EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

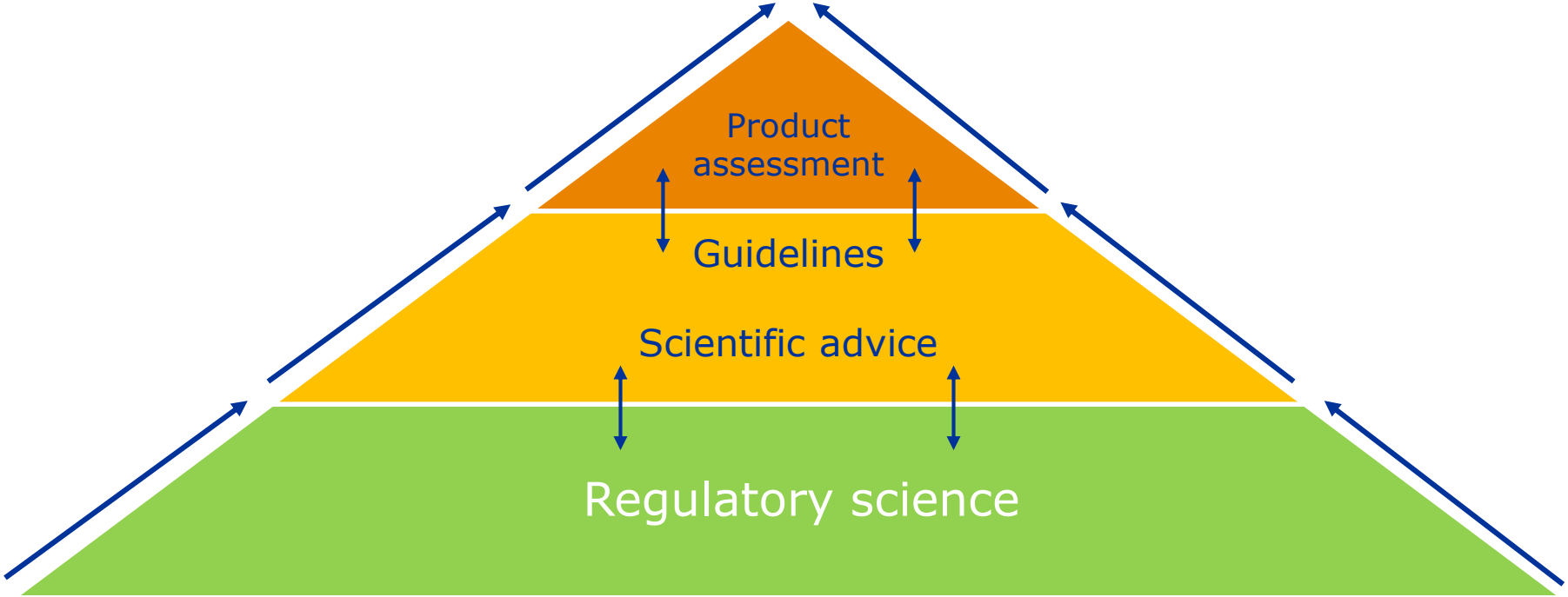
The EMA regulatory science agenda

LEVERAGING THE VALUE OF COLLABORATION from regulatory science to regulatory innovation

Regulatory Science Network Netherlands

Presented by Tony Humphreys on 17 November 2020
Head of Regulatory Science and Innovation Task Force

The role of regulatory science at EMA



EMA Regulatory Science to 2025

Cluster 3: Researchers

EUROPEAN MEDICINES AGENCY

Relevant and comprehensive. Ambitious in nature

- Facilitate greater collaboration and communication with stakeholders
  - To improve evidence generation
  - To close gap from approval to access
  - To encourage data sharing across EU network
- Ensure funding bodies are aware of RSS goals – regulatory science research questions to align funding priorities
- Align internationally to improve efficiency during development
- Show leadership in enhancing patient engagement
- Develop a set of 'patient important outcomes' to be measured in all trials
- Bolster efforts on 3Rs through qualification of novel methods and communicating acceptability
- Ensure regulatory preparedness for nanomedicines and borderline products

Cluster 5: Industry

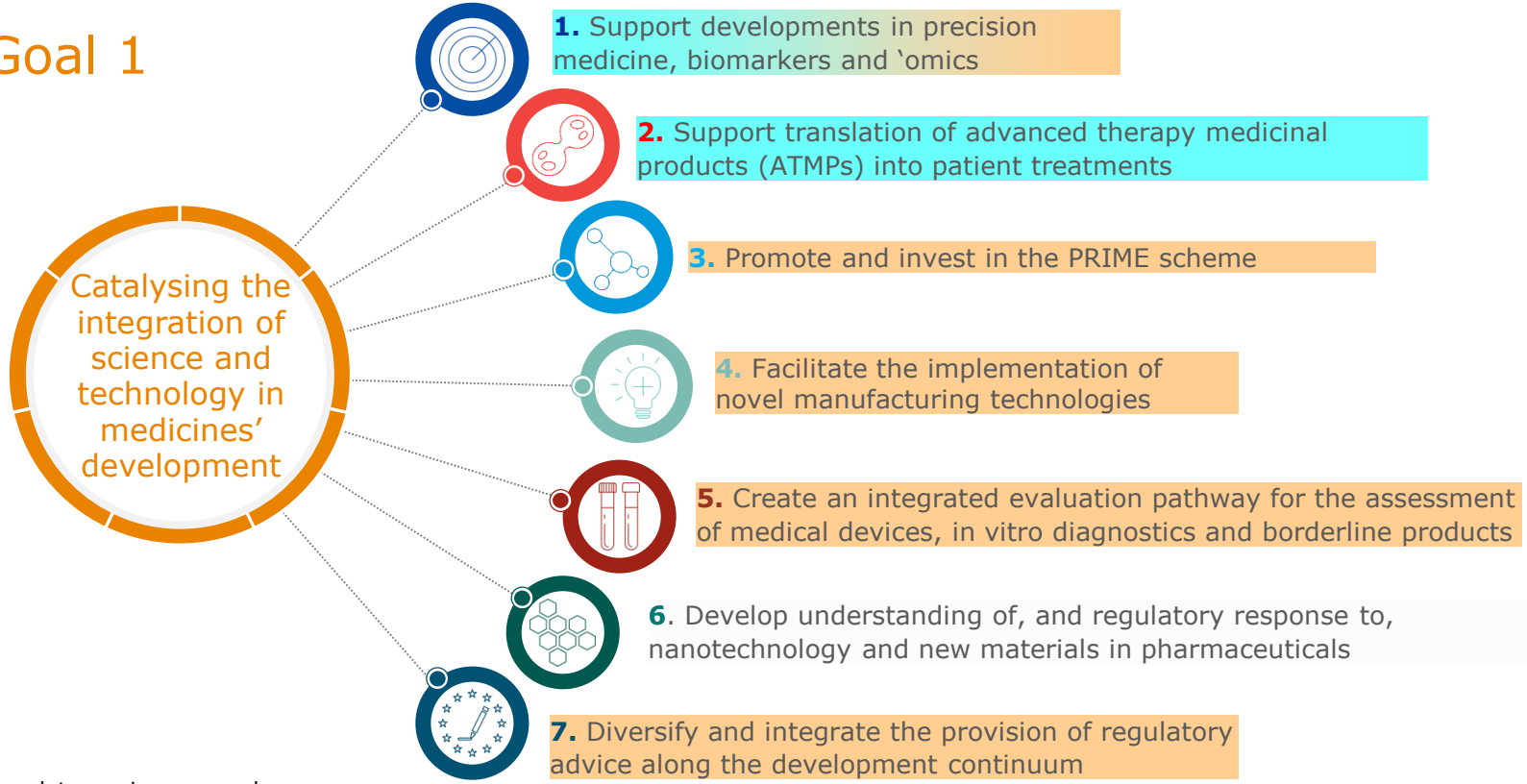
EUROPEAN MEDICINES AGENCY

Comprehensive – welcomed focus on innovation, consultative process and forward looking activities involving collaboration between stakeholders

- Importance of efforts to reduce complexity of EU system, reach global alignment and advance patient-centred access
- Alignment of regulatory science and frameworks with FDA/ICH etc. e.g. RWD
- Alignment of CT innovation, patients, NCAs, HTAs, and health systems
- Support increased regulatory science knowledge exchange – Cloud-based systems
- Importance to improve flexibility and harmonisation of scientific advice including stakeholders
- Imperative best use of new technology and data to support new healthcare paradigms
- Optimise emerging/new mfg approaches and develop new regulatory frameworks (complex generic, biosimilars, ATMP/ follow on biologics)
- Leveraging R&I – IT partners, expertise ehealth, AI, wearables etc.

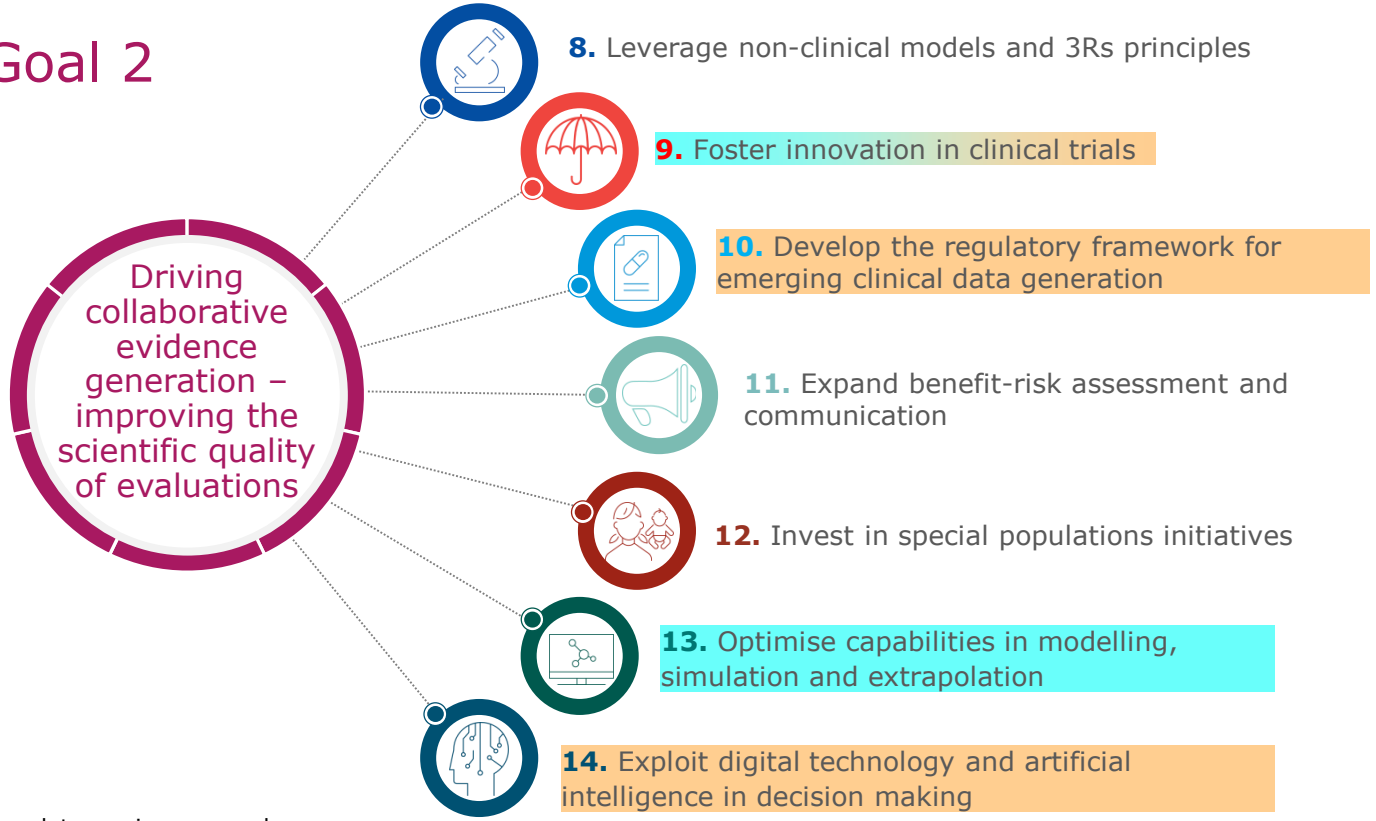
Five goals for human medicines regulation

Goal 1



Five goals for human medicines regulation

Goal 2



Five goals for human medicines regulation

Goal 3

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

15. Contribute to HTA's preparedness and downstream decision making for innovative medicines

16. Bridge from evaluation to access through collaboration with payers

17. Reinforce patient relevance in evidence generation

18. Promote use of high-quality real-world data (RWD) in decision- making

19. Develop network competence and specialist collaborations to engage with big data

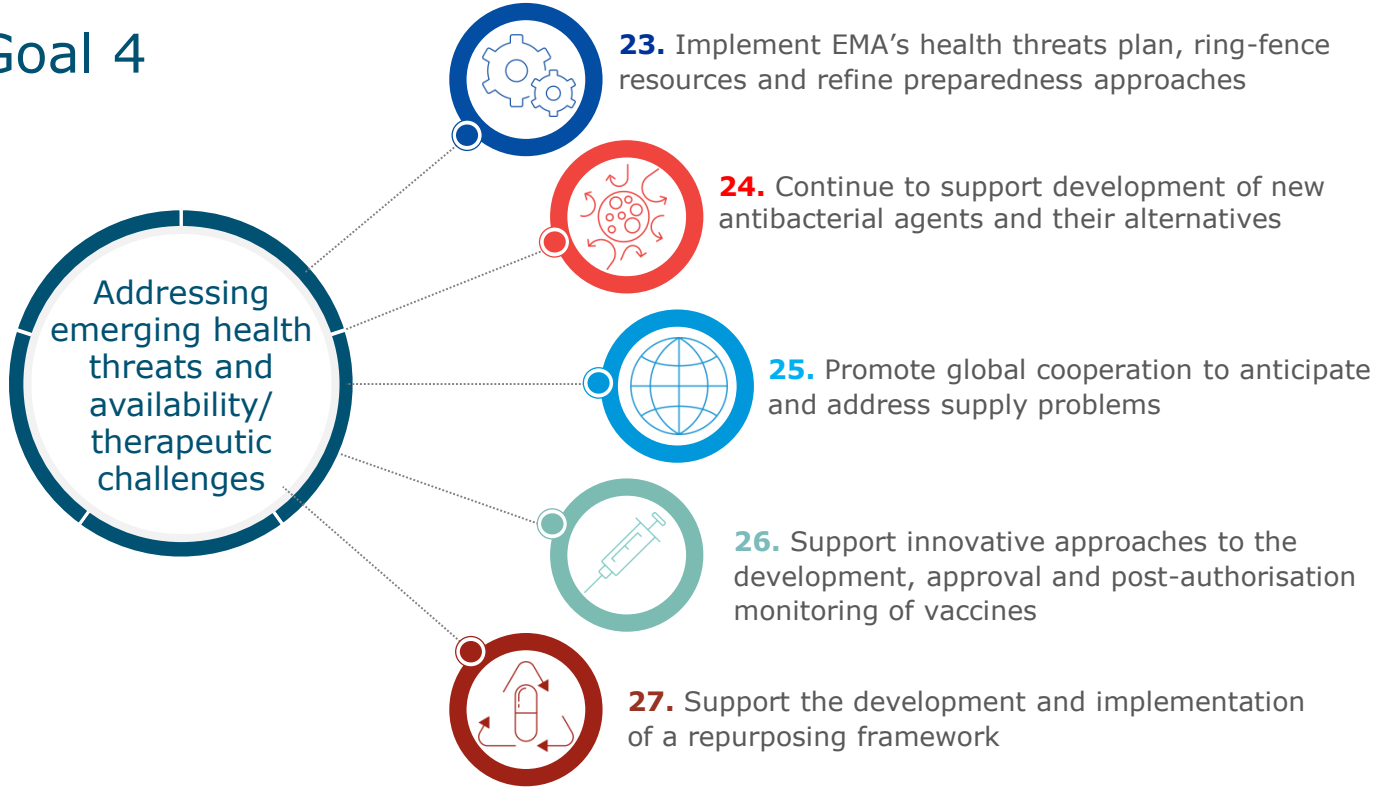
20. Deliver improved product information in electronic format (ePI)

21. Promote the availability and support uptake of biosimilars in healthcare systems

22. Further develop external engagement and communications to promote trust and confidence in the EU regulatory system

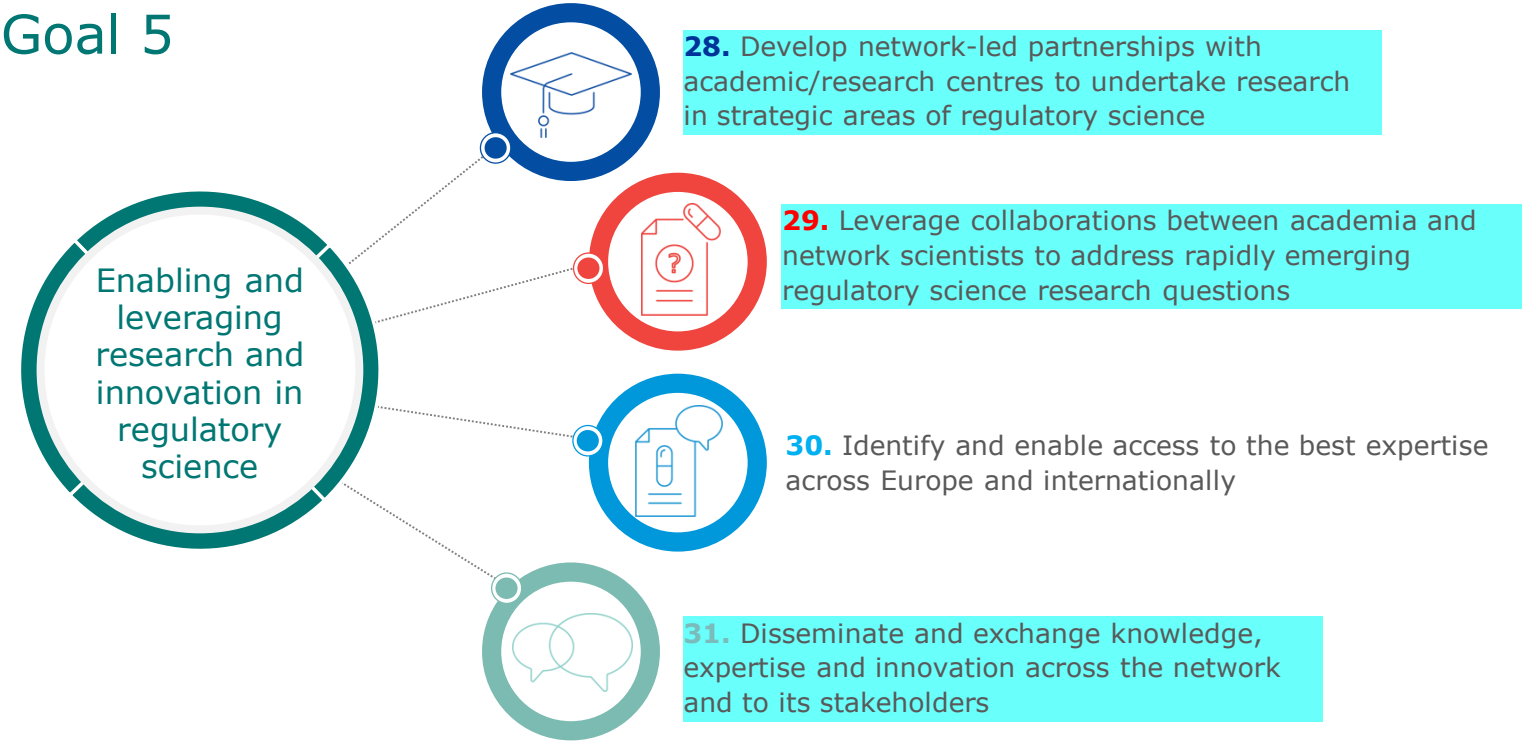
Five goals for human medicines regulation

Goal 4



Five goals for human medicines regulation

Goal 5



28. Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science

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

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

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

EMA organisational changes come into effect

Share

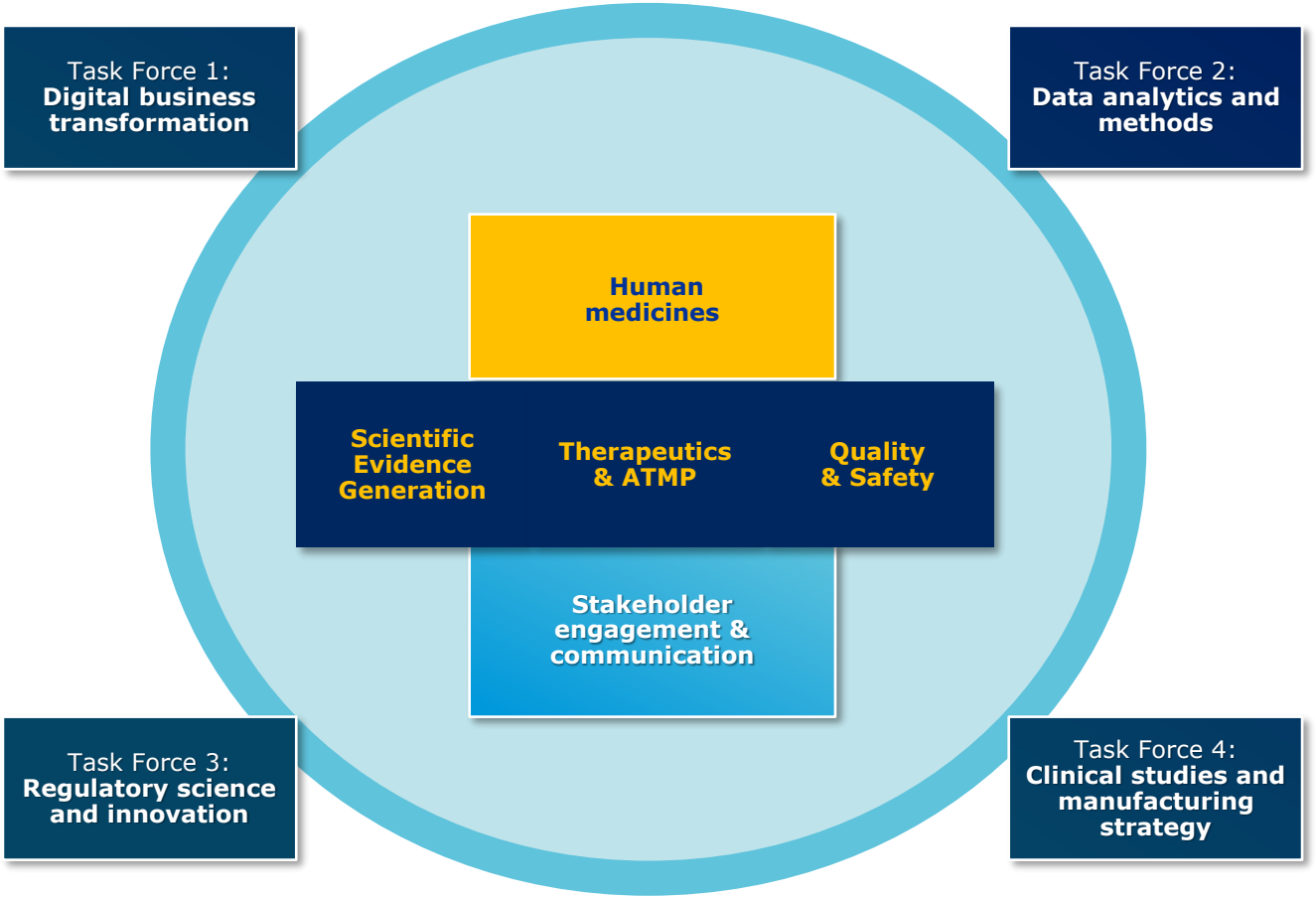
News 02/03/2020

As of today, Monday, 2 March, EMA has implemented changes to its organisational structure.

The purpose of the re-organisation is to ensure that the Agency operates as efficiently as possible to deliver high quality outputs for public and animal health. The exercise takes into account the rapidly evolving landscape for pharmaceutical research and development that requires regulators to keep up with advances in science and technology and prepare for future challenges at an ever-accelerating pace.

Innovation at the heart of a future-proofed organisation

EUROPEAN MEDICINES AGENCY



Innovation at the heart of a future-proofed organisation

EUROPEAN MEDICINES AGENCY

Task Force 1: **Digital business transformation**

- The '**transformation engine**' of the Agency, responsible for driving complex change initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU Network, its partners and stakeholders.

Task Force 2: **Data analytics and methods**

- The '**service provider**' on data analytics and methods, responsible for transforming the Agency into a modern data driven organisation, delivering robust evidence for benefit risk decision-making (evidence by design) and increasing knowledge of product performance.

Task Force 3: **Regulatory science and innovation**

- The '**observatory**' enabling the continuous future-proofing of the regulatory system by addressing key scientific and technological trends and their translation through the development of regulatory science strategy, planning and governance.

Task Force 4: **Clinical studies and manufacturing strategy**

- The '**touchstone**' for clinical studies and manufacturing, responsible for guiding Agency strategy at EU and global level to support the facilitation of clinical studies and manufacturing, that supports a learning regulatory system as both enabler and gatekeeper.

A future-proof regulatory framework

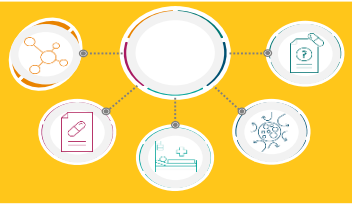
EC Pharma Strategy

1. International dependency and manufacturing
2. Access to affordable medicines
3. Innovation
4. Environmental sustainability and health challenges

EMRN Strategy to 2025

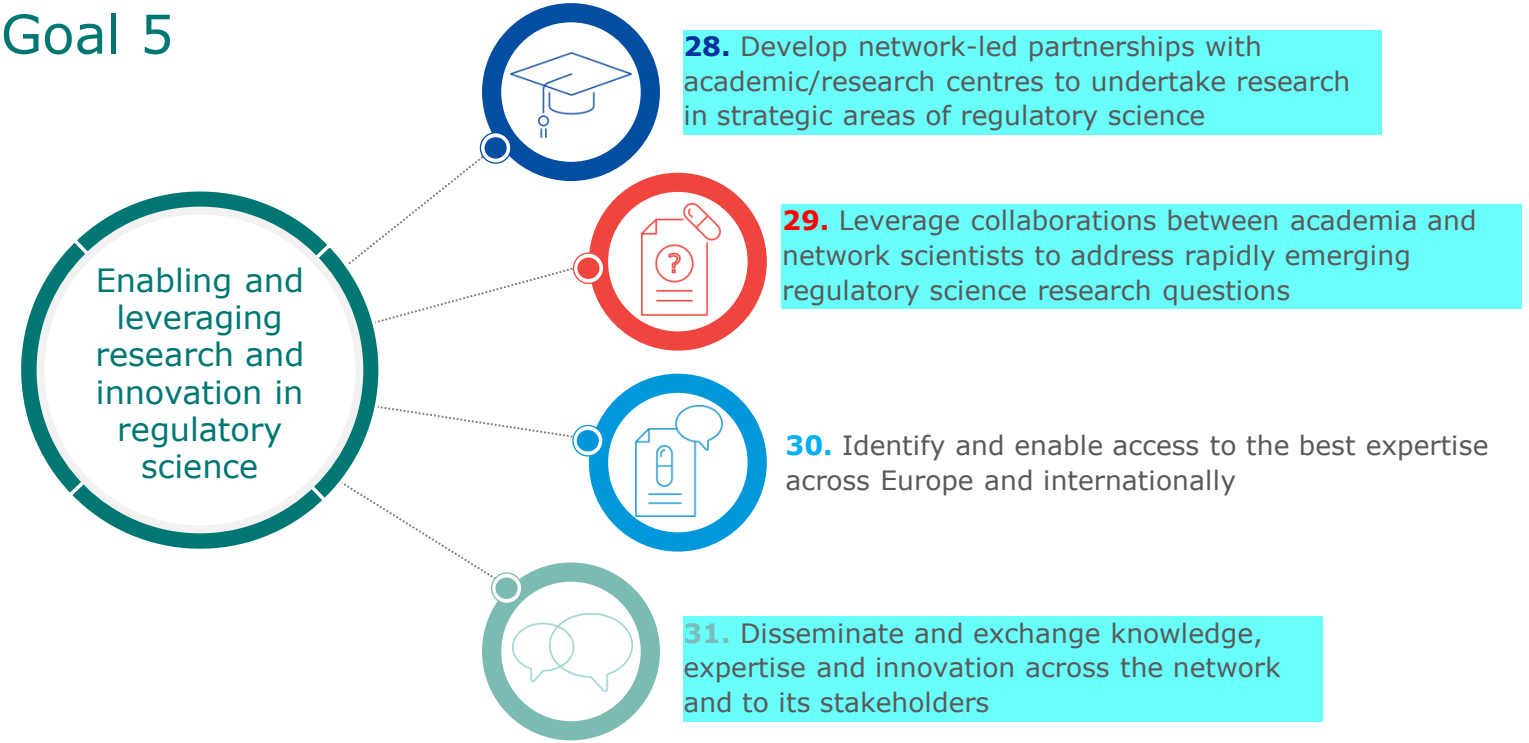
1. Availability and accessibility of medicines
2. Data analytics, digital tools and digital transformation
3. Innovation
4. Antimicrobial resistance and other emerging health threats
5. Supply chain challenges
6. Sustainability of the Network and operational excellence

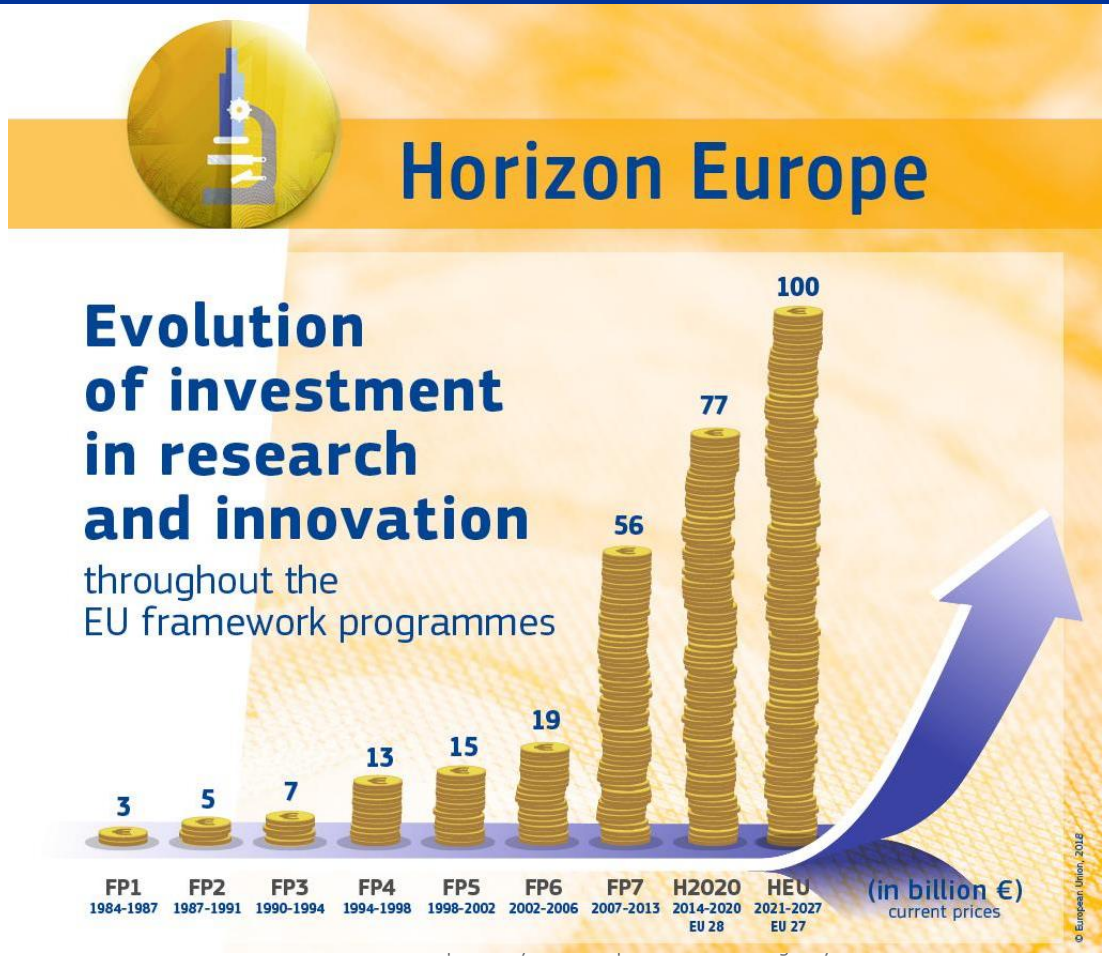
EMA Regulatory Science Strategy to 2025



Five goals for human medicines regulation

Goal 5




Horizon Europe
Evolution of investment in research and innovation
throughout the EU framework programmes
3
5
7
13
15
19
56
77
100
FP1 1984-1987
FP2 1987-1991
FP3 1990-1994
FP4 1994-1998
FP5 1998-2002
FP6 2002-2006
FP7 2007-2013
H2020 2014-2020 EU 28
HEU 2021-2027 EU 27
(in billion €) current prices
© European Union, 2018

HORIZON SCANNING

- Payers
- Nanotech
- New materials

- New antimicrobial alternatives
- Translation of ATMPs
- Vaccine development & PAM

DATA

- Precision medicines, biomarkers, omics
- Digital technology, AI, Decision-making
- RWD/E
- Big data

METHODOLOGY TECHNIQUES

- Novel non-clinical, 3Rs
- Innovation in clinical trials
- Novel manufacturing technologies
- Modelling, simulation & extrapolation
- HTA's preparedness
- Regulatory framework for emerging clinical data generation
- Relevance of evidence generation
- Special populations initiatives

COMMUNICATION

- ePI
- Biosimilars
- External communication
- Expansion of benefit/risk

DATE ^	TOPIC	UPDATE	MORE INFORMATION
21/07/2020	Treatments and vaccines for COVID-19	EMA is applying exceptional transparency measures for treatments and vaccines against COVID-19 that are approved or are under evaluation, to address the high interest in information on COVID-19 medicines and to support global research.	
21/07/2020	Treatments and vaccines for COVID-19	EMA signed a contract with Utrecht University to study the impact of COVID-19 infection and medicines in pregnancy. This project completes EMA's infrastructure to support the real-world monitoring of COVID-19 treatments and vaccines.	COVID-19: EMA sets up infrastructure for real-world monitoring of treatments and vaccines
16/07/2020	Treatments and vaccines for COVID-19	EMA had finalised 9 scientific advice procedures for potential medicines to treat COVID-19, with a further 13 ongoing. It had also been in contact with the developers of 148 potential COVID-19 treatments and 36 potential COVID-19 vaccines.	

Leveraging collaborations between academia and EMA

Collaborating Expert

The Collaborating Expert Programme is addressed to scientists and professionals who can share their expertise in a particular area of European Medicines Agency's activities or are interested in collaborative research projects related to EMA's scientific work.

The aim is to provide a mechanism for EMA and external researchers to collaborate in identifying and tackling important research questions to support regulatory decision-making.

This will help ensure that regulatory science remains at the cutting edge so that EMA can deliver its fundamental mission of protecting human and animal health and facilitating the availability of medicines to patients.

To this end, we are piloting a new programme of expert collaborations across the areas of EMA's work. These experts will be salaried by their home institution but hosted by the EMA, either in person, or remotely.

You may review the programme and identify which profile you are most interested in here.

You can find further information about the programme in the menu below.

Working together: international regulatory science cooperation

- EMA will therefore pursue a continued deepening of international cooperation with a focus on horizon scanning and science-based innovation.
- Nearly all the topics considered in this strategy are relevant to other regulators, who share these challenges, and exchanging views on how to tackle them and to adapt is mutually beneficial.
- This should be pursued through all of the channels currently opened between regulators ranging from high level fora such as ICH, ICMRA, ICDRA as well as more specialist focus channels such as the range of cluster meetings with which the Agency is involved.

Any questions?

Further information

Anthony.Humphreys@ema.europa.eu

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
For deliveries refer to www.ema.europa.eu/how-to-find-us
Send us a question via www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on
@EMA_News