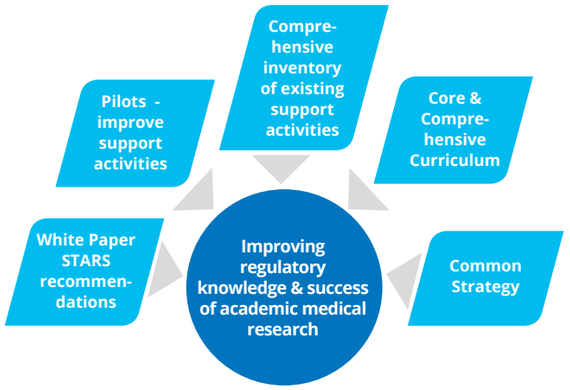
WP6: Communication and dissemination

- Dissemination and communication of the intermediate and final outcomes;
- Development and implementation of strategies and tools for the communication on the national, European, and global level;
- Communication with relevant stakeholder within the innovation and health care environment;
- Two European stakeholder workshops and the subsequent global conference;
- Launch and maintenance of the project's website.



Activities and expected results of the STARS consortium

Project partners in alphabetical order of acronyms

AEMPS	Spanish Agency of Medicines and Medical Devices
AGES	Austrian Agency for Health and Food Safety
AIFA	Italian Medicines Agency
ANMS	National Agency for the Safety of Medicine and Health Products (France)
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
DLR-PT	DLR Project Management Agency (Germany)
EMA	European Medicines Agency
FAMHP	Federal Agency for Medicines and Health Products (Belgium)
Fimea	Finnish Medicines Agency
HPRA	Health Products Regulatory Authority (Ireland)
INFARMED	National Authority of Medicines and Health Products (Portugal)
MEB	Medicines Evaluation Board (The Netherlands)
MHRA	Medicines And Healthcare Products Regulatory Agency (United Kingdom)
MA	Medicines Authority (Malta)
MPA	Medical Products Agency (Sweden)
OGYÉI	National Institute of Pharmacy and Nutrition (Hungary)
PEI	Federal Institute for Vaccines and Biomedicines, Paul-Ehrlich-Institut (Germany)
SAMLV	State Agency of Medicines of Latvia (Latvia)
SÚKL	State Institute for Drug Control (Czech Republic)
URPL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Poland)
VVKT	State Medicines Control Agency (Lituania)

Cooperating partners in alphabetical order of acronyms

HALMED	Agency for Medical Products and Devices (Croatia)
NOMA	Norwegian Medicines Agency
SAM	State Agency of Medicines (Estonia)

Contact

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QPR code of the STARS webpage

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STARS
STRENGTHENING REGULATORY SCIENCE

STARS

Strengthening Training of Academia in Regulatory Science

Project Details:

STARS – Strengthening Training of Academia in Regulatory Science

EU funding scheme:
Coordination and Support Action (CSA)

Project coordination:

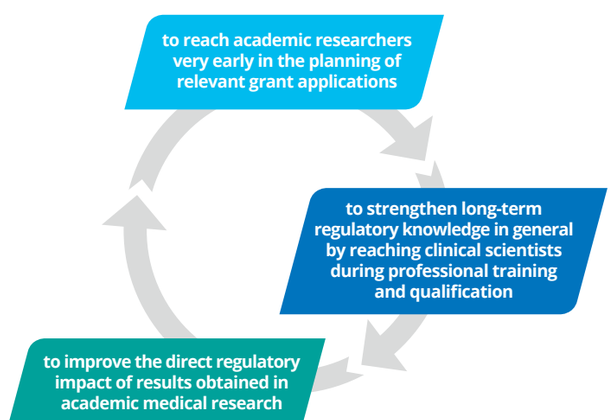
- **BfArM - Federal Institute for Drugs and Medical Devices (coordinator);**
- **PEI - Federal Institute for Vaccines and Biomedicines;**
- **DLR-PT - Project Management Agency of the German Aerospace Center.**

Limited knowledge in regulatory science delays the development of **new clinical treatment strategies** or restraints the chances that promising innovations will reach patients. STARS aims at analysing the current situation of the regulatory knowledge in academia and at improving **training of academia in regulatory sciences** in order to enhance regulatory knowledge. Professional education and targeted training programmes for academic scientists will promote the regulatory impact of medical research, thus they will support successful outcomes in scientific adviceand protocol assistance in clinical studies. Finally, this enables academic health research to have a full impact and benefit for the patient.

Activities and Methods

- Set up and sustain a **Comprehensive Inventory (CI)** of existing support activities based on a detailed analysis of the currently established programmes;
- Perform **Survey Studies** to analyse the status quo of regulatory sciences and collect feedback from academia regarding their needs and experiences with regulatory scientific advice and protocol assistance procedures;
- Develop and consent a **Common Strategy** to strengthen regulatory sciences;
- Establish a **Core Curriculum** on essential knowledge for the professional training of clinical scientists and a **Comprehensive Curriculum** defining relevant knowledge for specific post-graduate programmes and
- Implementation of three academic-regulatory **Pilot Projects**.

STARS aims



Work plan and work packages (WP)

WP1: Project management and coordination

- Intermediary for all communications between the beneficiaries and the European Commission (EC);
- Continuous management and monitoring of the work by the whole STARS consortium and all WPs.

WP2: Establishment of the Comprehensive Inventory

Currently, there is little comprehensive information available about existing regulatory support activities for academic researchers. The main objective of WP2 is to establish, regularly update and disseminate a comprehensive inventory (CI) of existing support activities for regulatory scientific advice and protocol assistance in Europe. Therefore, a survey is implemented to obtain the required information. The target groups for the surveys are:

- Academic clinical centres;
- Academic researcher groups and projects;
- Funding organisations active on national and European level.

The results from the surveys will be the basis for the activities of STARS. STARS will identify best practices which are suitable for implementation in other countries. A further objectiveis to analyse the needs and gaps in regulatory guidance for academic health research.

WP3: Effectiveness analysis and strategy development

WP3 will provide comprehensive information on the experience of the regulatory agencies carrying out scientific advice requested by academic groups. This information will be used to develop the common strategy, which will become the STARS road map for planning and implementation of support activities such as training programmes. The common strategy will be based on the information provided by the surveys carried out in WP2 and 3, but will also include specific actions:

- Development and implementation of the core curriculum and the comprehensive curriculum in order to harmonize and strengthen regulatory knowledge of clinical scientists;
- Analysis and support of three pilot projects.

WP4: Implementation of the STARS Pilots

WP4 will design and implement **three pilot** projects to demonstrate that selected support activities can be implemented efficiently via the methodical approach proposed by STARS.

- **Pilot I:** Successful transfer of a selected best practice example to one or more European Economic Area (EEA) countries;
- **Pilot II:** Initiate a novel regulatory support activity in one or more countries in order to address identified gaps;
- **Pilot III:** Establishment of the comprehensive curriculum developed by WP3 within one or more existing post-graduate programmes in EEA countries.

WP5: Additional mechanisms to support academic groups

- Assessing the need for additional mechanisms to sustainably support academic groups in regulatory scientific adviceand protocol assistance procedures;
- Providing recommendations to address the identified needs and gaps. The recommendations will be published and disseminated on a national, European and global level.