# **EMA Regulatory Science to 2025**



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

*Click on each goal to find out more* 







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### **EMA Regulatory Science to 2025** Five goals for human medicines regulation





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



Goal 2

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Goal 3

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Goal 4

Goal 5

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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

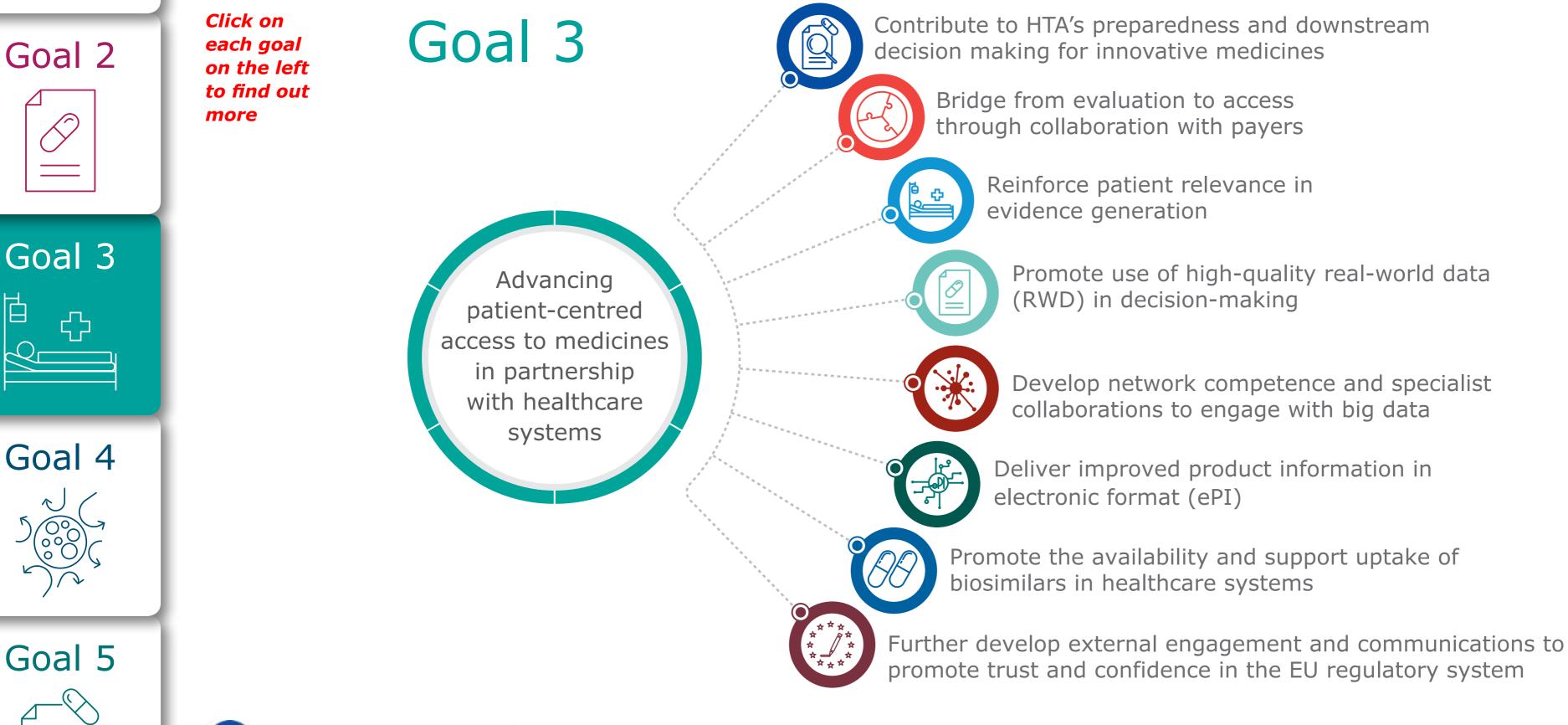
Optimise capabilities in modelling, simulation and extrapolation

Exploit digital technology and artificial intelligence in decision making



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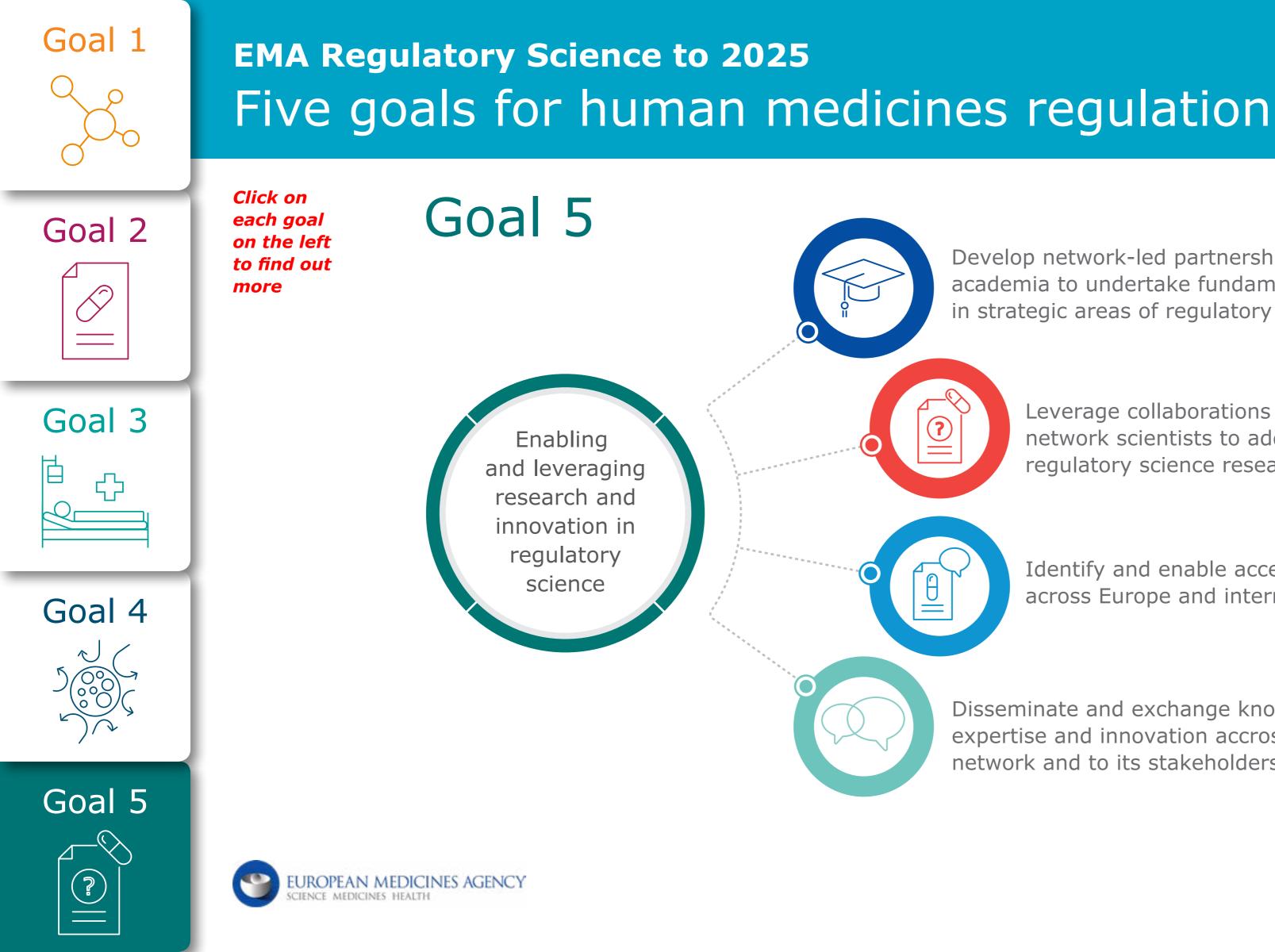
Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches

> 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





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 accross the network and to its stakeholders