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Strengthening regulatory science in academia: STARS, an EU initiative to bridge the translational gap

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Abstract

Truly disruptive medicine innovation and new treatment paradigms tend to start in non-commercial research institutions. However, the lack of mutual understanding between medicine developers and regulators when it comes to medicine development significantly delays or even prevents the access of patients to these innovations. Here, we outline what regulatory-related barriers hamper the translational development of novel products or new treatment paradigms initiated in academia, and propose key steps towards improved regulatory dialogue among academia, funding bodies and regulatory authorities. Moreover, we briefly describe how the STARS (Strengthening Training of Academia in Regulatory Science) project aims to reach out to medicine innovators in academia to bridge the regulatory knowledge gap and enhance this dialogue to facilitate the implementation of academic research findings in clinical practice.

Introduction

Truly disruptive medicine innovation and new treatment paradigms tend to start in non-commercial research institutions [1]. Indeed, many important advances in clinical practice, such as precision medicine, biomarker-oriented research (including biomarker validation), immunotherapy or advanced therapeutic medicinal products, have their roots in academia [2,3]. In particular, academia has a key role in fundamental research on drug discovery and development [4].

Translating research findings into medicinal products for clinical practice requires knowledge, skills and facilities that typically reside in pharmaceutical companies and not in public research institutes. Such companies have the resources to, for example, develop a product that complies with quality and manufacturing standards, compile a dossier that meets all requirements for regulatory acceptance, and upscale the manufacturing process. Even though some successful academic projects find their way to the patient through collaboration with industry [1] (Yegros, A. *et al*. 'Research trends in big pharma': https://www.cwts.nl/blog?article=n-r2s2b4&title=research-trends-in-big-pharma), the bulk of academia-driven therapeutics innovation remains in the early development phase and does not advance further along the translational chain [2,5,6]. This is a result of various factors.

First, there is a lack of mutual understanding between medicine developers and regulators when it comes to medicine development in clinical practice, and it is important to understand how to navigate the medicine regulatory system [2,7–9]. In Europe, this system includes research governance, regulatory and legislative requirements at the local, regional, national

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FIGURE 1

Main goals of the STARS project, in which 18 European national competent authorities (NCAs), four associate countries and the European Medicines Agency (EMA) are involved.

(within the 27 member states) and European levels. Developments in regulatory science are helping to overcome some of these factors.

Second, other factors play a role, such as reproducibility and reliability, which can hamper the recognition and utilization of academic research findings. In innovative basic and non-clinical drug research, there is less emphasis on quality control and the implementation of best practices (good manufacturing or good laboratory practices), which can result in a failure to attract private investors, and lead to the premature discontinuation of projects and unnecessary repetition of studies after pharmaceutical companies acquire the product [8,10–12].

Other areas of medicine development, such as drug repurposing, whereby approved drugs are used for new indications, are predominantly carried out by academic researchers who, by being in direct contact with patients, are in a good position to spot new possibilities in drug use [13]. And even though such research aids the development of best practice and treatment guidelines, it rarely leads to the licenced indication of a product. This is, however, often due to distinct legal and commercial issues [14,15].

Translational gap between academic innovations and patient treatment: an EU regulator's perspective

Collectively, there is often a gap between academic drug R&D and the translation of study results into clinical practice and patient care [16]. This article introduces the EU-funded project Coordination and Support Action on Strengthening Training of Academia in Regulatory Science (CSA STARS, https://www.csa-stars.eu/), a collaboration between 18 European National Competent Authorities (NCAs), four associate countries and the European Medicines Agency (EMA). The project aims to reach out to medicine innovators in academia to bridge the regulatory knowledge gap and enhance the dialogue between academia and regulatory authorities by means of, for example, scientific advice, qualification advice and bidirectional knowledge exchange (Fig. 1).

As part of the project, four online survey studies are being performed in the EU, which have received responses from 40 funding bodies, 88 academic institutes, 449 academic researchers and 21 regulatory agencies. On the basis of the results of these studies, an inventory will be made of existing support activities, and pilot support activities will be initiated to close the gaps in regulatory knowledge and support. Further, the STARS consortium envisions the development of curricula for training and education in regulatory knowledge, requirements and affairs. Building a harmonized curriculum will help to ensure that relevant scientific professions throughout Europe have access to regulatory knowledge. All of these activities will be supported by the various communication and dissemination strategies organized by the STARS consortium.

Communication framework and its gaps

Although some understanding exists between regulators and medicine innovators in academia regarding how to bring disruptive medicine innovations to the market, novel approaches are needed to deal with some of the challenges in applying the current legislative framework to the type of medicines being developed today. With this in mind, the STARS consortium seeks to better understand what regulatory-related barriers hamper the translational development of novel products or new treatment paradigms initiated in academia. One aim, therefore, is to enhance communication between different stakeholders, using a multi-pronged approach.

The communication framework presented in Fig. 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, 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 information provided by the regulatory authorities to innovators is based on years of

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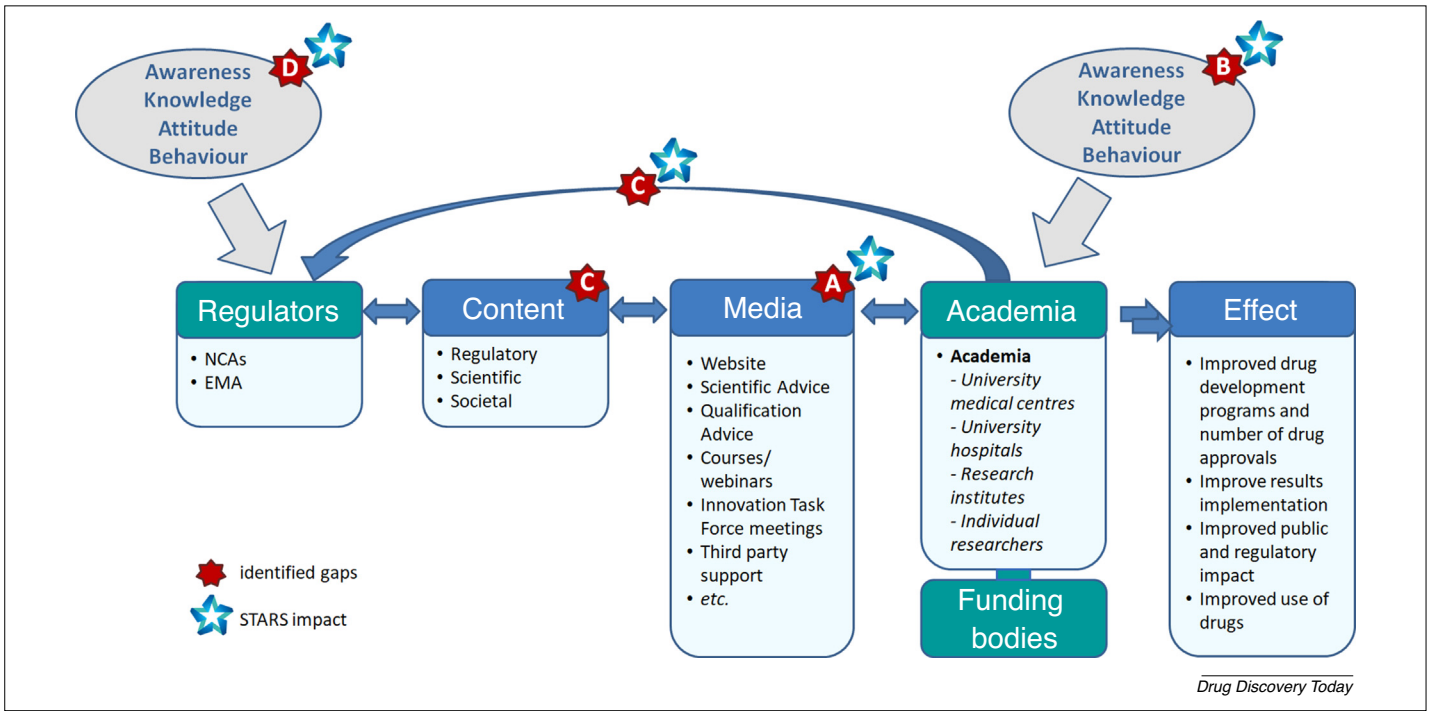

FIGURE 2

Information flow and identified gaps in the regulatory communication framework.

experience in the assessment of clinical and non-clinical product development dossiers and product life cycles, including the post-authorisation phase. Regulatory authorities provide information about regulatory strategies, requirements and guidelines that cover areas of pharmaceutical and medical R&D (regulatory content), as well as scientific support on manufacturing, formulations, protocol development and clinical-trial design (scientific content). Moreover, input can be provided by relevant national and European public stakeholders, such as patient and health-care professional representatives, and health-technology assessment bodies (clinical and societal content).

Regulatory authorities use various channels to reach drug developers and clinical investigators. Web portals direct academic researchers and funding bodies to key drug-development guidelines, whereas face-to-face meetings at national and European levels lend themselves to the provision of more specific dialogue. Examples of the latter include meetings with the Innovation Task Force (https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines) as an early exchange platform; the qualification of novel methodologies (https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/qualification-novel-methodologies-medicine-development) to obtain regulatory opinion on the acceptability of new concepts in measuring the effects of medicines, such as patient-reported outcomes or biomarkers for specific uses; scientific advice regarding clinical development plans; and the PRIME procedure (https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines) to stimulate the development of drugs that could be potential game changers in areas of unmet need. Last, regulatory authorities are present at scientific conferences, and they can offer various support activities such as training programmes, workshops and stakeholder meetings.

The aim of this dialogue with regulatory authorities is to help ensure a high-quality clinical development dossier and thus regulatory acceptability of the design of non-clinical and clinical studies when stakeholders apply for marketing authorisation. This should increase the scientific and societal output of invested funding, ultimately leading to more successful drug-development programmes that result in the approval and implementation of academic research findings in clinical practice. Importantly, the communication between regulatory authorities and recipients is bidirectional; for example, innovative studies and findings might stimulate the modification of regulatory requirements.

On the basis of the literature, the preliminary results of the survey studies and ongoing knowledge-sharing activities in the STARS project, we have identified several gaps in this regulatory communication framework, the bridging of which might help to improve the public health impact of academic research. First of all, academic researchers are less aware than the pharmaceutical industry of the support tools provided at national and European levels by regulatory authorities. This might indicate that the media channels and tools currently used by regulatory authorities to reach out to researchers are inadequate, often being too slow or too rigid (gap A, Fig. 2). Also, there is lack of awareness and knowledge of regulatory requirements and their relevance to the work of academic researchers and funding bodies (gap B, Fig. 2). Academic researchers might perceive regulatory support as being something exclusively for industry or for drug developers who are already in an advanced phase of drug development. This lack of attention to regulatory or ethical issues, however, might later make regulatory authorities reluctant to accept findings [8,11] or might be detrimental when attempting to attract investors.

Another important gap is the limited collaboration on regulatory requirements and guidelines between academic researchers and regulatory agencies, which leads to these bodies not being in tune with emerging research paradigms [2] (gap C, Fig. 2). This limited collaboration is, for example, reflected by the fact

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TABLE 1

Key steps towards improving regulatory dialogue.

Group	Further steps
Academia	- Implementation of regulatory science in educational programmes of medical, biomedical and pharmaceutical professionals - Implementation of regulatory science in the translational research plan by planning an early dialogue with regulators - Proactive communication with regulatory authorities and funding bodies throughout development - Timely attention to the translation of findings into clinical practice or the next development stage
Funding bodies	- Proactive communication with regulatory authorities when taking funding decisions - Scrutinize grant proposals in the area of applied and translational research for the adoption of best practices - Actively encourage dialogue between academics and regulators to help ensure maximum impact of the research - Interest in a more-defined public impact of funded research projects - Reward projects that are of high public impact independently of their novelty (i.e., projects that involve paediatric formulations, new dosing regiments or new treatment combinations)
Regulatory agencies	- Active dialogue versus one-way communication - Open-minded communication - Continuous learning about upcoming innovative therapies through knowledge exchange with academia (i.e., invited lectures and conference attendance) - Timely alignment of regulatory requirements with evolving developments - Involve academia in guideline development

that academic groups, in contrast to the pharmaceutical industry, are not directly involved in the drafting of European (EMA) and global regulatory guidelines [i.e., the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH, https://www.ich.org/)]. Academic groups can often only contribute to a guideline when it is open for public consultation. Also, regulatory authorities benefit from collaboration with academia and funding bodies by learning about innovative developments and methodologies created by academic researchers that often require an individually tailored approach and certain flexibility (gap D, Fig. 2).

Changing the mindset

Stakeholders (academic researchers, regulatory authorities and funding bodies) need to change their mindset and attitudes to help ensure the maximum impact of innovative-medicine research. They need to become aware of the current gap in regulatory knowledge and implement appropriate solutions. Key aspects are summarized below and in Table 1.

Open-minded dialogue

It is important to realize that the information flow presented in Fig. 2 is bidirectional. Regulatory authorities need input from academia to gain knowledge on innovative technologies (and to potentially align regulatory acceptance with evolving developments), to address the achievements made by researchers and to work together on joint solutions. Conversely, academic groups and learned societies need to become more involved in policy-making and guideline development. In general, researchers and regulators should be in communication from the start of a project to ensure that later development plans are feasible and to create a win-win situation for all parties [17].

Although regulatory requirements and rules serve to harmonize the drug-development process and to guarantee the quality, efficacy and safety of medicinal products, a more-tailored approach might be needed in certain settings to address the different needs of the various parties involved. A good example of an adapted and time-saving approach that regulators can apply in exceptional situations is the current effort of NCAs and the EMA in providing advice to academia and the pharmaceutical industry on the COVID-19 pandemic (Box 1).

Closing the gap between research and regulation

Although the value of regulatory science can be especially relevant to applied or translational science, basic fundamental research is increasingly being affected by higher demands for transparency and evidence of scientific integrity. An early exchange of information can help to highlight the regulatory issues that are relevant to the further development of a product. This might result in a slight shift in research focus, but at the same time it might make the project more appealing to venture capitalists (funding) and industry (collaboration), and bring the product more swiftly to the patient [9,18]. In any case, it is crucial not to miss the right time to start focusing on the translation of the product or findings to clinical practice. It is important to realize that good study results alone do not imply that the findings can be implemented in health-care practice [19]. Additional steps are needed to ensure that patients and/or the public benefit from the new product or technology.

Training basic, applied and clinical scientists in regulatory affairs is important [18]. Further, it is crucial to foster and build up a network of trained local representative units and support

BOX 1

EU regulators and scientific advice during the COVID-19 pandemic

Regulators have stepped up their efforts to provide advice to academic- and industry-driven initiatives to study medicinal products that might be beneficial to patients infected with COVID-19 (see EMA response to COVID-19: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19). Regulators have set up teams to rapidly provide clinical investigators with practical advice on how best to organize their studies. The emphasis is on expedited review, with an open view to novel designs, such as factorial design studies and sharing placebo control. In times of a pandemic, it is clear that regulators and researchers should adapt to the clinical situation, but at the same time they should safeguard key research principles to ensure that lessons are learned and that the evidence generated is reliable. Derek Angus published his plea of 'Optimising the trade-off between learning and doing in a pandemic' on 30 March 2020 at the height of the COVID-19 crisis [25]. The STARS project aims to stimulate tailored access to scientific advice both during and after the pandemic, with the aim of accelerating access to treatments that matter to patients.

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offices in academic clinical research centres not only to create awareness of the importance of regulatory requirements at a staff level, but also to function as a point of contact for NCAs to communicate with academia.

Change in the reward system in academic research

To change values in the existing system, it is important to understand what motivates the different stakeholders. Despite small positive changes, there is currently not always a clear incentive for academic applied or translational researchers to comply with regulatory requirements. Although academic research does strive to target public needs and benefit patients, the academic community still often sees publishing in scientific journals or presenting results at scientific meetings as the main indicators of success [11]. The system should move beyond this, and shift towards efforts to translate research findings to clinical practice.

Funding bodies could play an important part in promoting regulatory science in academic research by adapting their funding practices and requirements. Currently, European funding bodies seem to have adjusted their funding strategies to include more translational projects of clearer benefit to society and patients [2] (i.e., the Seventh Framework Program of the European Union, Horizon 2020, continuing into the plans for Horizon Europe). However, calls for clearer benefits and the tailoring of corresponding topics are not sufficient by themselves. Thus, regulatory and funding bodies should scrutinize grant proposals in the area of applied and translational research for the adoption of best practices (quality control and good laboratory, manufacturing and clinical practices). They should also request that scientists seek regulatory dialogue in advance of grant submission and during the research project, thereby enhancing the chance that the project will be a success and the findings can be translated into clinical practice.

It is also important to recognize that some academia-driven health research projects, such as those investigating better dosing regimens and treatment combinations or those developing paediatric formulations, might seem to be 'unattractive' from an innovation perspective, but are of high societal relevance. Here, a better understanding of the regulatory framework might be of benefit to academia: for example, the paediatric-use marketing authorization offers a 10-year period of data and market protection for paediatric formulations that are developed specifically for children. This applies to previously authorised products that are no longer protected by a patent or supplementary protection certificate (see 'Rewards and incentives for paediatric medicines', EMA website: https://www.ema.europa.eu/en/human-regulatory/research-development/paediatric-medicines/rewards-incentives-paediatric-medicines).

STARS: an EU way to tackle old problems?

The gap between (academic) inventions and products has led to a number of initiatives across the globe to address this challenge. For example, in the EU, such initiatives include the Innovative Medicines Initiative (https://www.imi.europa.eu/), Safe and Timely Access to Medicines for Patients (https://ec.europa.eu/health/documents/pharmaceutical-committee/stamp_en), Drugs for Neglected Diseases Initiative (https://www.dndi.org/), the European Clinical Research Infrastructure Network (https://www.ecrin.org/), the European initiative to boost translational biomedical research [20], EU Innovation Network initiatives, and various other ongoing initiatives from the EMA and NCAs [21]. All of these initiatives aim to provide essential knowledge and tools for bringing ideas to the patient. The EMA also offers some specific instruments to stimulate academic developments, such as providing an earlier entry point into the PRIME scheme for academic research groups or small and medium-sized enterprises (SMEs) by accepting applications based on promising non-clinical data and first-in-human tolerability data [22], and the EMA has introduced a fee waiver for academia for scientific advice for orphan medicines. Such initiatives are not limited to the EU: for example, following publication in 2012 of the report on 'Propelling Innovation in Drug Discovery, Development and Evaluation' in the United States [23,24], several initiatives have been launched to increase the returns of basic research and to accelerate drug discoveries (e.g., the Critical Path Initiative, https://www.fda.gov/science-research/science-and-research-special-topics/critical-path-initiative; SPARK initiative, https://sparkmed.stanford.edu/; and Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability Initiative, https://datascience.nih.gov/strides).

However, it is clear that current efforts and existing examples of cooperation do not sufficiently address the regulatory challenges along the translational chain [17]. The EMA 'Regulatory Science to 2025' strategic paper stresses the need for collaboration between academia and regulatory authorities to ensure early-career training of researchers in regulatory science, to address new trends in drug development and to ensure the translation of academic research into new drug products or regulatory tools [17]. Through further implementation of regulatory science in academic drug research, the STARS consortium aims to help improve the efficiency of drug-development processes and provide benefits to patients by strengthening the dialogue between academia and regulatory authorities.

Given the universal and multifactorial nature of the gaps in the current interaction between regulatory authorities and academia, it is clear that a harmonized approach is needed to strengthen regulatory science, improve the regulatory environment and increase support for this approach. Consisting of 18 EU regulatory agencies, the STARS network is equipped to contribute to the harmonization of regulatory support at a European level. This coordinated approach will assist in bringing academia, funding bodies, regulatory authorities and other stakeholders closer together. It will promote the sound development of new products and shorten the time between development and approval. The project is expected to stimulate a bidirectional knowledge exchange between academia and regulators by promoting scientific advice offered by various NCAs and the EMA; by developing a curriculum on regulatory science for academics; by promoting the education of regulators by academic researchers on modern therapeutic developments; and by opening a dialogue on regulatory practices and guidance that are not conducive to new scientific developments.

Importantly, the information and analysis provided by STARS will form the basis for other activities aimed at improving the mutual understanding of regulatory requirements and strengthening academic research in Europe. The goal is that this will result in a more-efficient and faster drug-development process, a higher number of successful projects and greater scientific and public impact of academia-driven health research, thereby accelerating the translation of research findings into approved drugs and diagnostics for the benefit of patients and health care in general.

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