



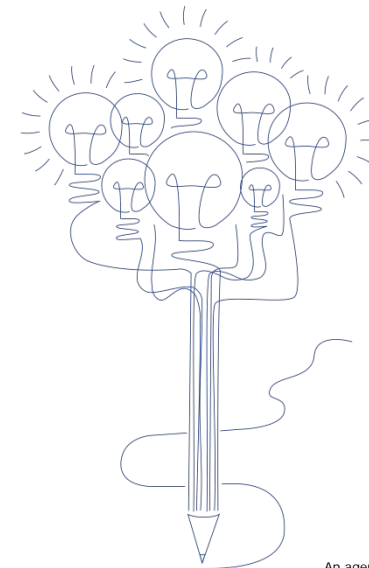
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enabling and leveraging research and innovation in regulatory science

EMA's core recommendations

Human Stakeholders Workshop

Presented by Alison Cave on 24 October 2018
Principal Scientific Administrator in the Surveillance & Epidemiology Service



An agency of the European Union

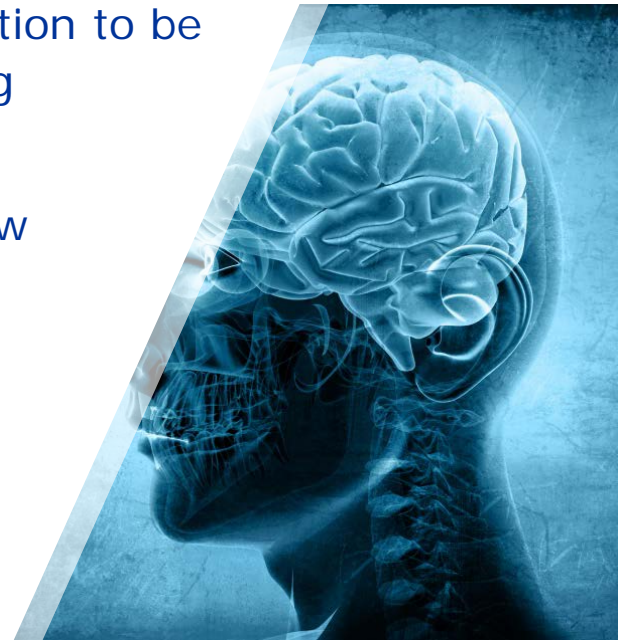




Enabling and leveraging research and innovation in regulatory science

To catalyse and enable regulatory science and innovation to be translated into patient access to medicines in evolving healthcare systems, we must:

- apply cutting-edge regulatory science to the review and approval process
- be continuously informed of scientific innovation relevant to regulatory decision-making, and
- capitalise on EMA's framework for collaboration with academia to articulate regulatory needs and challenges





Core recommendations



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 share knowledge, expertise and innovation across the regulatory network and to its stakeholders



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



Identify, in consultation with academia and relevant stakeholders, fundamental research topics in strategic areas of regulatory science



Proactively engage with DG Research & Innovation, DG-SANTE, IMI and MS funding agencies to propose and issue calls to establish research collaborations

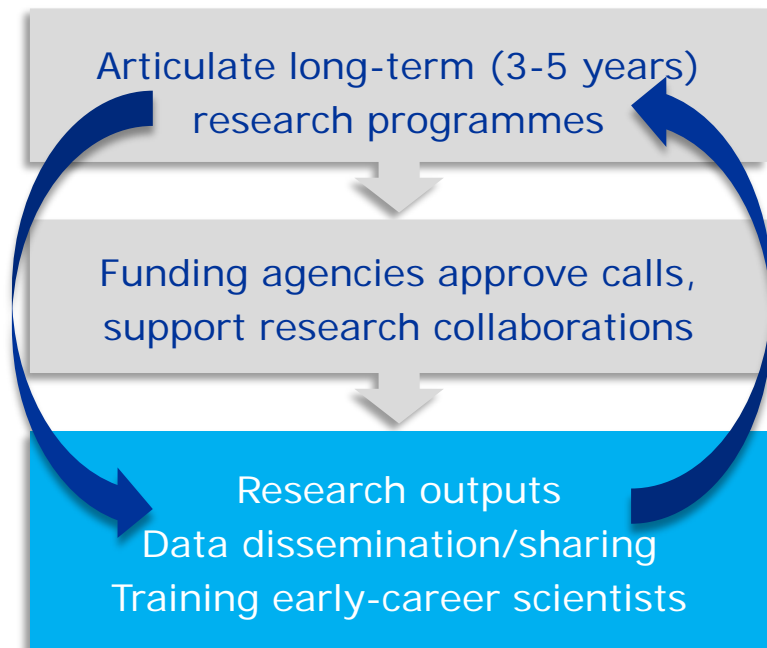


Research areas include: PROs, omics-based diagnostics, drug-device combinations, modelling and simulation, Big Data, and AI.





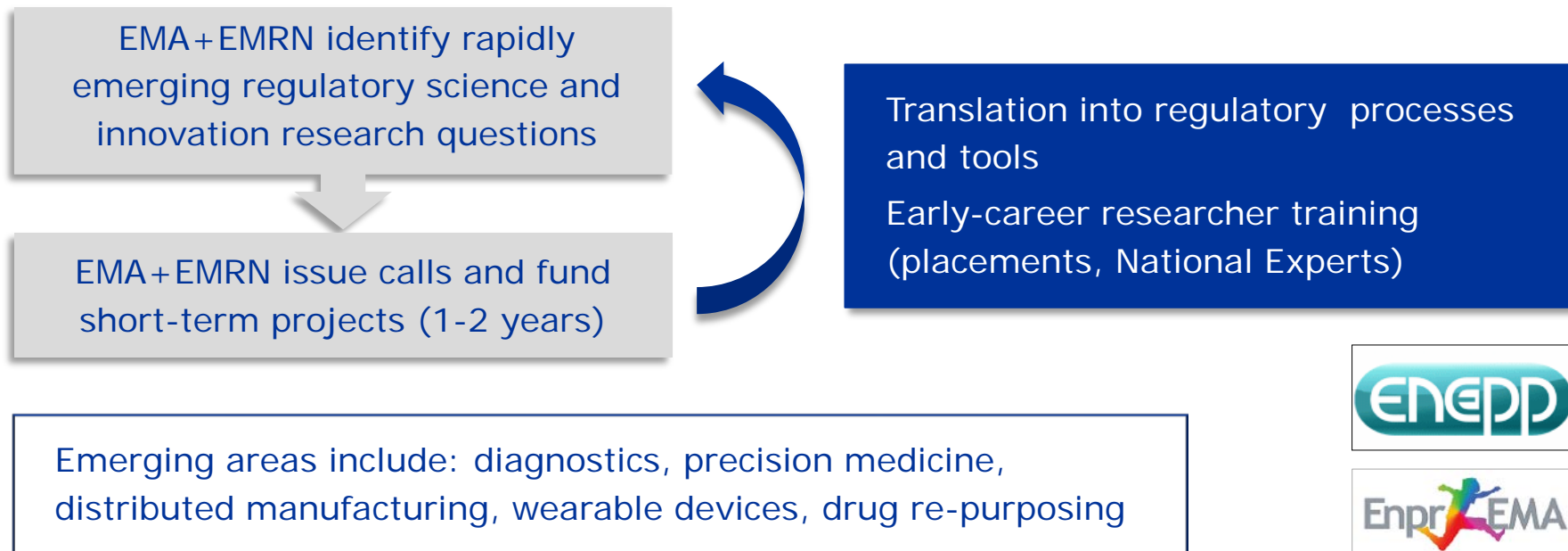
Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science



An iterative and interactive engagement between regulators, funders and academia



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



Invest in a knowledge management system to track innovation, share information, enable linkages and create new insights across the product lifecycle



Facilitate more flexible access to expertise in regulatory science and increasingly specialised areas of innovation





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



Engage with academia to develop regulatory training modules, including describing innovation of new medicines and their progression from laboratory to patient



Conduct horizon scanning in key areas of innovation via collaborations between academia and the EU-Innovation Network and ICMRA



Drive a data-sharing culture to foster open science which is mutually beneficial for all stakeholders





European
Commission

Stéphane Hogan,
European
Commission



Serena Scollen,
ELIXIR



Utrecht University



Olaf Klungel,
University of Utrecht



European
Reference
Network

Luca Sangiorgi, ERN
Research Working
Group



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Wiebke Löbker,
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