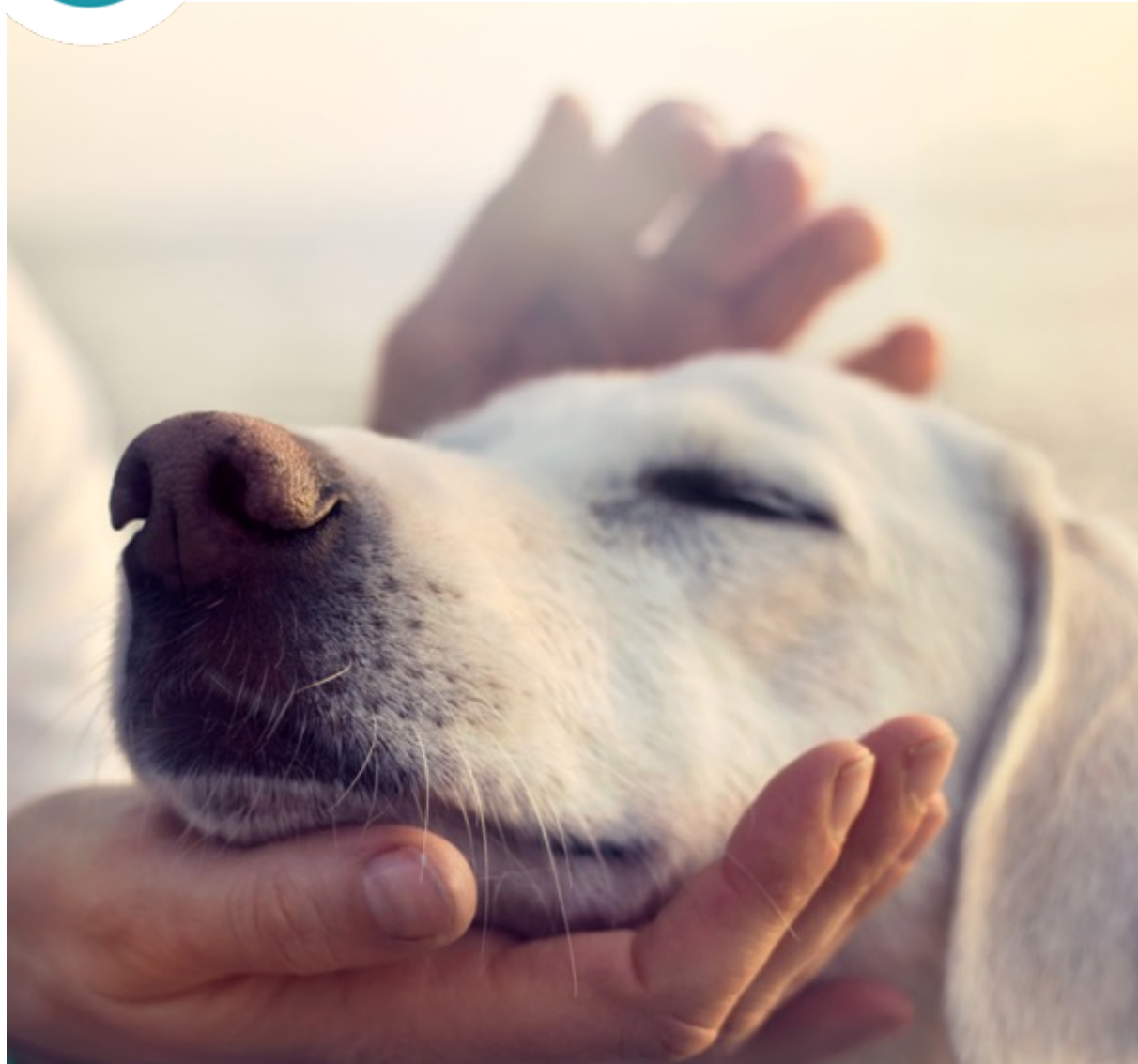







THE VOICE
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2nd Veterinary Big Data Stakeholder Forum

23 November 2022

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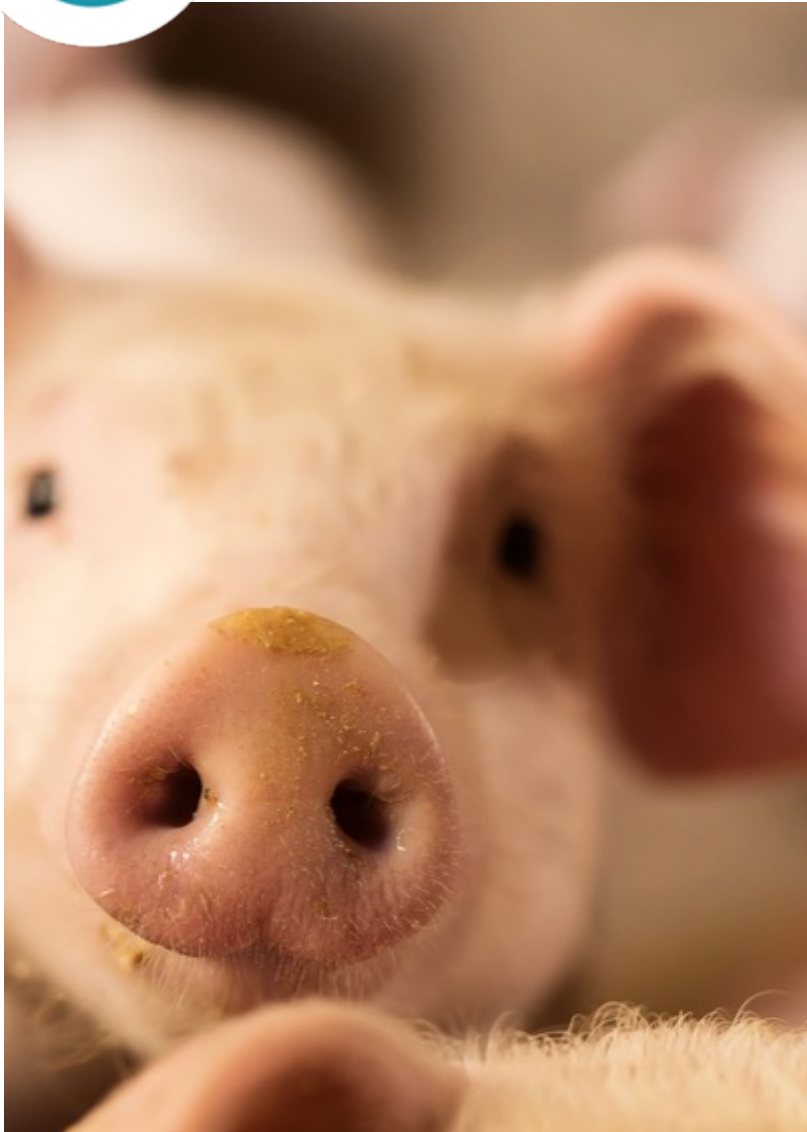
Introduction

AnimalhealthEurope member companies

- Are interested in this topic
- We want to engage with this topic

BUT

- Not a current priority
- No 'bandwidth' to engage
 - Fully occupied implementing Regulation 2019/6
 - 'Significant' additional work and admin burden



Background

Regulation 2019/6 on veterinary medicinal products

- **Requires significant new IT infrastructures**
 - 3 interconnecting databases
 - Procedures/processes to entering, updating and interrogating data
- **Objectives**
 - More efficient processes supported by IT
 - Reduction in the administrative burden (regulators and MAHs)
- **Status**
 - Currently significantly more admin burden than before
 - Delivery of new IT infrastructures - one year late + teething problems
 - New UPD/Vnra/SD procedures - implementation over-engineered



Background

Priorities

- **Focus on the basics for regulatory data management**
 - Focus on data quality and accuracy is critical for efficient functionality
- **Industry priorities - business cases vs reg use cases**
 - Innovative business applications using data analytics

Assumptions

- **Modern IT solutions bring efficiencies to reduce admin burden**
 - Outcome: in reality it has led to increased work 😞
- **Big data will bring benefits and support regulatory decisions**
 - Outcome?: our expectation (based on above experience) – more increased work 😞



Priorities survey - regulatory use cases

The six use cases rated as more relevant and consequently chosen for the forum are:

Use case	Prioritisation	
	All Stakeholders	AnimalhealthEurope
1. Vet Meds Product Information	1.A and 1.B	1.A and 1.D
2. Pharmacovigilance	2.A and 2.B	2.A and 2.D
3. Antimicrobial Resistance	3.A and 3.E	3.A and 3.E

Industry priorities

- efficiencies to reduce admin burden
- Innovation (e.g. see session 3)

- 
- Use Case 2A on pharmacovigilance and signal detection
 - Innovation



Use Case 2A: pharmacovigilance & SD

- 2.A. To implement a solution which compares Signal Detection outcomes across MAHs ensuring quality control and obtaining harmonised safety outcomes.**
- 2.D. To perform a process analysis and identify areas where digital technologies could be implemented to automate safety risk assessments by pharmaceutical industry and provide a 'single routine surveillance tool' to enable efficient safety outcomes elaboration and robust decision-making by regulators.**



Use Case 2A: pharmacovigilance & SD

AnimalhealthEurope supports initiatives that

- improve safety through more efficient pharmacovigilance procedures

➤ Efficient in detecting the important signals with least admin burden

- prioritise the basics required by Regulation 2019/6

- Still working on Signal Detection basics
- Need to allow the system to bed in and mature
- Adding further functionalities is somewhere in the future
- Fully occupied with new PhV work = difficult to reflect on future topics



Industry priority - Innovation

Data supporting -

- **investment decisions - what products are needed**
- **product development and registration**
 - RWE, digital data capture, alternate data sources
 - Understanding validation expectations for new data sources
 - e.g. GCP trials and validation of RWE approaches to support indications
 - C.f. big data in human health (BDSG stakeholder meeting Oct2022)
- **product use and benefits in market**
 - Reduced disease burden
 - Impact on AMR
 - Improved health and production efficiency
 - Animal welfare benefits
 - Assessment of the benefit-risk (c.f. revision of CVMP B-R guideline)



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A close-up photograph of a person's hands gently holding the face of a white dog. The dog's eyes are closed, and the scene is bathed in a warm, golden light, suggesting a moment of care or affection.

Thank you!