STAMP 11/47
STARS overview

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

The EU Coordination and Support Action – STARS: Strengthening training of academia in regulatory sciences & supporting regulatory scientific advice is a 3 year EU funded project. The consortium, including national competent authorities, is led by German Federal Institute for Drugs and Medical Devices. The main objective of the project is to complement coordinate and/or harmonise efforts among Member States and at European level in order to support the main target group: academic clinical scientists. The aim is to reach these researchers very early in the planning process for relevant grant applications. A further aim is to strengthen regulatory knowledge in general by reaching clinical scientists during professional training and qualifications.

The table below summarises the planned activities and highlights those which are of potential relevance for repurposing of medicines related activities.

STARS activity	**Relevant to repurposing related activities?**
<u>Aims and Objectives</u> *Overall aims:*	
- to improve the direct regulatory impact of results obtained in medical research.	**yes**
- 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.	**yes**
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.	**yes**
➢ To complement, coordinate and harmonise regulatory efforts among Member States and at European level to support academic health research for the benefit of patients.	**yes**
Methods/Plans	
• To develop and sustain a Comprehensive Inventory of existing support activities based on a detailed analysis of the currently established programmes.	**yes**

• To develop and consent a Common Strategy to strengthen regulatory sciences	**yes**
• 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 programmes.	
• 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.	