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Data Governance in a Zettabyte World

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LUCID CONSULTING 2023

DATA GOVERNANCE IN A ZETTABYTE WORLD: **IMPLICATIONS FOR R&D**

Data governance is the framework we use to establish strategy and objectives for enterprise-wide data and consists of five pillars, namely; digital strategy; policy, standards and processes; compliance; information architecture, data flow and integrations; and, reporting and analytics (Figure 1). Data management is the operational influx, processing and storage of data in a compliant manner. Both data governance and data management are becoming more complex.

The biopharmaceutical industry is faced with ever-increasing sources of data, a step-change in the quantity of data we need to collect and analyse, and a more challenging regulatory and data privacy environment. Over three decades the industry has moved from paper-based processes, through electronic capture of discrete data, to the ability to receive, collect and analyse continuous data from multiple, remote, patient-managed devices.

In this article, we will explore a high-level data governance framework; strengths, weaknesses, opportunities and threats (SWOT); specific challenges and an approach to defining an operating model to support the future of data governance.

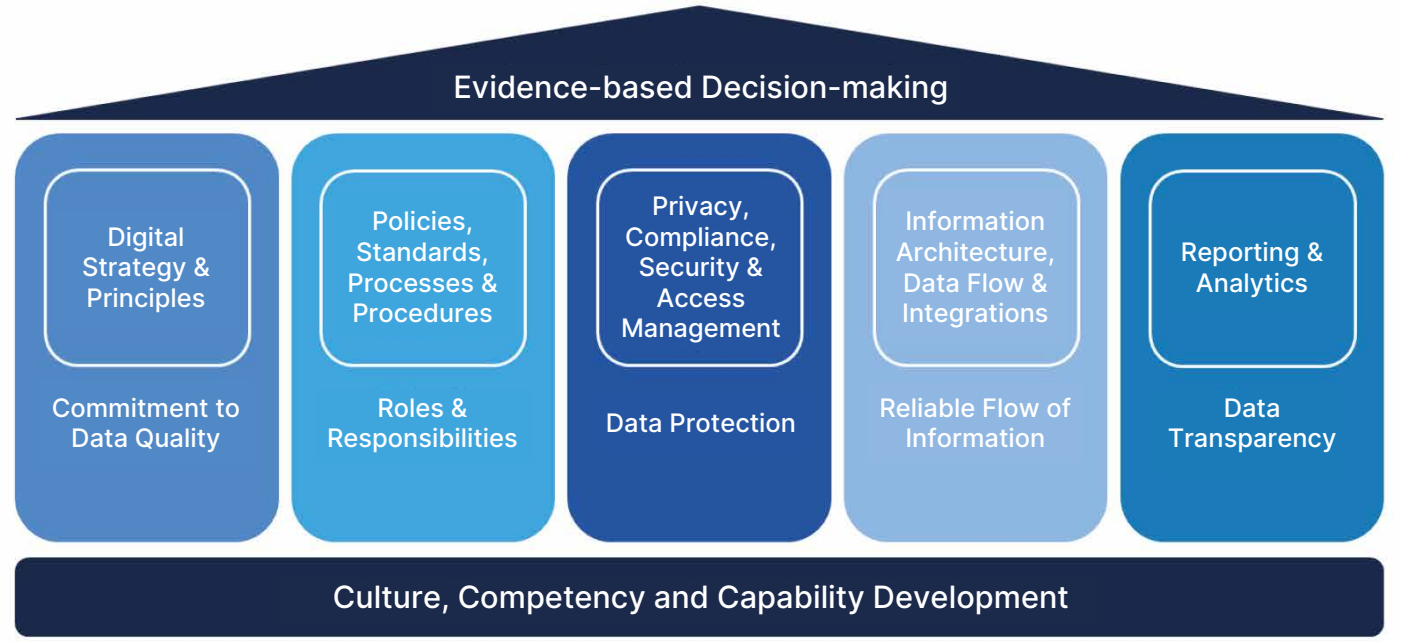

Figure 1. Data governance framework.

The data governance framework visualises the essential elements, with each element both critical and integral to successful data governance. The pillars of the framework are underpinned by the organisational culture and the competencies of its people. Definition and communication of a clear strategy sets the direction and expectations for the organisation. Architecture, data flows and integrations are governed through clear roles and responsibilities documented in the quality management system (QMS). Data are protected through controls and security and an individual's personal data protection is mandated by lawmakers through data privacy legislation. Finally, visibility to data e.g., through dashboards, provides transparency and promotes effective decision-making.

The data governance framework described is industry agnostic, and the principles can be applied at the enterprise level within a biopharmaceutical company. Our industry routinely meets the demands of the regulators with respect to data integrity in regulatory submissions, and has established risk management practices and a robust approach to quality management (Figure 2). The industry is also adept at protecting data and intellectual property through physical and digital means.

However, we are challenged by a patchwork of legacy IT systems and a historical desire for system customisation, resulting in high levels of year-on-year investment to maintain the existing infrastructure.

Within R&D, we continue to rely on manual and semi-automated processes and fall behind leading industries on the digital transformation journey e.g., financial and telecommunications[1].

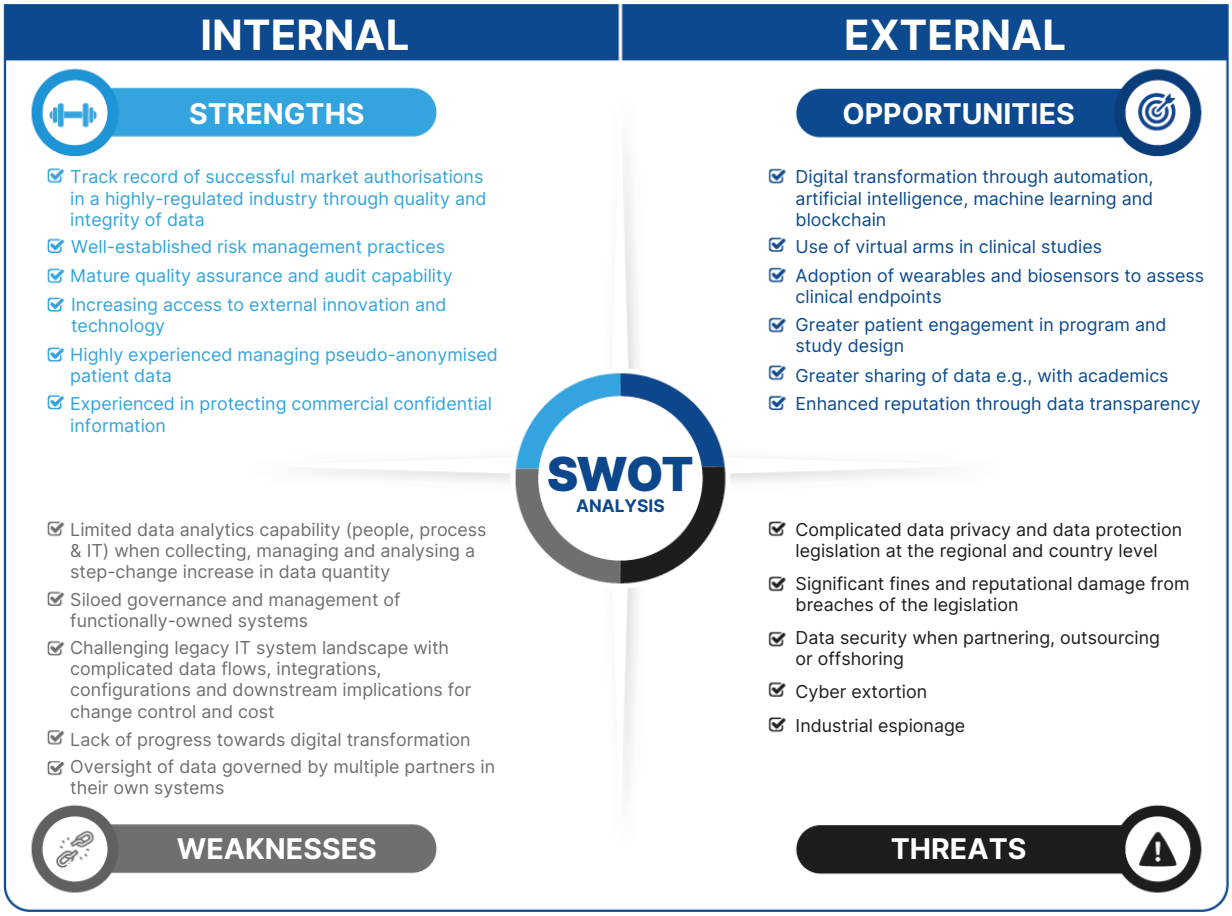

Figure 2. Indicative value and feasibility assessment of our 'Favorite 5' opportunities.

[1]Grebe, Rüßmann, Leyh, Franke and Anderson (2021) The leaders' path to digital value. www.bcg.com/publications/2021/digital-acceleration-index

R&D organisations are at the beginning of their digital transformation journey. Opportunities to automate and leverage machine learning have not gone beyond experimentation or use in highly discrete processes. Leveraging digital technology and connected devices e.g., wearables and biosensors, will drive greater data-driven insights and support the optimisation of patient care.

As with other industries, prevention of security breaches, fines and reputational damage remains critically important. In addition, maintaining awareness of local and regional data privacy legislation and how these interrelate with global clinical, medical and compliance guidelines continues to be a challenge.

IT Landscape in R&D

For many of the larger-scale biopharmaceutical companies, the IT systems landscape has evolved over time (Figure 3). Historically, these IT systems contained high levels of configuration, which are more difficult to manage on an ongoing basis than the off-the-shelf equivalent.

Integrations enable essential data flow between the various systems. The patchwork approach means that as IT systems come to the end of their lifespan and need to be replaced, a significant effort is required to understand the impact of incorporating a new IT system.

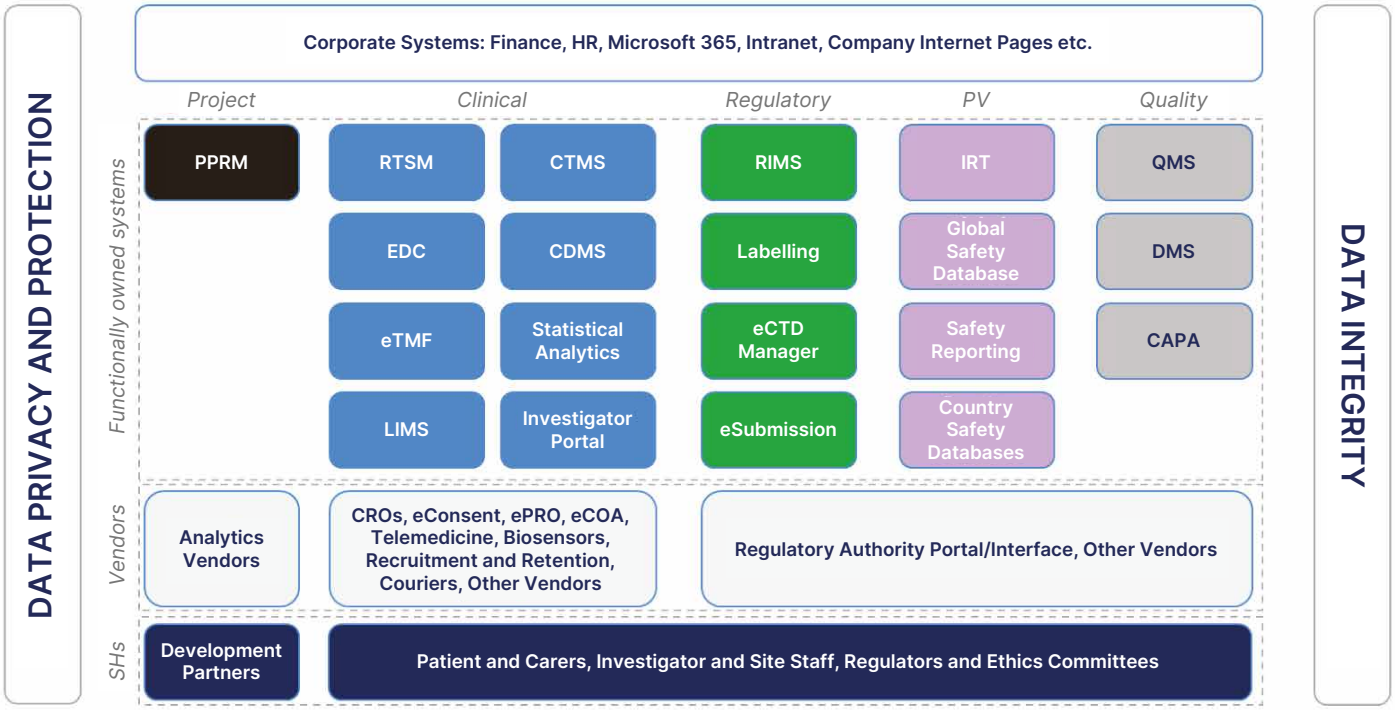

Figure 3. Simplified IT landscape across R&D

Challenges for R&D

Governance of data flows is made more complex when we consider new, decentralised ways of conducting R&D clinical trial activities.

There are four key drivers which make this more challenging than historical ways of working:

1. **Quantity and quality of data**
   The quantity and quality of data developed by digital devices is a step-change to what has been managed previously, requiring new, secure storage solutions and analytical methods to gain insights from the data.

2. **Network of digital vendors**
   The external digital vendor environment is becoming more complex. Device, software and application companies are able to provide insights directly from the patient. Supplier audits to determine computer software validation, incorporation of multiple, new external data flows into analyses and real-time access to medical data to inform patient safety are examples of the challenges faced.

3. **Data privacy legislation**
   Data privacy and data protection legislations require organisations to obtain consent, be transparent, be accountable and ensure security and accuracy of data processing. Within European Economic Area countries, the Clinical Trials Regulation EU No 536/2014 is now fully implemented. In addition to adapting to this new framework, sponsors must also interpret correctly and incorporate the General Data Protection Regulation Eu No 2016/679 into their processes and procedures. Individual countries and US States have different standards and legislation, adding to the complexity faced by sponsors. The international rules on the transfer of data between geographies must also be understood. Practical considerations include:

   - The validation of data acquisition tools,
   - Controlled access to data with defined access rights,
   - The type and scope of personal data to be collected,
   - Confidentiality measures for remote access to data,
   - Encryption and enhanced security levels for digital devices.

4. **Artificial Intelligence (AI)**
   The application of AI in medicines development is currently in its infancy, nevertheless, with potential for use along the entire lifecycle of a medicine. These potential uses include AI to:

   - Design molecules,
   - Accelerate the identification of target candidates,
   - Improve diagnoses e.g., imaging,
   - Manage data flow and correct data errors,
   - Manage the rapidly increasing volume of Individual Case Safety Reports,
   - Help a patient manage their condition.

   The FDA has been approving on average ~100 AI-based medical devices annually (2020-22), with the largest share in radiology[2]. Approximately, 99% of these go through the 510(k) regulation which requires substantial equivalence to another marketed device, and does not require clinical trials. Recently, the FDA published “Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products” requesting feedback from developers, manufacturers, regulators, academic groups and other stakeholders[3].

[2]Mesko (2023). The current state of 521 FDA-approved, AI-based medical devices. LinkedIn. 14th June 2023
[3]https://www.fda.gov/media/167973/download

As AI-based medical devices and applications have become more prominent, legislation is being developed which will provide greater regulation of AI in the medical-setting[4]. In June 2023, the European Parliament approved draft legislation that AI systems are overseen by people, and are safe, transparent, traceable, non-discriminatory and environmentally friendly. Compliance with this legislation will be in addition to other compliance systems such as the Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR). The law takes a risk-based approach to regulation with breaches resulting in penalties of 30 million Euros or 6% of worldwide turnover, whichever is higher. The *AI Act* is expected to come into law later in 2023.

Whereas there is significant potential for AI in the medical setting, regulators will be implementing legislation which protects fundamental rights, personal data and privacy. Data governance standards and policies may need to be updated to reflect these new technologies and regulations.

Designing an Operating Model

A framework to design an operating model is shown in Figure 4. The framework is hierarchical, with interdependencies between each of the operating model components.

Figure 4. Operating model framework to address governance of data.

Considering the interdependent parts of the model and taking a more holistic approach facilitates the development of a more robust and integrated design.

1. **Strategy**
   Establish a unified vision for the organisation's digital capability; broad engagement across the organisation is necessary. Alignment on a clear strategy to achieve the desired future is codified in design principles, risk mitigation and expected benefits.

2. **Process**
   Identify data processes and determine clear roles and responsibilities for data governance within the organisation. Capture this in a governance charter and supporting processes.

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

3. **Capabilities**
   Identify all existing data capabilities across the organisation. In a large biopharmaceutical company, there will be many such capabilities located within functions and across geographies. Define the new skills, competencies and digital investments required to transform data governance.

4. **Information Management**
   Outline the existing IT systems landscape e.g., corporate and functional digital systems and business process owners. Identify data governance gaps and overlaps to capture efficiency, simplification and compliance enhancement options.

5. **Organisation Structure**
   Identify functional data governance and reporting structures. Whereas line reporting and hierarchies may not require refinements, it will be important to determine resources needed to implement capabilities and ways of working. As part of the overall implementation, stakeholders will need to be supported through the change.

6. **Performance Management**
   Establish key performance indicators (KPIs) and key quality indicators (KQIs) to evaluate whether the objectives have been achieved and expected benefits of the transformation have been achieved.

Conclusion

The biopharmaceutical industry is at the beginning of its digital transformation, and R&D functions will need to invest in its long-term digital capabilities. Tackling the challenges and constraints of the legacy IT environment will provide the budget to gain greater data-driven insights to optimise patient care. Implementing a data governance framework underpinned by the organisational culture and the competencies of its people will guide the digital transformation.

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The author would like to thank Aidan Walker and Dimitrios Alexopoulos for their contributions.

About Lucid Consulting

Lucid Consulting is the consulting division in Lucid Group focused solely on the life sciences industry. We bring a combination of deep health & life sciences expertise with the capabilities, discipline and resources of a leading management consulting firm. Our consulting teams have worked extensively in R&D and Medical Affairs. We continue to focus on emerging trends, needs and best practices across the industry.

Abbreviations

PPRM: Project Portfolio Risk Management

RTSM: Randomisation & Trial Supply Management

EDC: Electronic Data Capture

eTMF: electronic Trial Master File

CTMS: Clinical Trial Management System

CDMS: Clinical Data Management System

RIMS: Regulatory Information Management System

eCTD: electronic Common Technical Document

IRT: Interactive Response Technology

QMS: Quality Management System

DMS: Document Management System

CAPA: Corrective Action/Preventative Action

ePRO: electronic Patient Reported Outcomes

eCOA: electronic Clinical Outcome Assessment

LIMS: Laboratory Information Management System