Big Data in Veterinary Medicines Regulation

A Data Landscape Analysis

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4th Veterinary Big Data Stakeholder Forum

14th October 2024

Outline

Take off

The road map

The journey

The landscape

Towards destination

Next steps

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Wageningen Bioveterinary Research, Lelystad

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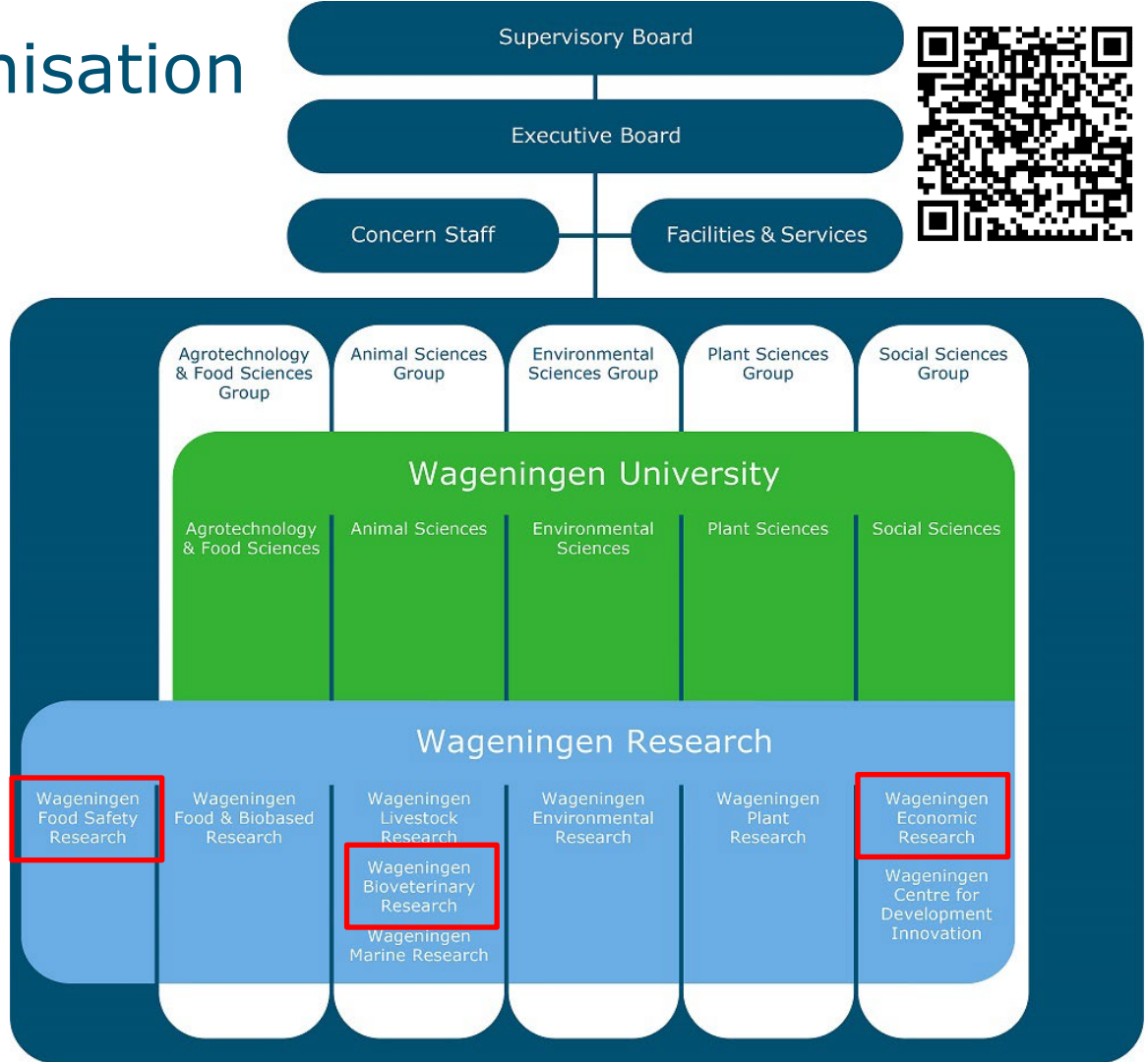
Our organisation



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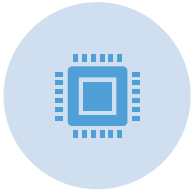
Why are we doing this?

because big data has tremendous **potential** to revolutionise animal health and improve the **evidence** available to support **benefit-risk decisions** and facilitate getting better medicines to animals



the speed of both the development and application of **digital technologies** in animal health is **increasing exponentially**

the digitalisation of **veterinary diagnostics**, **monitoring** and **predictive technologies** are providing more, better and earlier data

these data are increasingly being aggregated to build **veterinary intelligence** systems to generate cumulative **knowledge** to enable **better health outcomes**

data are collected as part of **routine care and management of animals**, including their health and productivity

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Project objectives

To carry out a data landscape analysis to **identify data sources** in animal health that can be used to support key regulatory activities through the life cycle of veterinary medicines

To **characterise** the identified data sources

To select a sub-set of identified data sources and propose a **proof of concept**

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The road map

The journey

Identified sources

- Survey
  - 51 eligible data sources
- Literature/desktop search
  - 385 data sources
- Direct contact with stakeholders
  - 216 data sources
  - Relationship with stakeholders influences the identification

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Criteria for landscape characterisation

What is the data about?

- Data source name
- Data source acronym
- Description
- Data source type

Who owns the data and for what purpose is it used?

- Target species
- Purpose of animal use
- Data source nature
- Data custodian
- Stakeholder

Which country does it come from?

- Data source countries
- Data source regions

Can we access the data?

- Data source website
- Availability

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Landscape characterisation

- 652 eligible data sources identified and characterized based on 13 metadata items
- Majority sources can be linked to specific countries
    - International sources, Global sources
- Quantitative findings – careful interpretation, the identified data sources are not weighted

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Landscape characterisation

- Most frequently identified data sources
- Majority of the sources originate from public sector
- 50% of the sources can be directly accessed
- ~30% of the sources on production, 7% on companion animals
- ~71% of the sources were databases, websites and raw data

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Gaps in data landscape

- Data sources owned/maintained by private sector stakeholders are more difficult to identify and access
    - Limited data sources from companion animals, primarily found within private sector
    - Limited sources from pharmaceutical, food producing and insurance companies
- Not all identified data sources are accessible without restrictions, even from public sector stakeholders

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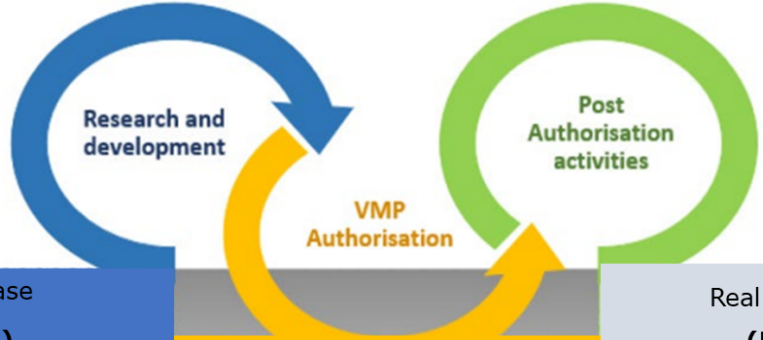
Application examples



Regulatory lifecycle	Pre-clinical phase **(Use Case 1)**	Clinical phase(s) I-III **(Use Case 2)**	Real World Evidence **(Use Case 3)**
Regulatory Areas	Innovation of medicines	Regulatory submission and evaluation	Pharmacovigilance
Business use case	Monitoring and facilitating relevant 3R methods by fostering cooperation of research and industry e.g. to identify alternative methods for animal trials.	Enabling a digital transformation to increase efficiency and reduce regulatory burden & Gaining efficiency and consistency in the regulatory assessment.	Signal evaluation: exploring the use of data from e.g. veterinary clinics, laboratories to evaluate the possibility of early signalling of a possible causal relationship between a product and an adverse effect.
	Setting study designs for drug testing before authorization	**Faster authorization with real-world data (veterinary emergency)**	**Detecting side effects in animals**

Figure. Schematic representation of the regulatory areas and the business use cases proposed in this project.

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Validation workshop

Cases on setting study design (Use Case 1) and detection of side effect (Use Case 3)

- Usefulness of RWD for these cases recognised by workshop participants

Case on faster authorization with RWD (Use Case 2)

- Workshop's participants stressed that this can only be done when there is sufficient supportive evidence and confidence in the efficacy and safety of a Veterinary Medicinal Product (VMP), coming from closely-related VMPs

Proposed example for future: linking Farm Management Systems with Veterinary Information Systems and Antimicrobial Use databases

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Qualitative assessment of selected data sources

- Veterinary data collections systems
- Veterinary Practices Systems
- Farm Management Systems
- Activity monitoring sensors
- Scientific literature
- Diagnostic data
- Pets' apps (information indicated by owners)
- Social media
- Insurance claims

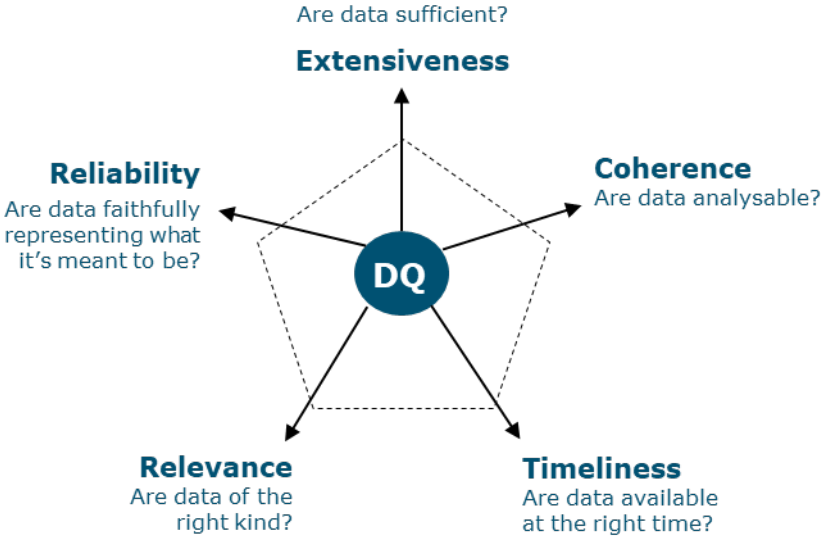

Figure source: EMA/326985/2023, Data Quality Framework for EU medicines regulation.

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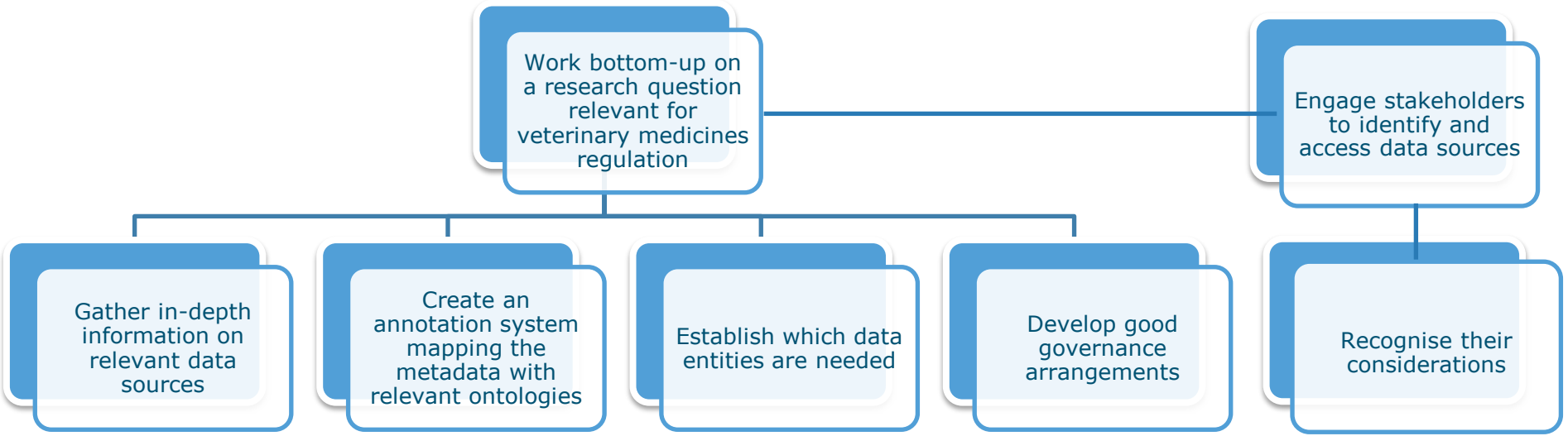
Potential next steps



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Our landscape analysis of the veterinary datasphere revealed use cases exploring the potential of RWD to support the regulatory activities, with stakeholders' engagement being crucial for progress.

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