

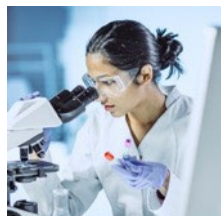
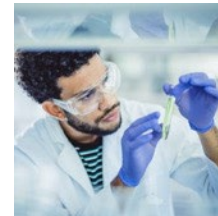
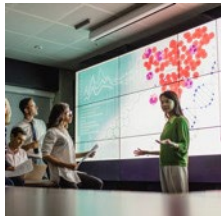


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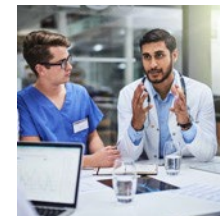


# STARS - Facilitating the Translation of Academic Research into Clinical Practice – How to Move Forward

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Regulatory Science



# Facilitating the Translation of Academic Research into Clinical Practice – An industry perspective



## Potential knowledge gap

- Academic researchers may not be aware of the entire product lifecycle from drug discovery to lifecycle management and the different regulatory requirements or areas of expertise needed. A **basic understanding of regulatory science** is needed
- **Exchange with industry in company specific programmes; including potential internships**
- Increasing the awareness of **Regulatory Science as an academic research field** may lead to better awareness on regulatory amongst academics in general

## Potential solutions

- Training curricula to provide basic education end-to-end **tapping into the pool of regulatory experts from agencies AND industry**. Previous IMI examples, Emtrain and Lifetrain, resulted in an oncourse catalogue which was discontinued but had courses delivered by industry or co-created by industry
- Make **academic researchers aware of opportunities on company offerings and offer internships** in training curricula
- Develop network-led partnerships with academic/research centres to **undertake research in strategic areas of regulatory science**; make academia aware of the fact that Regulatory Science in itself is a field where they can contribute. Regulatory Science would benefit from input by academic researchers, e.g. driving research into under-served disease areas

# Important regulatory science aspects to train academic researchers - an industry perspective

## Potential knowledge gaps

- Limited **knowledge on essential product development aspects** from an R&D and regulatory approval perspective.
- Lack of awareness that some **academic research topics are relevant for regulators.**
- **Potential conflict of interest for academics** working in specialised areas/cutting edge science who may be sought after by both industry and regulators for their expertise.

## Potential solutions

- Training curricula to introduce utilization of the **'Target Product Profile' as a tool to enhance research activity.** TPPs typically include: Identification of the mechanism of action, intended indication (in regulatory accepted terms), the intended patient population (including pediatric considerations), the efficacy claims (including relative to current standard of care), the safety/tolerability profile; dosing/administration considerations, formulation, device, storage.
- **Conduct horizon scanning in key areas of innovation via collaborations with academia, the EU-Innovation Network and ICMRA;** make sure that academia are aware of the fact that very new developments can be very relevant for the regulators.
- Academic researchers need to **be aware of opportunities for input & partnering with both regulators and industry** but need to be aware of potential conflict of interest and implications thereof.

# Important regulatory science aspects to train academic researchers - an industry perspective

## Potential knowledge gaps

- Full understanding of the **legal frameworks of clinical trials** and related research.
- Requirements for **Clinical Trial data transparency**
- **Practical impact of wording of Informed Consent on the later options to use collected samples** for respective research activities.
- **Use of Big Data** and industry constraints regarding use of data (data protection, informed consent etc)
- Lack of knowledge of **EU environmental provisions** that ban or strictly control many substances (e.g. Triton X-100, titanium dioxide, ethanol) as well as the use of some techniques and instruments

## Potential solutions

- Training workshops beyond GCP workshops, also covering the country specific legislation
- Training curricula to cover
- Briefing Book on typical wordings with ethical rationale and related practical impact on research options
- Develop a Big Data training curriculum and strategy based on a skills analysis across the Network, collaborate with external experts including academia, data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI.
- Training curricula to cover



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Thank you!

