

Veterinary Big Data Work Plan

2022 to 2025

Presented by Dr. Sandra Bertulat





Strategy paper adopted by HMA and CVMP in 2022



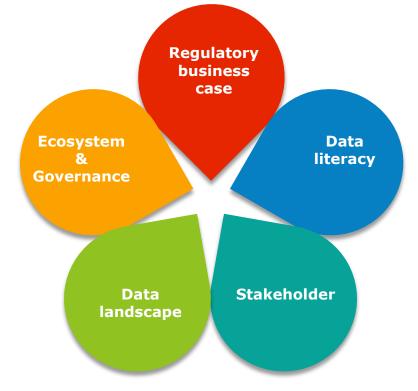
European Veterinary Big Data strategy 2021 - 2027

A strategic vision towards implementation of new digital solutions in the Veterinary regulatory domain

1. Introduction and background

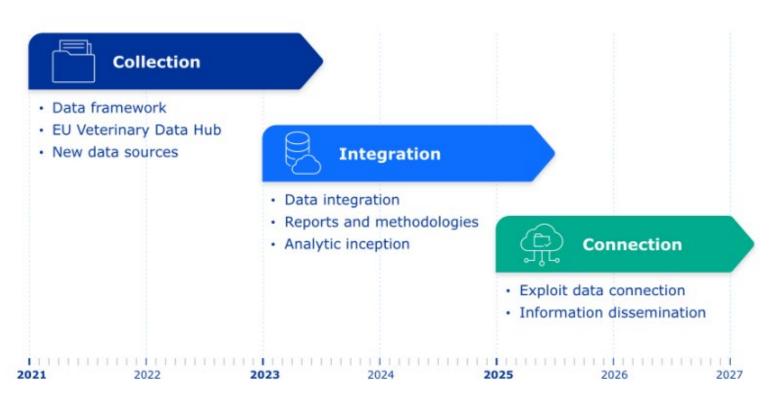
The European Medicines Regulatory Network (EMRN) is revising its procedures, and regulatory and scientific guidance and takes leadership in the implementation of new digital technology, as anticipated by the BDSG initiatives, throughout the whole live cycle of veterinary and human medicines, during development, registration and marketing. In the Veterinary area, this goes in parallel with the implementation of the revised Veterinary legislation where significant efforts have been invested for the implementation of new digital technology (IT) systems which will made available an increased amount of data across the EU Regulatory Network. Moreover, outside the regulatory environment, it is to be considered the ongoing digital revolution which will produce higher amount of data (e.g. sensor | data in farm management and animal healthcare practises) offering the potential to unlock scientific knowledge and increase regulatory (Ficiency, responsiveness and robustness.

It is therefore compelling that the Veterinary Regulatory Network is prepared to absorb and uptake the challenges and opportunities that digital transformation offers and continue building upon the overall





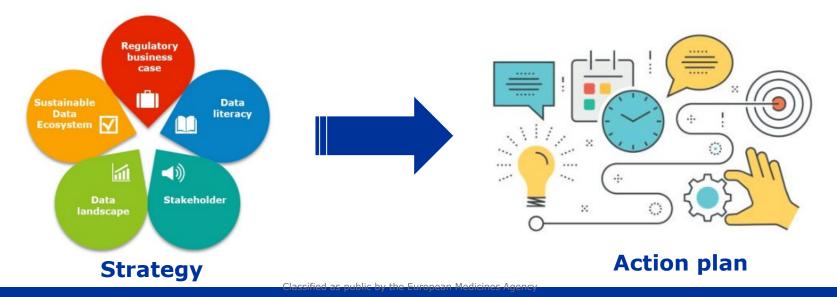
Implementation phases





2nd EU Vet Big Data Stakeholders Forum 2022

"In addition to progressing on enriching data quality in the veterinary systems established under Regulation (EU) 2019/6, an **EU Veterinary big data workplan** is to be developed to identify and prioritise use cases for the coming years."





Use cases: identification & discussion



VMP Availability

- Monitoring veterinary medicines availability and anticipate shortages
- Data-driven identification of unmet medical needs and alternative treatments

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Pharmacovigilance

- Signal detection, comparison and harmonisation of safety outcomes
- Enhance regulatory activities such as risk-based safety and compliance monitoring



Antimicrobial Resistance

Develop analytical methods to: understand the association of antimicrobial use and resistance development, inform risk management, identify emerging issues, and evaluate the impact of reduction of antimicrobial use on AMR development.



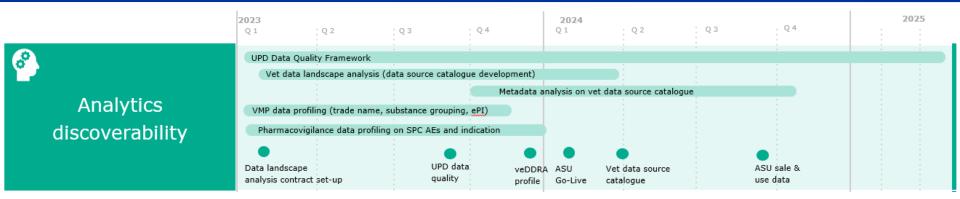
EU Vet Big Data workplan

Transposition of the EU Vet Big Data Strategy pillars into three workstreams



Focus on Analytics discoverability



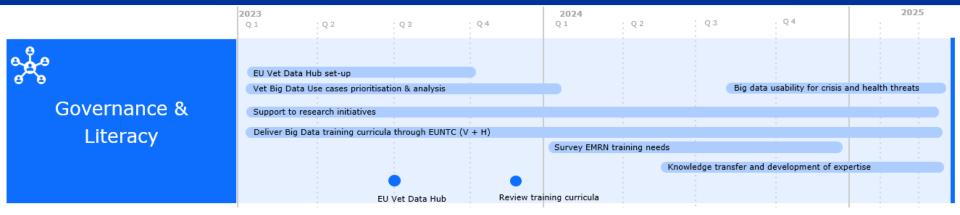


Key milestones:

- Q1 2023 UPD Data Quality Framework launch
- Q1 2023 Data landscape analysis research project launch
- Q4 2023 VeDDRA data profiling established
- **Q1 2024** Antimicrobials Sales and Use database go-live
- Q1/Q2 2024 Metadata analysis research project launch
- **Q2 2024** Veterinary data sources catalogue

Focus on Governance & Literacy





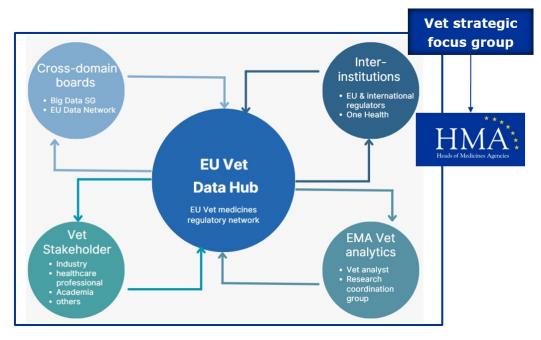
Key milestones:

- Q2 2023 Establishment of the EU Vet Data Hub
- from Q1 2023 Support to research initiatives
- from Q1 2023 Analyse and prioritise use cases to support vet regulatory activities
- **Q4 2023** Review of network training curricula
- from Q1 2024 Contribute to the survey on network training needs
- from Q3 2024 Assess big data usability for crisis and health threats monitoring



Vet Data Hub

"the Vet Data Hub is a multidisciplinary forum of experts from the EU medicines regulatory network contributing to the definition of technical and structural guidance on utilization and implementation of new digital technologies to support veterinary regulatory activities."







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Bundesamt für Verbraucherschutz und

Lebensmittelsicherheit

Focus on stakeholder engagement



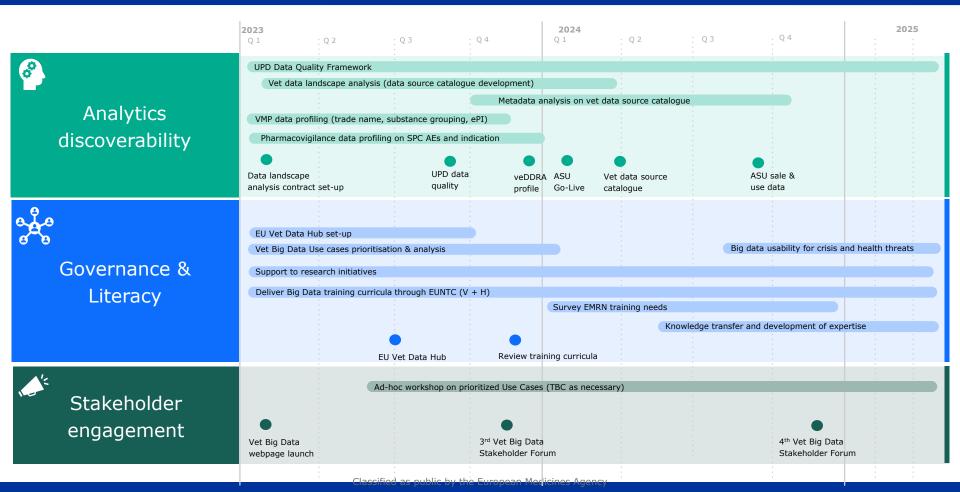


Key milestones:

- **Q2 2023** Launch of the EU Veterinary Big Data webpage
- from Q2 2023 Report on Vet Big Data progress within the EMA Vet newsletter
- Q4 2023 Vet Big Data Stakeholder Forum
- Q4 2024 Vet Big Data Stakeholder Forum

EU Veterinary Big Data work plan to 2025







Thank you for your attention

Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands **Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us **Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

