



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA's Engagement with Academia

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Academia Info Day 10 November 2023

Maribel Rico-Salas, Academia Liaison  
Regulatory Science and Innovation Task Force



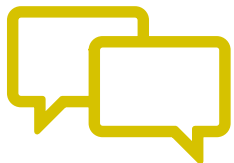
# Academic Sector

Non-For-Profit  
Organisations & Representatives  
pursuing

EDUCATION AND RESEARCH  
in all fields relevant to the work of EMA

# ACADEMIA LIAISON

Your contact point for interaction with the EMA  
[Framework of collaboration with Academia](#)



## ***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

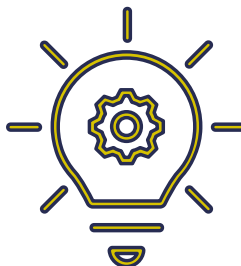


## Research

Regulatory Science

Project  
Collaboration

Advice to Funders

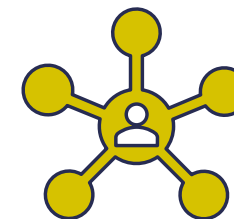


## Innovation

Academia Briefings

Incentives

Pilot programs



## Communication & Training

Information Requests

Targeted  
Communication

Events- *Info Day*



## Research

The range of **scientific disciplines** that

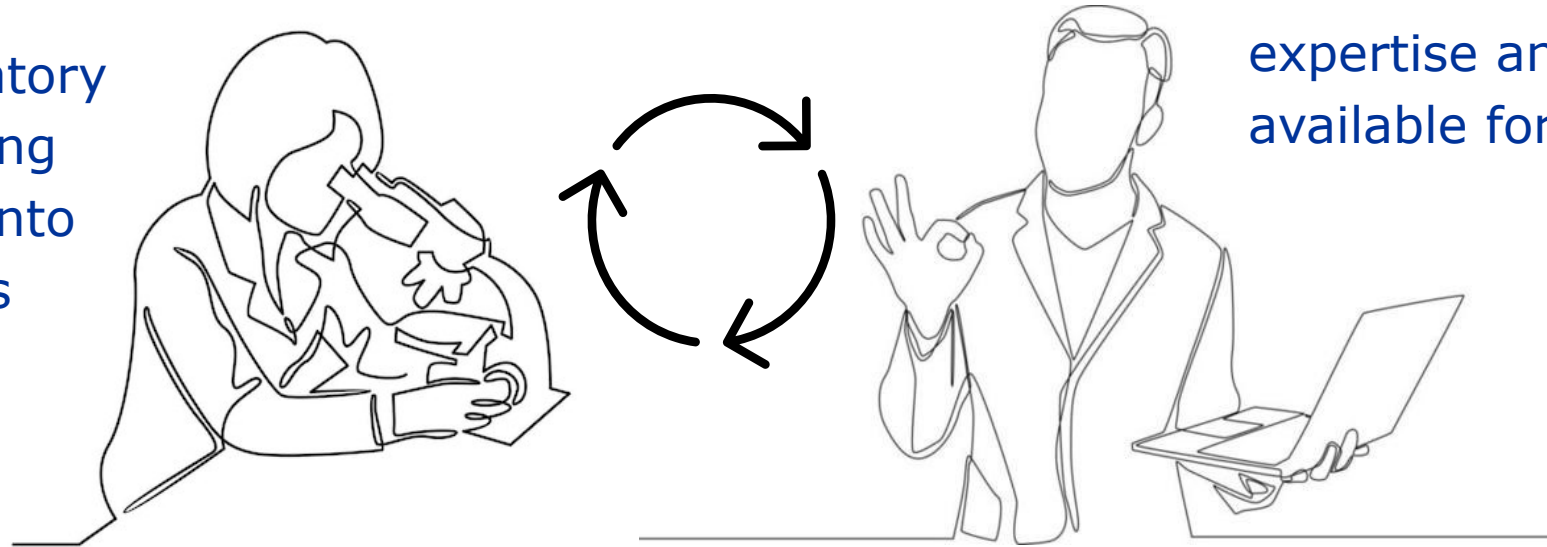
- Are applied to the assessment of quality, safety or efficacy of medicinal products
- Inform regulatory decision-making throughout the lifecycle of a medicine.

It encompasses basic and applied biomedical and social sciences and contributes to the **development of regulatory standards and tools.**

## **Academic Developers:**

EMA provides regulatory support for translating academic research into novel methodologies and medicines.

## **Virtuous cycle**



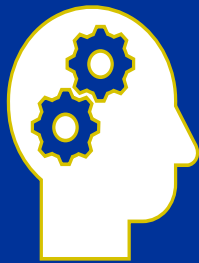
## **Knowledge Gaps:**

Ensure best scientific expertise and research is available for regulators.

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



- EMA published **Regulatory Science Research Needs**
- Seeks to **stimulate research** to address
- Featuring 110+ topics where research is needed to fill **regulatory knowledge gaps**
- Researchers in academia, organisations companies; patients also to be involved
- EMA invites **funders to consider supporting**
- List v1.0 published December 2021, periodically updated with new topics



Learnings from science and technology  
evolve the regulatory framework

<https://www.ema.europa.eu/en/news/ema-launches-regulatory-science-research-needs-initiative>

## Regulatory Science Strategy goals

## Number RSRN topics

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



**12 H + 9 V**

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



**25 H + 16 V**

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



**23 H**

Goal 4 (H) / 3 (V): Addressing emerging health threats and availability/therapeutic challenges



**12 H + 11 V**

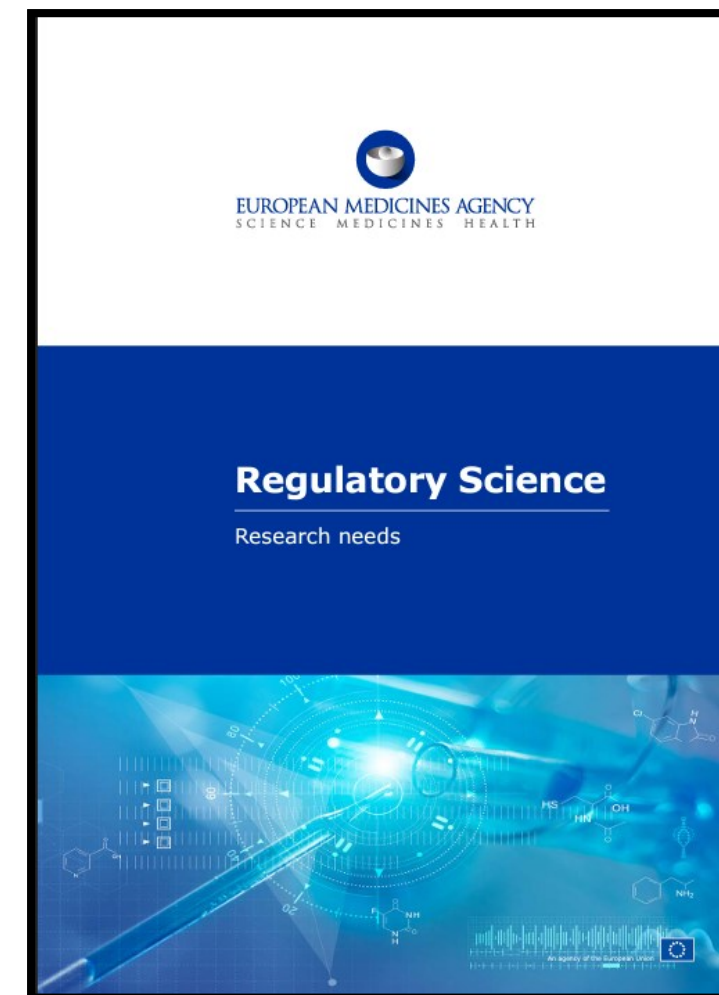
Goal 5 (H) / 4 (V): Enabling and leveraging research and innovation in regulatory science



**2 H + 1 V**

[https://www.ema.europa.eu/documents/other/regulatory-science-research-needs\\_en.pdf](https://www.ema.europa.eu/documents/other/regulatory-science-research-needs_en.pdf)

**Total: 111**



# Project Collaboration and Advice to Funders




COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN



**ERA4Health Partnership**

Funding for ground-breaking transnational research in the health domain across Europe and beyond.



**ONE HEALTH**

Prevention and control of foodborne zoonoses, antimicrobial resistance, and emerging threats



**EU-PEARL**  
EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Developing sustainable and replicable patient-centered Integrated Research Platforms (IRPs) for collaborative adaptive platform trials. prevention and control of foodborne zoonoses, antimicrobial resistance, and emerging threats

**M6ATCELL**

Exploiting fundamental insights of m6A methylation on CD8 T cell differentiation and function to boost medicinal T cell products




**REPURPOSING OF MEDICINES 4ALL**

Building a sustainable European innovation platform to enhance the repurposing of medicines for all



**innovative health initiative**

Public-private partnership funding health research and innovation



**MINDED**

Revolutionizing the diagnosis, detection and treatment of complex genetic diseases



**EUROPEAN JOINT PROGRAMME RARE DISEASES**

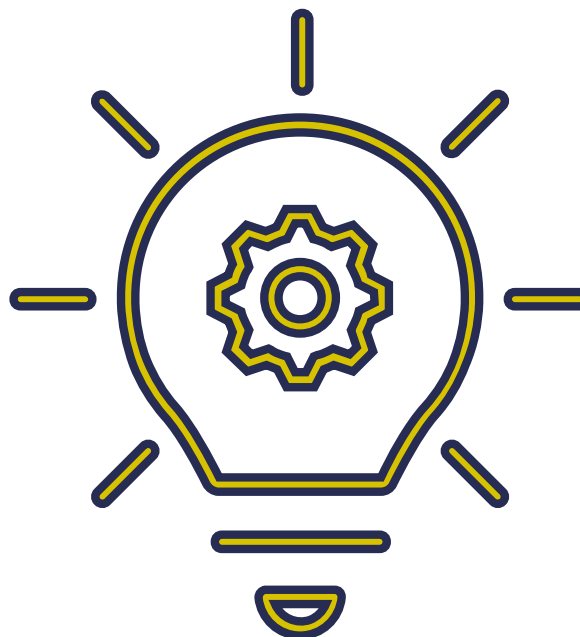
Sustaining research, innovation and medical care in rare diseases

**EU4health**

Working together to protect European's health



- **Academia Matrix Action Plan:** to address actions defined in the *Regulatory Science Strategy 2025 (RSS)* that are geared to the academic sector.
- **Exchange information** internally regarding new developments and Regulatory Science Research Needs.
- **Coordinate activities** under the Framework of Collaboration with Academia.



## Innovation

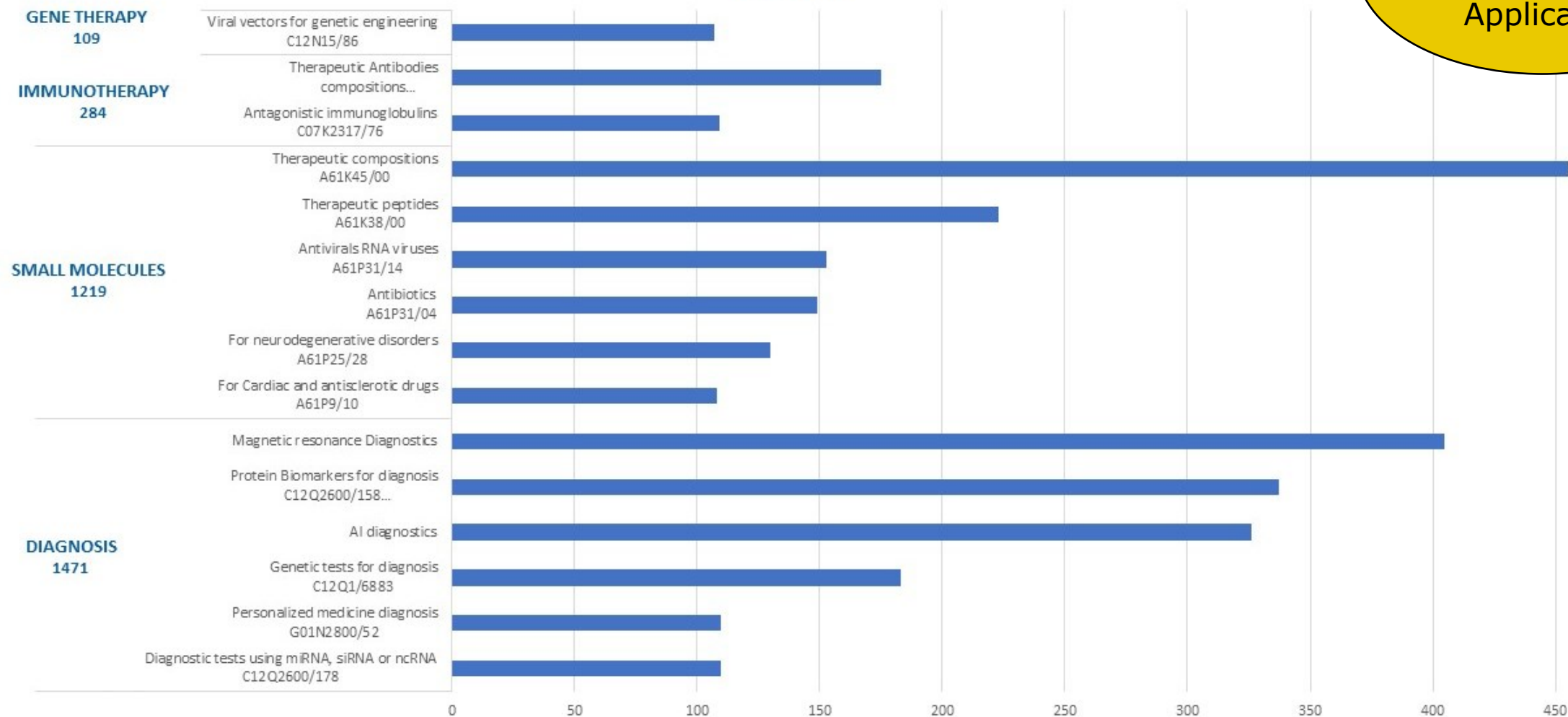
# Innovative Potential of European Academic Sector



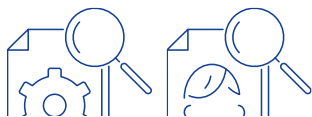
EUROPEAN MEDICINES AGENCY

Only European  
Academic  
Applicants

## ACADEMIC MEDICAL SOLUTION PATENT APPLICATIONS 2017-2022



# Entry points for academia developers to **obtain EMA support**



**Early  
Research**

**Non-clinical and  
First in Man**

**Clinical  
exploratory**

**Clinical  
confirmatory**

- **Authorisation**
- **Access decision**
- **Post-licensing evidence**

Academia Briefings

**Innovation Task Force and EU-IN**

**Scientific Advice/Protocol Assistance**

PRIME support

ATMP certification

Orphan Drug Designation

**Paediatric Investigation Plan**

**Qualification of Novel Methodologies**

**SME briefings**



## 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





Pilot for Repurposing of  
Authorized Medicines

**Academic  
Sector**  
*Scientific Advice*

Pilot for Development of  
Advanced Medicinal Products

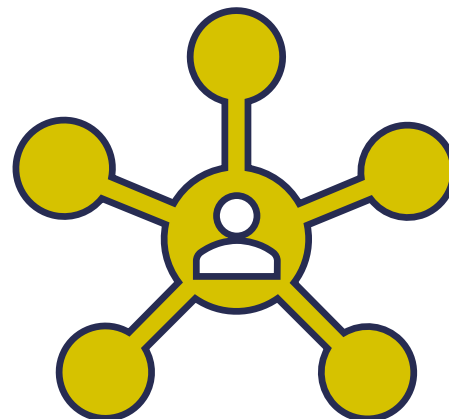
**Academic Sector**  
*Scientific Advice*  
*Inspections*  
*Marketing*  
*Authorization App.*

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**



## Communication & Training

## Send a Question to the European Medicines Agency

Use this form to send a request for information from the 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](mailto: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? \***

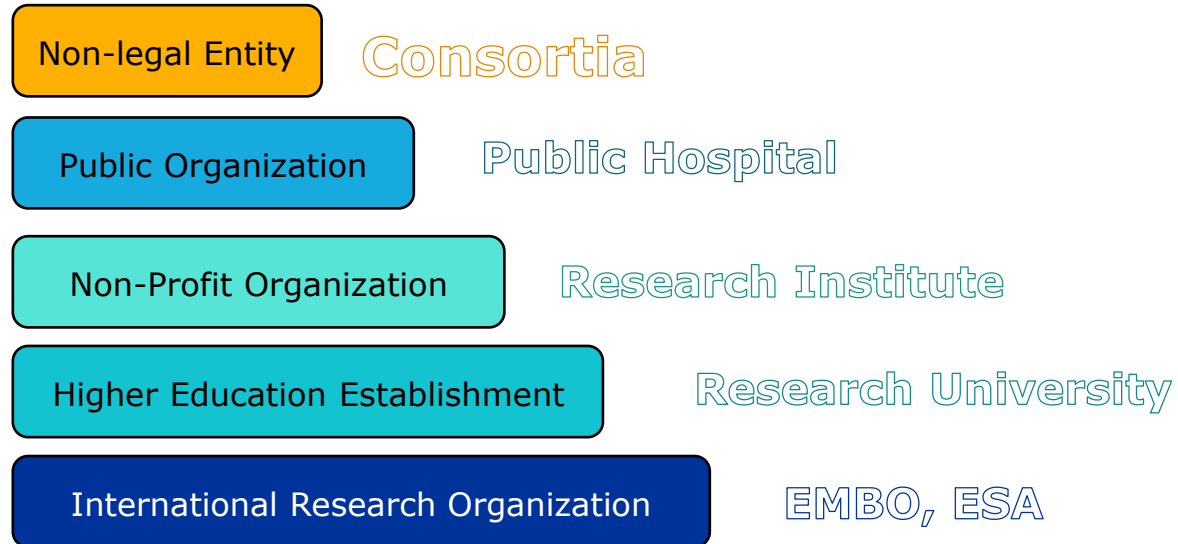
**Your question(s) \***

# Targeted Communication: Stakeholders Database



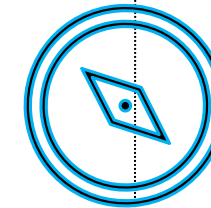
EUROPEAN MEDICINES AGENCY

Pursuing **education or research** in all fields relevant to the work of EMA:



Scholars

Invitation to Register



Academia Briefings



**Validated**

DB Registration

Collaborations

Fee Reductions

Incentives

Informal consultation

Speaker in Workshops

Targeted communication



## EMA Workshops

## Training Collaborations

### EMA workshop on RNA medicines Applications of RNA technologies - clinical

*RNA targeting for brain disease*

February 2<sup>nd</sup> 2023

**David C. Henshall, PhD**

Physiology & Medical Physics, RCSI University of Medicine & Health Sciences  
FutureNeuro SFI Research Centre, Ireland

RCSI DEVELOPING HEALTHCARE LEADERS WHO MAKE A DIFFERENCE WORLDWIDE



### EMA and EATRIS Present:

Scientific advice for advanced therapy medicinal products (ATMPs):  
What and when to ask

**Webinar - 10 June 2022 at 13:00-14:00 CEST**

**EMA Speakers: Anna Tavridou, Milton Bonelli & Dolca Rogers**



**Moderator: David Morrow- EATRIS**



# Thank you for your attention



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Maribel Rico-Salas



Ralf Herold (RH)

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## Any Question?