Proposal for an European Veterinary Big Data Strategy

From data collection to data connection

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Drivers

The implementation of the Veterinary Regulation (VMP-Reg) is a catalyst for the EU Regulatory Network to:

- Embrace a data culture
- Join Veterinary regulatory requirements with the use of novel data-technology
- Be the pioneer of the digital transformation across the EU Medicines Regulatory Network

Vision is to establish a strategy to evolve from a data collection to data connection

Goal and objectives

Goal of the EU Vet Big Data Strategy: (…) to "*increase interoperability across regulatory systems, that shall be operated by an optimized set of scientific resources to reduce administrative and economic burden and enhance consistency, transparency and responsiveness.*"

Objectives:

- Implement sustainable processes and systems
- Integrate systems powering re-usability of the data across different domain and processes
- Deliver accurate, ethical and reliable information to promote public and animal health

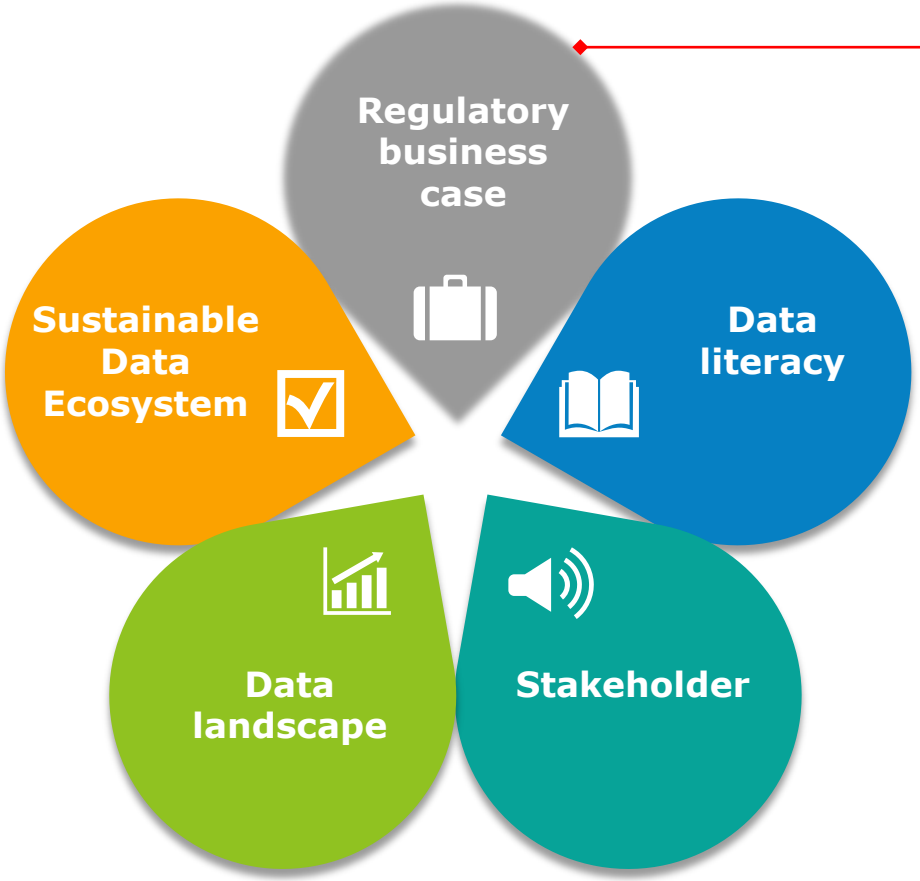
Scope

The Veterinary Big Data Strategy aims at defining:

- **Data framework** for the implementation of advanced digital solution in key regulatory areas to support regulatory activity and promote public and animal health in a more sustainable and efficient way
- **Strategic direction** focusing on the development of a data culture to address and anticipate data analytics needs which may arise in future
- **Implementation strategy approach** targeted at realising regulatory benefits in a short, medium and long term phase

Framework

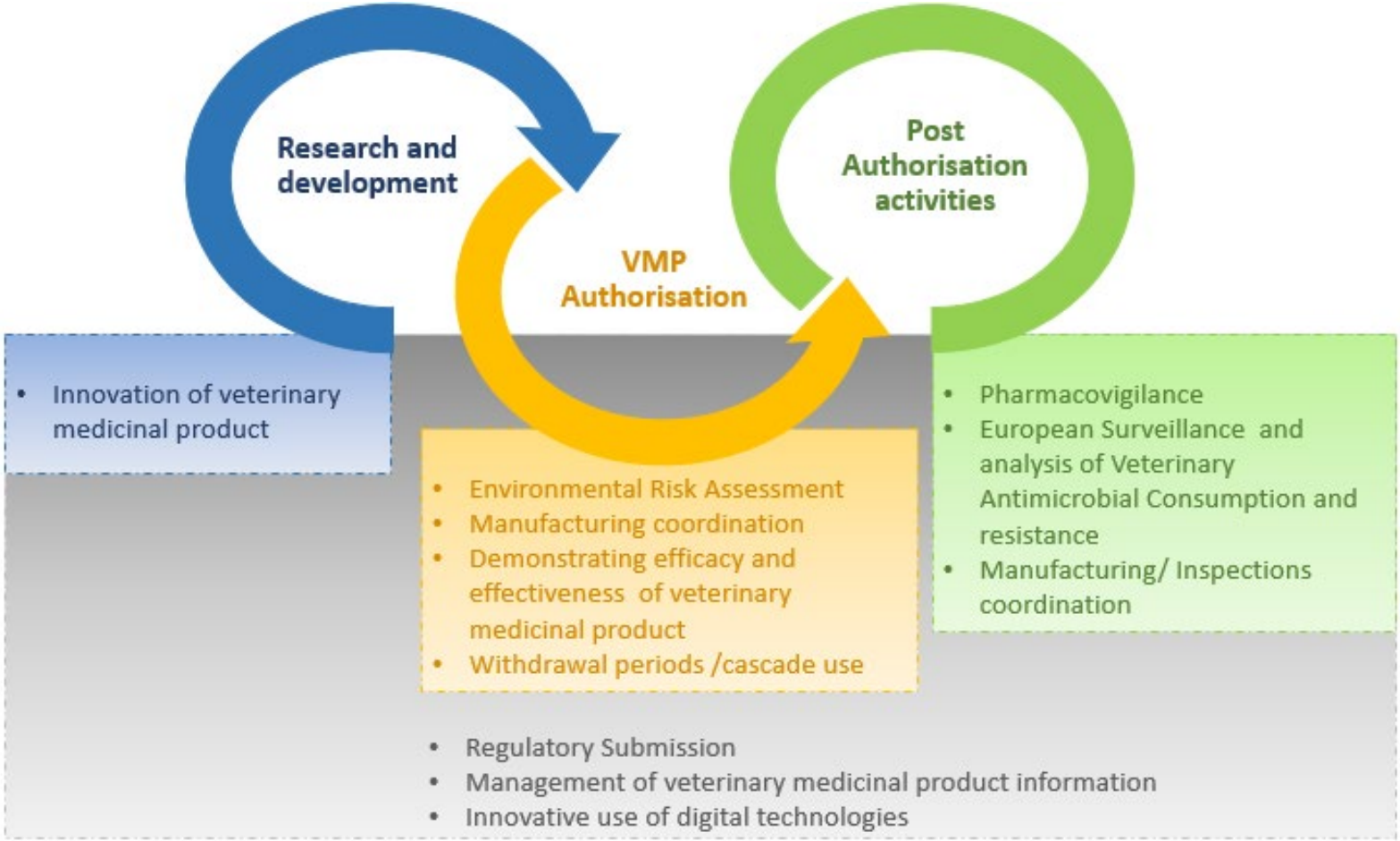
Regulatory business case



Regulatory areas:

- Veterinary medicines information management
- Pharmacovigilance
- Antimicrobial Resistance
- Environmental Risk assessment
- Determination of withdrawal periods /cascade use
- Demonstrating efficacy/ effectiveness of VMPs
- Coordination of manufacturing/ inspections
- Regulatory Submission framework
- Innovation of VMP development and Innovative use of digital technologies

Regulatory business case across product lifecycle

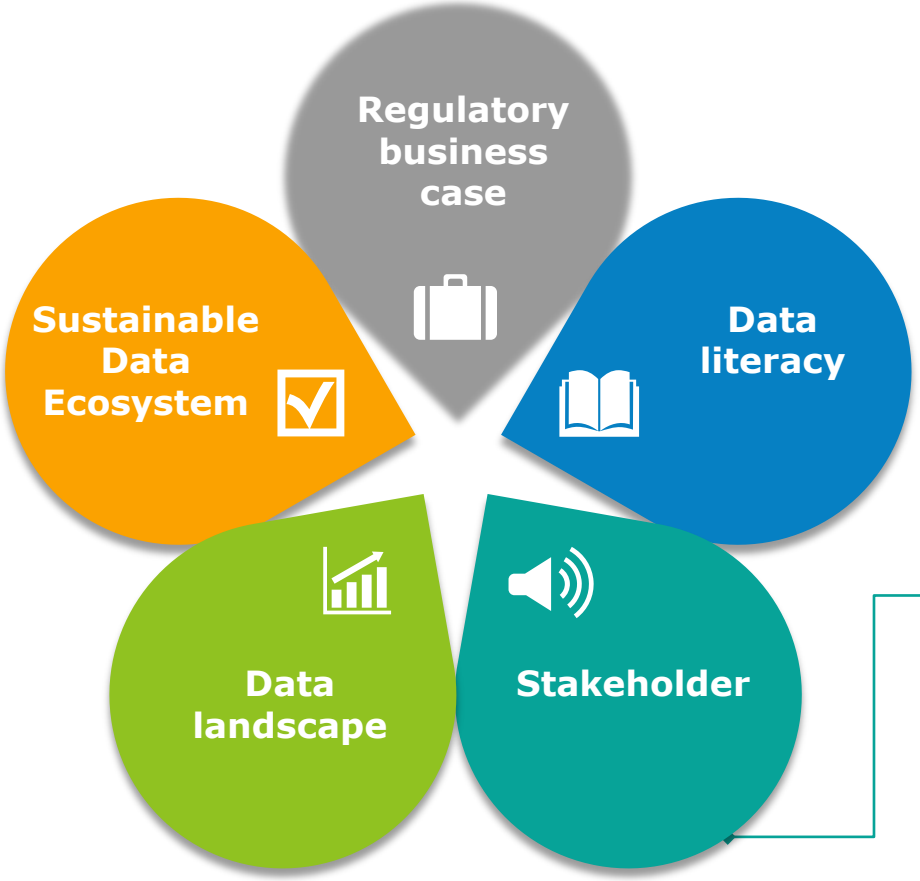


Data literacy

EU Veterinary Data Hub:

- To establish data culture across EU network
- To connect experts with a cross-sectional ambition (e.g. quality, safety, immunological)
- To identify and answer research questions and data analysis request for regulatory purpose

Stakeholders



Stakeholders:

- EU regulators including EU Agencies and institutions
- Other Regulators (e.g. FDA, Health Canada)
- Industry
- Vet practitioners
- Farm and companion animal health system providers
- Academia

Data ecosystem

Ecosystem:

- Sustainable in managing increasing data sources
- Encompassing use of innovative solutions (machine learning, artificial intelligence, Natural Language Processing)
- connecting and retrieving evidences from a complex variety of data to support regulatory decision making in a reliable, auditable and legal way.

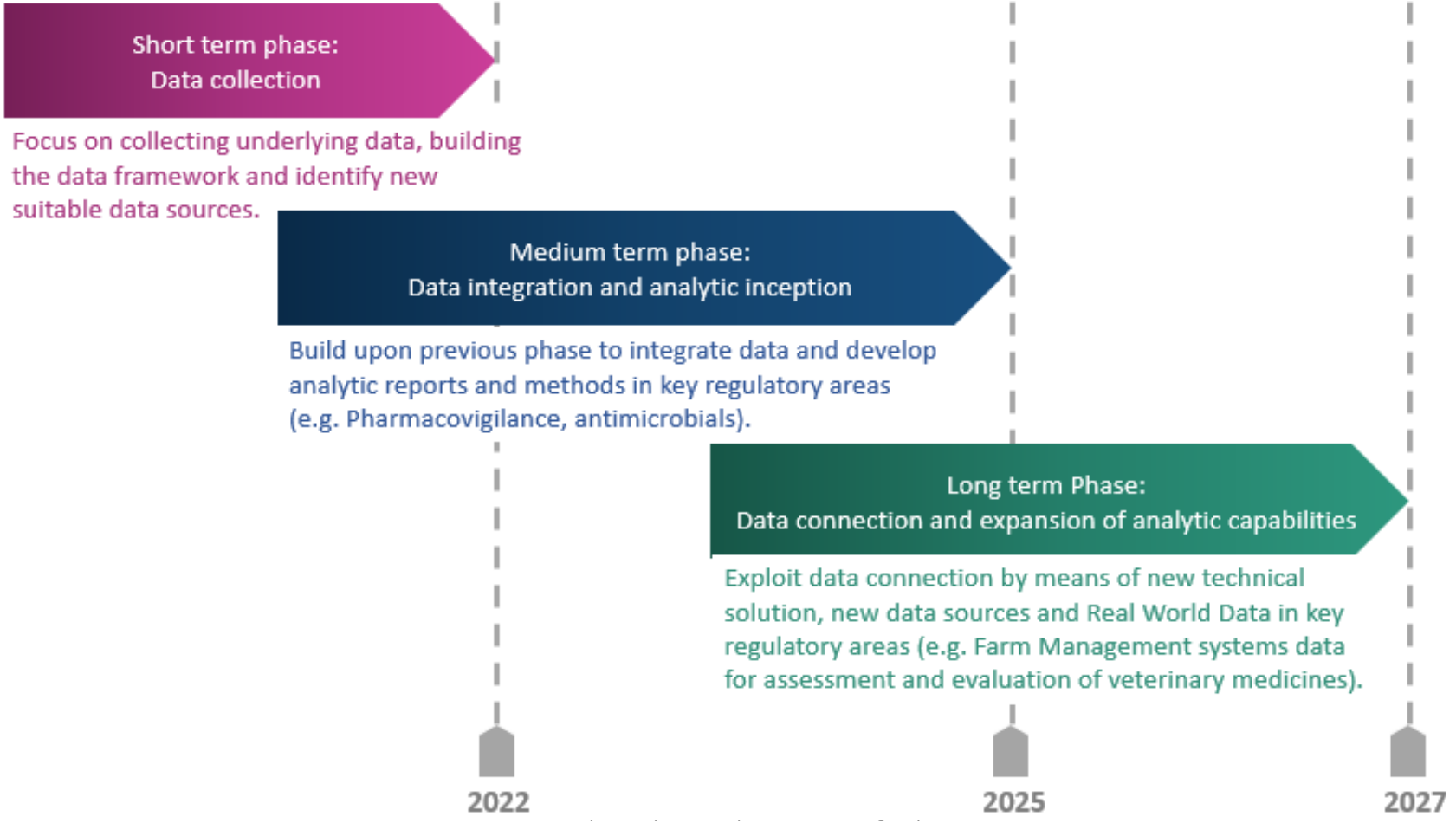
Data Landscape

Data Landscape:

- Caracterising new data sources and data nature (public Vs. commercially confidential)
- Define data standards
- Identify data quality and metadata
- to develop and improve advance analytical methods, modelling & simulation to address regulatory questions
- To define data access and governance

Implementation Strategy

Implementation Strategy: proposed phased approach



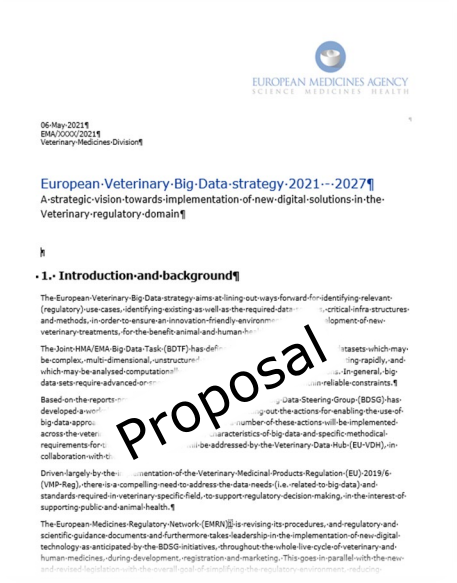
HMA Vision - an NCAs view

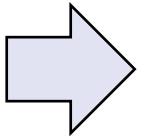
Current situation

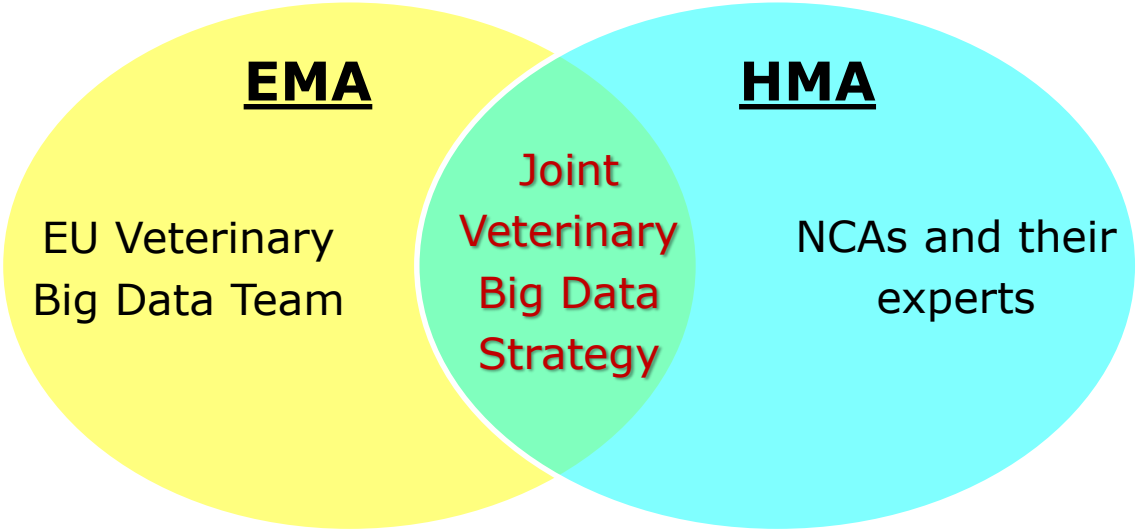
- Focus on New Vet Regulation EU 2019/06
- Applicability of Big Data/ New Technologies/ Advanced Analytics
  - Implementation of Union Product Database (UPD) and Database EudraVigilance Veterinary (EV-Vet)
  - Antimicrobial consumption and resistance development (ESVAC)
  - Pharmacovigilance and signal detection

only a Pan-European strategy allows a coordinated approach

Joint efforts necessary







Exploring synergies

EMA

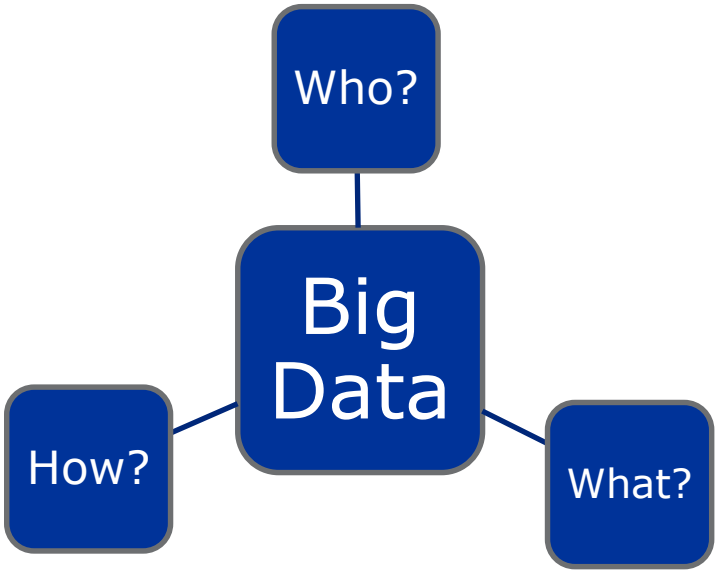
- transparent and clear strategic goals
- transparent timeframe including milestones
- open communication
- coordinate/ organize training options for national experts
- provide digital/ IT solutions

HMA/ NCAs

- adjust the network to accommodate new tasks related to Big Data
- support cooperations
- provide resources
- adjust internal organizational structures
- further develop IT infrastructure
- create jobs/ align employment decisions
- develop skills of experts

Open questions

- Data ownership
- Data access modalities
- Responsibility for data processing
- Provision of technical/IT solutions
- Reimbursement
- Responsibility for training and education



Pillars of a successful Veterinary Big Data Strategy

Any questions?

Further information

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