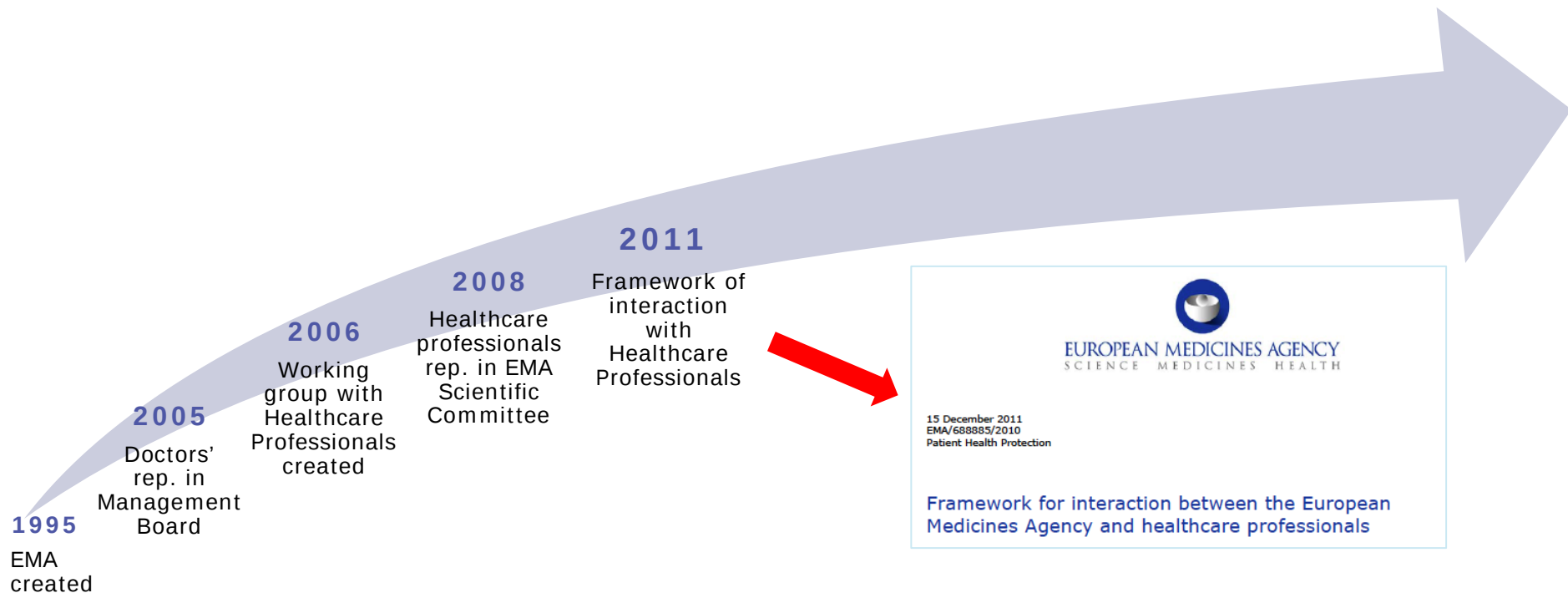
Presented by Rosa Giuliani and Sergio Bonini on 15 June 2016
HCPWP topic group on academia, learned societies and healthcare professionals co-leaders

An agency of the European Union





Collaboration of EMA with healthcare professionals





As is...



Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**



Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines

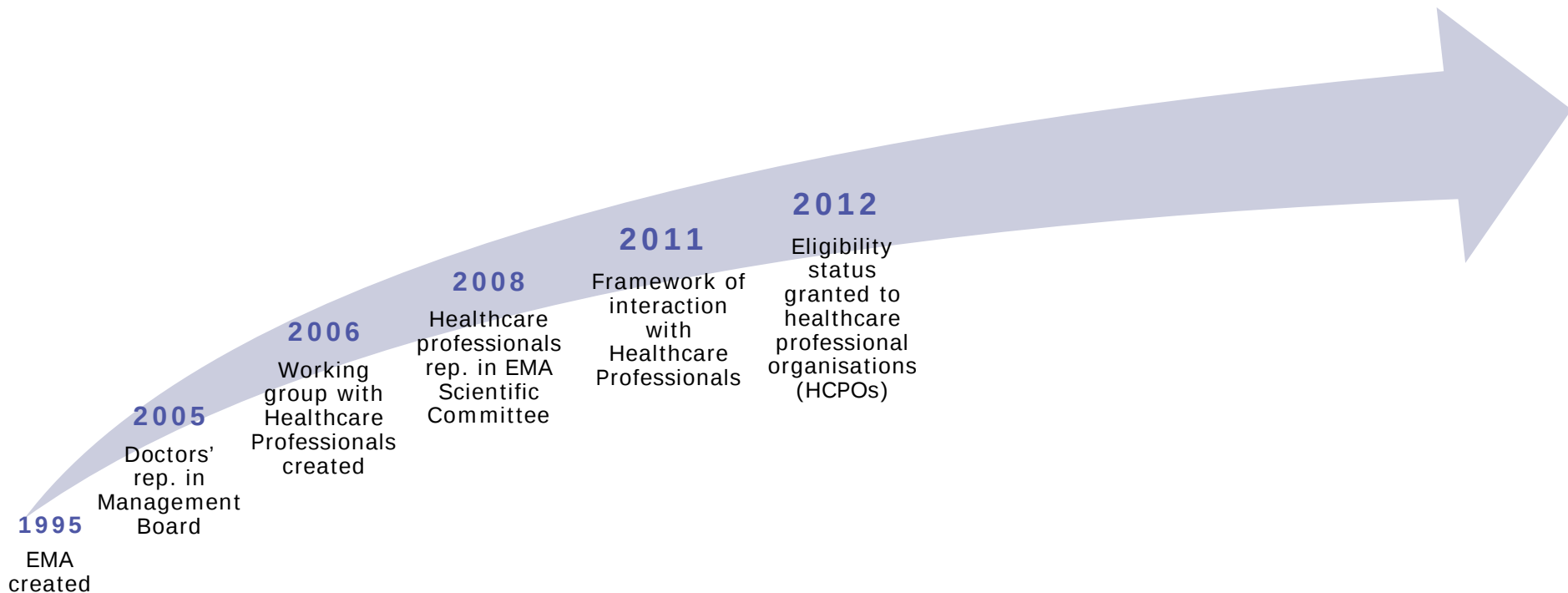


Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations



Collaboration of EMA with healthcare professionals



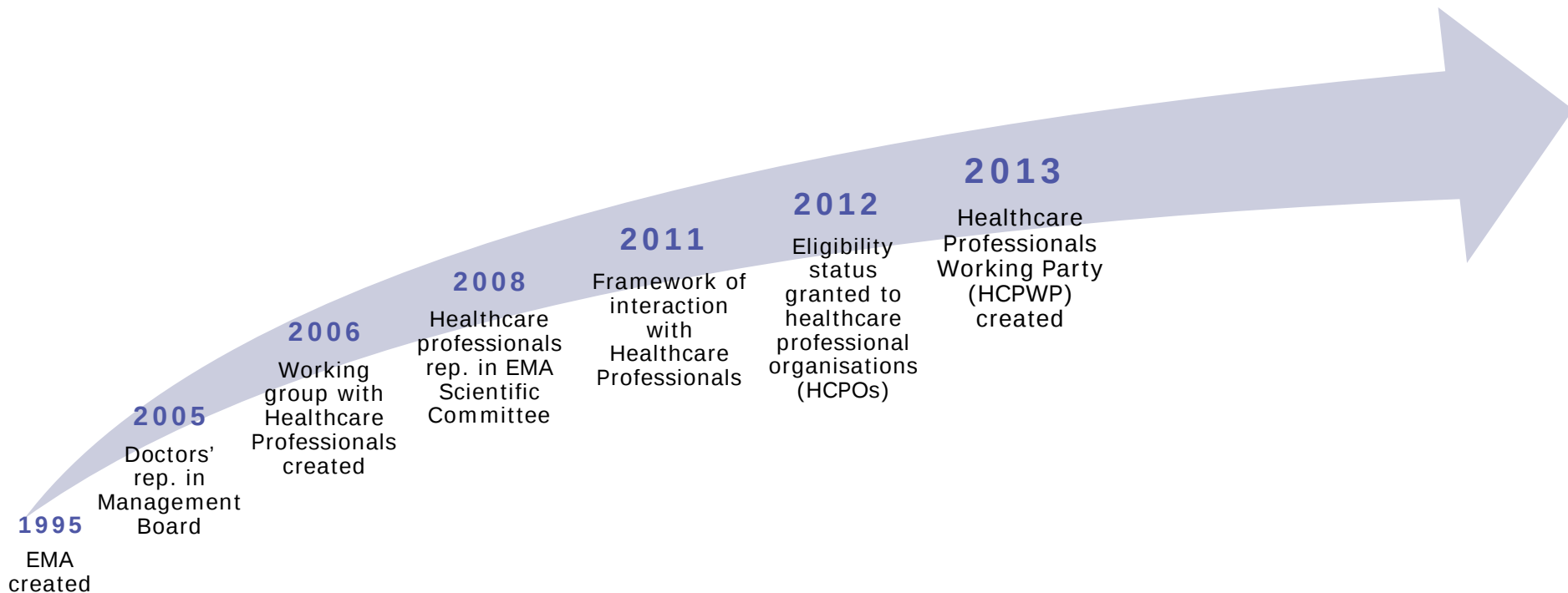
EMA network of European healthcare professional organisations



30 eligible organisations by May 2016



Collaboration of EMA with healthcare professionals



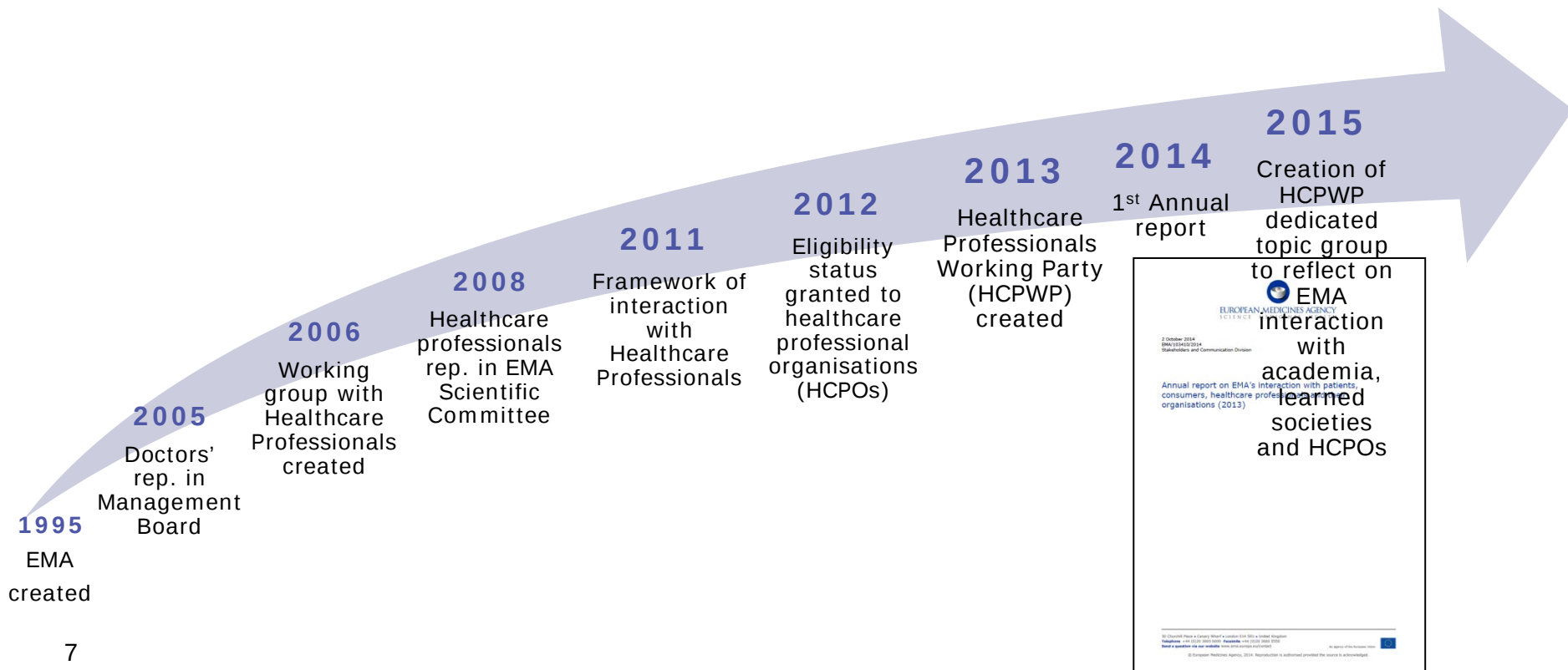
Healthcare Professionals Working Party (HCPWP)

Platform for dialogue and exchange on relevant issues concerning medicines;
The HCPWP provides recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to healthcare professionals





Collaboration of EMA with healthcare professionals



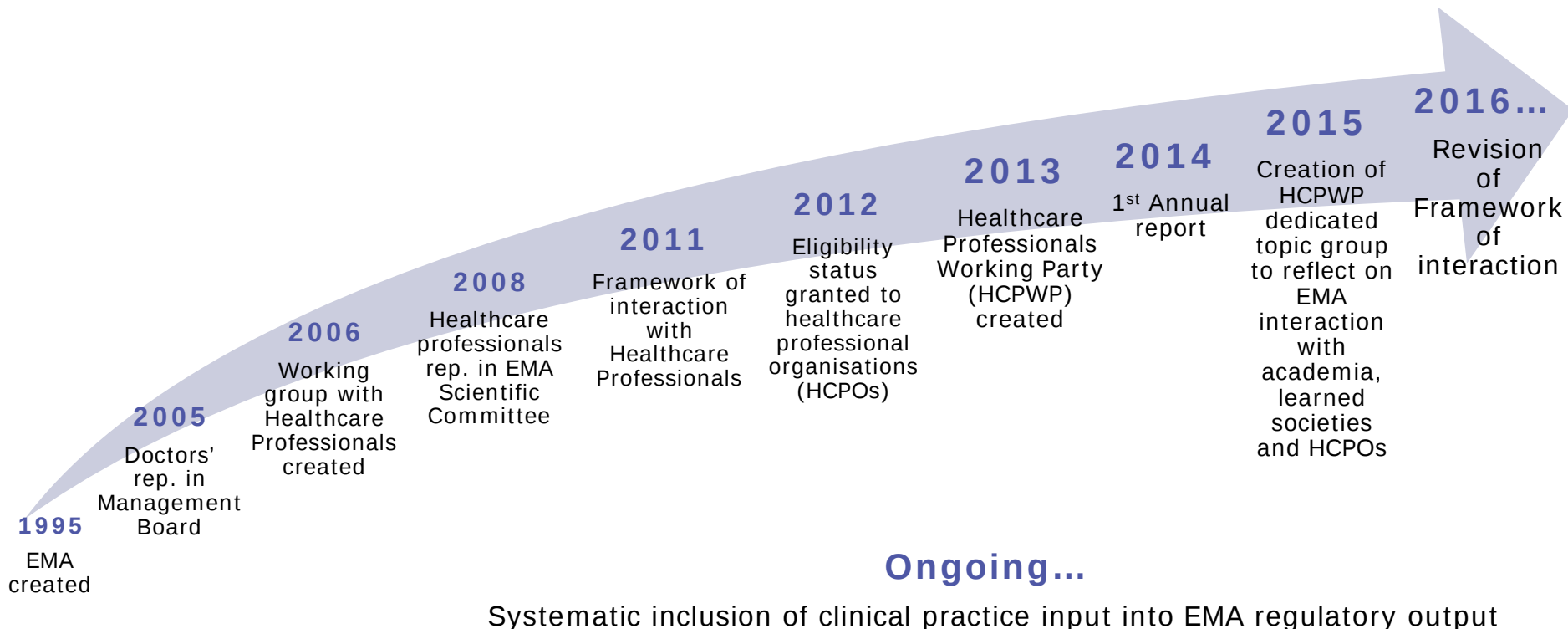
General objectives of the Topic Group

- Reflect on the need to review the EMA framework of interactions with HCPs
- Support the development of the EMA framework for collaboration with Academia
- Identify current practice with involvement in regulatory activities
- Discuss areas for improvement and foreseeable changes

- 
- The 2011 Framework document should be up-dated to adapt to a more relevant role of HCPs in drug development and monitoring
 - HCPs should significantly contribute to the drafting of an updated version



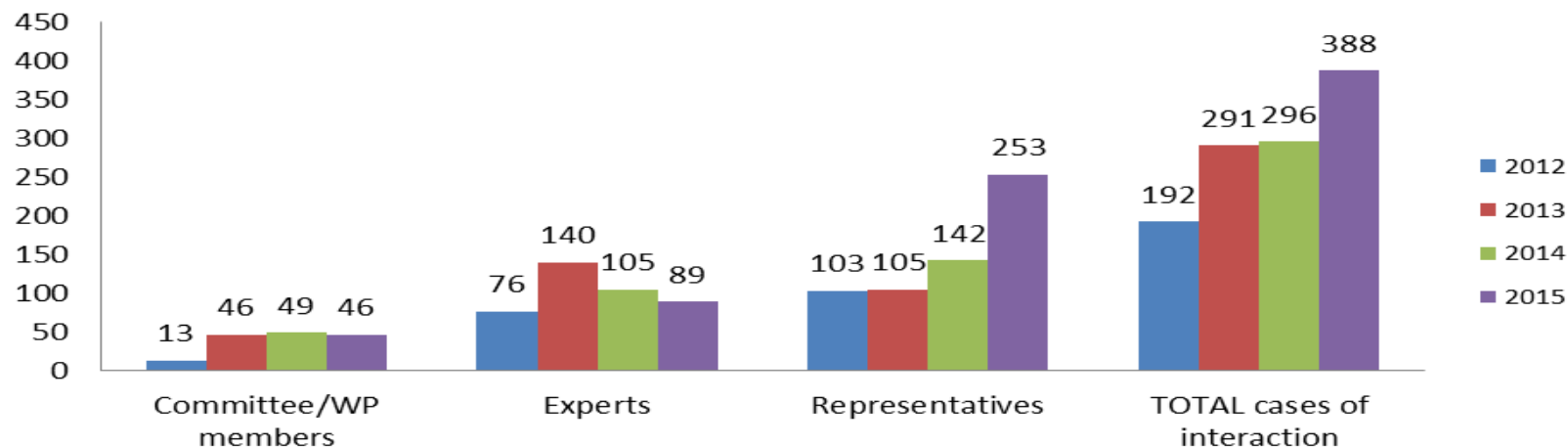
Collaboration of EMA with healthcare professionals





Involvement in core activities

Comparison of involvement as committee / WP* members, experts and representatives of organisations



*WP – working parties



Scanning the horizon...what lays ahead





Where do the regulatory and clinical contexts come together?

Benefits/risks balance



Risk management and communication



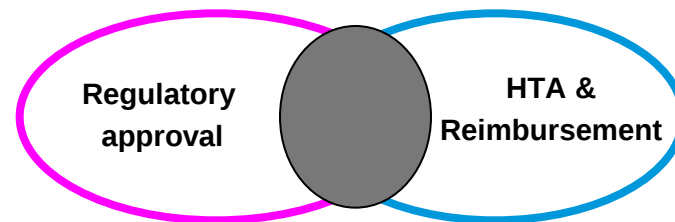
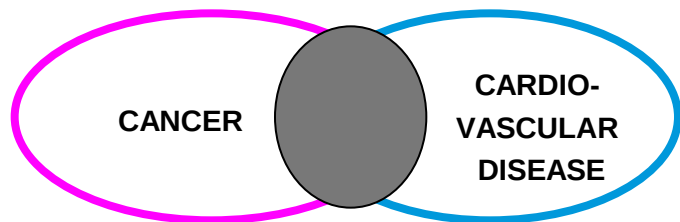
Medicines information

Hallo Alo duit
Halla Hej Olá
Halla Bonjour Dia
Здравейте Hei
Pozdravi Bok Cześć
Hello Ahoj Sveiki
Holla
Ciao Tere
Helló Για σας

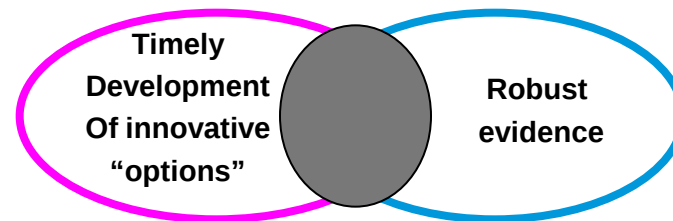
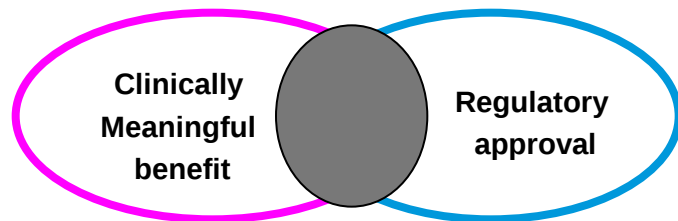
24 official languages

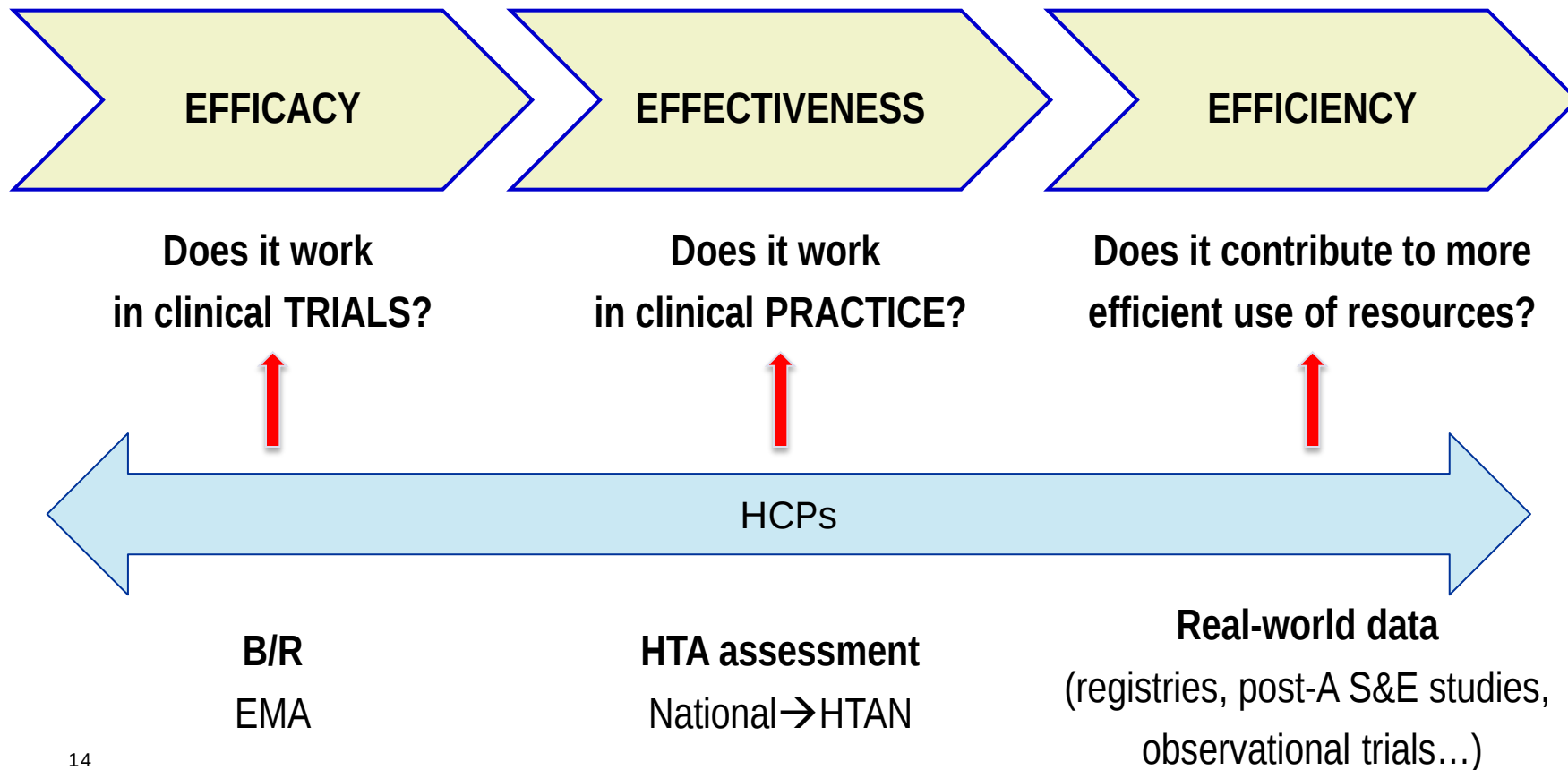


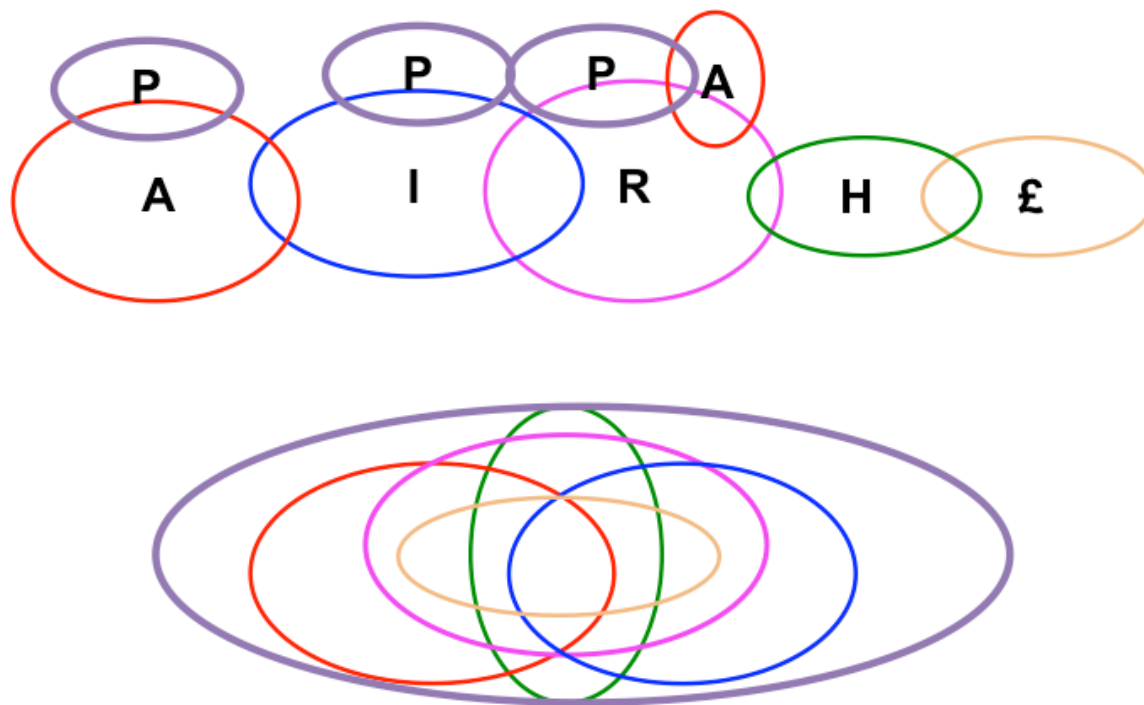
>>>> 50 Shades of grey....



HCPs/Academia organizations may contribute to clear grey areas
(sometimes we create them..)







Promotion of
platforms/forums for
interaction and
collaboration

Alignment with regulators' strategic objectives

- EU Medicines Agencies Network Strategy to 2020
- EMA priorities
- EMA Multi-annual programme

Consistency and complementarity amongst stakeholders

- Framework for stakeholder relations management
- Framework of collaboration with academia (focus on research, education and training)
- Further strengthening link with patients (should we identify specific areas of focus e.g. health literacy?)

Inclusion of healthcare professionals' fields of activity and areas of interest

- Focus on health care (should we define the full spectrum e.g. from primary care to highly specialised care?)
- Aspects deriving from HCPs' role: not only prescribers but partners in the development and monitoring of medicines
- How much detail should be included in relation to areas of interest? (e.g. collection of data (eHealth and registries); personalised medicine; ...)

Continuous improvement on the basis of acquired experience

- As the foundation is now set, should we consider additional levels of granularity for interaction? (e.g. on the basis of maturity of interaction; response/ engagement capacity; level of interest)
- Where to direct efforts? 'Expansion' / 'diversification' / 'integration' / 'specialisation' (e.g. per types of activity; therapeutic areas; ...)

Annexes to the framework document

- Action plan with outline of specific actions and estimated timeframes for completion – will be detailed in annex I
- EMA activities where healthcare professionals are involved and modalities of interaction – will be described in annex II

Eligibility criteria – outside scope of revision of the framework

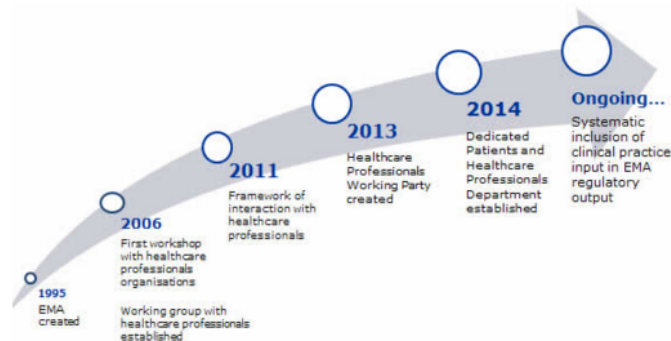
- Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities
- Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility'



Healthcare professionals

The European Medicines Agency (EMA) has been interacting with European healthcare professionals in various areas of its work since it was founded in 1995. As prescribers and handlers of the medicines that the Agency evaluates, healthcare professionals are key stakeholders in the Agency's work and have specific knowledge and expertise to offer. The Agency is committed to maintaining a strong working relationship with this group.

Key milestones of EMA interaction with healthcare professionals



Related documents





Thank you for your attention

Further information

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