



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory Science and Research in Veterinary Medicines – an overview of activities

Breakout session 4.2: Collaboration with academia

EMA Veterinary awareness day

Presented by Ana Vidal on 13th September 2023
Veterinary Strategy and Support Office

An agency of the European Union





Outline

- EMA RSS to 2025 – Veterinary Goals
- Veterinary Regulatory Science Research Needs
- Engaging with externally-funded regulatory science
- EMA procurement mechanisms to support research
- Summary



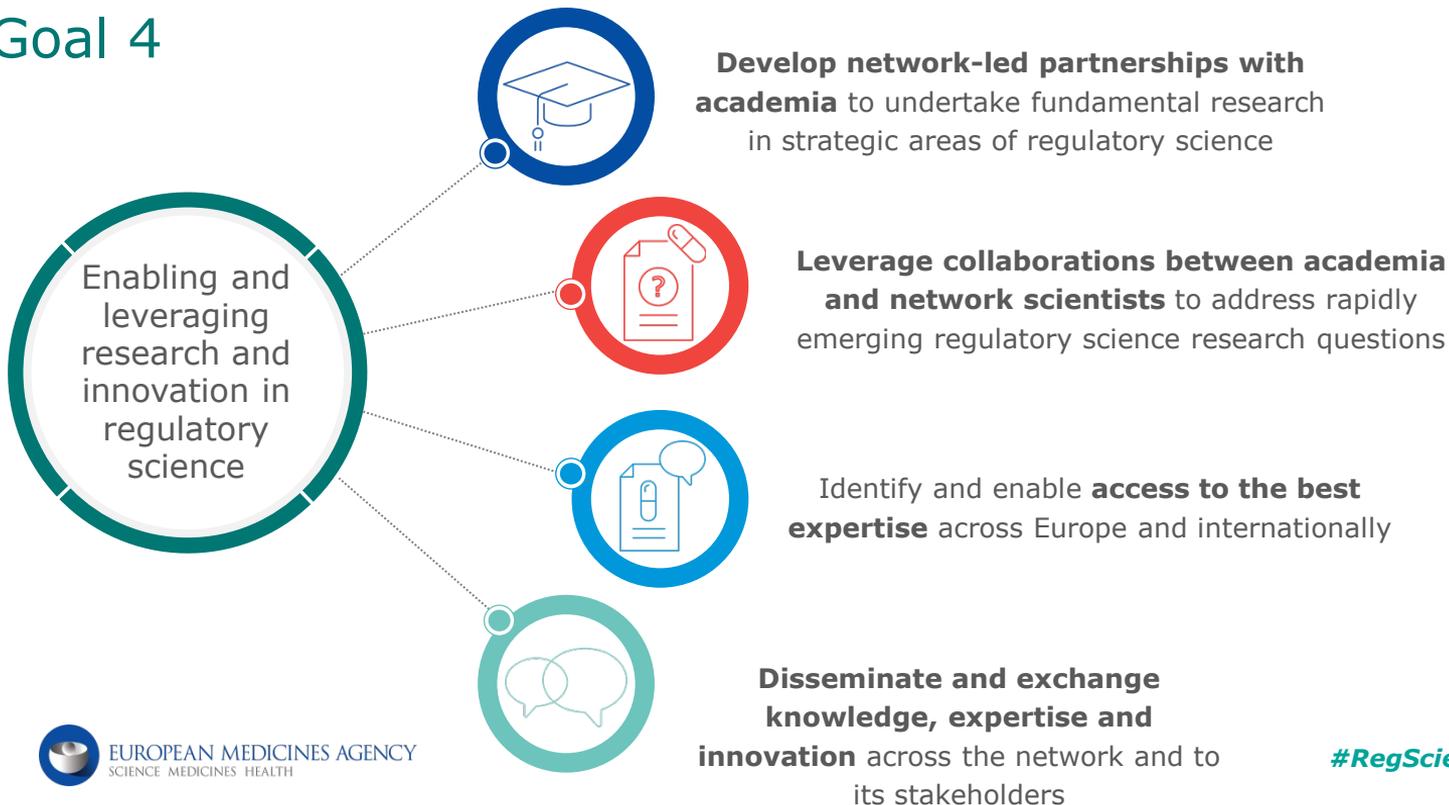
Regulatory science & research in Veterinary medicines

"Regulatory science is defined as the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the lifecycle of a medicine. It encompasses basic and applied biomedical and social sciences and contributes to the development of regulatory standards and tools"

"Successful implementation of regulatory science, including engagement with diverse stakeholders, will allow the Agency to fulfill its mission today while being prepared for the new challenges of tomorrow"



Goal 4

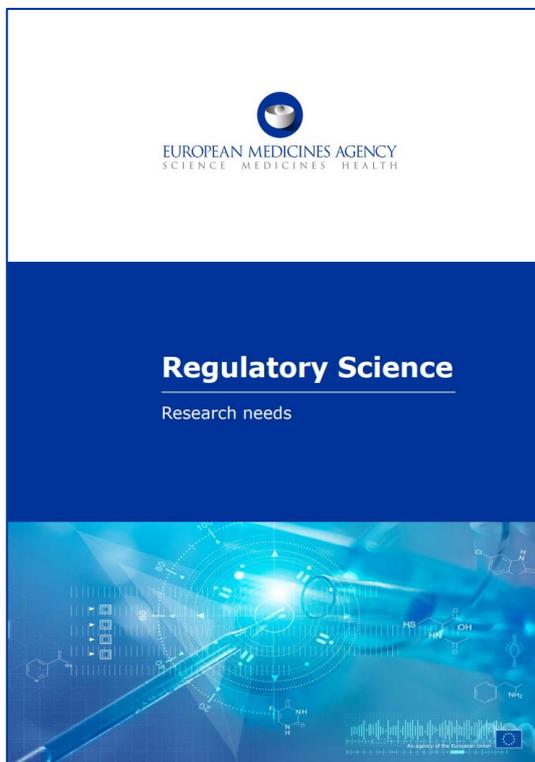




Veterinary Regulatory Science Research Needs



Veterinary Regulatory Science Research Needs



Emerged from stakeholder consultation that underpinned the RSS to 2025

Organised according to core recommendations (RSS)

Specified with topic details, objectives and anticipated impact

Inspired by what some NCAs have already implemented

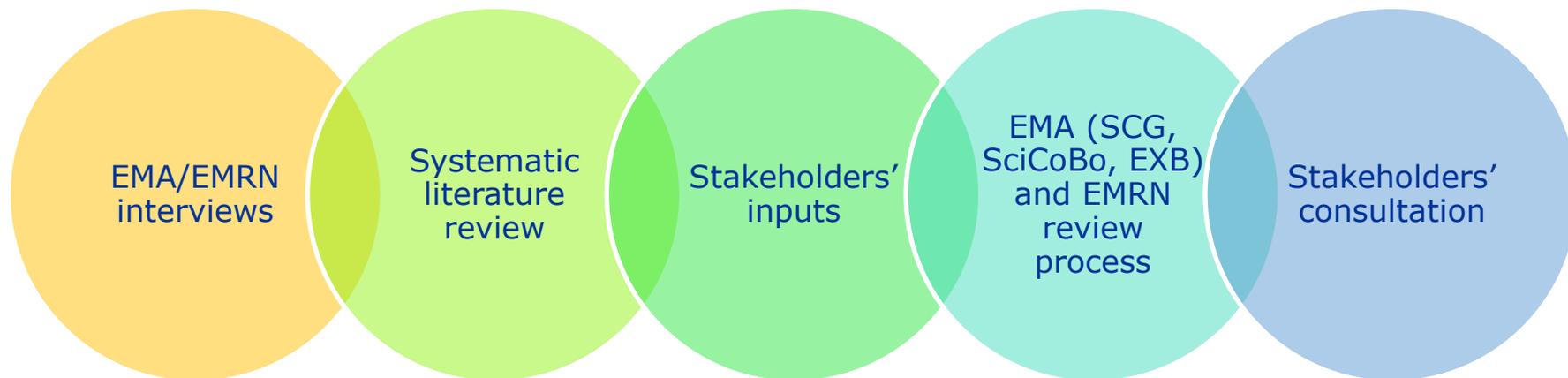
More than 100 research questions: Human (80+) and veterinary (40+)

[Regulatory science research needs list - version 1.0 \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/image/asset-detail/Regulatory-science-research-needs-list-version-1.0)



Veterinary Regulatory Science Research Needs

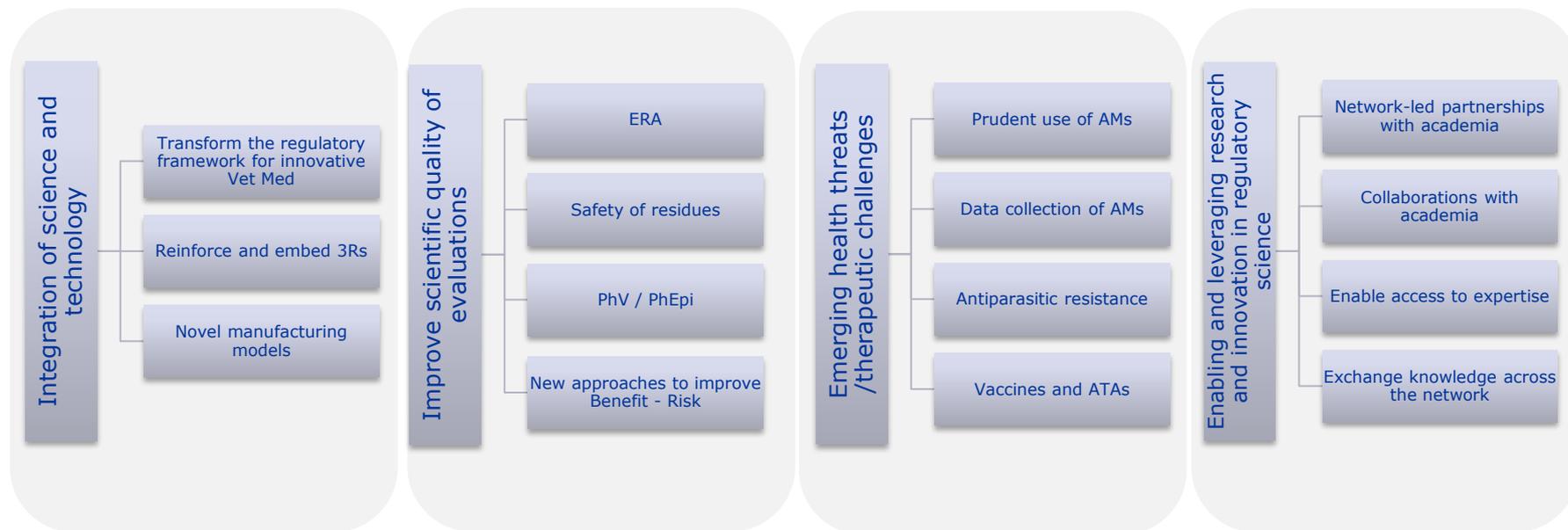
How was the list created?





Veterinary Regulatory Science Research Needs

What are the needs?

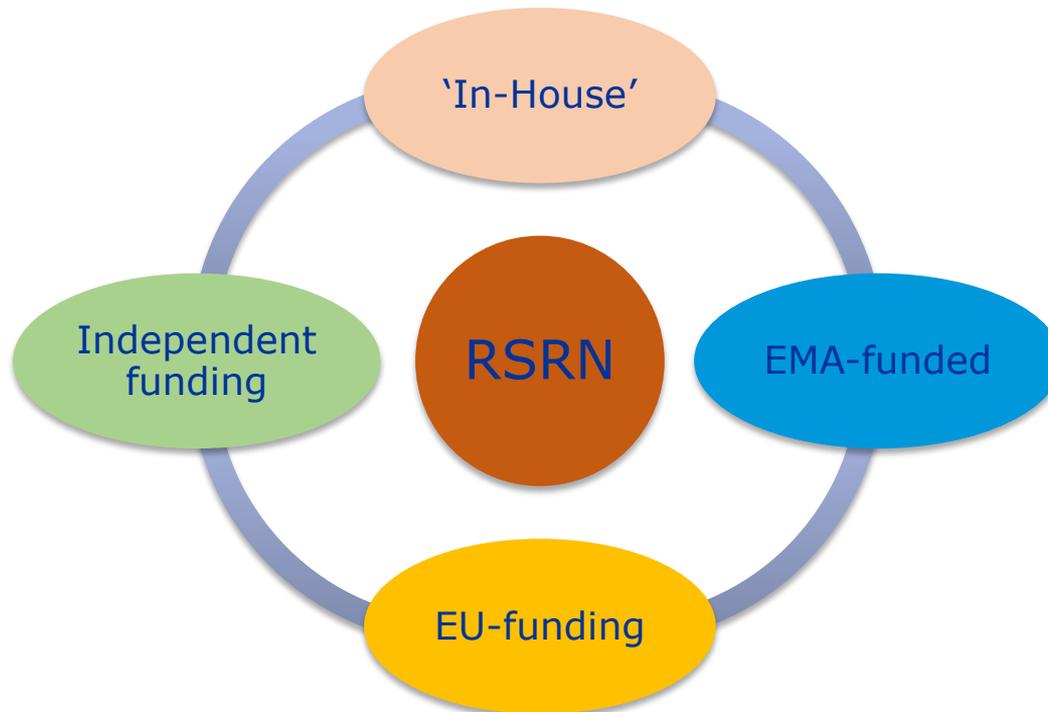


[Regulatory science research needs list - version 1.0 \(europa.eu\)](https://europea.eu)



Veterinary Regulatory Science Research Needs

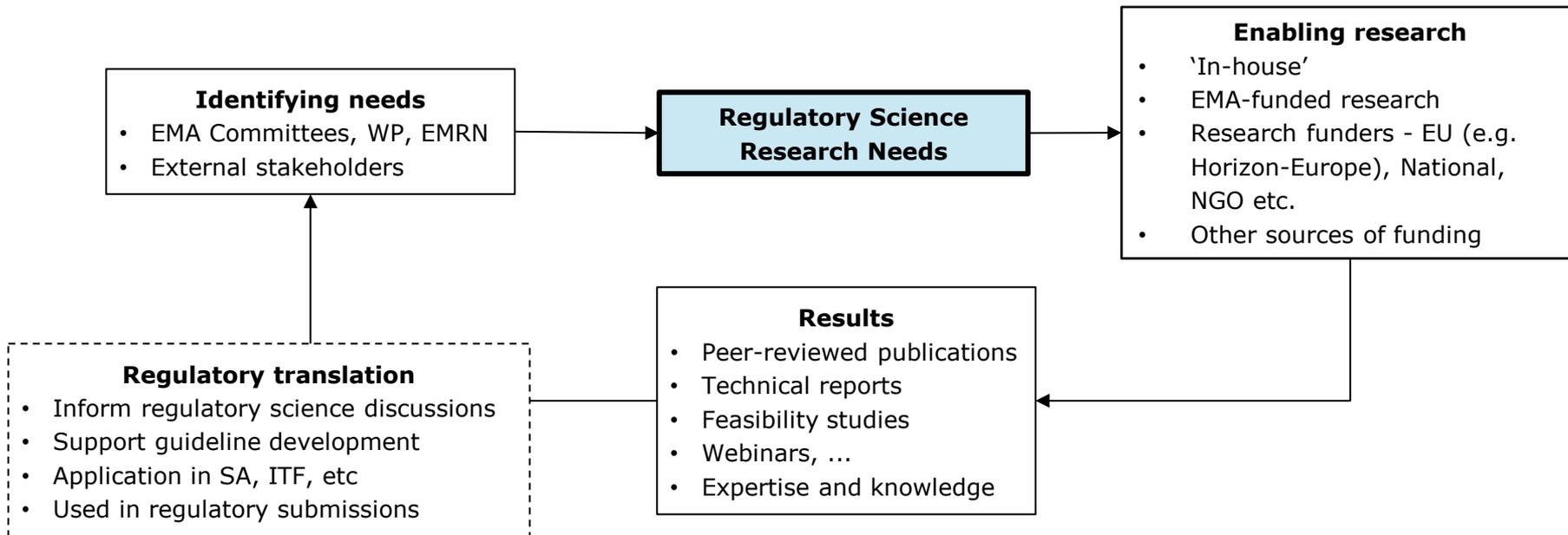
What are the enabling mechanisms?





Veterinary regulatory science research needs

A life cycle





Engaging with externally-funded regulatory science



Engaging with externally-funded regulatory science – Why?

- To **increase understanding of EMA's public health role** among academic stakeholders
- To ensure that EMA can have **access to the expertise of its academic partners** to inform its decision-making
- To **collaborate on advancing the field of regulatory science** by fostering the development methodologies and tool.
- To **facilitate the translation of academic research into novel methodologies and products** which meet EMA's standards and address public and animal health needs



Engaging with externally-funded regulatory science

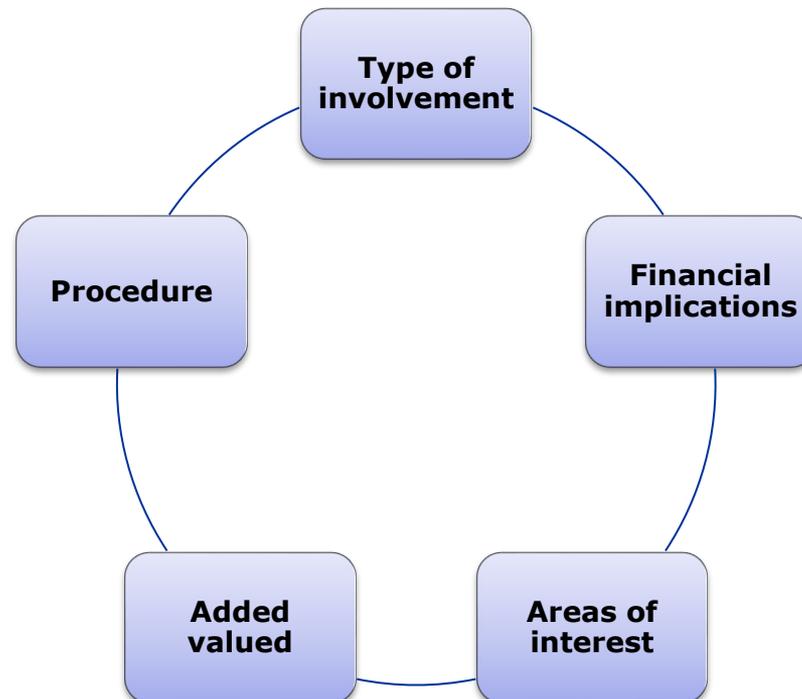
05/03/2019
EMA/130095/2019
Human Medicines Research and Development Support

European Medicines Agency process for engaging in externally funded regulatory sciences and process improvement research activities for public and animal health

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[Criteria and process for engaging in externally funded regulatory science projects for public and animal health \(for publication\) \(europa.eu\)](#)



Engaging with externally-funded regulatory science

Why is this important?

EMA's contributions	EMA's interest
<ul style="list-style-type: none">• Guidance on use of EMA support tools• Regulatory knowledge and guidelines• Regulatory data• Experience from previous involvement in other regulatory science projects• Active contribution to work packages• Insights into regulatory thinking• Recommendations derived from consultations with other regulators	<ul style="list-style-type: none">• Awareness of innovative research• Learnings from dialogue with researchers• Identification of gaps in regulatory science• New or improved methodologies or standards• Dissemination of results and visibility (publications, conference presentations)• Research networks and access to expertise• Outputs tailored to regulators' demands and patients' needs

Saesen-R et al. Frontiers in Medicine 2023 <https://doi.org/10.3389/fmed.2023.1181702>

Engaging with externally-funded regulatory science

- Since January 2022, more than 30 Horizon Europe applicants sought EMA involvement, including by consortia applying for Horizon Europe funding (“pre-grant” situation)
- Ongoing work to inform EU-level and other funders about EMA priorities
 - Agencies are part of the knowledge cycle
- EMA involved in consortia or partnerships (beneficiary, advisory, or associated)
- Translation of outputs from regulatory science research is discussed at EU and international level



EMA-funded research



EMA-funded research



Lot 1: Pre-clinical research



Lot 2: Veterinary studies



Lot 3: Statistical research



Lot 4: Qualitative research



Lot 5: Pharmacoepidemiological research



Lot 6: Quality of medicines

EMA-funded research projects – an example



Lot 2: Veterinary studies

What

1. Studies on the use, efficacy and safety of vet medicines
2. Observational studies
3. Descriptive studies
4. Using of existing data sources
5. Impact research
6.

Who

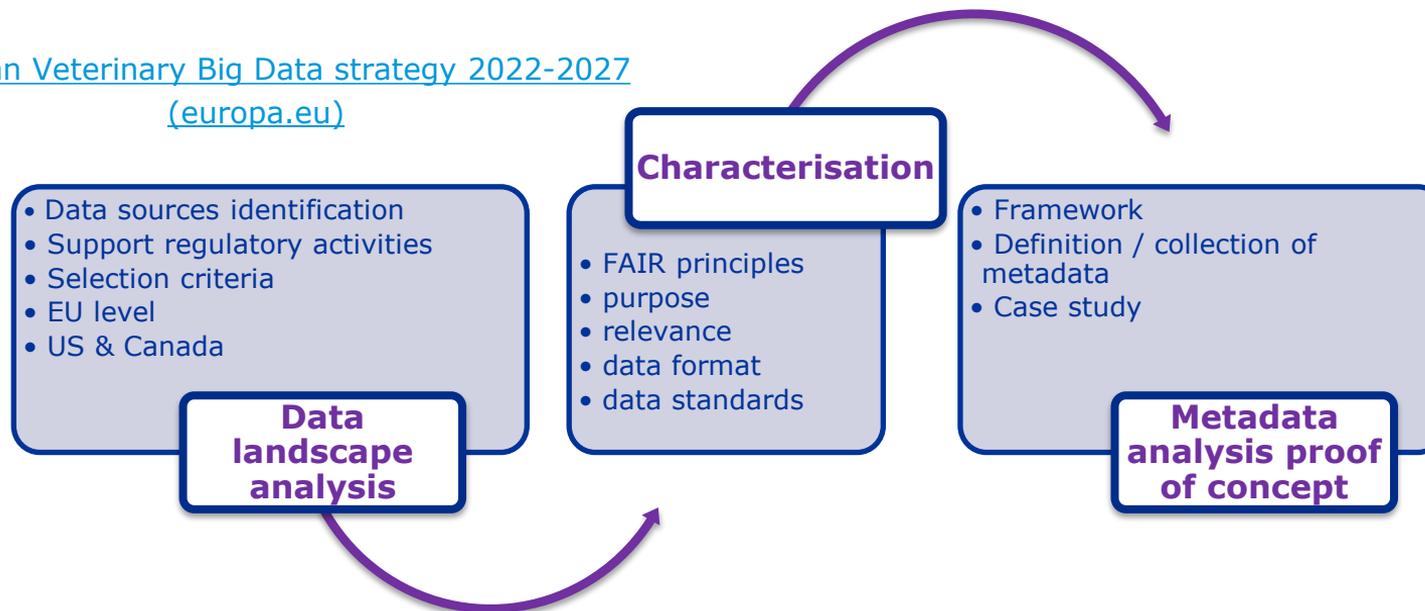
1. **Royal GD** BV (Gezondheidsdienst voor Dieren BV)
2. **PKPDM consortium** (Utrecht University - Faculty of Veterinary Medicine & Ecole Nationale Vétérinaire de Toulouse)
3. Stichting **Wageningen Research** (WR)

[Services - 575628-2021 - TED Tenders Electronic Daily \(europa.eu\)](#)

EMA-funded research projects – an example

Big Data in Veterinary Medicines Regulation: a data landscape analysis

[European Veterinary Big Data strategy 2022-2027](#)
([europa.eu](#))



By [Stichting Wageningen Research \(WR\)](#)



Summary

- Engagement with research activities is central to the work of the Agency
- Regulatory Science is one of the guidance principles of the Agency's mandate
- Defined in the EMNS, EMA RSS and in the Agency's work programme
- Importance and relevance of identifying regulatory research needs
- Collaboration and engagement with research partners (researchers, funders, etc) are essential to advance regulatory science



Acknowledgements

- Tony Humphreys, EMA Regulatory Science and Innovation Task Force
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Any questions?

Further information

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