EMA
EUROPEAN MEDICINES AGENCY

Engagement with Academic researchers for mutual support

EMA Veterinary Innovation Day

Session 4: Deep dive into three support structures

14 March 2025

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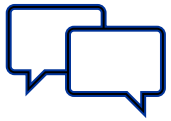
Regulatory Science and Academia Workstream
Regulatory Science and Innovation Task force

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

Frequent topics in exchanges with academic researchers and developers

Research

Regulatory science

Project collaboration

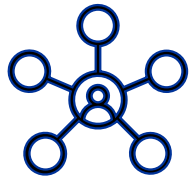
Advice to funders

Innovation

Academia briefings

Incentives

Pilot Programs



Communication & training

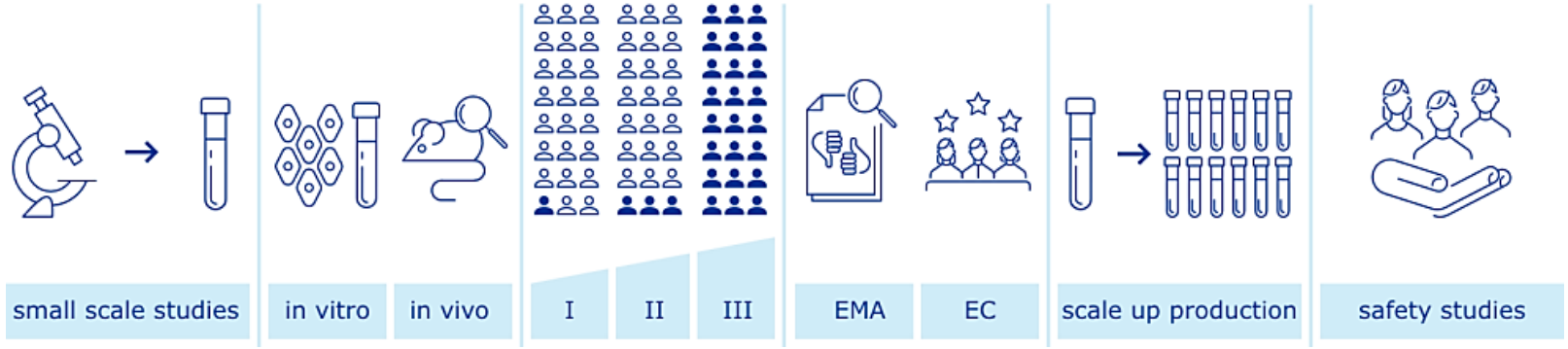
Information requests

Targeted communication

Events, e.g. today

Challenges: generating evidence…

…on a particular medicine under investigation



Product research, development and evaluation

…on methods and their application in developments

Investigating and establishing tools and methods for specific activities in drug development

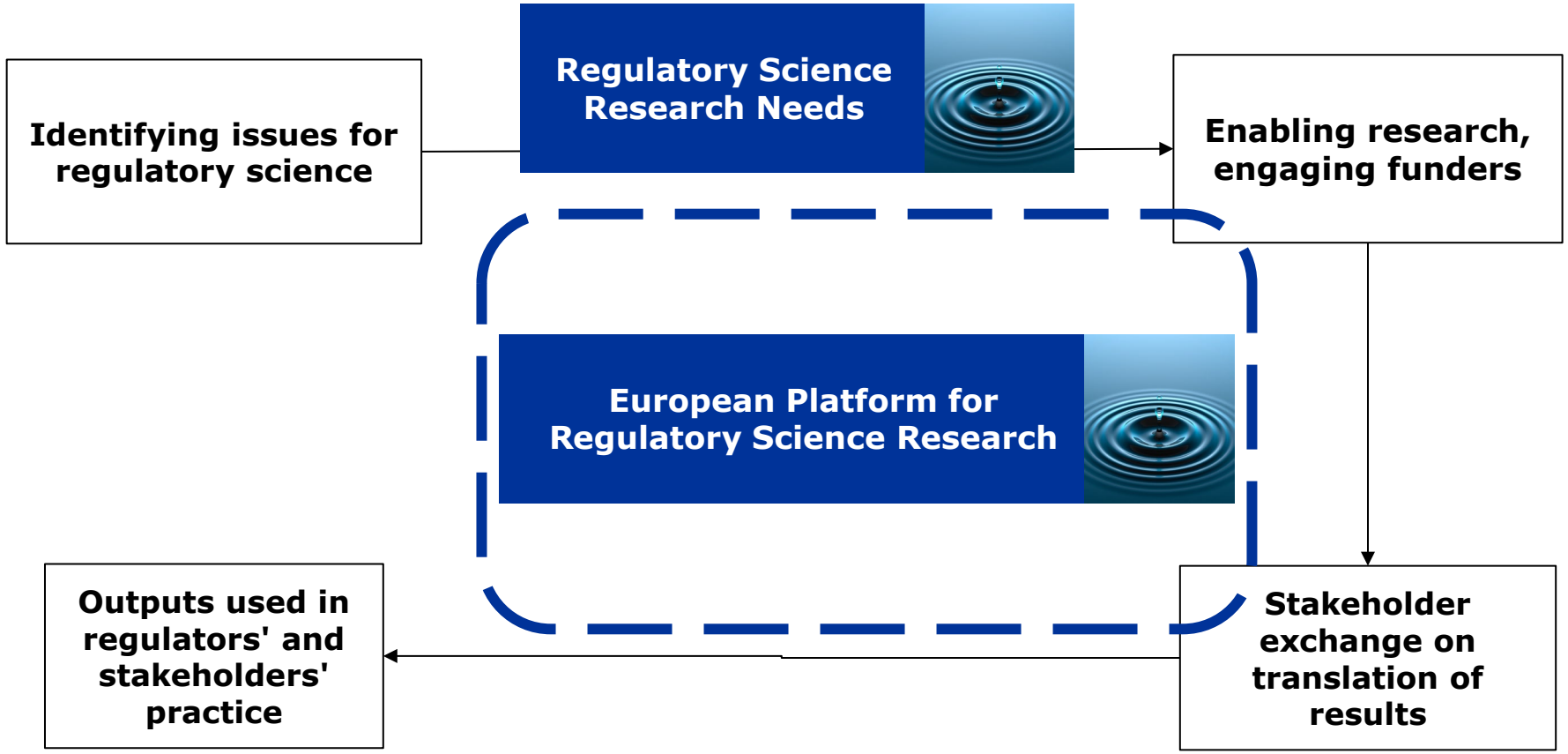
Investigating and establishing approaches for optimising the evidence generation

Investigating and evolving the regulatory activities and system

Regulatory science R&D

- Pre-competitive
- Product-independent
- Open science approach
- Often academia leading
- Often multiple stakeholders
- Often publicly financed

A strategic approach to Advancing regulatory science research



Updated Regulatory Science Research Needs

1. Research needs to improve clinical research

- Statistical analysis in clinical trials
- Innovative approaches in clinical trials design
- Clinical trials optimization in specific therapeutic areas

2. Research needs to improve regulatory system evolution

- Going beyond current regulatory pathways
- Shortages
- Communication
- Data management

3. Research needs to foster technologies for development of specific types of medicines

- Platform technologies and vaccines
- Antimicrobial resistance
- NAMs / Non-animal models / 3Rs
- Non-animal models / ATMPs
- Real-world data / real-world evidence
- Biomarkers

4. Research needs to advance specifically animal health and the regulation of veterinary medicines

- NAMs / Non-animal models / 3Rs
- Environmental risk assessment
- Antiparasitic resistance
- Pharmacovigilance
- Novel therapies and innovation
- Vaccines
- Antimicrobial resistance
- Veterinary big data

https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/regulatory-science-research-needs

Call for tenders – open until 2025-04-30

“EMA seeks to procure services of research organisations to perform pre- and post-authorisation studies on the quality, safety and efficacy of human and veterinary medicines generating complementary evidence to support regulatory decision-making”

nationally and centrally authorised medicinal products, non-product related topics

Studies may concern research under 7 Lots, including:

- Lot 1 translational research;
- Lot 2 veterinary research;
- Lot 3 methodological/statistical research;
- Lot 4 qualitative research;
- Lot 6 innovative technologies;

Please read Lot 2 tender specification, examples: observational research (excl. experimental and pre-clinical research) … retrospective and prospective studies … identification of RWD sources … research topics antimicrobial resistance and environmental risk assessment … rapid-response studies … emerging diseases or adverse event reactions

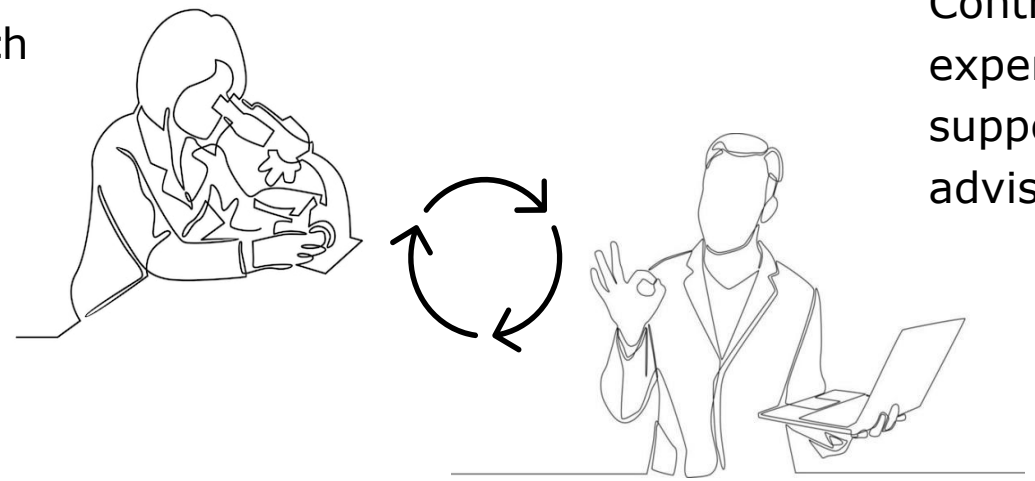
https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/72456246-9cd8-4978-9703-f90cf4e86227-CN

European Partnerships (EPs)

- **Innovative Health Initiative (EMA Science and Innovation Panel) 2023**
- **EP OH AMR OneHealth Anti-microbial resistance (EMA Partner) 2024**
- **European Partnership on Animal Health and Welfare (EMA Partner) 2024**
- EP ERA4Health (EMA Collaborating Expert) 2023
- EP PerMed Personalised Medicines (EMA in contact) 2024
- EP Rare Diseases (EMA in contact) 2024
- EP Brain Health (EMA in contact) 2025
- EP Transforming Healthcare Systems 2023
- EP Innovative SMEs (InnovativeSMEs) 2024

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 free Scientific advice



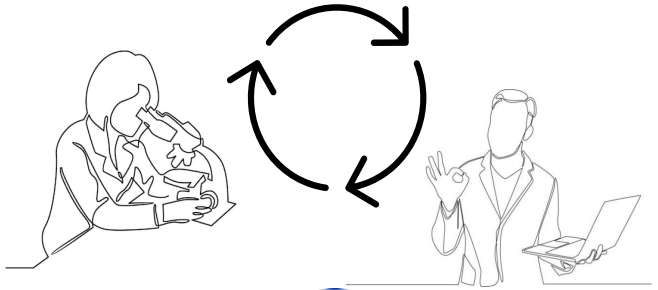
Knowledge gaps:
Contribute best scientific expertise and research to support regulators in advising & decision-making

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

Academia briefing meeting

- 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
  - Possibility of follow-up

Email: Academia@ema.europa.eu



Veterinary scientific advice incentive

- Incentivized: advice for certain entities and requests
  - Check https://www.ema.europa.eu/en/partners-networks/academia and write to academia@ema.Europa.eu
  - Scientific advice for veterinary medicines https://www.ema.europa.eu/en/veterinary-regulatory-overview/research-and-development-veterinary-medicines/scientific-advice
  - New fee regulation working arrangements, section 1.8 https://www.ema.europa.eu/en/documents/other/new-fee-regulation-working-arrangements_en.pdf
  - Annex I General questions and answer, section 1.2 https://www.ema.europa.eu/en/documents/other/annex-ii-questions-answers-fees-charges-remuneration-assessment-procedures-services-relating-veterinary-medicinal-products_en.pdf

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How else to interact?

Submit comments on guideline consultation

Access information on medicines

Participate in workshops

Request Innovation Task Force briefing

Send a question to EMA

Register as academic research(er) or entity

Get involved as external expert

What is scientific advice?

For a medicine to be authorised, medicine developers have to demonstrate that it is effective, safe and of good quality.

During a medicine's development, a developer can request guidance and direction from EMA on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. This is known as scientific advice.

Then, when applying for a marketing authorisation, the developer submits all the data generated on the medicine to EMA. The Agency assesses this information and determines whether or not the medicine is safe and beneficial to patients.

Scientific advice:

- is not a pre-assessment of the benefits and risks of a medicine
- does not guarantee that a medicine will receive marketing authorisation

Read more: From lab to patient - journey of a medicine

Why does EMA provide scientific advice?

EMA provides scientific advice to support the timely and sound development of high-quality, effective and safe medicines, for the benefit of patients.

EMA provides scientific advice because:

- Better designed studies are more likely to generate robust and complete data to show whether or not a medicine works and is safe. The sooner it can be shown that a new medicine works and is safe, the sooner it can be made available to patients.
- Providing advice means that patients are not deprived of beneficial medicines simply because poorly designed trials failed to demonstrate that the medicine works and is safe.
- Better study designs avoid patients taking part in studies that will not produce useful evidence.

Did you know?

Two out of three development programmes submitted for scientific advice were considered not suitable for a future assessment of the medicine's benefits and risks, according to an analysis done in 2015. Following scientific advice, 63% of these trials were modified to include a better way to

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Thank you

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