FIVE GOALS
for human medicines regulation

- Catalysing the integration of science and technology in medicines development
- Enabling and leveraging research and innovation in regulatory science
- Addressing emerging health threats and availability/therapeutic challenges
- Advancing patient-centred access to medicines in partnership with healthcare systems
- Driving collaborative evidence generation - improving the scientific quality of evaluations

Click on each goal to find out more #RegScience2025
EMA Regulatory Science to 2025
Five goals for human medicines regulation

Goal 1
Catalysing the integration of science and technology in medicines development

- Support developments in precision medicine, biomarkers and ‘omics’
- Support translation of advanced therapy medicinal products (ATMPs) into patient treatments
- Promote and invest in the PRIority MEdicines scheme (PRIME)
- Facilitate the implementation of novel manufacturing technologies
- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals
- Diversify and integrate the provision of regulatory advice along the development continuum

Click on each goal on the left to find out more
Goal 2

Driving collaborative evidence generation and improving the scientific quality of evaluations

- Leverage non-clinical models and 3Rs principles
- Foster innovation in clinical trials
- Develop the regulatory framework for emerging clinical data generation
- Expand benefit-risk assessment and communication
- Invest in special populations initiatives
- Optimise capabilities in modelling, simulation and extrapolation
- Exploit digital technology and artificial intelligence in decision making
Goal 3

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

- Contribute to HTA’s preparedness and downstream decision making for innovative medicines
- Bridge from evaluation to access through collaboration with payers
- Reinforce patient relevance in evidence generation
- Promote use of high-quality real-world data (RWD) in decision-making
- Develop network competence and specialist collaborations to engage with big data
- Deliver improved product information in electronic format (ePI)
- Promote the availability and support uptake of biosimilars in healthcare systems
- Further develop external engagement and communications to promote trust and confidence in the EU regulatory system
EMA Regulatory Science to 2025

Five goals for human medicines regulation

Goal 4

Implement EMA’s health threats plan, ring-fence resources and refine preparedness approaches

Continue to support development of new antibacterial agents and their alternatives

Promote global cooperation to anticipate and address supply problems

Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines

Support the development and implementation of a repurposing framework

Addressing emerging health threats and availability/therapeutic challenges
Goal 5

Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science.

Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions.

Identify and enable access to the best expertise across Europe and internationally.

Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.

Enabling and leveraging research and innovation in regulatory science.