



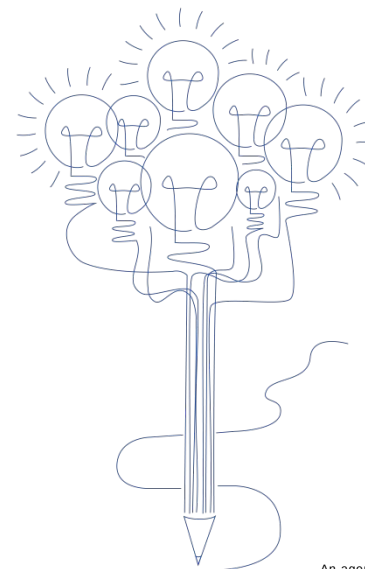
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enabling and leveraging research and innovation in regulatory science

EMA's core recommendations

Veterinary Stakeholders Workshop

Presented by Tony Humphreys on 6 December 2018
Head of Scientific Committees Regulatory Science Strategy Division, EMA



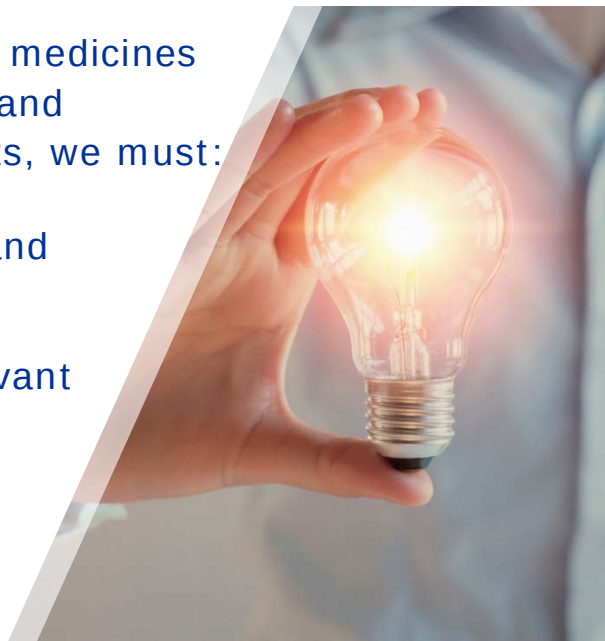
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Enabling and leveraging research and innovation in regulatory science

To foster scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health while facilitating and promoting innovation and access to novel medicinal products, 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 exchange knowledge, expertise and innovation across the 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 and MS funding agencies to propose and issue calls to establish research collaborations



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





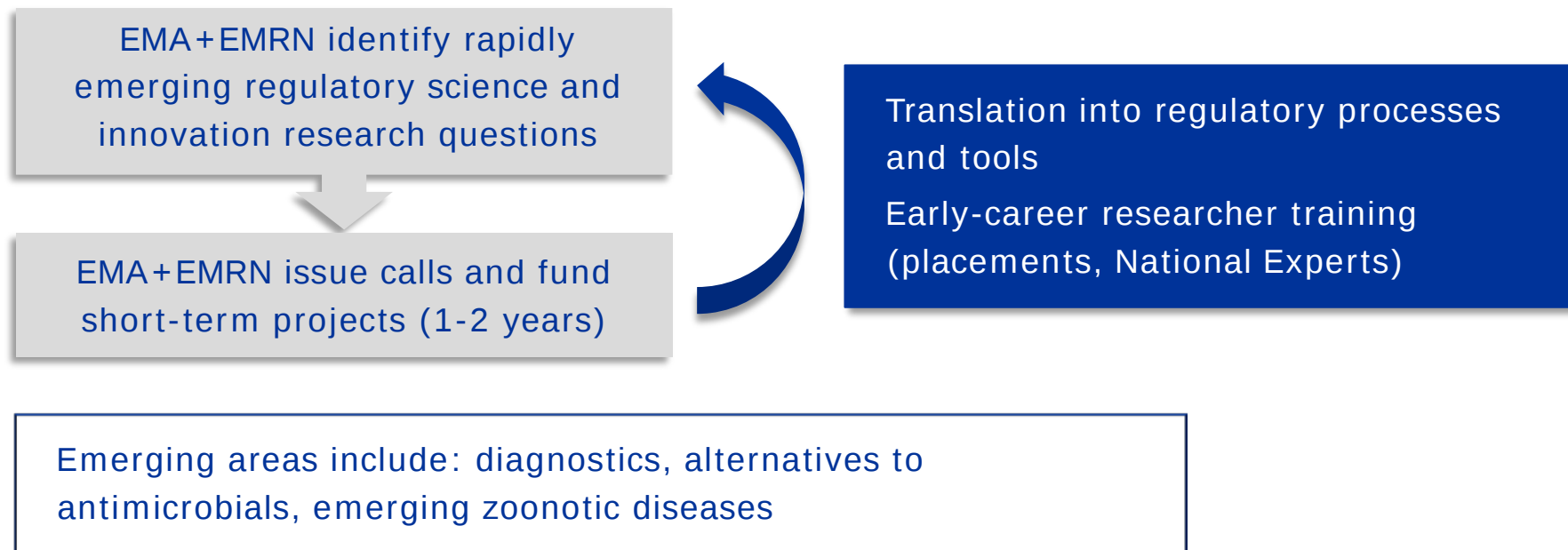
Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science



An interactive and iterative 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 exchange 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



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





European
Commission

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