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Veterinary Medicines Division

European Veterinary Big Data strategy 2022- 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 make 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 practices) offering the potential to unlock scientific knowledge and increase regulatory efficiency, 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 goals set by the VMP-Reg of simplifying the regulatory environment, reduce administrative burden, stimulate the development of innovative veterinary medicines and improve the functioning of the internal market for veterinary medicines.

Hence, the implementation of the Veterinary Medicinal Product Regulation should be a catalyst for the entire Regulatory Network to investigate the convergence of the traditional systems development with the advancement offered by emerging digital technologies.

Based on the reports provided by the BDTF, the HMA/EMA Joint Big Data Steering Group (BDSG) has developed a workplan[1] specifying recommendations and setting out the actions for enabling the use of emerging digital solutions in the regulatory context primarily focused at human domain needs. While a number of these actions will serve both the veterinary and the human areas, specific characteristics and requirements applicable to the veterinary domain are still be fully explored and assessed. This in-depth characterisation of digital veterinary specifications and requirements necessitates a coalition of the willing across the Veterinary EU Regulatory Network and the establishment of a multidisciplinary

[1] Big Data Steering Group Workplan 2021-2023 (europa.eu)

cooperation forum to leverage synergies, reduce administrative and economic burden and enhance consistency, transparency and responsiveness within the EMRN.

In line with the European Medicines Regulatory Network (EMRN) strategy to 2025, and building upon the recommendations defined by the HMA/EMA Big Data Task Force, this European Veterinary Big Data strategy proposes an overview of the vision and direction that the Veterinary EMRN should follow in setting a data framework on how veterinary data resulting from newly available solutions should be managed to support key regulatory activities in a short, a medium and a long term phase, ensuring efficient and timely development of the respective regulatory use cases in specific veterinary regulatory areas. This document proposes ways forward for identifying relevant (regulatory) use cases, existing and additional data sources, critical infrastructures and methods to ensure an innovation-friendly environment for the development of new veterinary treatments for the benefit animal and human health and well-being.

2. Big Data strategy pillars

The ultimate goals of this proposed strategy focus on increasing interoperability across regulatory systems that shall be operated by an optimized set of scientific resources, reducing administrative and economic burden and enhancing consistency, transparency and responsiveness within the Agency. The primary objectives are, therefore, focused at:

- Implementing sustainable processes and systems;
- Integrating the systems powering re-usability of the data across different domains and processes;
- Delivering accurate and reliable information to promote public and animal health as well as environmental safety.

The EU Veterinary Big Data Strategy is defined based on the following pillars:

2.1. Regulatory business use cases

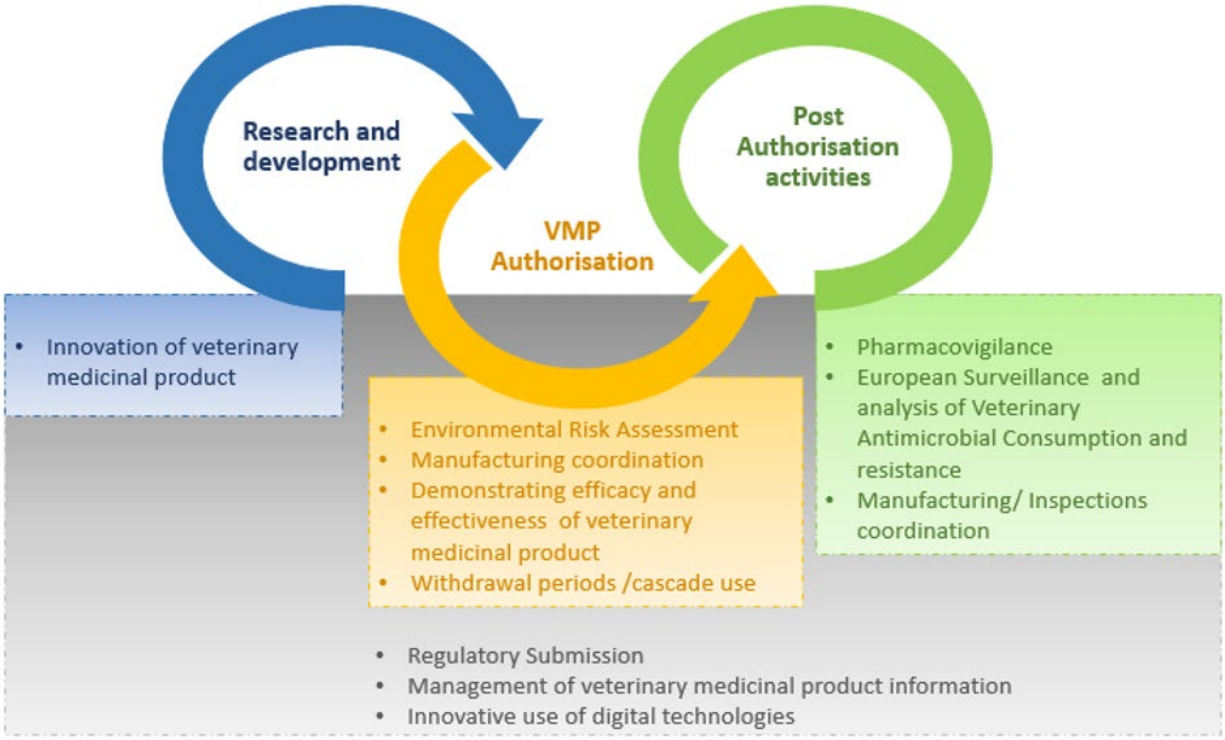
The following business areas are, among others, expected to benefit from the implementation of new digital technologies and the principles illustrated in this strategy:

- Management of veterinary medicinal product information (notably integrating and complementing data as available in the Union Product Database [UPD])
- Pharmacovigilance (notably integrating and complementing data as available in the Union Pharmacovigilance Database [EV-Vet])
- European Surveillance and analysis of Veterinary Antimicrobial Consumption and resistance[2]
- European surveillance of availability of veterinary medicinal products
- Environmental Risk Assessment
- Determination of withdrawal periods/cascade use
- Demonstrating efficacy and effectiveness/ safety of veterinary medicinal product
- Coordination of GxP inspections including manufacturing processes
- Regulatory Submission Framework
- Innovation of veterinary medicinal product and possible alternatives therapies
- Innovative use of digital technologies

More detailed descriptions of exemplary business use cases per business area that are driving the principles outlined in this document are presented in the **Annex**.

In order to identify the benefits realisation in specific regulatory domain, it is pivotal to represent each business use cases in the context of the regulatory lifecycle as follows:

[2] Comprising antibiotics, antifungals, antiprotozoals and antivirals



The information related to the business areas and business cases shall be reviewed continuously to ensure that the deliverables meet the necessary objectives.

2.2. Data literacy and EU Veterinary Data Hub

Since the Veterinary Medicines Regulatory Network will be exposed to increasingly higher volume of data of a variable nature, it is pivotal that a data culture is established within the Veterinary Medicines Regulatory Network to be ready to absorb, tackle and drive future needs and demands by means of emerging digital technologies.

This workstream proposes to:

1. define a **data literacy programme** with the objectives of identifying knowledge gaps, defining a training and data literacy strategy thus developing the EU expertise capable to define the technical, methodological and structural needs required to address data-related requests in a prompt, responsive, consistent and coordinated way;

2. establish the **EU Veterinary Data Hub** (EU-VDH): a multidisciplinary forum formed by a variety of experts from the network with a cross-sectional ambition (e.g. encompassing quality, safety, immunological experts…) and being able to contribute to the definition of technical and structural guidance; the objective of the EU VDH includes the identification of research questions and data analysis methodology and the identification of data sources suitable to support regulatory activities.

The primary step to establish the EU-VDH foresees the need for training and info sessions targeted towards experts within the network. The Big Data Steering Group (BDSG) work plan 2021–2023[3] recommendation IV (i.e. the learning initiative) anticipates the availability of a set of trainings to develop EU network skills in big data. In establishing the EU-VDH, the Veterinary Medicines Regulatory Network shall benefit from the Big Data training curriculum, which will be made available by the BDSG. The scope, mandate and governance framework under which the EU-VDH will operate need to be

[3] Big Data Steering Group Workplan 2021-2023 (europa.eu)

established in a dedicated terms of reference document and in line with the EMA/EU Data Governance model that will be defined.

2.3. Stakeholders

For the purpose of the principles outlined in this EU Veterinary Big Data strategy the following are identified as concerned stakeholders:

- EU veterinary medicines regulators including EU Agencies and institutions
- Other global regulators (e.g. FDA, Health Canada)
- Veterinary pharmaceutical industry (including affiliated CROs and wholesalers)
- Veterinary practitioners
- Farm and companion animal health system providers
- Academia

This strategy proposes that a detailed analysis on the relevant benefits and interests for each individual stakeholder group is carried out to estimate benefits realisation and facilitate the prioritisation of implementation of advanced digital solutions in the identified business regulatory areas.

2.4. Data landscape framework

In order to respond adequately to upcoming requests, there is a compelling business case for the regulators to take advantages of new digital technologies to integrate, connect and utilise national, EU and global data sources. Data on animal health, pharmacovigilance, antimicrobial resistance, zoonoses monitoring, wildlife population, environmental and human health have the potential to inform regulatory policies, to leverage effectiveness of regulatory measures to be used in predictive tools to anticipate health emergency threats.

For the implementation of the principles and approaches outlined in the European Veterinary Big Data strategy, an in-depth knowledge of the 'data landscape' characterising the relevant data on national and European level is needed and the development of a veterinary data landscape framework is proposed. The veterinary data framework aims at providing a comprehensive overview on the content and characteristics of the veterinary **data sources** available across the public sector (i.e. regulatory data sources and monitoring and surveillance systems) as well as the private sector. This workstream is targeted at identifying overlaps and duplication of efforts in relation to data management practices, at driving integration and powering re-usability of existing data across different domains, at listing the existing and identifying newly required **data standards** and common data models (CDMs) and at identifying **data quality** and **metadata framework** requirements. Hence, the data landscape framework intends to cover the following aspects:

1. **Data sources** analysis and characterisation
2. **Data standards** requirements identification
3. **Data quality** framework definition
4. **Metadata framework** definition
5. **Advanced analytical methods, modelling & simulation** definition and validation

Data sources: data in the veterinary domain may be retrieved from a large variety of sources and may be available based on diverse structures such as on the level of animal, farm or country. Data sources characterisation should take into account if a single dataset may be linked with other datasets and the complexity becomes sufficiently large or difficult to analyse. The following data sources types are available to support veterinary regulatory activities:

- Regulatory data[4]
- Monitoring and Surveillance systems including biosecurity data[5]
- Private data sources[6]
- Research and data from academic and institutional public sources

The source of veterinary data is either public or commercial in nature: public data sources are primarily regulatory data or data coming from monitoring and surveillance systems which are implemented mostly based on the EU legal framework; further national programs may exist from academic institutes; private data sources are primarily of commercial nature and available in veterinary healthcare environment and livestock farming context. These data sources vary widely in their availability. Regulatory, Monitoring and Surveillance data are mainly known and already available for regulatory purposes. However, data from academic institutes and private sectors still have to be identified and potentially made available to support regulatory activities as necessary.

Data standards: data collected or connected from the aforementioned sources types vary widely in their format and usability. In order to improve interoperability of the available dataset and comparability of the analytical results, the use of common standards and harmonised practices is pivotal.

From a standardisation stand point, the regulatory data sources are relatively mature since they are mostly based on agreed standards and codification systems which ensure consistency and interoperability across different EU national systems[7]. On the other hand, private data sources such as animal health data records from veterinary practices, health service providers and farm management systems vary significantly and often information is not standardised and frequently incomplete. In addition, the ambition of connecting regulatory data sources with additional data sources, such as monitoring and surveillance programs developed from the academic or industry sector, and private data on animal health services and production and farm management systems, drives the need for adapting, adopting or developing additional standards.

In the context of the HMA/EMA BDSG international Activities work stream (recommendation IX), an EU Data Standardisation Strategy has been drafted. The Data Standardisation Strategy should serve as a roadmap to improve the way data is dealt with within the EU and to support the development of globally applicable standards for the human and veterinary regulatory domains. The Data Standardisation strategy proposes that requirements should be assessed against what has already been implemented in order to prevent the use or creation of overlapping and competing standards. The assessment should include both human and veterinary needs so that one standard that covers both

[4] Regulatory data sources examples includes: Union Product Database, the Eudravigilance Human and Veterinary, TRACES - Trade Control and Expert System.
[5] Examples are: European Surveillance of Veterinary Antimicrobial Consumption (ESVAC Report), Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA Report), Monitoring program on avian flu in the Netherlands to implement the directive on monitoring of zoonoses and zoonotic agents, Notification of animal disease within EU, Animal Disease Information System (ADIS), Summary reports on zoonotic infections and foodborne outbreaks produced by the EFSA in cooperation with the ECDC, database on food residues and RAFSS alert, data from slaughterhouses
[6] Examples are: health data from insurance companies, health data from veterinary practices, performance data from farm management systems
[7] Such as the Union Product Database format, the reporting template for suspected adverse reactions in the Veterinary Eudravigilance system and the controlled terminologies maintained in the SPOR system

domains can be used where possible. The data standardisation strategy will be maintained by being reviewed annually and revised as necessary according to new requirements and priorities that will arise in the future (e.g. following the finalisation of this proposed EU Veterinary big data strategy).

Data quality framework: considering the current development of data discoverability, the establishment of veterinary specific data quality indicators is advised. Externally maintained veterinary data and evidences need to be assessed, validated and transformed into reliable, traceable, auditable, legal and ethical information to inform reliable and conscious regulatory decision making. As data become more complex due to the broad variety of veterinary data sets, this strategy supports the definition of an EU framework for data quality practice (HMA/EMA Big Data Task Force recommendation 2). This framework should cover all types of data sources used by regulators and needs to be adapted to the special needs of the veterinary field where particular emphasis should be given on the prevention of bias caused by not only national and regional peculiarities (e.g. language variability) but also on domain-specific factors (such as different target species).

This framework proposes to define data quality metrics for the source data, for any transformed/mapped data and for the subsequent analysis providing the range of applicability, quality control measures and limitations of the selected data. The definition of the minimum acceptable requirements should also be set, recorded and transparently communicated depending upon the intended regulatory purpose of the data analysis performed. The following quality attributes may be used as criteria:

- Conformance: defining the intended format
- Uniqueness: to avoid duplications within or across identified databases
- Completeness: setting the acceptable threshold to ensure the lowest frequency of missing values
- Accuracy: ensure correctness and integrity of the used data
- Plausibility: defining the data values or distributions based on defined gold standards

Metadata framework: understanding metadata leads to a plausible selection of the most appropriate data elements and data sources to perform data analysis. Metadata is defined as a set of data that describes and gives information about other data such as information on the generation, location, and ownership, key variables and the format (codified, structured versus unstructured) including the provenance and time span of the data, the storage, handling processes, access, and governance of data. Based on this definition, metadata can be categorised as:

- business metadata, that refers to glossaries of definitions of data elements along with the reference libraries of each data element (e.g. look-up values, intervals allowed, data type etc.)
- operational metadata, that characterises data movement such as frequencies, record counts, missing values and additional information related to the description of data quality

Currently, publicly available metadata are limited, not coherent between different sources, and not defined based on a regulatory purpose mind-set. These limitations restrict the possibility of replicating studies from one setting to the other. This workstream proposes the definition and access to a standard electronic catalogue of complete and accurate metadata information with the ambition of describing the data sources planned to be used in a study protocol or research proposal, and contributing, for instance, to the assessment of the reliability and value of the results.

Advanced analytical methods, modelling & simulation: Big data is a relatively new field in the analysis of data and different structures and data sources have to be connected and analysed based on a suitable advanced analytical method, model and simulation. One of the potential uses of these

approaches has been recognised in providing prognostic information (what is going to happen?), predictive information ('what is likely to happen?') and identifying trends and patterns based on Real-World Data (RWD) and evidence.

To fulfil the demand on these complex and rapidly accumulating data, this workstream recommends that a framework is established where advanced analytical methods should be either newly developed or existing models (also used in other domains such as human health, food safety, wild life population and animal welfare) assessed to evaluate their applicability to the pertinent veterinary regulatory business case. This framework should be led by the EU-VDH encompassing a network of biostatistics, modelling and simulation experts across the EU that should identify gaps in cross-domain models and define additional methods as required by the veterinary regulatory business cases.

To ensure regulatory acceptance of the results derived from advanced analytics technologies, validation criteria of the 'advanced statistical models and simulations' should be established to ensure that the relevant regulatory decision is reliable, auditable and ethical. Integrating big data related to animal, human and environment information from national or EU level offers major opportunities but the suitability of the big data models has to be confirmed as a first part of the analysis. In validating the analytical methods, the following characteristics should be taken into account:

- **Usability** of the models especially in their use in cross-domain applications
- **Scalability** of the models to different regulatory areas
- **Data issue** aspects addressing data quality, data quantity (i.e. missing values) and biases
- **Trust** in the technology used and the results produced.

2.5. Ecosystem and governance

Together with the data characterisation and curation, the definition of a **sustainable ecosystem** is necessary to leverage the use of increasing volumes and the variety of data. This workstream intends to define how data sources and systems should interact with each other to exchange, consume and alter data to produce information in support of regulatory and scientific activities. Such ecosystem shall provide an environment for creating, managing and sustaining data sharing initiatives based on FAIR principles (Findable, Accessible, Interoperable and Re-usable). The veterinary data ecosystem should have the capacity of managing the increasing volume and variety of new data and encompassing the use of innovative digital solutions such as machine learning (ML), artificial intelligence (AI) and Natural Language Processing (NLP) technologies with the primary goal of connecting and retrieving evidences from a complex variety of data to support regulatory decision making.

A **data governance framework** is also to be established in cooperation with the EU Medicines Regulatory network and in line with the EU legislative framework. The limited application of GDPR in the veterinary domain offers the opportunity to streamline data governance architecture for the experimentation and roll-out of new digital solutions in a relatively innovation-friendly environment as it is recognised that the use of data collected from animals does not pose the same ethical and legal issues of sensitive health personal data.

Within the veterinary context, challenges for regulators to access commercially confidential data for regulatory purposes remains and could be addressed in the framework of a regulated data sharing "business-to-government" (B2G)[8] proposal. B2G data sharing is a collaboration in which a company or other private organisation makes its data available (or insights) to the public sector (local, regional, national or EU) for a public interest purpose. This collaboration should take place in a secure, privacy-

[8] https://ec.europa.eu/digital-single-market/en/good-practices-b2g-data-sharing

preserving, sustainable and ethical way. Health data from companion and farm animals (e.g. monitoring of zoonoses and zoonotic agents, data from prescribers and veterinary insurance companies) can provide EU regulatory authorities with insights to predict disease outbreaks, antimicrobial and antiparasitic resistance, improve diagnosis, forecast therapeutic needs and estimate medicines demand and availability in the EU territory as well as allowing regulators to react faster to health threats and emergencies.

Data governance and access is predicated to be also addressed and improved by new EU regulatory proposals such as the European Commission proposal on the Data Act[9] and this Veterinary Big Data Strategy will evolve based on the principles and opportunities that such legal framework will provide.

3. Implementation strategy

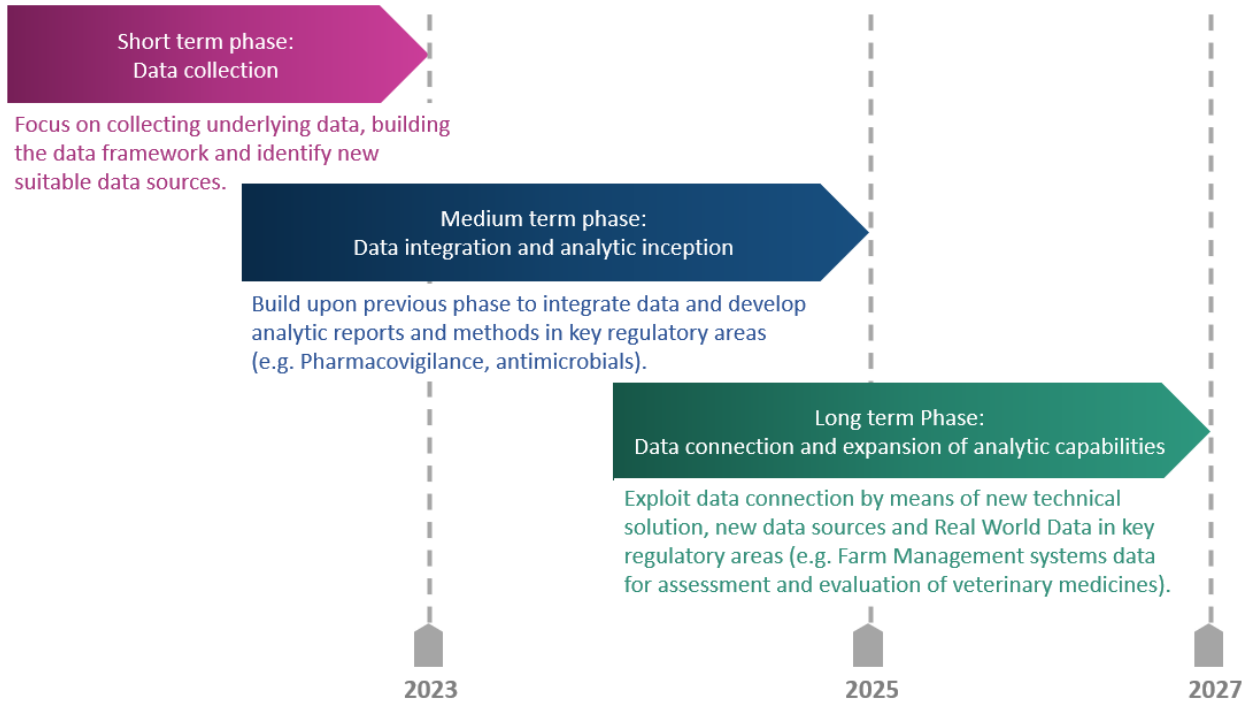
The vision for the implementation of the principles and methodologies described in this EU Veterinary Big Data strategy is based on a phased approach with detailed activities covering the next 5 to 7 years. The following key phases are envisaged:

Short-term phase: allow the implementation of systems and infrastructure for the **collection** of key underlying data and identify additional data sources to fulfil regulatory activities in the subsequent phases;

Medium-term phase: implement the **integration** of specific data sets into targeted regulatory processes and systems to allow inception of key data analytics solutions and optimisation of the regulatory procedures;

Long-term phase: power the data sharing, **connection** and information dissemination and expand **analytic capabilities** based on additional data sources and analytic methodologies.

The overall implementation timeline is summarised in the following figure:



[9] https://ec.europa.eu/digital-single-market/en/news/building-data-economy-brochure

3.1. Short term phase: Data collection

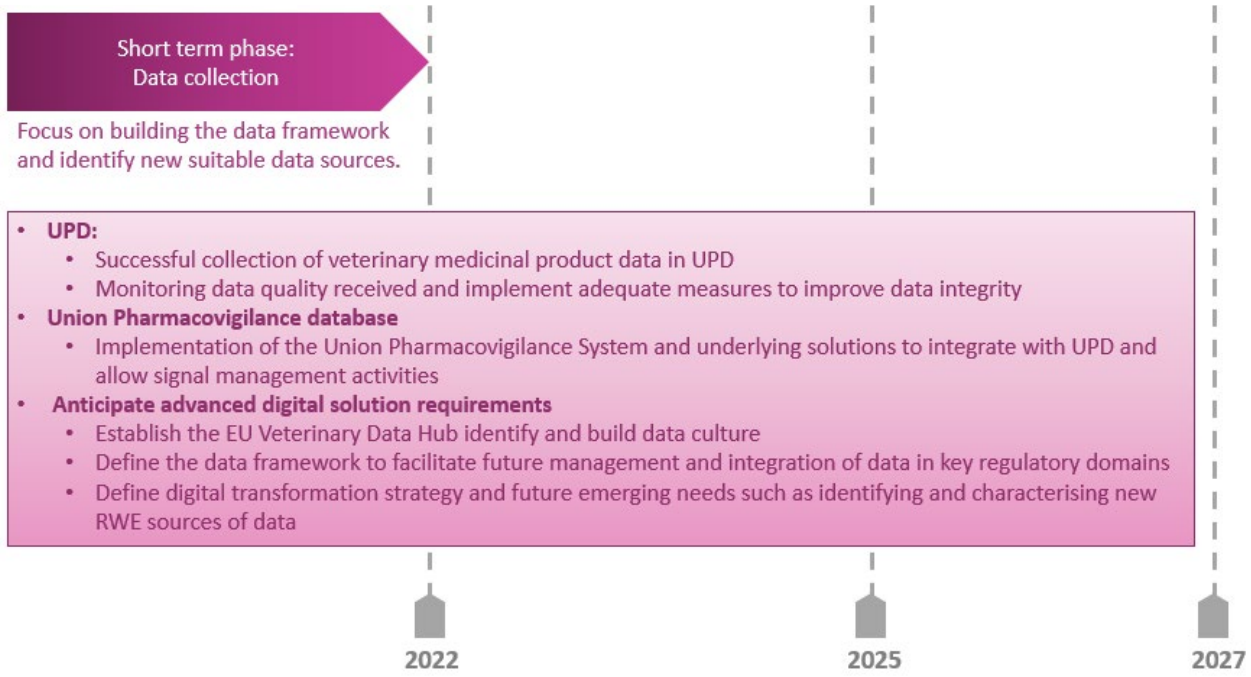
The short-term phase (covering around 1–2 years), emphasises the implementation of the systems as legally required. Focus is also placed on the completion of data within the established repositories.

The first deliverable should enable the collection of medicinal product information in the UPD database to enable further integration and data consumption by key regulatory systems. In addition, the implementation of the EudraVigilance Veterinary system as one of the first candidate consuming data from UPD needs to be achieved.

An analysis of available and potential new data sources suitable for supporting regulatory activities in the veterinary domain needs to be carried out. The identified new data sources should be made available and complement the data standards and Common Data Models (CDMs) currently used in the veterinary domain and as established in the context of the solutions implemented as required by the VMP Regulation. Reflection on the mapping and integration requirements to leverage the connection and use of the identified data sources needs to be addressed in order to define a robust data quality and data management framework. The identification of new data sources and the related characterisation will produce a living catalogue that will need to be prospectively monitored, updated and maintained to ensure an up to date overview of the European data landscape to support Veterinary regulatory business cases.

Concomitantly, it is pivotal to set the ground to anticipate and address future and emerging data needs within the Veterinary Medicines Regulatory Network by creating a data-culture and establishing the EU Veterinary Data Hub. Potential training of the VDH has to be conducted. Research requests have to be identified e.g. to handle new data source or to develop new advanced analytics for a better implementation of big data strategies.

The strategic objectives are summarised as follow:

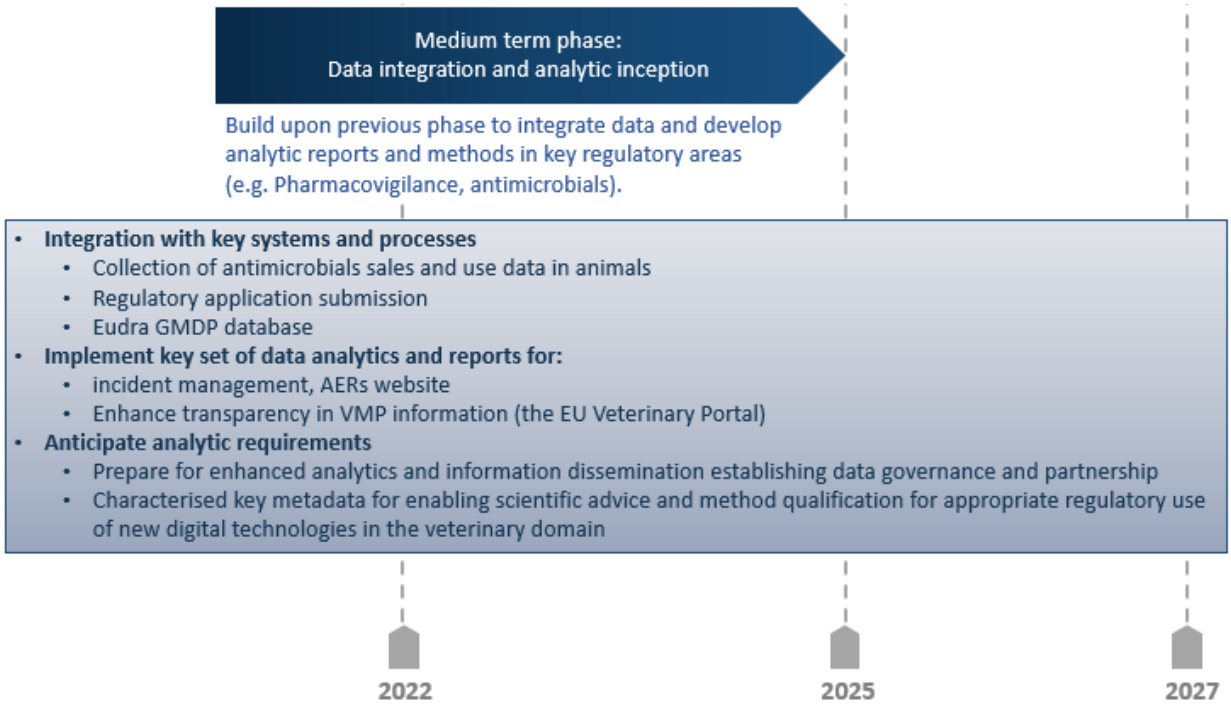


3.2. Medium term phase: data integration and analytics inception

The medium-term phase will continue for 2–5 years with specific emphasis on the integration of the collected data with the focal areas to support the identified business cases and realise related regulatory benefits. In addition, analytic capabilities should be expanded for the dissemination of reliable information based on collected data.

Within the European regulatory network, respective expertise and capacities will have to be established in order to appropriately assess applications employing advanced data processing and analytics technologies. In order to ensure an innovation friendly environment, adequate processes and infrastructures should be established, and missing tools or means should be identified.

The strategic objectives are summarised as follows:



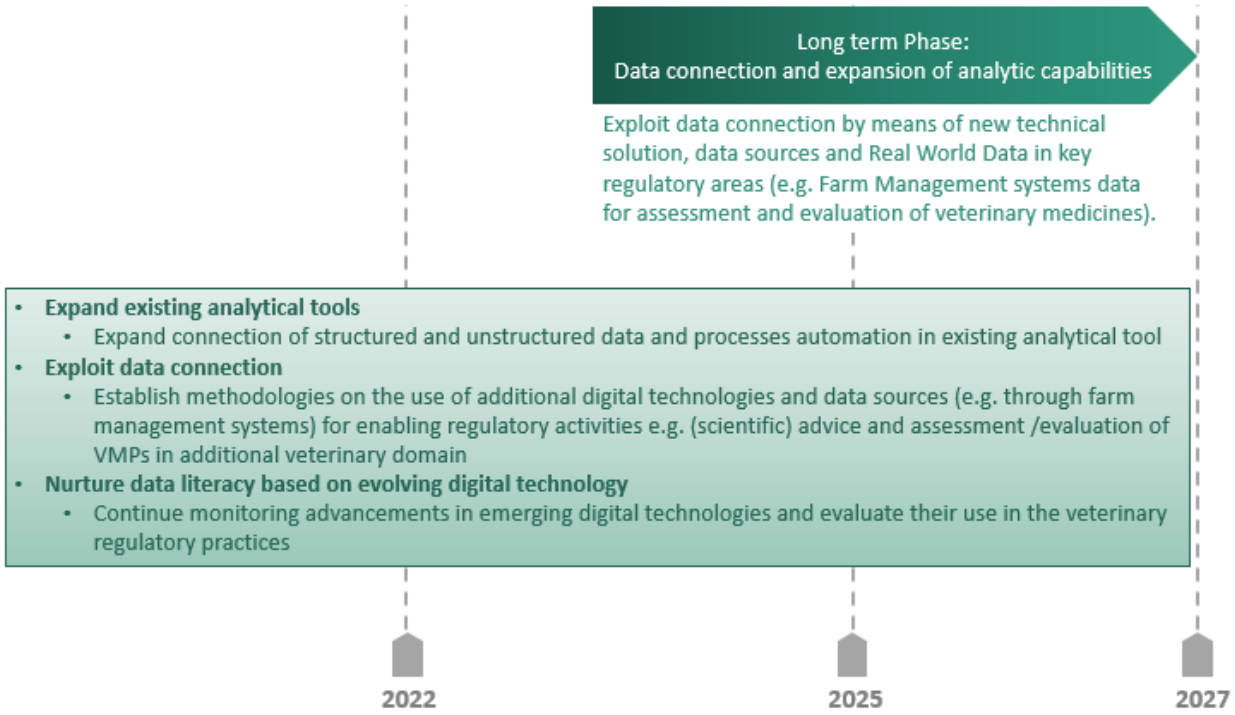
3.3. Long term phase: data connection and expansion of analytic capabilities

In the long-term phase (starting in 3–7 years), analytic capabilities will be expanded, building upon already developed solutions and making use of new data technologies with the ultimate goal of enhancing data connection and information dissemination to internal and external stakeholders.

Through the expansion of international and external cooperation to increase access, connection and sharing of data with additional sources, this phase will focus on two areas:

1. Expand existing analytical tools developed in the preceding phases by means of further integration of internal structured and unstructured data and internal process optimisation;

2. Exploit data connection by utilisation of Big Data and new digital technologies in regulation of veterinary medicines.



Expand existing analytical tools: Business intelligence solutions already developed could be enhanced to include additional statistics, epidemiological, real world data and advanced analytics models and methodology to:

1. Power the identification of alternative treatments and therapeutic options based on clinical and non-clinical data;
2. Prioritise and optimise pharmacovigilance and quality inspections;
3. Support integrated analysis of antimicrobial use in veterinary medicine and antimicrobial resistance data in animals;
4. Identify areas of unmet medical needs (with specifying their origin and impact);
5. Anticipate lack of medicines availability (such as due to safety, quality and efficacy issues, shortages, distribution issues or regulatory issues);
6. Establish solutions for the identification of counterfeit and falsified medicines.

New digital technologies in veterinary medicine applications: Whilst the focus in the short and medium-term phases has been on the collection, standardisation and integration of structured data, the long-term strategy should identify solutions to access and analyse unstructured and metadata not necessarily maintained in local EU systems. To leverage constraints in the budget and resource capabilities and issues related to access of additional data by the EU Regulators, it is proposed to explore the possibility to use new digital technologies and solutions to directly access externally maintained data, metadata and evidences and transform them into reliable, traceable, auditable, legal and ethical information. At the level of the European Regulatory Network, processes and methodologies on the use of new digital technologies for enabling regulatory activities such as qualified (scientific) advice and assessment of applications shall be established and reflected in the relevant scientific guidelines which will need to be amended and maintained prospectively. This should be fulfilled based on scientific analysis and discussion in close cooperation with the relevant stakeholders.

This phase should make use of Big Data and new digital technologies in the business areas outlined in section 2.1. Regulatory business use cases, to enhance regulatory activities and actions by:

1. Accessing and analysing retrospective risk assessments, regulatory outcomes and measures taken to identify future trends in environmental risks assessment;

2. Accessing and analysing regulatory outcomes related to Pharmacovigilance from other regulatory authorities (e.g. FDA) to power statistical analysis and coordinate regulatory actions with international regulatory partners;

3. Analysing pre-authorisation safety data (including MRL submissions), environmental toxicological data, veterinary antimicrobial use data/sales volumes received and post-authorisation/pharmacovigilance data for the overall safety characterisation and profiling of veterinary medicines;

4. Strengthening innovative use of digital technologies for pre-clinical evidence generation (e.g.: In silico models or modelling & simulation) and for improving (platform) technologies (e.g. bioinformatic algorithms, ML and AI) for manufacturing of VMPs.

5. Analysing the application and use of the Data Analysis Real World Interrogation Network (DARWIN) on additional metadata for data relevant for the environmental data and antimicrobial resistance risks to support regulatory assessment and identify emerging health threats;

6. Expanding the veterinary antimicrobial use/sales volume data to real world data, literature, metadata, antimicrobial resistance and human medicines data to power statistical analysis and allow a coordinated information dissemination;

7. Preparing EU-wide policies and procedures to support innovative and alternative approaches to data generation such as real word data and evidences generated by new methodologies (for example through animal health data from veterinary practices or farm management systems) for supporting signal detection and validation.

4. Annex: Regulatory business use cases

The following table gives more detailed descriptions of exemplary business use cases per business area that are driving the principles outlined in this document.

Regulatory Areas	Business Use Cases
Union Product Database (UPD)	➢ Improving transparency of veterinary medicinal products authorised in the EU; ➢ Supporting the harmonisation of product information in agreement with Art 69-71 EU 2019/06; ➢ Implementing a reliable tool for veterinary practitioners to elaborate on treatment options, and proceed in case of unavailability of a specific product in a Member State; ➢ Providing self-service access for stakeholders, such as supporting industry for certain regulatory activities (e.g enabling the management of variations that do not require assessment) or veterinary practitioners in case of VMP availability issues;

Regulatory Areas	Business Use Cases
Union Pharmacovigilance Database (EVVet)	➢ Strengthening signal-detection for veterinary medicines by integrating veterinary medicines information quality controlled and harmonised based on the UPD terminology; ➢ Reducing administrative burdens by increasing the use of IT tools; ➢ Ensuring compliance with PhV regulatory requirements; ➢ Coordinating Pharmacovigilance Inspections and facilitating information sharing on the outcome of EU inspections across the network; ➢ Improving harmonisation, transparency and accessibility of pharmacovigilance information; ➢ Cross-referencing to other databases e.g. sales data to improve monitoring of adverse events and identify cases of lacking efficacy; ➢ Ensuring adherence to international formats and standards (e.g. VICH); ➢ Implementing reliable signal management facilities serving as a single routine surveillance tool;
Pharmacovigilance	➢ Signal detection: integrating new data sources e.g. social media or vet forum discussions for the purpose of detecting signals ➢ Signal evaluation: exploring the use of data from e.g. veterinary clinics, laboratories to evaluate the possibility of a causal relationship between a product and an adverse event
European surveillance of antimicrobial sales and use in animals	➢ Identifying an off label as well as emerging use of veterinary antimicrobial substances; ➢ Comparing antimicrobial usage between human and veterinary medicine, time periods and countries; ➢ Identifying and interpreting patterns and trends on antimicrobial use in animals on EU level; ➢ Comparing veterinary antimicrobial usage and resistance data between and within animal species; ➢ Communicating and presenting exposure data and criticalities; ➢ Supporting focused and targeted research on the reduction of antimicrobial usage and the development of new antimicrobial products; ➢ Cross-referencing to other external databases (e.g. TRACES, EUROSTAT/National statistics); ➢ Evaluating the effectiveness of control measures implemented;

Regulatory Areas	Business Use Cases
Environmental risk assessment	➢ Identifying potential environmental hazards and risks; ➢ Identifying the need for risk mitigation measures; ➢ Ensuring that adequate risk mitigation measures are in place, where appropriate; ➢ Evaluating effectiveness of risk measures in place by users and healthcare professionals;
Regulatory submission and evaluation	➢ Enabling a digital transformation to increase efficiency and reduce regulatory burden; ➢ Gaining efficiency and consistency in the regulatory assessment;
Manufacturing/ inspections coordination	➢ Ensuring compliance with good distribution practices; ➢ Improving data sharing and coordination of actions between NCAs concerning manufacturing authorisations and GMP certificates; ➢ Sharing information on the outcome of EU inspections with certain non-EU regulatory authorities; ➢ Guaranteeing that veterinary medicines are procured, stored, transported and handled appropriately; ➢ Controlling the distribution chain and consequently maintaining the quality and integrity of VMPs; ➢ Preventing falsified medicines from entering the legal supply chain; ➢ Preventing the duplication of work between NCAs; ➢ If Big data are proposed as data sources or documentation for MA dossiers, data structuring and directory, software validation (for GLP/GCP data) and data ownership anonymization should be established and would have to be mentioned in the GLs (notably in those on data management and analysis).
Innovation of medicines	➢ To horizontal scan new technologies for Veterinary Medicinal products and to increase availability of vaccines for emerging diseases; ➢ Supporting the development and use of digital (platform) technologies (e.g. bioinformatic algorithms or AI) for manufacturing and surveillance of VMPs; ➢ Monitoring and facilitating relevant 3R methods by fostering cooperation of research and industry e.g. to identify alternative methods for animal trials; ➢ Monitoring the development of promising treatment methods and alternatives; ➢ Enabling the access of veterinary novel therapies to the market;

Regulatory Areas	Business Use Cases
	➢ Facilitating availability of vaccines or pharmaceutical products for emerging diseases or disease outbreaks;
Innovative use of digital technologies	➢ Demonstrating efficacy/effectiveness and safety of VMPs; ➢ Utilizing m-health technologies for cost saving and improving field trials, e.g. regulatory compliant 'virtual trials'; ➢ Guaranteeing an efficient high-quality RWE data collection on the farm level and on the individual 'animal patient' level; ➢ Facilitating the development of technical solutions for automatic data collection; ➢ Reducing the number of laboratory studies by standardizing clinical field settings and reducing potential bias or compensating for higher interindividual variability by generating larger data sets ➢ Combining VMP and medical device to allow complex treatment protocols.