# Il supporto all'innovazione e alla ricerca in ambito farmaceutico

TECHNOLOGY TRANSFER SCHOOL
Ministero della Salute, Network PerfeTTO, APRE

Eleonora Agricola

22/01/26

# Dichiarazione di trasparenza/interessi*

Le opinioni espresse in questa presentazione sono personali e non impegnano in alcun modo l'AIFA

| Interessi nell'industria farmaceutica | NO | Attualmente | Da 0 a 3 anni precedenti | oltre 3 anni precedenti |
|---|---|---|---|---|
| *INTERESSI DIRETTI:* | | | | |
| 1.1 Impiego per una società: Ruolo esecutivo in una società farmaceutica | ☒ | ☐ | ☐ | ☐ obbligatorio |
| 1.2 Impiego per una società: Ruolo guida nello sviluppo di un prodotto farmaceutico | ☒ | ☐ | ☐ | ☐ obbligatorio |
| 1.3 Impiego per una società: altre attività | ☒ | ☐ | ☐ | ☐ facoltativo |
| 2. Consulenza per una società | ☒ | ☐ | ☐ | ☐ facoltativo |
| 3. Consulente strategico per una società | ☒ | ☐ | ☐ | ☐ facoltativo |
| 4. Interessi finanziari | ☒ | ☐ | ☐ | ☐ facoltativo |
| 5. Titolarità di un brevetto | ☒ | ☐ | ☐ | ☐ facoltativo |
| *INTERESSI INDIRETTI:* | | | | |
| 6. Sperimentatore principale | ☒ | ☐ | ☐ | ☐ facoltativo |
| 7. Sperimentatore | ☒ | ☐ | ☐ | ☐ facoltativo |
| 8. Sovvenzioni o altri fondi finanziari | ☒ | ☐ | ☐ | ☐ facoltativo |
| 9. Interessi Familiari | ☒ | ☐ | ☐ | ☐ facoltativo |
| 10. Gravi ragioni di convenienza | ☒ | ☐ | ☐ | ☐ facoltativo |

* ELEONORA AGRICOLA, secondo il Regolamento per la prevenzione e gestione dei conflitti di interessi all'interno dell'Agenzia Italiana del Farmaco approvato con Delibera CdA n.9 del 12 febbraio 2025.

N.B. Per questo intervento non ricevo alcun compenso

# Research and Innovation for patients' benefit

European Medicines Regulatory Network (ERMN)

**European Innovation Ecosystem**

Academia
Research Institutions
KTO - TTO
Industry
SME
HCPs
Patients
Funders

# European Medicines Regulatory Network
## (EMRN)

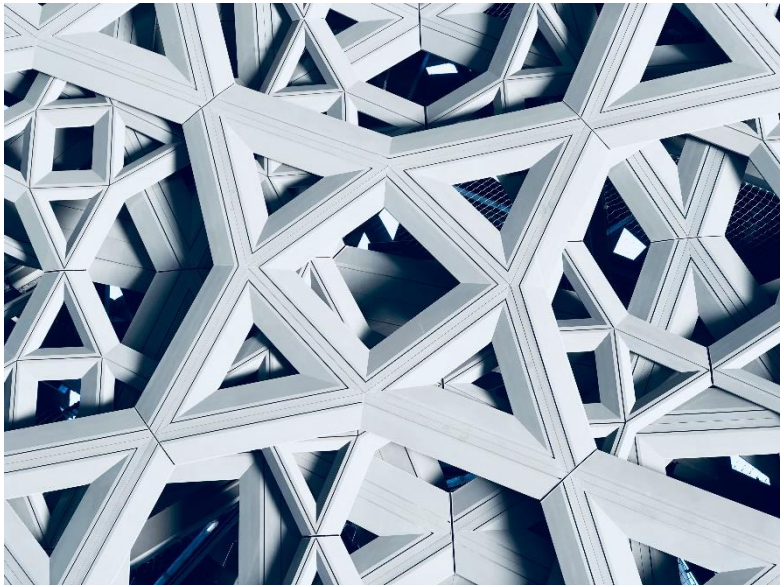
EMA
EUROPEAN MEDICINES AGENCY

**National Competent Authorities**
(NCA)

HMA
Heads of Medicines Agencies

# European Regulators


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



# Promote collaboration and integration across EMAN

Cross-contamination

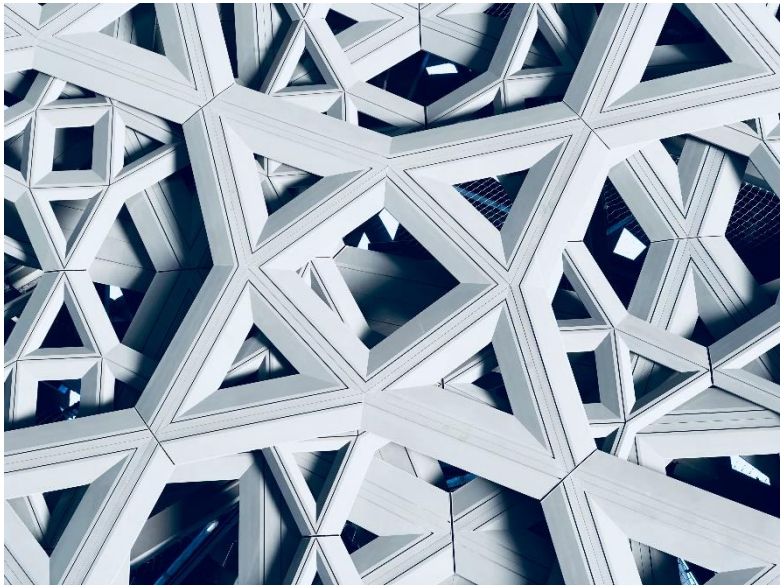
Sharing knowledge

Joint activities

Transverse topics

Ensure alignment

Avoid duplication



# What the

# European Medicines Regulatory Network

# IS NOT

# for Innovation

# The European Medicine Regulatory Network

## IS NOT

- an obstacole
- a brake

# Regulatory Science

**Developers** should **adhere** to regulatory standards from the early stage of development.

**Regulators** must **adapt** to rapid technological advancements.

Ongoing **dialogue** is essential.

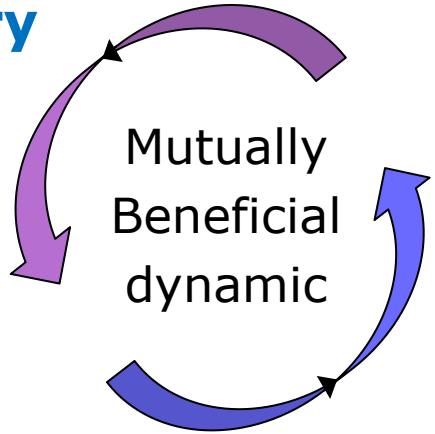
**Working together** for the common good.

***Regulatory Science**** to drive regulatory evolution

**a variety of **scientific disciplines** to **evaluate the quality, safety, and efficacy** of medicinal products, and to inform **regulatory decision-making** throughout the lifecycle of a medicine. It includes both basic and applied biomedical and social sciences, and contributes to the **evaluation of existing regulatory standards**, as well as the **development of new** tools, methods, principles, and standards used in medicine development, while also **informing the requirements for their evaluation**.*

# European Innovation Ecosystem

**European Medicines Regulatory Network (ERMN)**




**Academia**
**Research Institutions**
**KTO - TTO**
Industry
SME
HCPs
Patients
Funders

# Accademia and TTO: essential role in innovation

# ERMN and TTO

**EMAN 2028*: competitiveness** alongside data/AI, **regulatory science & innovation**, supply, preparedness and a strong Network.

**Competitiveness**: keeping research, development, authorisation and scale-up of innovative medicines and associated technologies in Europe.

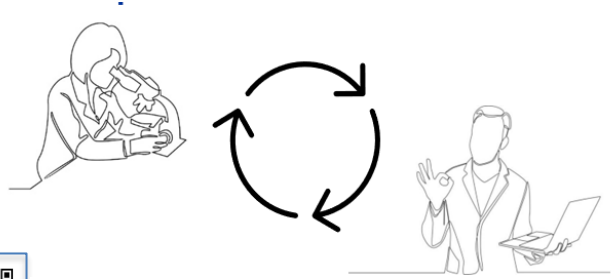
**TTOs: key enablers** in Member States as concrete entry points for early EMRN support via **local innovation offices**.

*

*AI-generated image - Copilot*

# ERMN collaboration with academia and TTO


IncreaseNET
Capacity.Competence.Confidence.

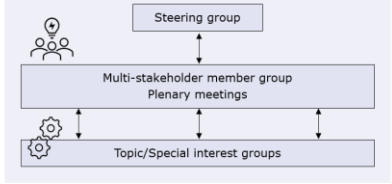


***European Platform for Regulatory Science***

**Participants**

- Not-for-profit research organisations
- Academic research groups and individual researchers from academic sector
- EMA, NCAs

- National and EU level funders
- Industry trade associations
- HTA bodies and policy makers
- Patients organisations




STARS
STRENGTHENING REGULATORY SCIENCE

# ERMN: activities and tools

- Translation of EU Strategies into tangible outcomes for the EMRN and stakeholders
- Use of regulatory supports at national and EU level


*AI-generated image*

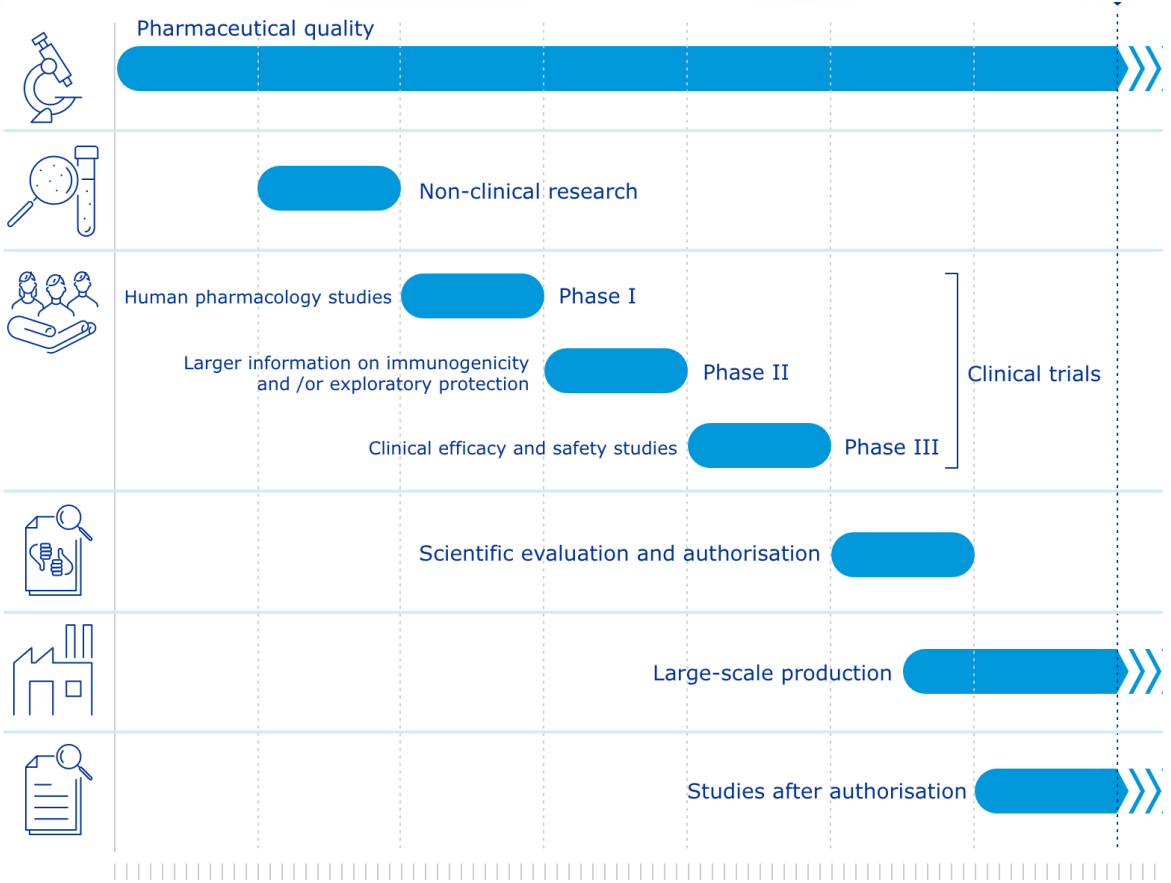
# Medicinal Product's lifecycle

Quality

Safety

Efficacy

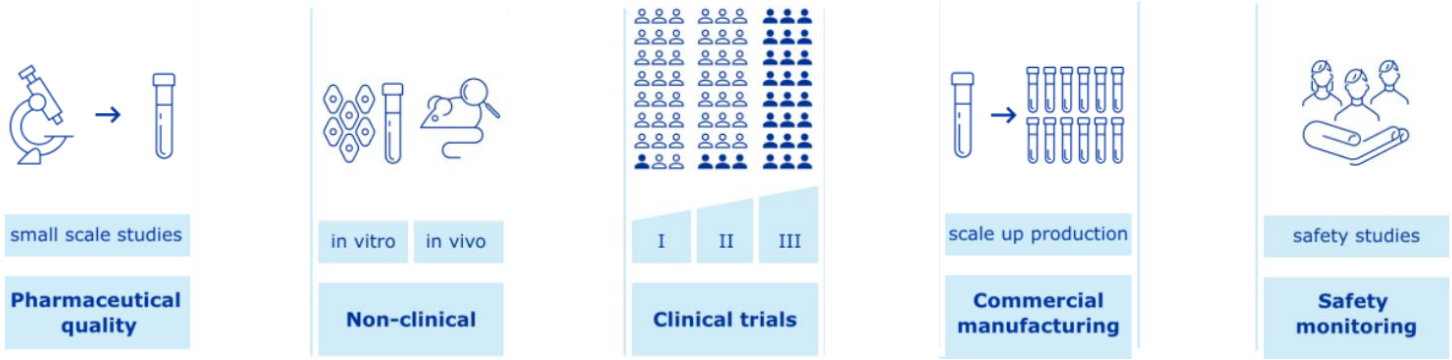
Positive B/R



# Adherence to regulatory standards

## Guidelines

how to interpret and apply the requirements for the demonstration of quality, safety and efficacy




from the early stage of development..

..to post-marketing

# Innovation meetings

**Scope**

- ✓ To start a dialogue at **an early stage of development** of innovative/emerging medicinal products, technologies, methodologies.
- ✓ To get inputs on **regulatory and scientific requirements** and on **available support tools**.
- ✓ Questions could be:
  - regarding a general understanding on the **future development** in compliance with regulatory requirements, especially when **guidelines are lacking** or clarification is needed;
  - specific to the project;
  - related to **regulatory, technical and scientific** concerns;
  - related to **quality, non-clinical, clinical and methodology** aspects.

**What to expect**

Regulators could:

- provide a **general guidance** on regulatory or scientific issues to be considered during development;
- provide **high level feed-back on the overall** product development;
- confirm/suggest any **appropriate and available guidance** to refer to during product development;
- give an overview of the regulatory **applicable framework** and suggest other **regulatory tools**, national or European, to be followed during the development.

**Output**

- ✓ Meeting **minutes**.
- ✓ The answers provided should not be interpreted as regulatory guidance or review recommendations for an application, but as a **preliminary set of scientific considerations** on the information presented.
- ✓ It is **not mandatory** for the Applicant.

# EMA Academia briefing meetings

**Scope**

Earliest entry point only for researchers and developers from the academic sector/Non-For-Profit sector to provide a bidirectional exchange on challenges and provides opportunity to discuss and support on regulatory aspects and R&D.
Exchange and discussion could aim:

- at acquainting stakeholders with the different regulatory pathways and incentives available for their developments.
- at exchanging information and views on topics mutually relevant.

**What to expect**

EMA experts could:

- provide recommendations on regulatory development plan, Clinical trial design development, regulatory interactions and pathways to consider
- provide support offerings for academic researchers, incentives
- identify grounds for potential collaborations
- provide feedback on regulatory development plan optimal, clinical trial design maturity to get Scientific Advice, appropriateness of PRIME or Orphan Medicines programme to the development

**Output**

Meeting minutes.

# SME briefing meetings

**Scope**

- ✓To discuss a **regulatory strategy** for the development of human or veterinary medicinal product and to provide information on relevant procedures, support tools, guidance, and incentives.
- ✓at the **early stages** of product development and during the entire development phase.

**What to expect**

Regulators could:

- Provide **general and specific guidance on requirements** for a development programme aimed at supporting a marketing authorisation application.
- Highlight **available tools** (e.g. PRIME, Scientific Advice, OPEN) and guidance to facilitate product development and authorisation.
- Discuss **regulatory aspects** such as eligibility and legal basis for a MAA, including considerations related to **data exclusivity, marketing protection, including orphan and paediatric aspects**.

**Output**

- ✓Meeting **minutes**.
- ✓The answers provided should **not be interpreted as regulatory guidance or review recommendations** for an application.

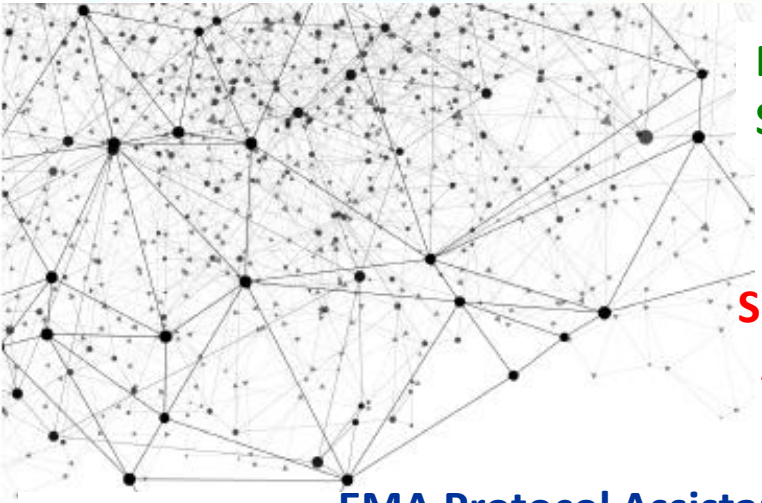
# Other EMA support tools

- **Orphan designation:**
  - for the **treatment, prevention or diagnosis** of a disease that is life-threatening or chronically debilitating;
  - the prevalence of the condition in the EU is **less than 5 in 10,000** or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment for its development;
  - no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

- **ATMP Qualification** to confirm that **a product is classified as an ATMP** in the context of research and development
- **ATMP Certification** of ATMP **quality and non-clinical data from SMEs** by the EMA CAT

- **Paediatric Investigational Plan (PIP)** details on the timing and the measures proposed to demonstrate quality, safety and efficacy. **Binding to the Applicant**.

# Scientific Advice



National Scientific Advice

EMA Scientific Advice

EMA Protocol Assistance

EMA Qualification Advice

**European Medicines Regulatory Network (EMRN)**

EMA EUROPEAN MEDICINES AGENCY

National Competent Authorities (NCA)

HMA Heads of Medicines Agencies

**Scope**

to provide prospective guidance and direction on the development of new and existing human medicinal products to be compliant to the EU scientific and regulatory requirements

# Regulatory tools fees

| Regulatory Tool | Fees for Academia |
|---|---|
| Innovation Meeting | Free of charge |
| EMA Academia Briefing Meeting | Free of charge |
| EMA SME Briefing Meeting | Free of charge |
| EMA PRIME – Submission request | Free of charge |
| Orphan Designation | Free of charge |
| ATMP Qualification/Certification | Free of charge |
| Paediatric Investigational Plan | Free of charge |
| Scientific Advice | Waived |

*The power to question is the basis of all human progress.*

**Indira Gandhi**

*It's better to know some of the questions than all of the answers.*

**James Thurber**

# MANY THANKS

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