EMA
EUROPEAN MEDICINES AGENCY

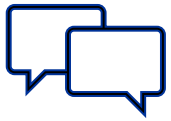
Engagement with Academic researchers for mutual support

24 September 2025

Ralf HEROLD
Regulatory Science and Academia Workstream
Regulatory Science and Innovation Task force

EMA engaging stakeholders – Framework of collaboration with academia

Inform
Announcement of review of policy or guidance, information days



Consult
Written – public consultation on policies or guidance, surveys

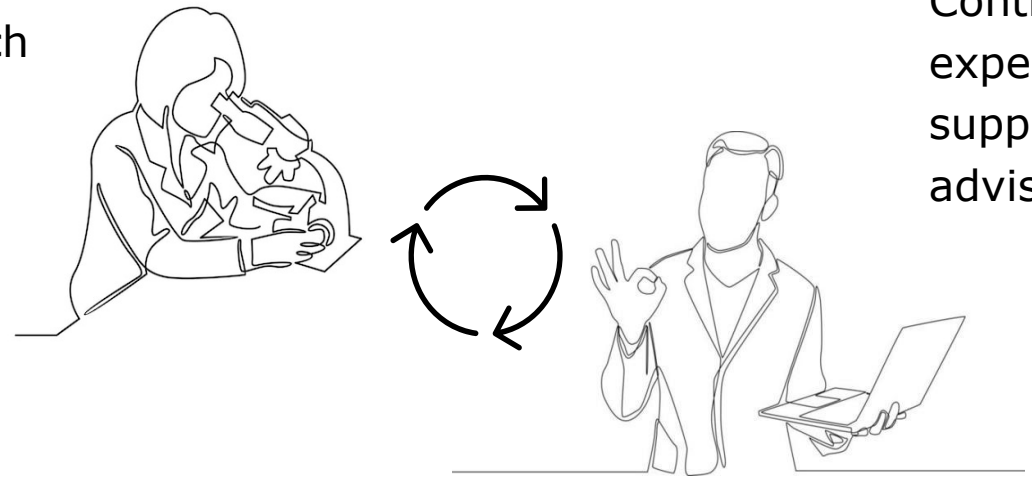
Involve
Direct interactions – stakeholder meetings, workshops, conferences, public hearings

Cooperate/Participate
Direct interactions – technical expert groups, focus groups

https://www.ema.europa.eu/en/partners-networks/academia

Academia as strategic partner for EMA in a virtuous cycle of mutual exchange

Academic developers:
EMA provides regulatory support for translating academic research into novel methodologies and medicines, including incentives such as for Scientific advice



Knowledge gaps:
Contribute best scientific expertise and research to support regulators in advising & decision-making

Regulatory science research needs: Collaborate on areas of research on regulatory science

Academia

Share

The European Medicines Agency (EMA) partners with academia to adapt to advances in science and technology. Areas of collaboration include regulatory science research, clinical trials and oncology.

Human | Veterinary | Medicines | Research and development | Scientific advice

Page contents

EMA is committed to a strong working relationship with European **researchers** and **developers** from the academic sector.

Academia plays an important role in advancing **medicines** and improving health systems through research.

EMA is fostering interactions between academics and European Union (EU) regulators. This helps to increase understanding of the regulatory environment.

EMA is also using various regulatory services to support academia deliver high-quality **research** and medicines.

Academia stakeholders that EMA is working with include:

- Universities, other public or private not-for-profit organisations or higher education establishments
- Consortia funded under public research programmes
- Individual researchers pursuing research independent from commercial control

Areas of collaboration include regulatory science research, clinical trials, oncology, quality of medicines, advanced therapy medicinal products and medicine repurposing.

For more information on EMA's work with its partners and stakeholders, including healthcare professionals, see:

- Partners & networks

Regulatory and scientific support

EMA provides regulatory and scientific support for the development of medicines, from the early phases of research in the laboratory all the way to the **patient**.

The support for **academic researchers** and **developers** covers topics such as:

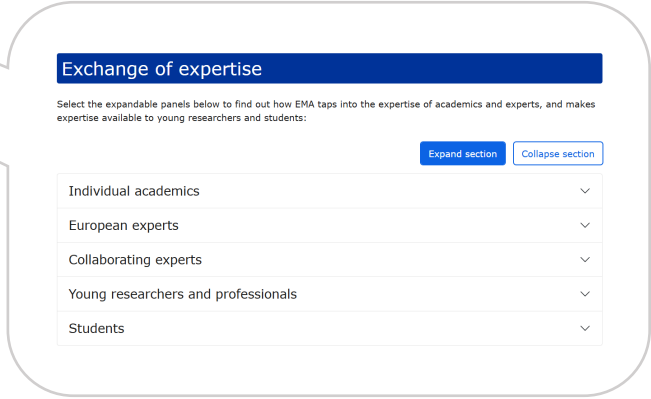
- New or innovative medicines
- Repurposing of medicines
- Advanced therapies
- Drug development tools
- Novel methodologies
- Clinical trials and research methods
- Regulatory science research projects
- Pre-competitive consortia or partnerships
- Involvement with externally funded projects

Researchers and developers can use the EMA services listed below:

- Academia briefing meetings
- Innovation Task Force briefing meetings
- Scientific advice and protocol assistance
- Qualification of novel methodologies
- Regulatory science research support
- PRIME scheme

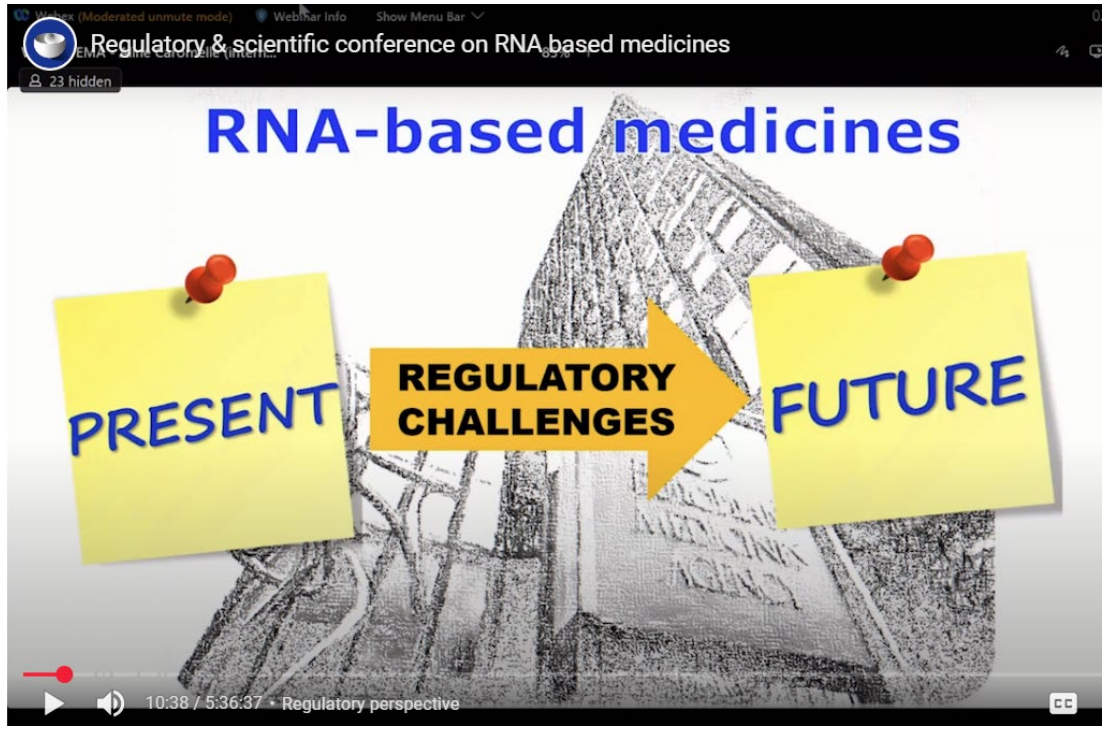
A broad set of support offerings for academia

https://www.ema.europa.eu/en/partners-networks/academia



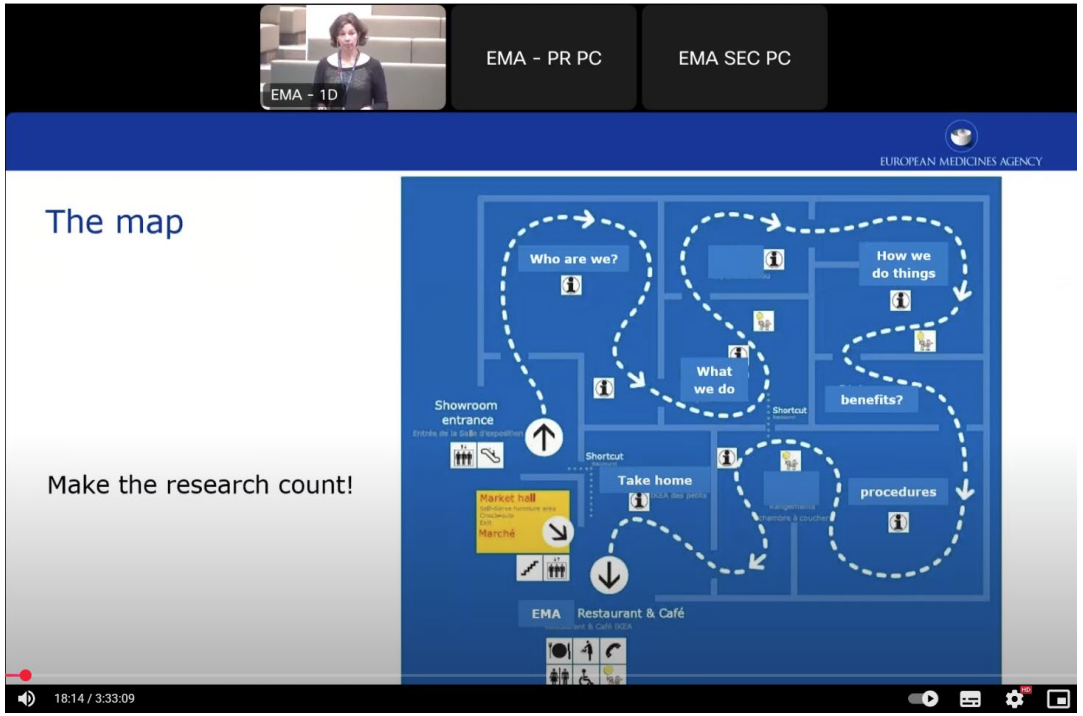
Examples – public engagement with researchers and developers in academia

- EMA's Regulatory and scientific virtual conference on RNA-based medicines



https://www.ema.europa.eu/en/events/regulatory-and-scientific-virtual-conference-rna-based-medicines

- EMA's Academia info day November 2023



EMA playlists:
https://www.youtube.com/@emainfo/playlists;
https://www.youtube.com/watch?v=vzSLBayIc5E

Examples – sharing experience with research and developments undertaken by academia

BJCP British Journal of Clinical Pharmacology

ORIGINAL ARTICLE | Open Access

Towards a better use of scientific advice for developers of advanced therapies

Anna Tavridou, Dolca Rogers, Milton Bonelli, Anja Schiel, Ana Hidalgo-Simon

First published: 25 November 2020 | https://doi.org/10.1111/bcp.14672 | Citations: 10

SECTIONS PDF TOOLS

Abstract

Scientific advice (SA) is an important tool offered by regulators to help developers generate robust evidence on a medicine's benefits and risks. Drawing on accumulated experience and looking at the SA provided by the European Medicines Agency in 2018 to advanced therapy medicinal products originally developed by public bodies, we discuss most commonly raised issues and the complexity and timings of the questions posed. Earlier and more frequent SA could help advanced therapy medicinal product developers to pre-empt delays at the marketing authorisation stage. Carefully addressing quality and nonclinical issues before entering the pivotal phase of development will clear the path for a smooth clinical development and successful marketing authorisation.

https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.14672

nature reviews drug discovery

View all journals | Search | Log in

Explore content | About the journal | Publish with us | Subscribe | Sign up for alerts | RSS feed

nature > nature reviews drug discovery > comment > article

COMMENT | 10 February 2025

A new European platform for advancing regulatory science research

Launching in 2025, the European Platform for Regulatory Science Research will bring together academia, regulators and other stakeholders to accelerate collaborative regulatory science research solutions.

By Liese Barbier, Pierpaolo Moscariello, Hubert G Leufkens, Ralf Herold & Anna Maria Gerdina Pasmooij

Regulatory science is essential for addressing issues and gaps encountered by stakeholders in medicines research, development and evaluation[1,2,3]. Research in regulatory science delivers solutions by providing better methodologies for medicines research and development, and improved tools for evaluating medicines based on outcomes that better align with patients' needs. It drives progress by identifying gaps in the evolving regulatory system and developing new approaches for generating evidence to support decision-making. Tangible impacts of regulatory science research include the revision or creation of new regulatory guidelines, or the qualification of novel methodologies such as biomarkers to support their use in medicines development.

Regulatory science research is multidisciplinary and involves a diverse range of methods

Related Articles

- European Medicines Agency – Framework of collaboration between the European Medicines Agency and academia
- European Medicines Agency – Regulatory science research
- European Medicines Agency – Regulatory science research needs
- European Medicines Agency – Public event: Advancing regulatory science research
- European Medicines Agency – Call for expression of interest for academia

https://doi.org/10.1038/d41573-025-00024-y

EMA

What’s new in 2025?

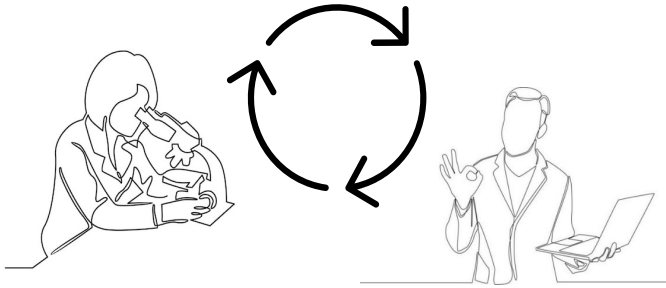
- Expanded capacity for Academia briefings and Collaboration management meetings (internal: Academia office and Matrix)
- Fee reductions for certain not-for-profit entities for scientific advice
- HMA / EMA European platform for regulatory science research
- Regulatory science research needs update 2025
- ACT EU support for non-commercial sponsors, needs for learning ecosystem
- Repurposing pilot report, continued efforts to support to academic developers
- Several EMA workshops with academic stakeholders (cancer, AI, external controls, Bayesian statistics, primary endpoints influenza / COVID, EU trial map, quality innovation, registries, gene editing, shortages platform, ...)

Academia briefing meetings, Collaboration management meetings

Welcoming researchers and developers from the academic sector, including not-for-profit entities and consortia or societies pursuing research

- EMA listens to understand researchers' challenges
- Bidirectional exchange through engaging on researchers' and on EMA's scientific challenges
- Support on how to advance R&D capacities
- Opportunity to discuss regulatory aspects
- No fee, no briefing book

Email: academia@ema.europa.eu, regulatory.science@ema.europa.eu



Scientific advice offered to developers

- EU level advice on tests and trials necessary to demonstrate quality, safety and efficacy and on applicable scientific requirements for marketing authorisation
  - Manufacture, non-clinical (in vitro, animal), clinical testing; methodology (3R, statistics, modelling & simulation) etc.
  - Type of marketing authorisation, development in children etc.
  - New or already authorized medicines; incl. ATMP, repurposing
  - Methodology in general (e.g., validation of biomarker)
- Provides EU-level answers to developer's questions
- Takes 2-4 months (without or with discussion meeting)
- Fees; fee reductions available for certain not-for-profit entities and certain research questions, for certain medicines (e.g. Orphan designated) and for targeted used (e.g. paediatric use)

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

academia@ema.europa.eu

Follow us