STARS

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

What is STARS? The bridge to close regulatory knowledge gaps!

The EC-funded STARS project aims to bridge the regulatory knowledge gap in academic research and to improve the direct regulatory impact of results obtained in academic medical research. It is observed that there is often a lack of specific relevant knowledge in regulatory science in academia that delays the development of new treatment strategies or limits the chances that promising innovations will reach patients. Therefore, **early exchange and communication** between academic researchers and regulators is crucial. In addition, support and training for academia needs to be tailored according to specific needs and challenges, e.g. a proactive communication with regulatory authorities and funding bodies throughout development.

The communication framework presented in the figure on page 2 outlines the information flow between different stakeholders in the regulatory system. Regulatory agencies are key players that act as licensing and supervisory authorities at national (NCAs) or European (EMA) levels, and generate and convey guidance on how to design successful drug-development programmes using specific channels to reach the **main stakeholders in academia**, namely, clinical researchers in university medical centres and hospitals. Other key stakeholders include research institutes, individual researchers working in drug R&D, and the public and private funding bodies supporting these research activities.

The figure was developed by the STARS consortium and published in the article "Strengthening regulatory science in academia: STARS, an EU initiative to bridge the translational Gap" (Starokozhko et al., 2020).
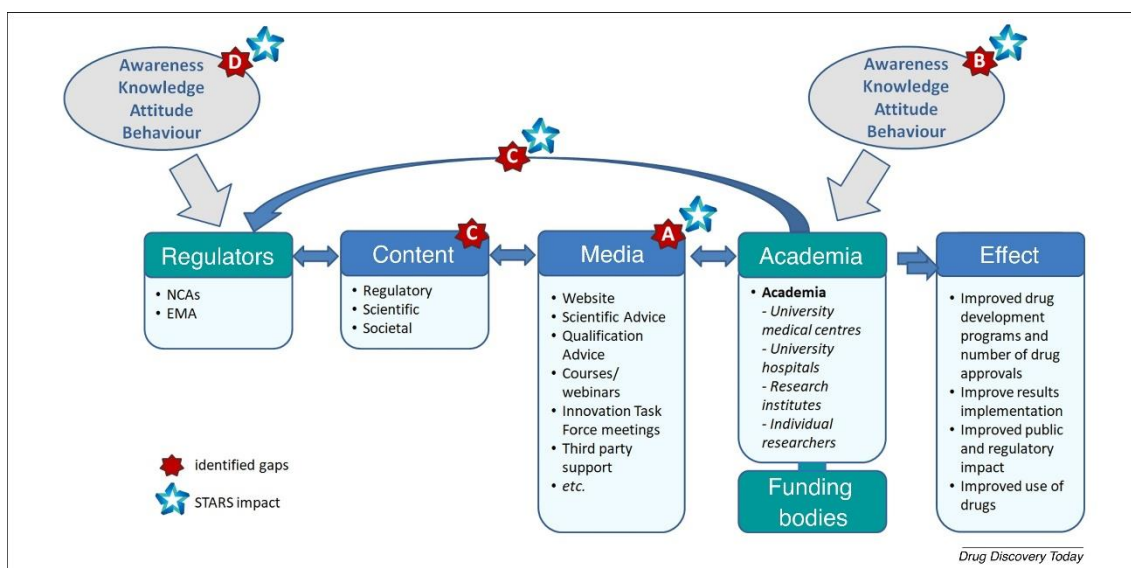
Figure 1. Information flow and identified gaps in the regulatory communication framework (cf. STARS White Paper by Starokozhko et al., 2020).

STARS has the **objective** and the **potential** to complement the gaps outlined on the figure above, to coordinate and to harmonise regulatory efforts among Member States and at European level to **support academic health research** for the benefit of patients.

The **aim** is to reach academic researchers very early in the planning of clinical research projects and relevant grant applications. A further aim is to strengthen regulatory knowledge in general by reaching clinical scientists during professional training and qualification.

STARS Activities

STARS has launched a [Comprehensive Inventory](#) of existing support activities based on a detailed analysis of the currently established programmes. The inventory assists European academic drug developers in finding support on regulatory affairs.

Three different pilot projects aim to **transfer a best practice example of a training** programme ([Pilot I](#)), **to establish a new support activity by addressing a gap in regulatory knowledge** ([Pilot II](#)), and to implement a [Comprehensive Curriculum](#) to ensure harmonized tutorials addressing **regulatory content**.

Finally, STARS will deliver consensual recommendations ensuring sustainable support of academic research and will propose additional support mechanisms based on a comprehensive analysis of needs. All activities will feed into a: Common Strategy, which is a major roadmap to strengthen regulatory sciences.