



'The Winding Road from a Brilliant Idea to Drug Approval: An Online Course in Regulatory Science for Academic Researchers' – Publication of the Training Material

The STARS consortium organised in February 2021 a 4-day online training for academia with topics on basic regulatory knowledge and specific regulatory requirements. Titled 'The Winding Road from a Brilliant Idea to Drug Approval' the course covered topics on essential regulatory knowledge, case examples, insights into the regulatory system, as well as direct interaction and question answer sessions with regulators and clinical assessors. The [training course presentations](#) are now available. This event represents [Pilot I](#) and is one of three STARS pilots foreseen by the EC funded consortium.

The aim of Pilot I was to transfer a **best-practice** example of a support activity for academia in the EU to another European Economic Area (EEA) state. The best-practice example was identified based on a comprehensive analysis of the STARS survey data. The data revealed that there is **an unmet need for a basic training on essential regulatory knowledge** for academic researchers. The data also revealed that several STARS partners offer specific training for academics, whereas other countries would have a great benefit from such a course. Thus, STARS partners from the Czech Republic and the Netherlands transferred their course to Austria, Hungary, and Italy. The overall feedback was positive and 94 % of participants would recommend such a course to others. In particular, the insights given on the regulatory system and framework and regulatory pathways were considered to be very helpful.

[All training presentations are now available](#). The slides represent a valuable source of information for academic researchers who are involved in basic research, drug development, non-clinical studies and clinical trials.

Further support in regulatory affairs is available in the [STARS Comprehensive Inventory](#), which assists European academic drug developers in finding support on regulatory affairs by listing various support services provided by national competent authorities, public actors and private entities.

[More...](#)

What is CSA STARS?

CSA STARS is the EU funded '**Coordination and Support Action on Strengthening Training of Academia in Regulatory Science**'.

The project aims to improve the direct regulatory impact of results obtained in medical research. 18 European countries are represented in the consortium through their national competent authorities, alongside academic and industry representatives, and associations with relevant experience.

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Imprint

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