EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Agência Europeia e ligação à academia

Aproximar academia e Assuntos regulamentares para supportar inovação

Reunião Anual do Colégio de Especialidade de Assuntos Regulamentares 2024

Presented by Ivana Silva 20 June 2024
Public and Stakeholders Engagement Department

An agency of the European Union

What does EMA do?

- Facilitate **development and access** to medicines
- **Evaluate medicines for EU approval**
- Monitor the **safety of medicines** across their lifecycle
- Provide **information on medicines** to healthcare professionals and patients

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… and doesn't do?

- Evaluate approval of **all** medicines in the EU (e.g. generics at national level)
- Evaluate applications for the authorisation of **clinical trials**
- Approve **medical devices**
- Evaluate **food supplements and cosmetics**
- Take decisions on the **price or reimbursement** of medicines
- **Control the advertising** of medicines
- Develop **treatment guidelines**
- Provide **medical advice**
- Develop **laws** concerning medicines
- **Issue** marketing authorisations

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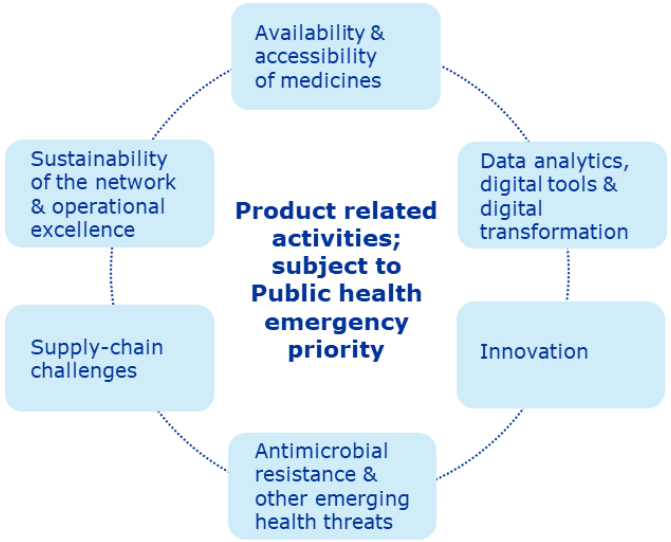
Protecting public health



Engaging with stakeholders to:

- Create awareness
- Map expectations and identify gaps
- Learn and share knowledge
- Increase impact

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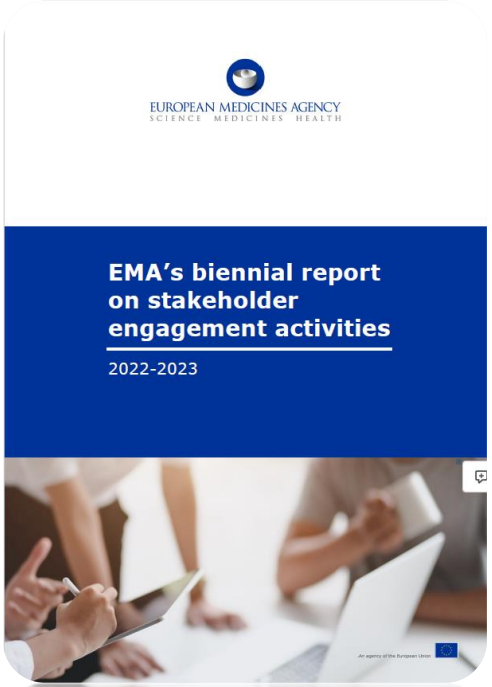
How is EMA engaging with stakeholders

- EMA is committed to listening to the voices of stakeholders and engaging with them
- Stakeholder engagement at EMA has been gradual and has been refined over time
- The aim is to
  - improve the **regulatory output**
  - harness all **expertise** available
  - increase the **confidence and trust** of European citizens in regulatory decisions concerning medicines



Read more: Stakeholder engagement biennial report

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How do we engage our stakeholders in our work?

EMA Stakeholder relations management framework

Overarching principles

Framework for interaction with patients

Framework for interaction with HCP

Framework for interaction with Industry

Framework for interaction with Academia

Key Stakeholder group

Inform – Consult – Consult/Involve – Cooperate/Participate

Stakeholder involvement

INFORM

e.g. dedicated web pages, relevant news items, Q&As, information days, information materials

CONSULT

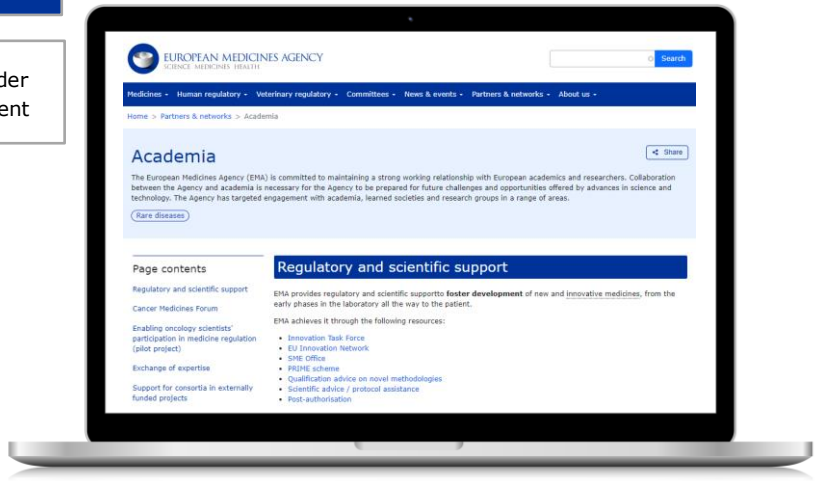
e.g. public consultation on policies or guidance, surveys

INVOLVE

e.g. meetings, workshops, conferences, development of regulatory guidelines

COOPERATE

e.g. on research projects, education and training, with established networks



Academia | European Medicines Agency (europa.eu)

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Regulatory Science and Academia

Research

- Regulatory Science
- Project Collaboration
- Advice to Funders

Innovation

- Academia Briefings
- Incentives
- Pilot programs

Communication & Training

- Information Requests
- Targeted Communication
- Events- *Info Day*

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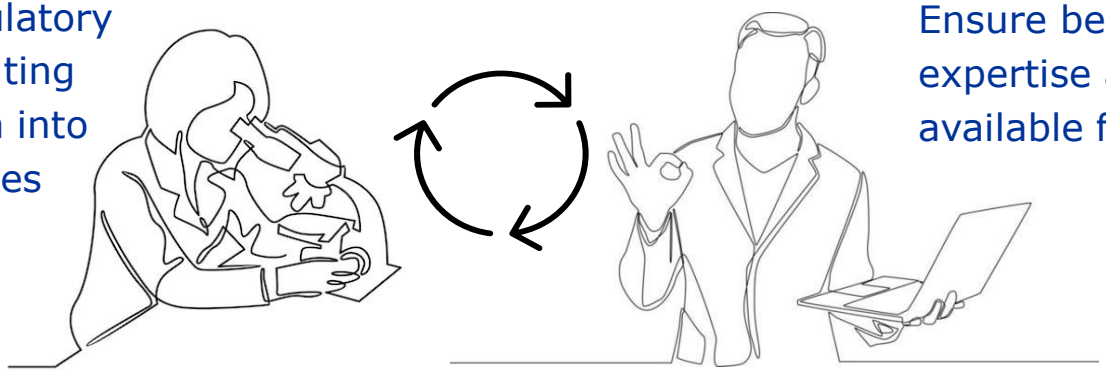
EMA strategic engagement with Academia

Virtuous cycle

Academic Developers:
EMA provides regulatory support for translating academic research into novel methodologies and medicines



Knowledge Gaps:
Ensure best scientific expertise and research is available for regulators

Regulatory Science Research Needs (RSRNs):
Collaborate on areas of research on regulatory science

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Research topics in regulatory science

Regulatory Science Strategy goals

Goal 1: Catalyzing the integration of science and technology in medicines development

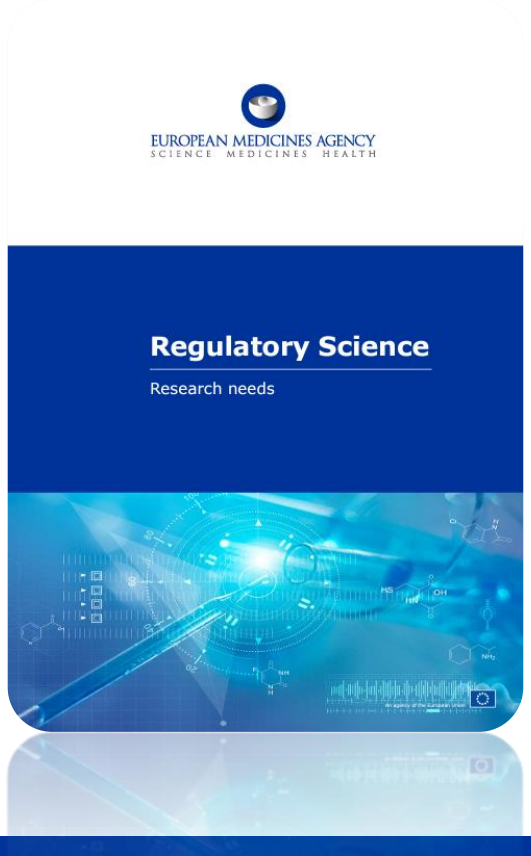
Goal 2: Driving collaborative evidence generation improving the scientific quality of evaluations

Goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems

Goal 4: Addressing emerging health threats and availability/therapeutic challenges

Goal 5: Enabling and leveraging research and innovation in regulatory science

https://www.ema.europa.eu/documents/other/regulatory-science-research-needs_en.pdf



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Project collaboration and advice to funders

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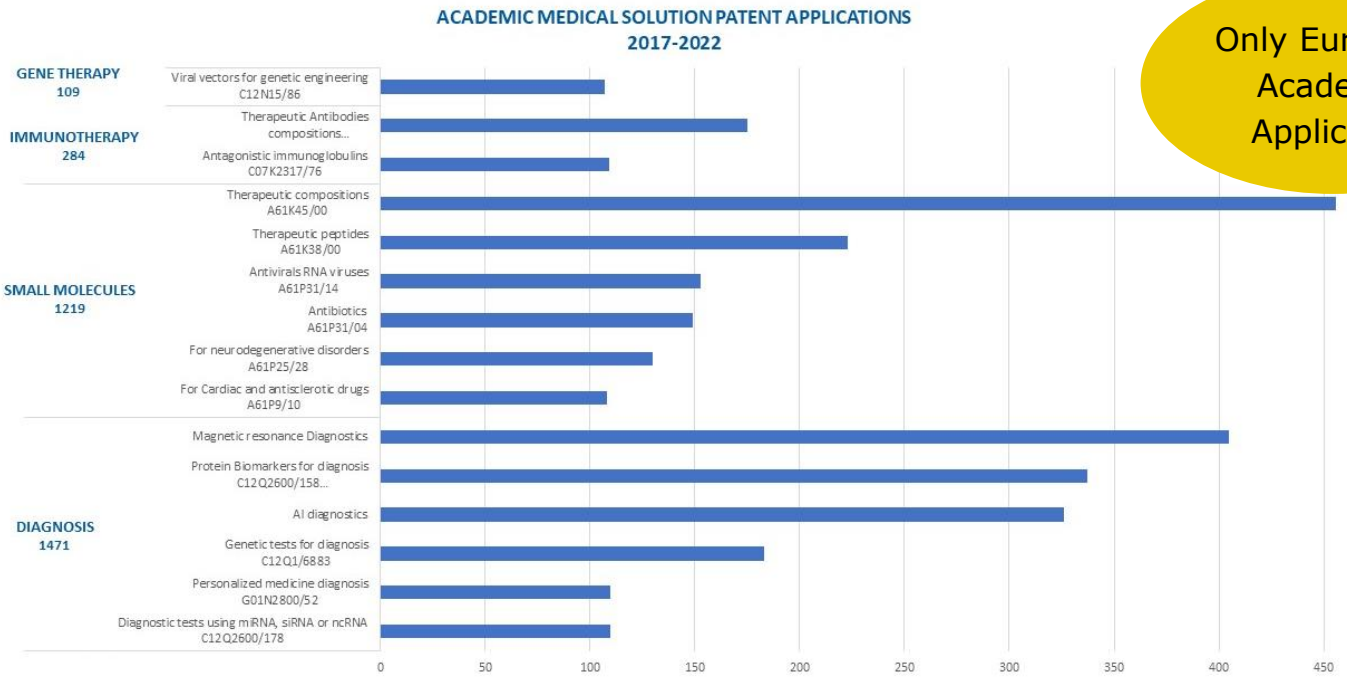
Innovative Potential of European Academic Sector



Only European Academic Applicants

Not aligned with regulatory standards or Investors needs

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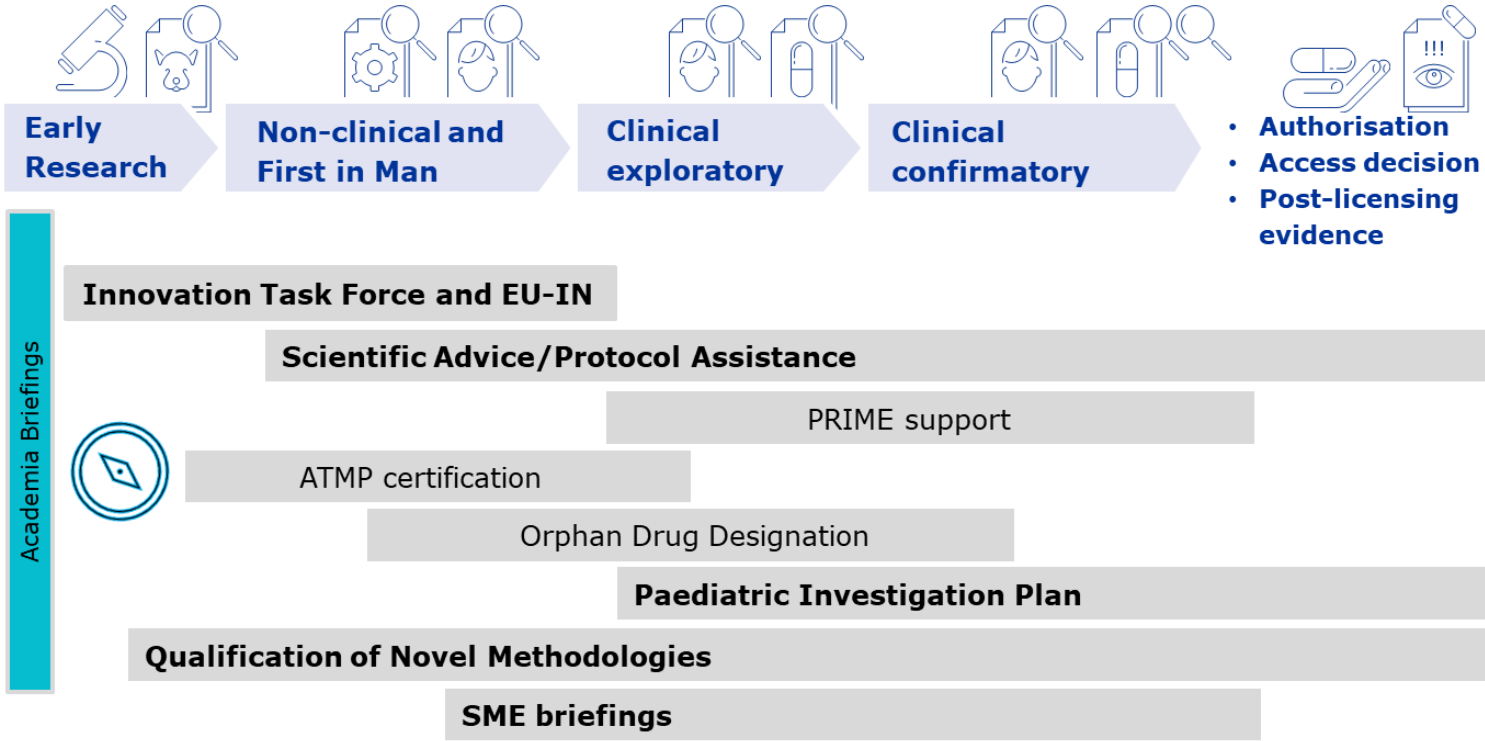
Entry points for academia developers to obtain EMA support



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Academia briefing

Welcoming **researchers and developers** from academic sector (incl. NFPs, societies):

- Bidirectional exchange through engaging on EMA's regulatory science challenges
- EMA listening to challenges faced by Researchers on regulatory matters
- Opportunity to discuss regulatory aspects of research programme
- Support on how to advance academic R&D in an evolving health system aligned with regulatory requirements
- No fee
- Possibility of iteration and follow up

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

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Academia briefing meetings: examples

Research network grantees
Pragmatic Clinical Trials
Funded under Horizon Europe

To understand how EMA could support their projects:

- Scientific advice regarding study design
- Safety reporting requirements and other study conduct requirements
- The role of independent pragmatic clinical trials in the medicinal product life cycle

European Consortium
In the area of
personalised medicines

To understand how EMA could integrate their project results in its regulatory practice and recommendations.

Research University Team
Pragmatic Clinical Trials
Funded under Horizon Europe

Assistance for understanding the regulatory system for developing an innovative product for the treatment of skin disease

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Incentives and pilot programs

Pilot for Repurposing of Authorized Medicines

Academic Sector

Scientific Advice

Pilot for Development of Advanced Medicinal Products

Academic Sector

Scientific Advice

Inspections

Marketing Authorization App.

New Fee Regulation (2025)

Incentives for *Scientific Advice* to

Non-for-Profit Organizations

New Pharma Regulation (2027)

Provision of Incentives to

Non-for-Profit Organizations

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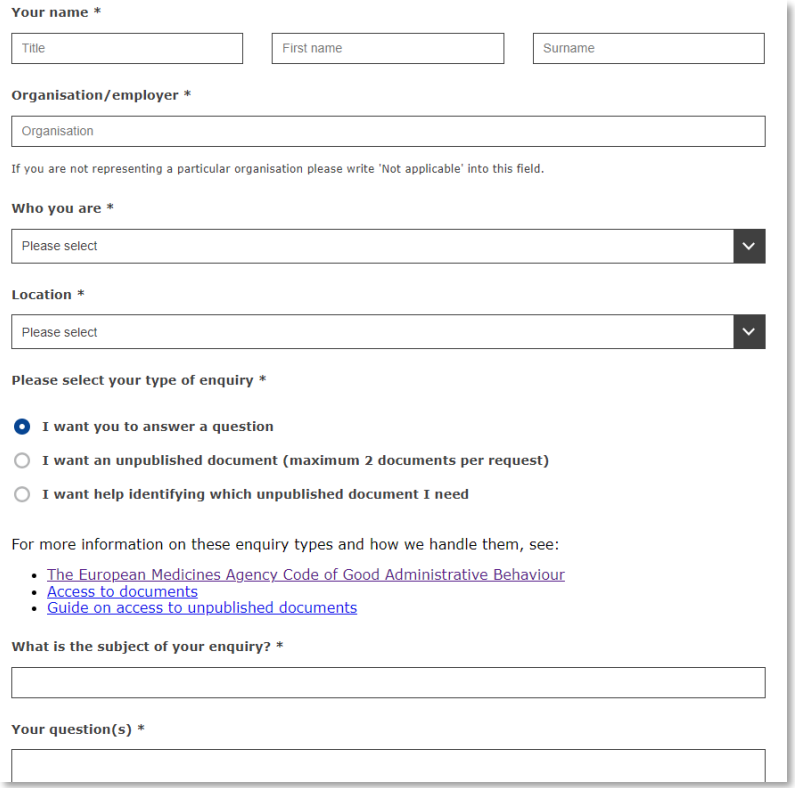
Information requests

Send a Question to EMA

Use this form to send a request for information from EMA or to make a formal request for access to EMA documents that are not already published on this website

https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency

Email: Academia@ema.europa.eu



Your name *

Title | First name | Surname

Organisation/employer *

Organisation

If you are not representing a particular organisation please write 'Not applicable' into this field.

Who you are *

Please select

Location *

Please select

Please select your type of enquiry *

- I want you to answer a question
- I want an unpublished document (maximum 2 documents per request)
- I want help identifying which unpublished document I need

For more information on these enquiry types and how we handle them, see:

- The European Medicines Agency Code of Good Administrative Behaviour
- Access to documents
- Guide on access to unpublished documents

What is the subject of your enquiry? *

Your question(s) *

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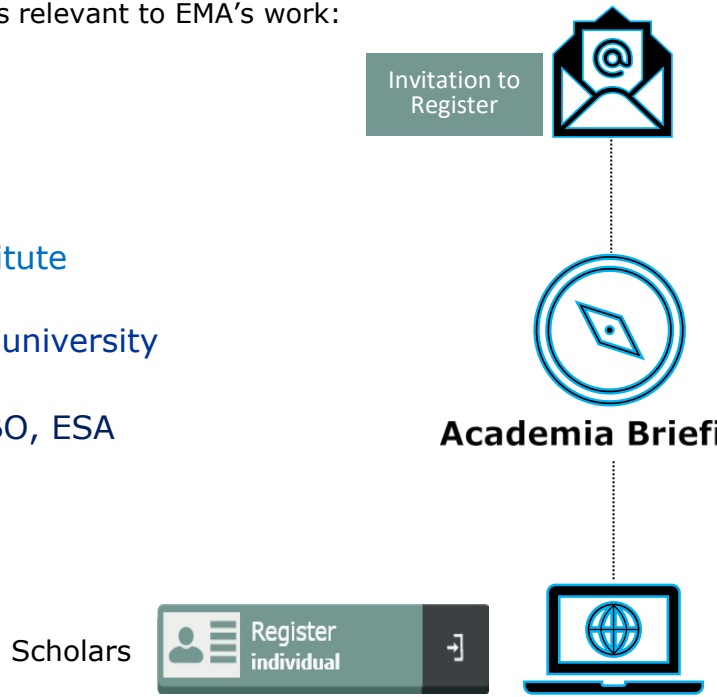
Targeted communication: stakeholders database

Pursuing **education or research** in all fields relevant to EMA's work:

- Non-legal Entity — Consortia
- Public Organisation — Public hospital
- Non-Profit Organisation — Research institute
- Higher Education Establishment — Research university
- International Research Organisation — EMBO, ESA



DB Registration

- Collaborations
- Fee Reductions
- Incentives
- Informal consultation
- Speaker in Workshops
- Targeted communication

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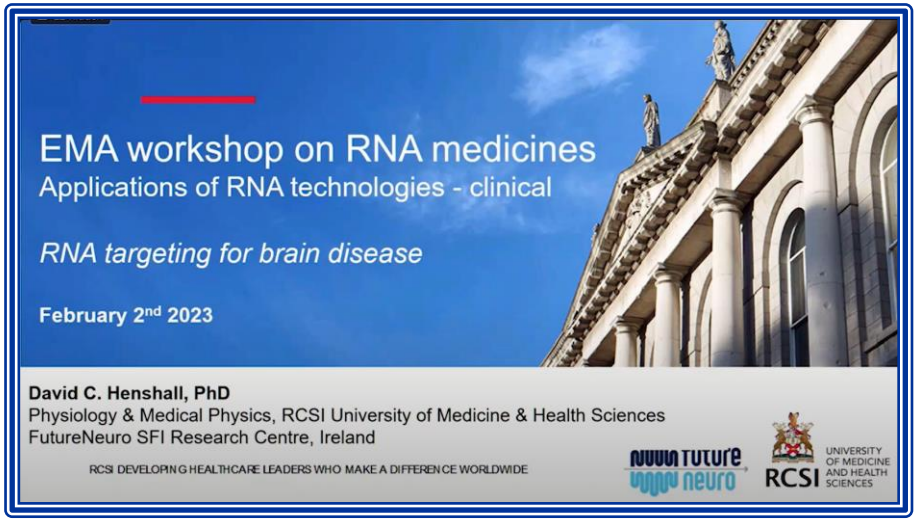
Training events

EMA Workshops



Training Collaborations

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Any questions?

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