

Proposal for an European Veterinary Big Data Strategy

From data collection to data connection

Presented by

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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

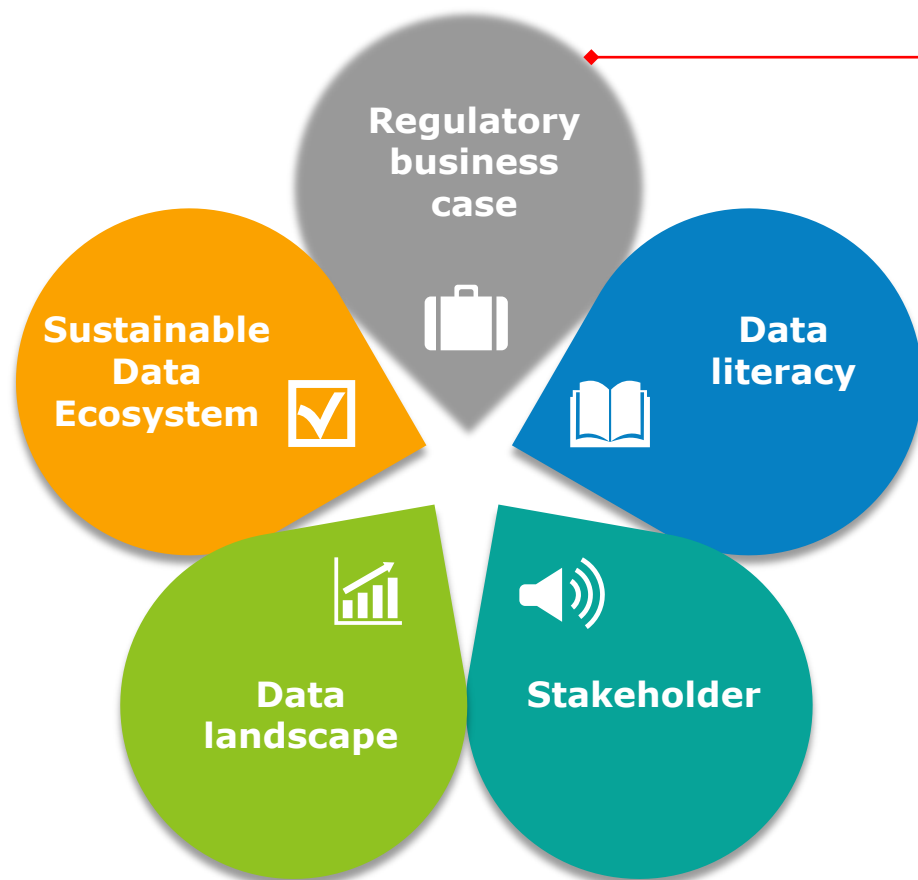
Scope

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

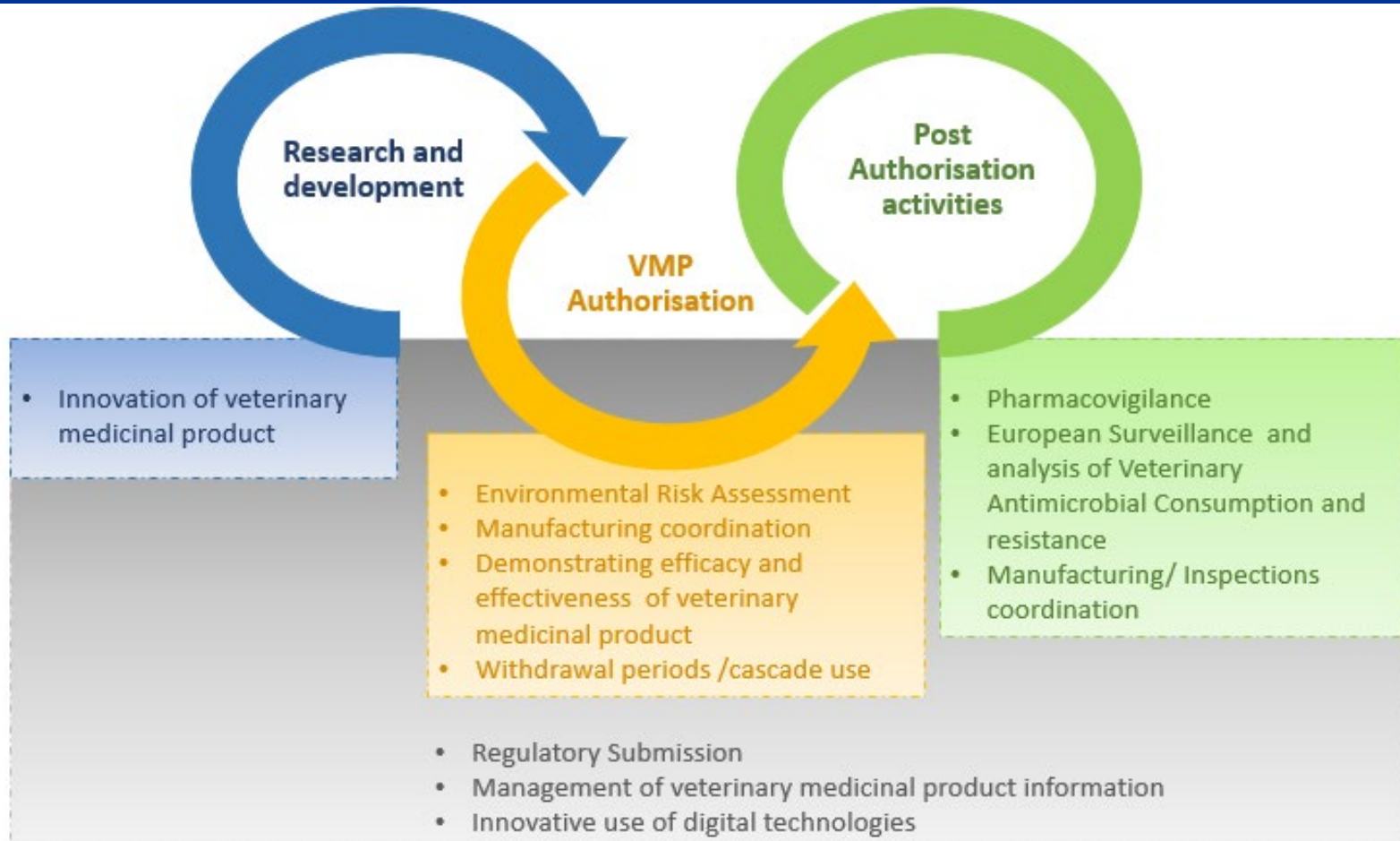
Framework





Regulatory 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



Sustainable
Data
Ecosystem



Data
literacy



Data
landscape

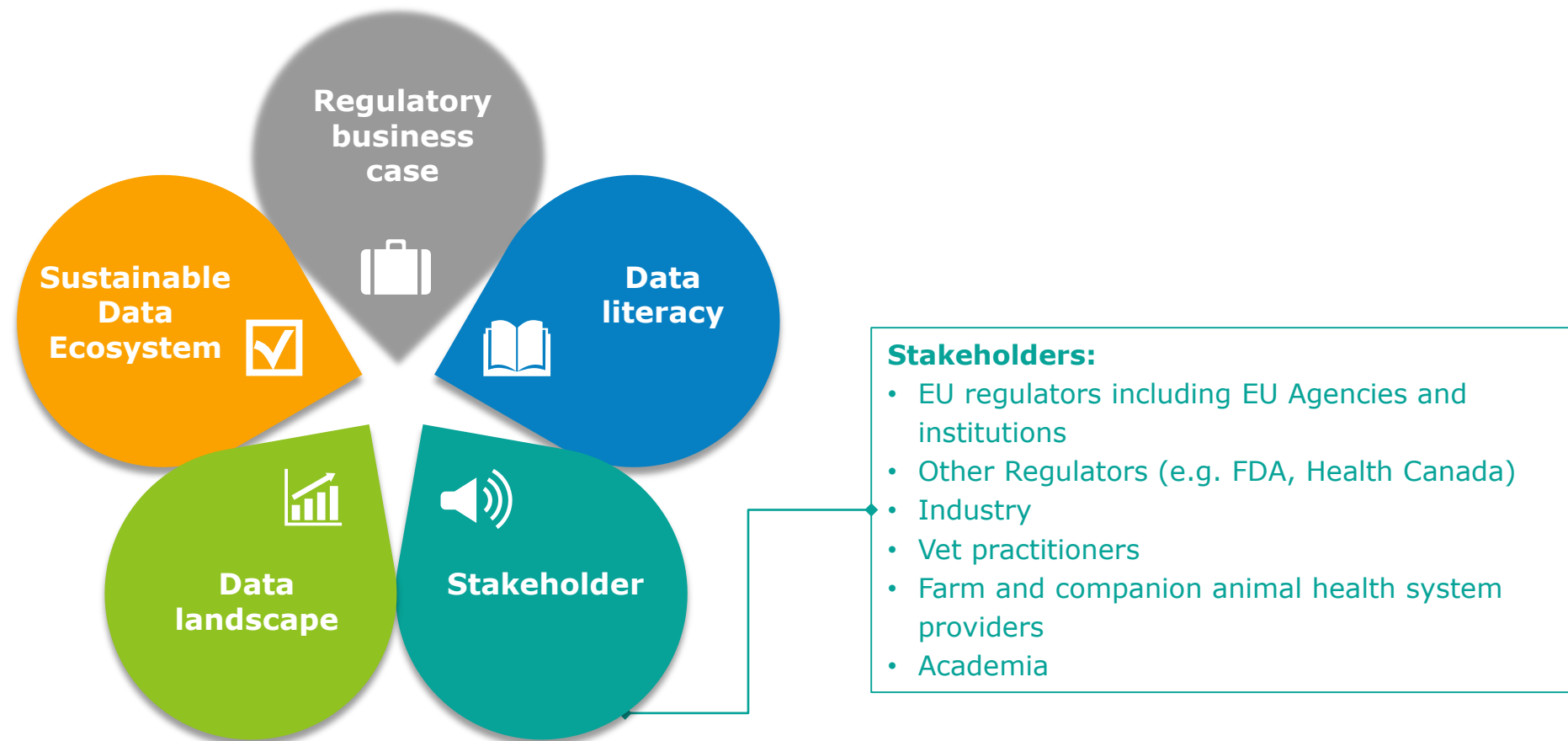


Stakeholder



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



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.



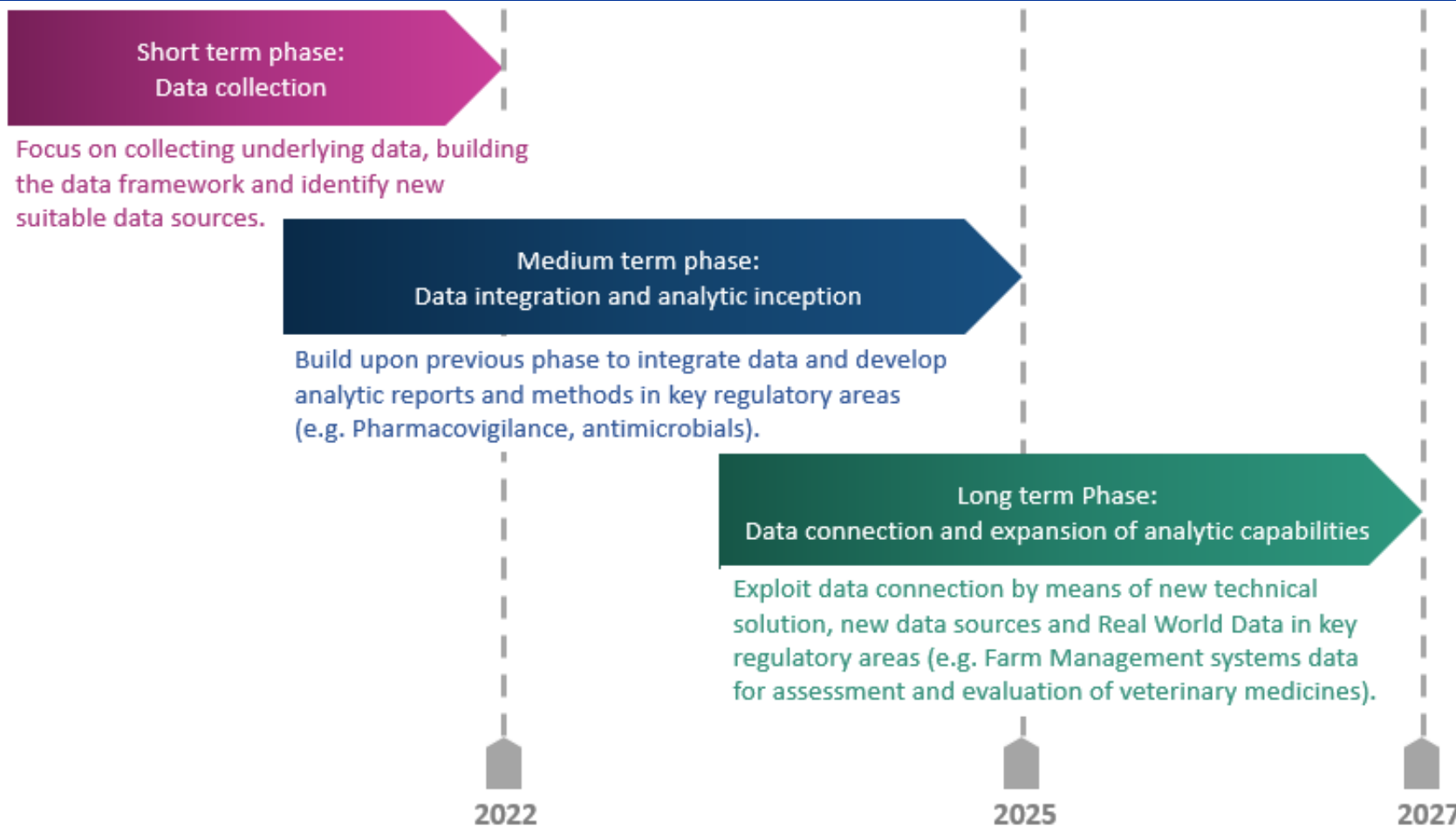
Data Landscape:

- Characterising 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



European Veterinary Big Data strategy 2021-2027
A strategic vision towards implementation of new digital solutions in the veterinary regulatory domain

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1. Introduction and background

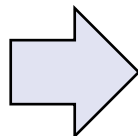
The European Veterinary Big Data strategy aims at laying out ways forward for identifying relevant (regulatory) use cases, identifying existing as well as the required data, critical infrastructures and methods, in order to ensure an innovation-friendly environment for development of new veterinary treatments, for the benefit of animal and human health.

The Joint EMA/EMA Big Data Task (BDT) has defined a set of data assets which may be complex, multi-dimensional, unstructured and which may be analysed computationally. In general, big data sets require advanced processing capabilities and reliable constraints.

Based on the reports of the Big Data Steering Group (BDSG), the BDT has developed a vision for the use of big data across the veterinary regulatory domain. The number of actions to be implemented across the veterinary regulatory domain will be addressed by the Veterinary Data Hub (EU-VDH), in collaboration with the relevant stakeholders.

Driven largely by the implementation of the Veterinary Medicinal Products Regulation (EU) 2019/6 (VMR), there is a compelling need to address the data needs (i.e. related to big data) and standards required in veterinary specific field, to support regulatory decision-making, in the interest of supporting public and animal health.

The European Medicines Regulatory Network (EMRN) is revising its procedures, and regulatory and scientific guidance documents and furthermore takes leadership in the implementation of new digital technologies as anticipated by the BDSG initiatives, throughout the whole life cycle of veterinary and human medicines, during development, registration and marketing. This goes in parallel with the new and revised legislation with the overall goal of simplifying the regulatory environment, reducing



proposal

EMA
EU Veterinary
Big Data Team

**Joint
Veterinary
Big Data
Strategy**

HMA
NCAs and their
experts

Exploring synergies

EMA

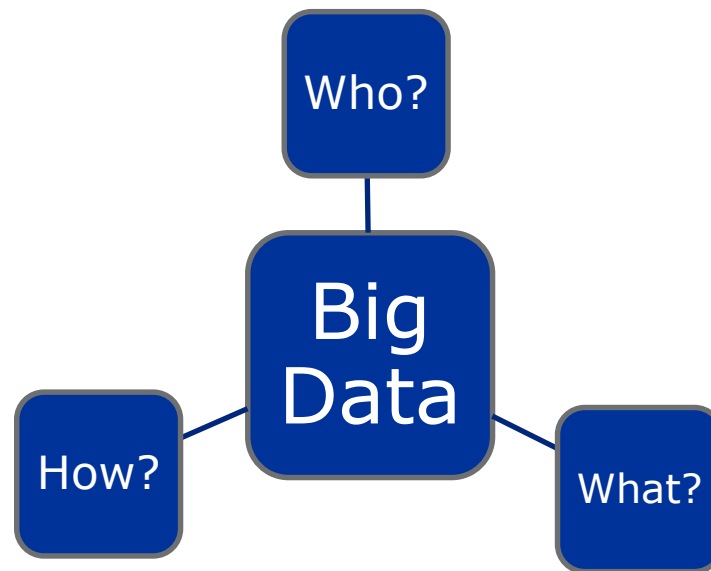
- transparent and clear strategic goals
- transparent timeframe including milestones
- open communication
- coordinate/ organize training options for national experts
- provide digital/ IT solutions

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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