

Generating Value Through Data Governance: The Case of Pharma

A structured approach to Data Governance is the key enabler for pharmaceutical companies to transform immense volumes of disparate, underutilized, and often poorly managed data into a value-generating asset. Data Governance ensures data quality and security while allowing the right level of accessibility and interoperability to foster data democratization, a data-driven mindset, and insight generation. Given the multitude of internal and external data sources, the sensitivity of managed data, and strict regulatory policies, pharma organizations face the challenge of establishing a clear and modern Data Governance system. In the following, we outline the benefits Data Governance may generate, pillars to successfully implement it as well as selected use cases illustrating its potential impact.

Pharma Data Assets

At its core, the pharmaceutical industry has always been data-driven. Throughout the R&D and post-approval activities, pharmaceutical companies collect and analyse a vast amount of data. It is estimated that a related healthcare industry generates data at a higher speed than more consumer-focused social media & entertainment, e-commerce, and financial services companies – a trend we can confidently assume for pharma as well.⁴

Emerging technological and methodological advancements open up a plethora of value-adding opportunities across the pharmaceutical value chain. At the drug R&D stage, for example, advanced analytical techniques allow to solve sophisticated molecular modelling problems, to predict drug toxicity, and inhibition, or to select the most-suited clinical trial participants based on demographics and historic data. At the commercialization step,

business intelligence tools enable defining and targeting the right customers with the right material via the right channels.

However, a strong backbone of Data Governance that enforces correct data ingestion, storage, organisation, and maintenance is required to unleash the power of data. Below we identify some of the implications.

Data Governance Benefits

Data Governance is a framework for ensuring rules and regulations for handling data within a company. In practice, Data Governance defines what actions, on what data, in which situation, and by whom can (and should) be performed. Data Governance is centred around several data management dimensions such as data quality, metadata, data security and others. Combined, they yield multiple benefits (see Figure 1).

Data democratization

Data Governance secures common principles of data architecture, modelling, and integrity. This makes data unified and structured and understandable across the company. As a result, employees have a broader and deeper understanding of available data and have more opportunities to work with it.

Improved operational performance

Available data that is tagged and easy to understand boosts operational performance. In addition, with the help of data interoperability, exchange of information between



Figure 1. Data Governance Model

departments becomes faster and easier. Data Governance makes overall business processes considerably more aligned and coordinated. As an example, dashboards prepared for drug portfolio management can be tailored to respective data from the trial sites, internal labs, as well as supply chain and legal departments.

Higher speed and quality of data insights

High quality of gathered data and unified storing principles enable advanced analytics. According to Forbes data scientists spend up to 60% of their time cleansing and understanding the raw data.³ Applying Data Governance practices significantly reduces this workload and leads to a faster and better insight generation.

Transparent and controllable data ownership

One of the main elements of Data Governance is data ownership. It refers to assigning customized permission rights (e.g., disseminating, analysis, editing) to the data asset. Consequently, it becomes possible to precisely assign and manage access rights to all corporate data that is being generated.

Enhanced data security

According to HIMSS human error was the initial source of a severe security incident in 35% the cases.² More than 20% of

those cases resulted in a data breach or data leakage. Considering the sensitivity of the stored patient and drug-research data, its security is a prime objective. Unified Data Governance principles of data access, operations, and distribution significantly increase data protection.

Created opportunities for analytical outsourcing

Provided by clear ownership policies, pharmaceutical companies can grant selected access to their data and expand analytical outsourcing. While pharma historically relies on data analysis, access to cloud computing services and data-focused providers may enhance the analytical process drastically. For example, it becomes possible to set up selective, non-compromising confidentiality access to a large volume of real-world data to analytics partners to derive treatment insights. Another application would be a structured data-sharing system within research alliances.

Higher employee performance and satisfaction

The ability to provide high-quality, structured, and reusable data across corporate departments eliminates a large burden of tedious tasks for the employees. In particular, clinical trial data validation is an arduous manual process

that resolves database queries and inconsistencies by checking data accuracy, completeness, and quality. With baseline guardrails to data operations and standards, this process can be simplified or even fully automated. This would result in higher satisfaction rates, reduces turnover rates, and would allow employees to focus on value-generating tasks.

Recommended Implementation Steps

Data Governance ideation and adoption involve the alignment of data vision among business units, require adjustment of the operating model, and cannot be realized without applied change management. A definite roadmap to implement a unified Data Governance system effectively and efficiently is needed.

Outline corporate-wide data vision and strategy

As shown previously one of the main applications of Data Governance is data quality, availability, and operability across the company. Achieving that is impossible without an alignment between every business department. To do so, enterprise-wide data vision and strategy with the focus on a data-driven paradigm have to be defined and reinforced.

Define data guiding principles and domains

At the core of strategy and vision must lay FAIR data principles. Standing for Findable, Accessible, Interoperable, and Reusable data, they ensure that the baseline ideas of Data Governance are met.

Once the business units are aligned in their pursuit of Data Governance, a corporate data landscape and data products can be defined. A data product is ready to consume, combined data assets across data domains. A domain, in turn, is a logical cluster of data organized with a business lens across the value chain. A pharma-related example of a data product would be a patient treatment prognosis that is built upon data from genomic sequencing, electronic medical records, and internal historic medical records. Respective domains, in that case, would include biometrics, clinical operations, and pharmacovigilance.

Set up an operating model

To sustain Data Governance principles and domain coordination, a clear understanding of the operating model has to be established.

In this report, we refer to the operating model as the combination of appropriate organizational structure, defined business processes, required technologies, and engaged people.

The choice of organizational model depends on the number and relations of data domains present across the company. In Figure 2 we provide an exemplary case of how a pharmaceutical company can arrange its data domains and subdomains in a Data Governance network.

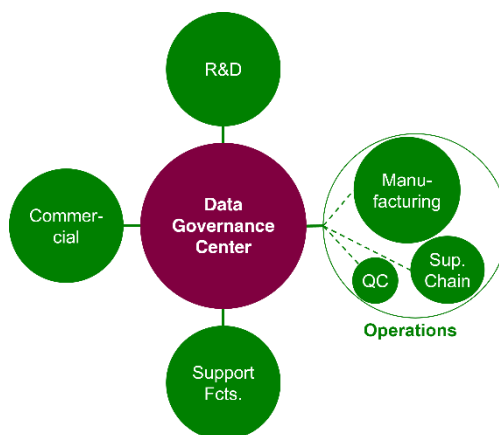


Figure 2. Exemplary Data Governance Domain Structure

The process part of the model involves decisions on what data will be stored, how it will be accessed and disseminated, and in which applications it is going to be used.

The technology aspect allows outlining required applications, platforms, and IT systems that will enable smooth execution of defined process steps (e.g. Aera, SAP NEXT, SFDC, etc.).

Lastly, team roles and responsibilities that reflect previous decisions must be defined. When conducting a Data Governance project it is advised to assign data stewards – accountable persons who secure data is accurate, in control, and readily available –, domain data experts, and cross-

domain Data Governance ambassadors. The exact staffing can vary depending on corporate organisational model.

Orchestrate change management

No matter how well-executed previous implementation steps are, Data Governance roll-out would not be possible without understanding, support, and active usage among the personnel. It is important to communicate the value that structured, properly governed data can offer to the team.

To achieve that, change management has to be applied. Different frameworks can be exploited to reach the target: Lewin's model, Nudge theory, or ADKAR model. The latter one, for instance, suggests building Awareness for the need of change, spurring Desire to be part of it by communication tailored benefits, providing Knowledge on how to utilize Data Governance, enabling stakeholders' Abilities to adopt it with provided tools and dedicated time, and Reinforcing change efforts through appraisal, attention, and rewards.

Combined, these actions reinforce data-driven corporate culture and promote transformational efforts.

Use Case: Streamlining Pharmaceutical R&D

The R&D process in pharmaceutical industry has advanced significantly with data-driven analytical capabilities becoming the key success factor.

For example, clinical trial premises are no longer the sole origin of valuable data – nowadays pharma shifts to Real World Data (RWD) and other new data sources. Industry research of Tufts Centre for the Study of Drug Development demonstrated that 70% of companies aimed to use data sources that are not exploited today.¹

At the same time we enter the phase of wider adoption of genome sequencing techniques. They are computationally challenging but enable so-called precision medicine – a prominent healthcare approach.

Consequently, more and more companies that specialise on advanced data analysis and predictive systems based on artificial intelligence and machine learning came into play. They provide capabilities that can be superior to those of classical pharmaceutical companies. Yet, collaboration with such partners can be problematic due to compliance issues.

Data Governance enables utilizing emerging analytical prospects and sustaining competitive advantage in a

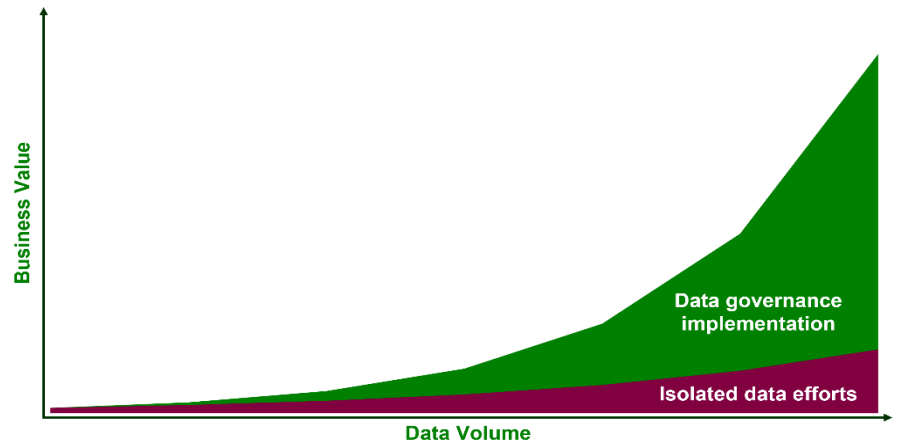


Figure 3. Data Governance Potential

large data volume environment (see Figure 3). This is achieved in the following 4 ways.

First, data is collected from various sources (e.g., internal research centres, clinical trial facilities, gene sequencing providers) under overarching guidelines of data quality, standards, and processes.

Second, it is stored within the company with defined ownership and access rules, making sure regulatory compliance is binding.

Third, backed by security policies and transparent data ownership, selective access to combined data is provided to analytics partner preserving confidentiality of sensitive data.

Lastly, enabled by interoperability of data and its clear, understandable structure outcomes of performed trials and related operations are fast-forwarded to regulatory institutions and communicated to key stakeholders.

As a result, managing R&D process under unified Data

Governance system allows to build effective cross-functional and cross-corporate data exchange, execute the process in a secure and compliant way, deliver insightful analysis, and reduce operational burden.

Summary

Pharmaceutical companies always operated a vast amount of data. A present increase in available data and analytical tools to mine insightful knowledge from it is paramount. Implementation of enterprise-wide Data Governance eliminates barriers such as low-quality, scattered, and unsecure data and enables data value generation. To conclude, if there is the right time to change compiled data from a liability into a business-driving asset, it is now.

Make a shift to data-driven business transformation through Data Governance with Vertwo – reach out to us for more information and use cases.

References

1. Getz, K. (2018). *Clinical Data Management Survey: Veeva*. Veeva Systems. <https://www.veeva.com/edc-survey/>
2. HIMSS (2022). *HIMSS Healthcare Cybersecurity Survey*. <https://www.himss.org/resources/2020-himss-healthcare-cybersecurity-survey>
3. Press, G. (2021). *Cleaning Big Data: Most time-consuming, least enjoyable data science task, survey says*. Forbes. <https://www.forbes.com/sites/gilpress/2016/03/23/data-preparation-most-time-consuming-least-enjoyable-data-science-task-survey-says/?sh=63530bca6f63>
4. *RBC Capital Markets: Navigating the changing face of healthcare episode*. RBC Capital Markets | Navigating the Changing Face of Healthcare Episode. (n.d.). https://www.rbccm.com/en/gib/healthcare/episode/the_healthcare_data_explosion