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.

Project partners in alphabetical order of acronyms

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

Cooperating partners in alphabetical order of acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HALMED</td>
<td>Agency for Medical Products and Devices (Croatia)</td>
</tr>
<tr>
<td>NOMA</td>
<td>Norwegian Medicines Agency</td>
</tr>
<tr>
<td>SAM</td>
<td>State Agency of Medicines (Estonia)</td>
</tr>
</tbody>
</table>

Activities and expected results of the STARS consortium

- Improving regulatory knowledge & success of academic medical research
- Comprehensive inventory of existing support activities
- Comprehensive & Comprehensive Curriculum
- White Paper STARS recommendations
- Pilots improve support activities

Contact

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Visit us on: https://www.csa-stars.eu
QPR code of the STARS webpage

Imprint

Coordination: Federal Institute for Drugs and Medical Devices (BFaRM)
Coordinator: Dr. Wiebke Löbker
Publisher/ Editor: DLR
Design: DLR

STARS is a coordination and support action (CSA) that has been granted for funding through the EU Framework Program for Research and Innovation ‘Horizon 2020’ under grant agreement no [825881].
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

- 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
- to improve the direct regulatory impact of results obtained in academic medical research

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 target-ed training programmes for academic scientists will promote the regulatory impact of medical research, thus they will support successful outcomes in scientific advice and protocol assistance in clinical studies. Finally, this enables academic health research to have a full impact and benefit for the patient.

**Activities and Methods**

- Establish a **Comprehensive Inventory** (CI) of existing support activities based on a detailed analysis of the currently established programmes;
- 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**.

**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 objective is 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 advice and 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.