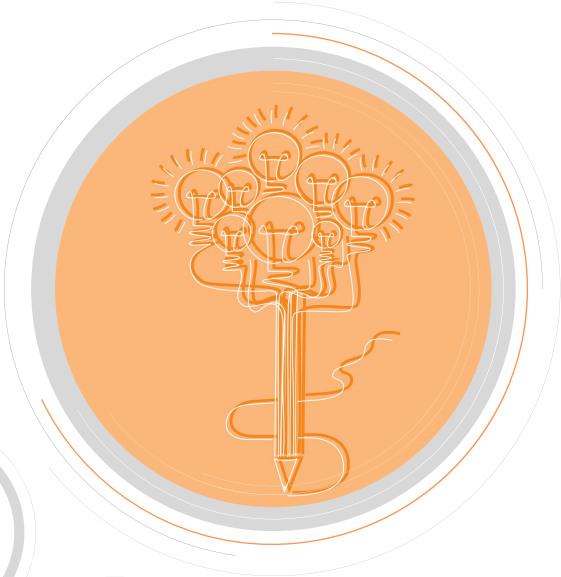
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Presented by Corinne de Vries, Hans Georg Eichler, Ivana Silva, European Medicines Agency on 19 November 2019

An agency of the European Union

Disclaimer

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Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

Identify, in consultation with academia and relevant stakeholders, fundamental research topics in strategic areas of regulatory science

Proactively engage with DG Research & Innovation, DG-SANTE, IMI and MS funding agencies to propose and issue calls to establish research collaborations

High level concerns/recommendations

- Suggestions for additional actions suggest **we should be more ambitious** and can be clustered under

1. ***Collaboration with academic research centres***
2. ***Role of industry in this partnership***
3. ***Training/education***
4. ***Funders***
5. ***Global consortia***
6. ***Regulatory science priorities***

Collaboration with academic research centres

- Collaboration with academic research centres, such as the Future Targeted Healthcare Manufacturing Hub as well as other non-commercial research institutions.
- The strategic plan should mention the opportunities that will arise from working with qualified clinical research networks on the development of clinical development programmes and the execution of clinical trials.
- Developing structured approaches for these networks to contribute to the work of the regulatory network (including training, quality control of expert advice, and work towards data sharing) will enhance the EMA's current *ad hoc* approach to engagement with academics.

Role of industry in this partnership

- It is important to include industry in this endeavour to maximize transparency and cooperation on regulatory science. The regulatory science discussion should be defined, fuelled, and driven by industry's pipeline – not as a siloed academic exercise.
- Dialogue should be encouraged between academia, regulators but also with developers and manufacturers so as to bring together the necessary scientific, regulatory but also practical and industrial considerations.

Role of industry in this partnership

- In addition to engagement with academics across the EU, we would encourage EMA to also prioritize work with sponsors, data vendors, patients, professional and clinical societies, and other stakeholders and to share learnings broadly. A diversity of opinions can provide valuable input to advance the regulatory science foundation, particularly as it relates to RWE, and ultimately advance patient care.
- Include pharmaceutical industry researchers in the network-led partnerships that direct priority areas for fundamental research based on the regulatory science strategy (e.g., PROs, 'omics, AI, drug-device combinations, M&S).

Training / education

- This proposal could also be extended to include collaboration with students, as it is critical for Europe to have a pipeline of talent to support the long-term future of regulatory science.
- Also, specific educational schemes for regulatory science should be promoted by EMA with educational postgraduate institutions and research institutions to provide educational tools to research communities.
- We are deeply concerned about the lack of experts in regulatory science within research institutions responsible for the development of the European research agenda. In this context, a specific recommendation to tackle this barrier should be introduced in the strategy.

Training / education

- We need to prioritize Regulatory science specific PhD training networks to train talented graduates on the regulatory tools and skillset required to develop their career further within a regulatory setting. We could also consider joint academic – regulatory graduate supervision models. There are already some good models in Europe e.g. www.pearrl.eu and https://www.regulatoryscience.nl/editions/2019/08/promovendi but we need to role this out EU wide.
- We advocate a graduate training model for PhD graduates to pursue careers in Regulatory settings.

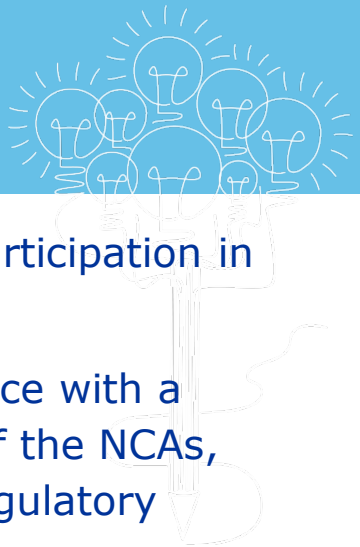
Training / education

- Academia could also play an important role in defining novel clinical trial designs and developing methods to enable adequate analyses of data obtained.
- PRIME: we want to insist on the need to have appropriate expertise available in the European regulatory network to guarantee access to PRIME to all categories of products, including prophylactic and therapeutic vaccines.

Funders

- Development of innovative funding models for translating bioscience research into new therapies, including advanced therapies.
- Explaining incentive models to all stakeholders, including from public research and public services (EU and national).
- Provide funding opportunities for collaborative regulatory science initiatives at regional levels within the EU.

Global consortia



- EMA resources could be more effectively leveraged through active participation in global consortia.
- It is proposed to actively develop systematic ties for regulatory science with a common Network strategy between all NCAs and the EMA. Several of the NCAs, including the MEB, have a long-standing experience in conducting regulatory science.

Regulatory Science Priorities

- Urge EMA to continue to expand its support of public-private partnerships (PPPs) and consortia-based programs...The work achieved through PPPs is made publicly available to maximize the benefits of its work. Stakeholder consensus allows a field to move faster and farther than an individual entity is able to. Precompetitive PPPs also provide a means for regulatory agencies to engage with stakeholders to align the work with regulatory thinking. In this paradigm, scientific research is focused on the regulatory processes of developing new medicines, which is often an afterthought without input from regulators. When successful, the benefits are felt by researchers, drug developers, regulators, and patients, with therapeutic areas that have lacked the interest of developers becoming revitalized. Further, the setbacks of inevitable failures are shared, and thus, the overall impact is minimized…

Regulatory Science Priorities

- …PPPs and consortia allow for the execution of the collaborative efforts found throughout the strategic vision and are the catalyst to innovation across drug development.
- We believe that a specific underlying action should be added to this recommendation, to create with these stakeholders, regulatory science priorities to be incorporated into national and European translational calls, particularly in the field of novel therapies.

More granular feedback for implementation

- Specifically, it is noted that the output of many IMI projects comprised of tools and methods with potential regulatory impact. IMI has developed guidance for projects to raise awareness of the various opportunities to interact with regulators in the framework of research on regulatory sciences with a potential impact on public health. We encourage EMA to post this guidance on its website. https://www.imi.europa.eu/resources-projects/guidelines-engaging-regulators

Any questions?

Further information

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