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Supplementary information

Strategic recommendations from the STARS project to foster academic drug development

In the format provided by the authors

Detailed STARS recommendations sorted by respective stakeholders or target groups to whom these recommendations are addressed (see also STARS Common Strategy).

(1) Regulatory authorities in Europe

#1 Provision and regular updating of targeted information material and user guides about the regulatory framework and legal approval procedures

- A basic knowledge of regulatory frameworks is a prerequisite for the successful translation of biomedical research. A good general level of expertise within the research community enables a better understanding of complex regulatory requirements that apply to the development of medicinal products and medical devices for licensing purposes.
- Provision of simple user guides specifically targeted at non-commercial researchers incorporating an overview of the main aspects of medicinal product legislation would be a useful starting point for academic researchers to develop an understanding of regulatory requirements and support 'regulatory readiness'. Information material should be up-to-date and adequate, user friendly and appealing; for example, short explanatory video clips, interactive web-tools, podcasts or information leaflets. Dissemination of practical guideline videos or checklists — for example, easy and clear support for clinical trial application forms — would be useful information material.
- The language should be wherever possible generally understandable, and so technical terms should either be avoided or if used, be explained; for example, by providing a glossary with regulatory vocabulary and abbreviations.
- The STARS Comprehensive Inventory, which provides a systematic overview of provider and contact points for regulatory support services for academia should be disseminated and further developed. It is important to provide a navigation through the regulatory landscape with information about whom to approach at different stages of development and where to find relevant material.

#2 Use of appropriate media channels to reach out to academia

- Academic research groups use the websites of the EMA and the national authorities in the first place to obtain relevant information. Therefore, all related websites should be clearly designed with the aim that academic groups navigated appropriate in order to quickly and easily find all necessary documents and information.
- Animated videos, decisions trees, information boards with chat boxes (as used by Pilot II, see STARS Common Strategy) or Q&A pages with a very good search function might be tools to use.
- Cross-linking NCA websites and the EMA website can be helpful.
- All outdated information needs to be regularly updated with valid, up-to-date information. Search engine optimisation and interlinking design should be established. High quality and reliability of the presented data must be ensured.
- Tailor-made subpages for academia could provide short video clips, an overview of contact points, specific training material, frequently asked questions and checklists. It is recommended to involve academic stakeholders (“customers”) in the development of such communication tools, in order to meet the specific requirements for academic researchers and to learn directly about their needs and challenges (targeted crowd-sourcing).

#3 Communication and networking events

- Interactive events, like local open house days, roadshows or innovation days organized by regulatory authorities, will encourage academia, NCAs and funding bodies to exchange information about relevant topics, needs and developments. Interactive sessions can contribute and stimulate collaboration between academia, NCAs, funding bodies and, where suitable, industry and other stakeholders. At such events, academia gets more insight into regulatory procedures, and can present and discuss their projects and ask scientific questions. Regulatory authorities would benefit from this multi-directional communication by learning about innovative developments and methodologies. This would foster constructive communication and where possible cooperation between the regulatory authorities, academia and other important players.
- NCAs and funding bodies should advertise their services and training courses given by them and by others. National and European societies might act as aggregation points.

#4 Low threshold for access to regulatory authorities

- The aim should be informal early communication between academia and regulatory authorities. In order to ensure early communication, a low threshold to access and specific contact points at NCAs for academia are recommended.
- Existing networks, such as national innovation offices or the EU-IN network, could support this purpose.
- Specific online communication platforms, like chat-based platforms with Q&A functions, could further support such offers and developments
- It is crucial to remove the misconception that reaching regulators is a high hurdle.

#5 Increased awareness and use of regulatory support tools

- The STARS surveys revealed that established regulatory support tools, like (informal) orientation meetings or scientific advice meetings are used with varying frequency across Europe. However, some academic groups are still not even aware of these tools. Therefore, it is important to increase awareness by advertising and communicating such offers, e.g. at conferences, scientific events, via innovation offices, funding bodies etc.
- In parallel a closer contact between regulators, research community and university technology transfer offices can be facilitated. A 'train the trainer' approach could be applied whereby regulatory authorities could target individuals within research centres who interact with researchers on a daily basis and provide them with key information that they can use / share on site. Existing research networks could also be used to disseminate knowledge and information.
- Collection and provision of existing regulatory support tools on European and/or national level. A 'one stop shop' approach similar to that employed in Pilot II could be helpful. The use of case studies highlighting previous cases where advice provided by competent authorities assisted academic researchers could help to overcome any hesitancy to engage with competent authorities.

#6 Support in the preparation of scientific advice for academia

- In contrast to pharmaceutical companies with in-house expertise in regulatory affairs, academic researchers often are not aware of how to prepare and ask the right questions in the most efficient manner. Low-threshold services at regulatory bodies like informal meetings that provide information about the advice procedure, the preparation of data presentation, question and forms can be a helpful source for academia to make to most out of a formal scientific advice meeting.
- Consider transfer the information about the advice procedure, the preparation of scientific advice briefing books and presentations to local Technology Transfer Offices/ Innovation Offices to lower the threshold and increase efficiency.

#7 Low threshold to apply for regulatory advice

- Next to a low threshold communication and contact point, academia has to consider financial aspects. Reduction of costs or fee waivers need to be considered (e.g., the EMA has introduced a fee waiver for academia for scientific advice for orphan medicines).
- Concept of pre-grant advice (see STARS Common Strategy for more details).

#8 Expanding and promoting existing structures within NCAs

- Ensuring that available structures such as innovation offices or the EU-IN innovation network are easily accessible and are tailored to the needs of academia.
- Consideration of whether existing support at EU and national level is suitable for academic researchers, who often require more individual support and flexibility.
- Establishment of new and/or expansion of existing structures for early support of academia by regulators, ensuring that these are easily accessible and are specifically tailored to the needs of academia.
- Maintenance and expansion of the STARS Comprehensive Inventory, which gives an overview and contact points of regulatory support services for academia across Europe.

#9 Harmonisation of the regulatory processes between the member states is expected to be beneficial for all stakeholders, including academics

- Strengthen the European environment for clinical trials via the ACT EU initiative (Accelerating Clinical Trials in the EU), which is co-led by the European Commission (EC), Heads of Medicines Agencies (HMA), and the EMA. EU ACT has identified ten priority actions for 2022/2023, including enabling innovative trial methods, establishing a multi-stakeholder platform, and supporting the modernisation of good clinical practice.
- While academic researchers may tend to engage initially with their national regulatory authority, harmonisation of regulatory processes will assist them to seek input from other regulatory authorities. The harmonisation should include adapted and standardised forms and processes as well as mutual online service platforms.
- Procedures such as simultaneous national scientific advice can facilitate such engagement and facilitate multinational research.

(2) Academic researchers and institutions

#10 Optimize engagement and collaboration of academia

- Foster closer interaction between research groups.
- Incentives for academia for data sharing and networking: highlight the advantages of open communication (for example, avoidance of same hurdles by different researchers/research groups).
- Incentives for academia in form of certifications and diplomas, scholarships to motivate scientists to complete on-line regulatory courses (= career building).
- Implementation of a new regulatory science extensive/comprehensive network: academia (+ ethic committees) + funding bodies + regulatory agencies + European research networks (such as ECRIN). Highlight the advantages of such networks (for example, timely regulatory support).
- Establish and maintain more specific research networks/data sharing platforms on a national level, and if possible, on a European level (for example, platforms for development of cell and gene-therapy or real-world evidence).

#11 Encouraging compliance with clinical trial results reporting requirements on EudraCT

- It should be an obligation to publish clinical trial results in the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT).
- Agreement and implementation of minimum standards for promoting academic sponsors to report in EudraCT should be developed.

#12 Early communication with regulators and HTAs before starting a research project

- Foster common scientific publications between regulatory and academic people and create awareness for the challenges performing regulatory conform clinical research.
- Involve patients as early as possible in the process.
- Needs agreement on innovative funding schemes for academia to approach regulators in proposal application procedures.

(3) European Commission, ministries and funders

#13 Introduction and implementation of regulatory needs and aspects for funded biomedical research projects

- Funders, researchers and regulators should develop settings and agreements for translational research and clinical trial approaches to increase the attention paid and weight given to regulatory aspects when evaluating research proposals / funding applications.
- Enhanced cooperation between funding bodies and regulatory authorities could enable key regulatory considerations to be described in funding calls to signpost these to academic researchers and ensure that they are considered and addressed in funding submissions.
- It is suggested that where appropriate, regulatory experts should join the reviewing processes for funding applications in order to assess the regulatory readiness of a research proposal.

- The awareness of funders and researchers of the significance of regulatory considerations, especially in late clinical research and/or clinical trials, should be increased in order to ensure early and appropriate consideration of regulatory aspects in the development of research calls or in grant application processes. This will help to maximise the potential impact of the funding by ensuring that appropriate regulatory standards are implemented, which in turn will increase the likelihood of regulatory approval and ultimately the application of the outcomes of research in clinical practice.
- Funders should consider reimbursing fees for regulatory support and related tools as well as for regulatory training of researchers.

#14 Monitoring compliance with regulatory affairs during the project

- Not only regulatory bodies, but also funding bodies should consider the integration of a monitoring of fulfilment of the regulatory requirements in the project reporting.
- Reporting of clinical trial protocols and results into the EU databases provided for this purpose (EudraCT) in order to ensure transparency in clinical trials should be strongly encouraged.

#15 Sustainability of the STARS achievements and tools

- The work done by STARS and the implementation of the recommendations should be sustained by initiatives and European programmes such as the European Partnerships in Horizon Europe.
- The STARS comprehensive inventory should be sustained.
- Pilot I, Pilot II and STARS curricula should be considered for future developments (see STARS Common Strategy for more details).

#16 Support of research of regulatory processes by specific funding measures

- To ensure up-to-date regulatory decision; for example, usage of real world data.
- Proactively engage with funders and academia to explore new funding mechanisms.

#17 Implementation of a pre-grant advice

- Pre-grant advice should be implemented as part of translational research calls as a mechanism to ensure that appropriate consideration is given to regulatory aspects in funding submissions and grant applications.
- Consideration should be given in advance of issuing a call as to whether pre-grant advice would be applicable/desirable given the nature of the call and the proposed research and the need to make the most effective use of available resources.
- Such advice could be complementary to informal advice given at an earlier stage via support such as innovation offices.
- See STARS Common Strategy for comprehensive details on the pre-grant advice concept.

(4) Industry

#18 Early contact and dialogue between academic researchers/institutions and start-ups, small medium enterprises and industry should be fostered reciprocally

- Such a communication might support later steps, such as regulatory approval or in translating the research results successfully into health systems.
- Suitable formats or platforms should be developed and established for public–private partnerships such as the Innovative Medicines Initiative, which could be used for lessons learned.

(5) Education

#19 Continuous education and training of regulators

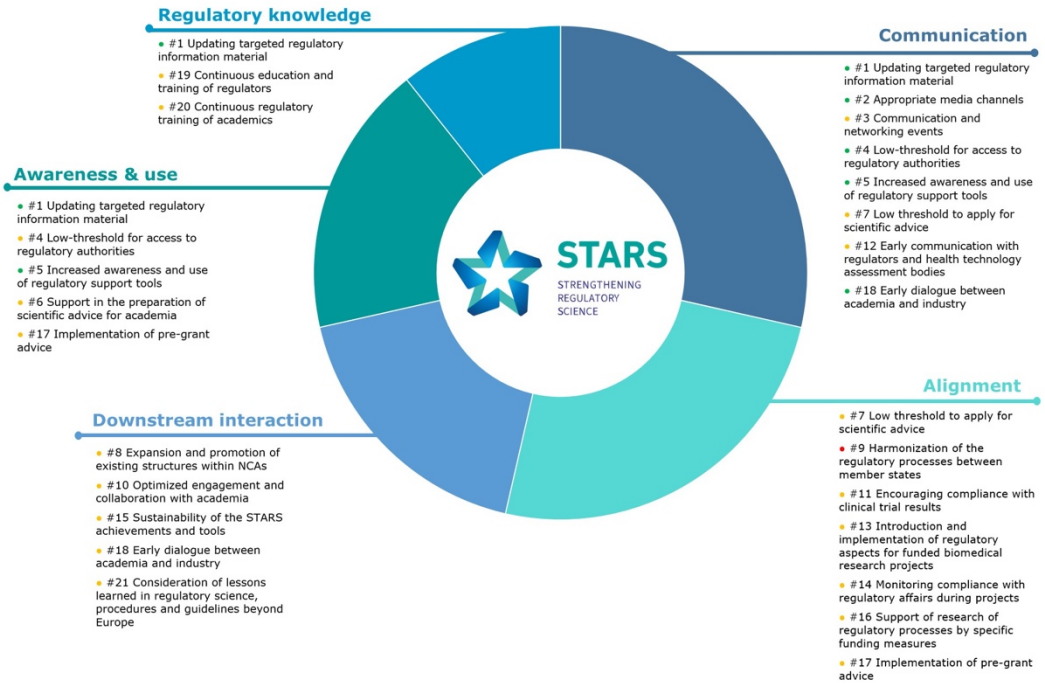
- Education of regulators, such as visiting conferences, doing courses and training such as in the EU Network Training Centre in order to ensure up-to-date decision-making standards.

#20 Continuous regulatory training of academics

- Education and training of academics at all career levels, beginning early during graduate studies of medical and life science students.
- Provision of a superordinate curriculum with recommendations on harmonised training and education approach across Europe to achieve a common level of regulatory knowledge in academia.
- Implementation of the "train the trainer concept" and knowledge exchange on local level.
- Support the harmonization of the curricula for academia in Europe.
- Researchers should be encouraged to take part in regulatory courses. Funders might ask researcher to complete courses as a condition of funding.
- To ensure common language used between academia and regulators.
- Influence the public and policymakers to support this recommendation to provide high-level impact on the economy, employment and public health.
- See STARS Common Strategy for details and specifications on the STARS curricula.

(6) Cross-cutting recommendations

#21 Consideration of lessons learned in regulatory science, procedures and guidelines beyond Europe; for example, along with the STARS global conference in 2022



Supplementary Figure 1 | **Overview of the recommendations**.