https://doi.org/10.1038/d41573-023-00021-z

Strategic recommendations from the STARS project to foster academic drug development

Viktoriia Starokozhko, Anne Heß, Wiebke Löbker, Wolfgang Ballensiefen, Eleonora Agricola, Bettina Ziegele, Marko J. Kallio, Laurence O'Dwyer, Yoana Nuevo, Peter G. M. Mol & Anna M. G. Pasmooij

Improved understanding of regulatory requirements by academic researchers can accelerate the translation of new medical interventions to the clinic. Here, we highlight the recommendations of the 'Strengthening Training of Academia in Regulatory Science' (STARS) project to improve the interaction and knowledge exchange between academics and regulators, and thereby advance academic drug development.

Introduction

Academia plays a key role in drug discovery and development, especially for innovative medicines and technologies[1,2]. However, progressing projects into clinical development is often challenging for academic drug researchers[3], in part owing to a lack of knowledge regarding regulatory requirements and skills for navigating the regulatory system[4].

Acknowledging this issue, the STARS project was set up as a European collaboration of 21 regulatory partners from 18 countries, including the majority of the European national competent authorities (NCAs), the European Medicines Agency (EMA) and the German Aerospace Center Project Management Agency. The aim of this project was to improve regulatory knowledge among academic researchers and enhance their use of support tools provided by regulatory agencies, and thereby increase the likelihood of successful translation of academic biomedical research projects.

The STARS project comprised four surveys[5], three pilot projects and two workshops aimed at identifying the needs of stakeholders, resulting in 21 recommendations in five strategic areas. These recommendations address the main gaps and barriers identified in the current regulatory support system: lack of communication between regulators and academia; lack of awareness and use of regulatory support tools by academia; insufficient regulatory knowledge among academics; suboptimal alignment of regulatory support with the needs of academia; and suboptimal downstream interaction with industry.

The recommendations to address these gaps are targeted towards academics, regulators and other stakeholders, such as industry, funders and the European Commission. Some of these recommendations can be implemented in the short term (up to 1 year) or within a moderate period of time (1–3 years), but others may require more than 3 years. Here, we highlight the main points of these recommendations. More details on the recommendations are provided as Supplementary information and in the STARS Common Strategy, which serves as a road map for the implementation of regulator support activities and training programmes for academic drug researchers in Europe.

Recommendations in five strategic areas

General communication. Limited interaction between academia and regulatory authorities is one of the main shortcomings in the current regulatory system. Therefore, 8 out of the 21 recommendations focused on the improvement of general communication between key stakeholders. For example, we observed that academic researchers frequently search the websites of NCAs and the EMA to obtain regulatory information. Therefore, NCA websites should include tailor-made pages for academia, where up-to-date, relevant, user-friendly information is presented in clear language (recommendations 1 and 2). Importantly, a low threshold to access regulatory authorities should be established, with specific points of contact at NCAs for academic researchers to facilitate engagement with regulators (recommendations 4 and 7). At the EMA, such contact points are already established.

Moreover, it is important to increase the level of awareness among academics by advertising and proactively communicating about the available support tools at conferences and scientific events, or through funding bodies (recommendations 3 and 5). In addition, establishing closer contact among regulators, researchers and university technology transfer offices should be simultaneously facilitated (recommendation 18). This can help establish early contact and dialogue between regulators and academic researchers/institutions, start-ups, and small and medium-sized enterprises. This improved interaction can, in turn, increase the understanding of NCAs of novel topics in academic drug development through two-way communication and the development of specific regulatory support tools for academia[4].

Support tools. Optimizing existing support tools and developing new tools tailored to academia are a key area for improvement that is closely related to improved communication with academia. As mentioned, improving the websites of NCAs and the EMA and creating specific online communication platforms with different stakeholders can provide an additional support tool for academia (recommendations 1, 4 and 5).

Scientific advice on the appropriate tests and studies required in the development of a medicine or on the quality of a medicine can be provided to drug developers through formal meetings with European regulators. Although these meetings are the most prominent

regulatory support tool, the interactions are highly structured and require thorough preparation from both parties. Support for academia in preparing for these meetings, such as informal meetings, should be considered (recommendation 6). In addition, pre-grant regulatory advice should be provided for translational research fund applications (recommendation 17).

Education and training. Education and training of academia at all career levels, beginning early during the graduate studies of medical, pharmacy and life-science students, can help overcome the identified regulatory knowledge gaps (recommendation 20). Continuous education and training of regulators in scientific development and new technologies are also required (recommendation 19).

Regulatory framework and funding. The STARS project has indicated a need to optimize the regulatory framework to stimulate academic drug development. For example, the harmonization of the regulatory processes between European Union (EU) member states has been identified as a critical issue, and is expected to be useful for all stakeholders, including academics (recommendation 9).

To maintain a regulatory framework that stimulates academic drug development, the current funding conditions for regulatory support and training should be reviewed (recommendation 13). In addition, cost reductions or fee waivers should be considered for academia across Europe (recommendation 7), such as the fee waiver introduced by the EMA for scientific advice on orphan medicines. Funders should consider reimbursing the fees for regulatory support and training of researchers in regulatory science.

Cooperation between funders and regulatory authorities could enable key regulatory issues to be highlighted in funding calls to academic researchers, and ensure that they are considered and addressed in submissions (recommendation 13). Where appropriate, regulatory experts could join the review processes for funding applications in order to assess the regulatory readiness of research proposals.

Engagement with industry. The STARS project focused on improving communication between regulators and academia. Engagement and collaboration with industry and other stakeholders or platforms, such as funders, patient organizations and research networks, can also help translate academic research on new drugs towards regulatory approval and implementation of advances in healthcare systems (recommendation 18).

Conclusion

Implementing the proposed recommendations will require effort from all stakeholders, who may also need to modify their mindset and attitude towards each other[4]. Awareness of the current gaps in the regulatory support system and the importance of implementing regulatory requirements in drug development by academia will be crucial.

The pandemic has highlighted the value of advancing initial academic development of new drugs and new uses of existing drugs to address public health needs, which requires close collaboration with regulators and industry. Therefore, we urge the upcoming initiatives and European programmes, such as the European Partnerships in Horizon Europe, to consider the provided recommendations that promote academic drug development research. In addition, within the EU Innovation Network, regulatory agencies should continue implementing the recommendations of the STARS project. For example, the STARS project findings should be fed into the Accelerating Clinical Trials in the EU (ACT EU) project, which was launched in 2022 by the European Commission, Heads of Medicines Agencies and the EMA. This project aims to integrate regulatory scientific advice activities and downstream (health technology assessment) and upstream (clinical trial approval) bodies to create a competitive EU trial landscape, particularly for investigator-initiated (academic) trials.

Finally, it would be highly beneficial if lessons learned from the STARS project and any changes implemented were considered and mirrored outside Europe where possible, because drug development is global, and achieving alignment in drug regulation between regions and countries is crucial for improving its efficiency (recommendation 21).

Viktoriia Starokozhko[1,2] ✉, Anne Heß[3], Wiebke Löbker[3], Wolfgang Ballensiefen[4], Eleonora Agricola[5], Bettina Ziegele[6], Marko J. Kallio[7], Laurence O'Dwyer[8], Yoana Nuevo[9], Peter G. M. Mol[1,2,10] & Anna M. G. Pasmooij[1]

[1]Dutch Medicines Evaluation Board (MEB), Utrecht, The Netherlands. [2]Department of Clinical Pharmacy and Pharmacology, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands. [3]Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany. [4]German Aerospace Center (DLR), Project Management Agency, Health, Innovation for Disease Related Research and Personalised Medicine, Bonn, Germany. [5]Italian Medicines Agency (AIFA), Rome, Italy. [6]Paul Ehrlich Institute (PEI), Federal Institute for Vaccines and Biomedicines, Langen, Germany. [7]Finnish Medicines Agency (FIMEA), Helsinki, Finland. [8]Health Products Regulatory Authority (HPRA), Dublin, Ireland. [9]Spanish Agency of Medicines and Medical Devices (AEMPS), Madrid, Spain. [10]European Medicines Agency (EMA), Amsterdam, The Netherlands.

✉e-mail: vy.starokozhko@cbg-meb.nl

Published online: 8 February 2023

References

1. de Wilde, S., Guchelaar, H. J., Zandvliet, M.L. & Meij., P. Clinical development of gene- and cell-based therapies: overview of the European landscape. *Mol. Ther. Methods Clin. Dev.* **3**, 16073 (2016).
2. Kinch, M. S., Horn, C., Kraft, Z. & Schwartz, T. Rising academic contributions to drug development: evidence of vigor or trauma? *ACS Pharmacol. Transl. Sci.* **3**, 1427–1429 (2020).
3. Gilliland, C. T. et al. Putting translational science on to a global stage. *Nat. Rev. Drug Discov.* **15**, 217–218 (2016).
4. Starokozhko, V. et al. STARS consortium. Strengthening regulatory science in academia: STARS, an EU initiative to bridge the translational gap. *Drug Discov. Today* **26**, 283–288 (2021).
5. Kallio, M. J. et al. Translating academic drug discovery into clinical development: a survey of the awareness of regulatory support and requirements among stakeholders in Europe. *Clin. Pharmacol. Ther.* **113**, 349–359 (2023).

Acknowledgements

The STARS project was funded by Horizon 2020 (grant number 825881). We would like to acknowledge the support that we received from other STARS members while preparing the STARS Common Strategy, including the recommendations.

Competing interests

The authors declare no competing interests.

Additional information

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/d41573-023-00021-z

Related links

EMA. Accelerating Clinical Trials in the EU: https://www.ema.europa.eu/en/news/accelerating-clinical-trials-eu-act-eu-better-clinical-trials-address-patients-needs
EMA. EU Innovation Network: https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines
EMA. Partners & Networks: academia: https://www.ema.europa.eu/en/partners-networks/academia
STARS Common Strategy: https://www.csa-stars.eu/files/STARS_Common_Strategy.pdf
STARS website: https://www.csa-stars.eu/