

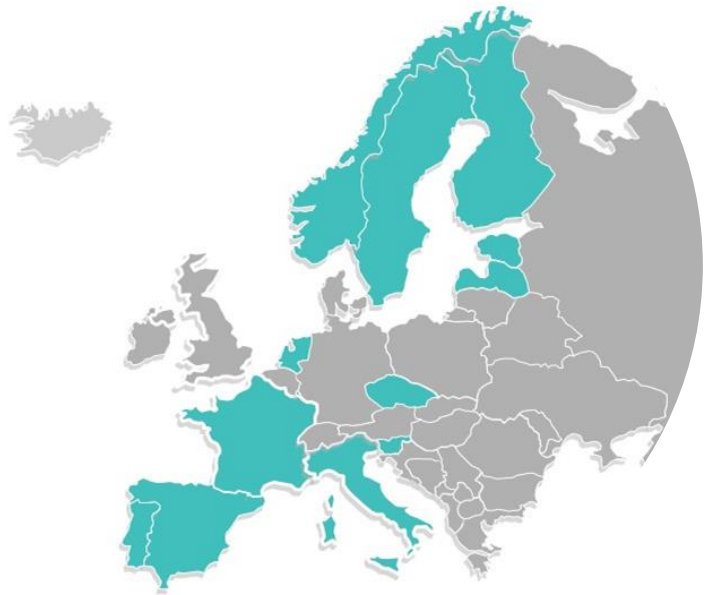
EATRIS ERIC - European Infrastructure for Translational Medicine
EMA - EU Innovation Network
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Areas of interest and operations



We support the development of **biomedical discoveries into interventions** for better health, e.g.

- **next generation translational tools** for better understanding of disease processes and drug performance
- **standardisation and quality** in the translational medicine pipeline
- **fostering timely interaction** with regulators and stakeholders

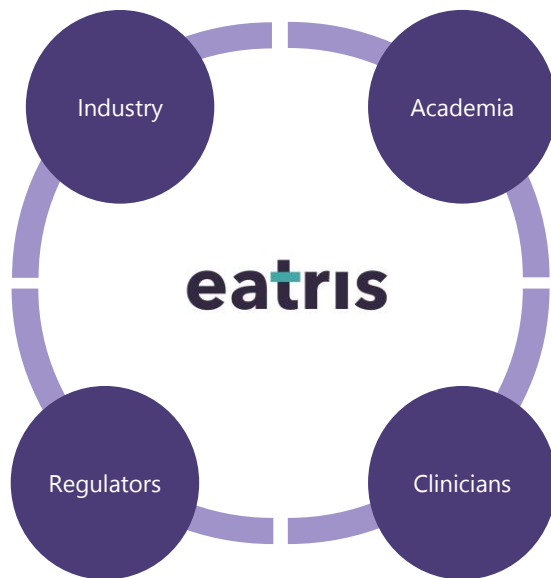
A distributed infrastructure

We coordinate 90 translational research institutes of excellence in 12 countries

- 45 University Medical Centres
- Latest in vitro and in vivo models, systems
- Deep and wide clinical expertise, patient cohorts

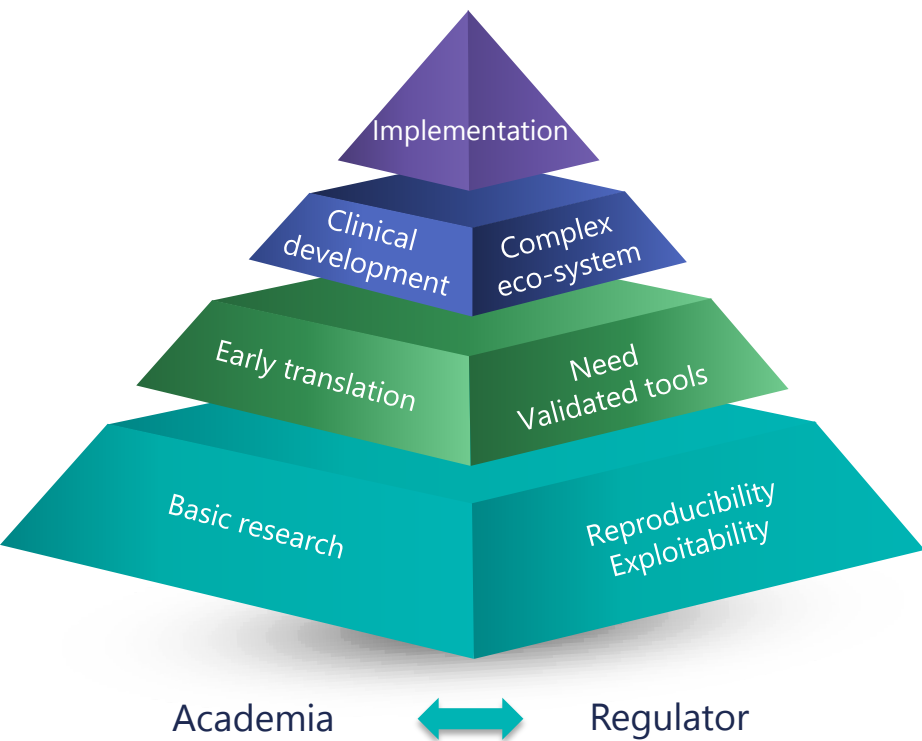
The Challenges

- **Access to regulatory expertise** within academia not easy
- There is a **lack of incentive (funding)** for academia to perform **validation studies and effective transition to clinic**
- Many **systemic bottlenecks** are due to weak/non-existent cross-sector cooperation
 - Accessing **latest translational tools**, e.g.
 - Molecular imaging (cell tracking for CTs),
 - The right potency assays,
 - Assays addressing collateral effects of new therapies (e.g CRS from ACT)
 - **EU multinational clinical research is complex**; lead times underestimated



Cross-sectoral collaboration is a critical success factor

Experience in interaction with reg. authorities



Regulators recognise that **academia need advice earlier** in the development life-cycle



Academia not aware of opportunities to interact, lack access to experts that 'speak the language'



Facilitate early interaction

EATRIS interacts with **Regulators** through various mechanisms (e.g. MoU with NCAs)



Active engagement

Participation of Regulators at EATRIS workshops, use of available platforms (e.g. EMA ITF and NCAs Innovation Offices)

What can EATRIS offer to you to advance Regulatory Science?

Publicly funded infrastructure

Experienced in working with institutions focused on translational research

Track Record

Active relationship with NCAs and working with SMEs and Academics

Cross-sector collaboration

Act as a focal point for advancing Regulatory Science in consultation with regulators

Coordinating a Research Agenda dedicated to developing next generation tools e.g.

- Platform for cell tracking
- Operational framework for adaptive platform trials (IMI EU-PEARL)
- Best practices, methodology, standardisation and quality in translational research



Thank you for your attention and
your engagement in Q&A

For further information and
collaboration, please contact us



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