Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

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

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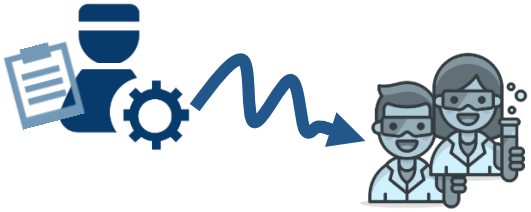
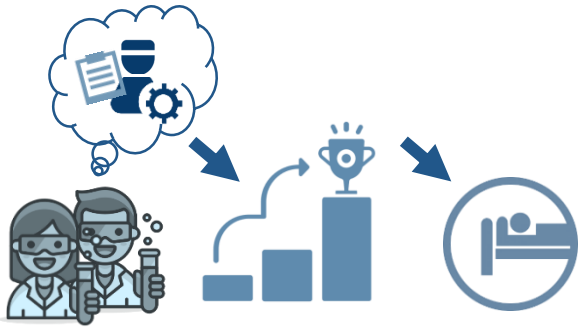
# STARS in a nutshell

- 22 EU/EEA countries
- EMA is one of the partners
- 36 month project 01/19-12/21
- https://www.csa-stars.eu/

# Factors behind the creation of STARS



Scientific advice and other support from the EMA and national competent authorities do not always reach academic health researchers



Educating academic researchers on regulatory requirements can increase the impact of their research findings for patients and healthcare systems

One way to improve the knowledge level is to provide targeted training programs and encourage researchers to seek scientific advice throughout the life cycle of a development project.

# Objectives of STARS

1) **Deliver recommendations** ensuring sustainable support of academic research (e.g. through development of scientific advice);

2) **Propose additional support mechanisms** based on analysis of academic researchers' needs;

3) **Coordinate and harmonise regulatory efforts at European level** to support academic health research;

4) **Reach academic scientists very early** in the planning of relevant grant applications;

5) **Provide support for academic researchers to increase the weight of their research results** for the benefit of patients and healthcare systems.

# Outputs of STARS

1) **Comprehensive Inventory** of existing regulatory support activities for academics;

2) **Core Curriculum** specifying essential knowledge for the professional training of clinical scientists;

3) **Comprehensive Curriculum** defining relevant knowledge for specific post-graduate training programs;

4) **Recommendations** to medicines agencies and stakeholders regarding development of support services and to address potentially identified shortcomings in the current service formats;

5) **Dissemination of project results:** White paper(s) and in seminars, conferences and the internet.

# Methods of STARS

**Online Surveys** in 22 EEA countries with four target groups:

*(i)* ***academic health research centers*** (clinical trial units, innovation offices, etc.);

*(ii)* ***academic research groups*** (principal investigators, clinical project leaders, etc.);

*(iii)* ***funding organisations*** financing academic health research (public and private);

*(iv)* ***national competent authorities***

**Three Pilot Projects** aiming to:

*(i)* ***transfer of an identified best support example*** to (an) EEA member state(s) where this activity is not yet implemented;

*(ii)* ***establish a new support activity addressing a gap*** in current regulatory knowledge of significant relevance;

*(iii)* ***validate the learning outcomes defined in the Comprehensive Curriculum*** by implementation into one European post-graduate training course.

# Current status and timetable of STARS

**The online surveys have been completed** (06-09.2019)

We received responses from 22 EEA countries
- nearly 100 academic health research centers
- ca. 450 academic research groups
- ca. 45 funding organisations
- the national competent authorities in the participating member states

- **Data analysis has started** (09.2019 – 02.2020)
- **The Comprehensive Inventory will be launched by summer 2020**
- **The work on Curriculums and Pilot projects is scheduled for 2020-21**
- **The white paper(s) will be published in 2020-22**

# What kind of data was collected in the STARS surveys?

- **Demographic information** about the center, groups or funding body
- **Field of research** (e.g. 59 research groups had selected “pediatric studies”)
- **Project information** (e.g. type of clinical study and current stage of development)
- **What kind of research partners are involved and what is their role**
- **Awareness regarding regulatory support services provided by EMA and NCAs**
- **Utility rates of these services**
- **Experiences from the support received**
- **Possible gaps identified in the existing support formats**
- **Main challenges in regulatory matters**
- **Needs for new regulatory knowledge and training**

# Fimea's Scientific Advice and Regulatory Guidance

Fimea offers **two different service channels** that provide guidance and advice on administrative and scientific issues related to innovation in life sciences.

***Informal Regulatory Guidance*** (FIN, "*Lääkeneuvola*") is provided at an early stage of development project for clients without sufficient experience of regulatory requirements. The meeting is free of charge.

***Formal Scientific Advice*** is primarily meant for more advanced development programs. Advice is provided on the quality, efficacy and safety documentation of medicinal products intended for human or veterinary use. The service is charged in accordance with the applicable Fee Regulation.

**More information at:**
https://www.fimea.fi/web/en/marketing_authorisations/innovation_office

**Procedure in short**: written request for advice to innovation.office@fimea.fi -> Fimea informs the applicant in writing of the acceptance or rejection of the request -> if accepted, a meeting is usually held at Fimea's premises -> The client submits the minutes of the meeting to Fimea for approval.

# Contact

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