

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

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The 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 medical research.
- to reach academic researchers very early in the planning of relevant grant applications.
- to strengthen 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 post-graduate 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

- European stakeholder workshops

- Months 18 and 34
- 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

