









# Strengthening training of academia in regulatory sciences and supporting regulatory Scientific Advice: STARS



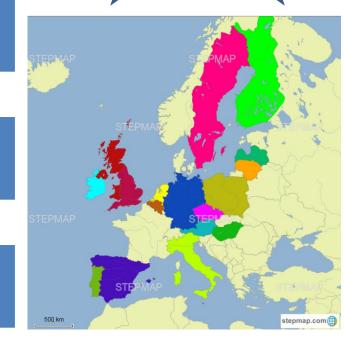
Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice: STARS

a in CSA STARS

Aims & objectives of the project

Brief outline of the methodology

Deliverables/outcomes expected







## Aims & Objectives

#### **Overall aims:**

- > to improve the direct regulatory impact of results obtained in (early) medical research.
- > to reach academic researchers very early in the planning of relevant grant applications.
- > to strengthen long-term regulatory knowledge in general by reaching clinical scientists during professional training and qualification.





## Aims & Objectives

#### **Objectives of STARS:**

- > To deliver consensual recommendations ensuring sustainable support of academic research.
- To propose additional support mechanisms based on a comprehensive analysis of needs.
- To complement, coordinate and harmonize regulatory efforts among Member States and at European level to support academic health research for the benefit of patients.



## Methods/Plans

- To develop and sustain a Comprehensive Inventory of existing support activities based on a detailed analysis of the currently established programmes.
- To develop and consent a Common Strategy to strengthen regulatory sciences
- To develop a Core Curriculum on essential knowledge for the professional training of clinical scientists and a Comprehensive Curriculum defining relevant knowledge for specific postgraduate programs.



## Methods/Plans

- To implement three academic-regulatory pilot projects with the aims
- (i) to transfer an identified best practice example for training programmes to other EEA countries,
- (ii) to implement a new support activity addressing a gap in regulatory knowledge of significant relevance
- (iii) to implement the Comprehensive Curriculum.





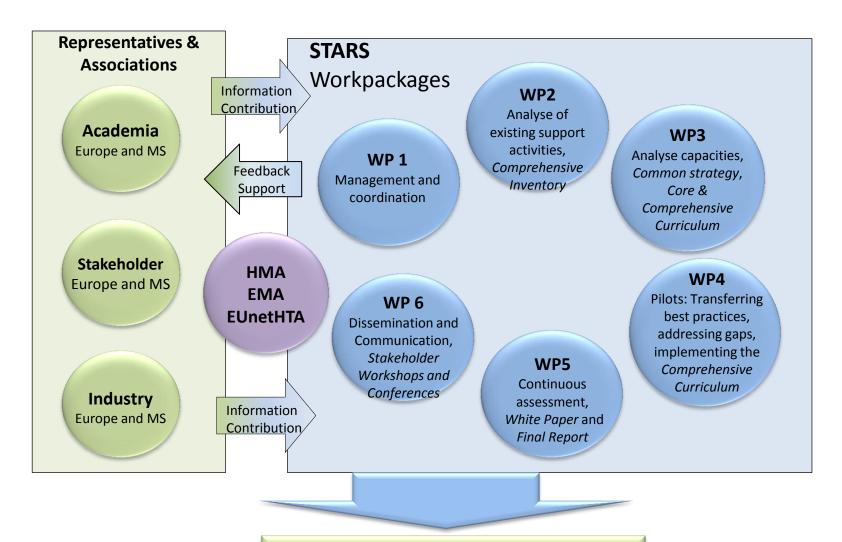
#### Dissemination and communication

- White Paper; Website; articles in lay press
- European stakeholder workshops
- Months 18 and 34 (follow-up)
- > Relevant national, European and global stakeholders
- The academic health research community
- National, European and global funding organisations active in health research support
- Global Regulatory Science conference
- ➤ Month 34
- Relevant global stakeholders
- The academic health research community
- Relevant international organisations, initiatives or projects
- > Patients, European citizens and broader public





## Outcomes and deliverables

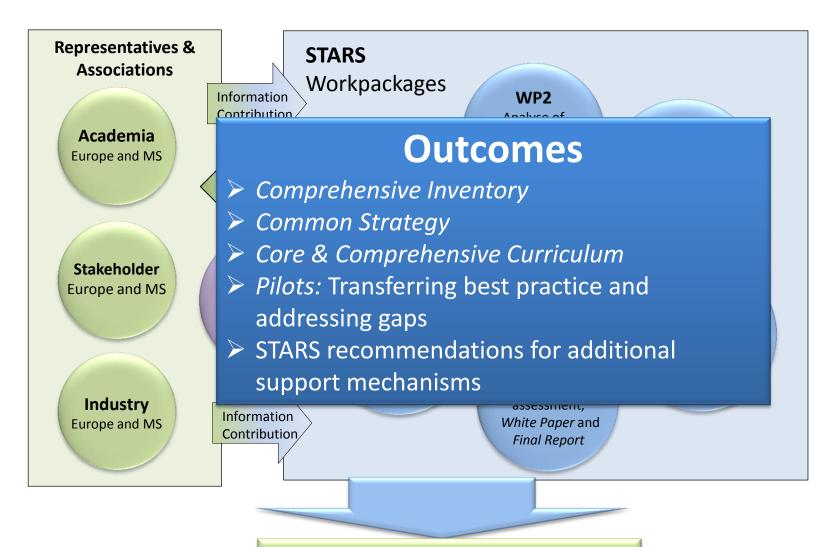




Improving regulatory knowledge, success and direct regulatory impact of academic health research



### Outcomes and deliverables





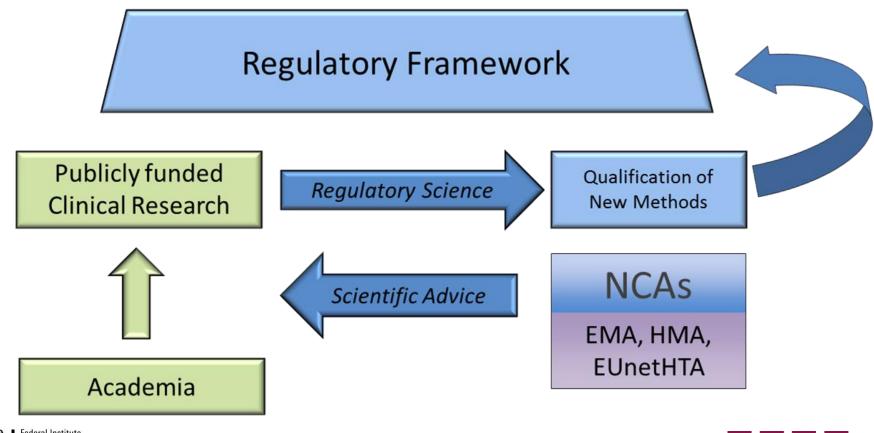
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## Regulatory Research

"... To fill the gaps in scientific needs for the support of regulatory decisions and the minimization of drug-associated risks in the general population"

(German Science Council 2014)







# Thank you very much for your attention!

#### Contact

Federal Institute for Drugs and Medical Devices

Kurt-Georg-Kiesinger-Allee 3 D-53175 Bonn

Contact person Dr. Wiebke Löbker innovation@bfarm.de www.bfarm.de



