DATA GOVERNANCE

Data Governance Myths and a Foundation for Success

Advanced Technologies' Value Necessitates Reliable data.

While artificial intelligence, machine learning, and analytics dominate the headlines, biopharmaceutical companies' ability to benefit from these advanced technologies is typically limited by a lack of solid data governance.

Despite these limitations, many businesses are hesitant to take the needed steps to develop a solid data governance foundation. This white paper discusses common data governance myths and lays out the key components of a successful data governance program that can be implemented by any biopharma company.

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Introduction

With so many new and promising technologies within the grasp of the life sciences industry, it is tempting to ignore data quality and hope that the technology and tools can make up for the challenges across enterprise data. Organizations are expending time, money, and effort to deploy solutions such as data warehouses or data lakes and claiming "success," only to find out later that the data is essentially useless in the absence of proper data governance. Garbage In, Garbage Out. As a result, people are still spending the majority of their time finding and cleansing data, rather than conducting analyses and deriving insights.

Data Governance: An Often Misunderstood Concept

Poor data quality is the "elephant in the room." Everyone knows it's there, but no one wants to acknowledge it or address it. Even fewer people tend to be interested in hearing the term "data governance" uttered. This term can be intimidating to some organizations, and few have the appetite to undertake a data governance initiative. In some cases, this is due to a number of misconceptions about what implementing a data governance program implies.

Some typical reactions to the prospect of implementing a data governance program might include:

- "Data governance will hinder our ability to innovate"
- "Data governance won't work here because our business is different than our peers"
- "Data Governance means time-consuming, large-scale remediation efforts"
- "Data Governance is not worth it if we cannot quantify the value to be realized"

If poor data quality is the elephant in the room, these types of misconceptions are, in fact, "red herrings."

Debunking the Myths of Data Governance

"Data governance will hinder our ability to innovate"

Innovation is at the very core of the life sciences industry, and the perception that data governance acts as an obstacle to innovation can be a significant source of apprehension. In reality, effective data governance doesn't hinder innovation, but rather serves as a critical catalyst to *enable and foster innovation.* The ability to unlock the wealth of available information to derive insights is commonly viewed as a critical key to innovation. But if one cannot rely on that information, how can it possibly be leveraged to innovate?

Data governance shouldn't entail a heavy-handed approach that dictates how to go about innovating. It's all about finding the right balance between flexibility and standardization. Standardizing the way data is organized or categorized does not equate to standardizing the approach used to analyze or derive insights from that data, or how those insights are then used to innovate.

"Data governance won't work here because our business is different than our peers"

All organizations have their own nuances as it relates to their business models and business processes which make them unique, and approaches to data governance should be no different. Data governance is by no means a one size fits all prescriptive plan. Although common principles and themes will always be present, organizations should apply data governance frameworks that work for them. Ensuring personal data is secure, for example, is not negotiable, but the types of data considered most important to leverage and re-use may vary. Approaches should always be *tailored and fit-for-purpose* in a way that best fits each organization, its culture, and its needs.

"Data Governance means time-consuming, large-scale remediation efforts"

Some interpret data governance initiatives as one-time, large-scale remediation and "clean-up" activities, but this does not at all reflect the essence of data governance. Such activities merely serve to address the symptoms of poor data governance. Without addressing the issues that cause those symptoms to manifest, the need to perform these exercises will continue to persist. As a result, efforts will lose credibility with leaders and diminish any appetite for addressing data governance, as it creates a "Been there, done that" mentality.

The focus of establishing a data governance program should be centered on moving forward by ensuring *right-sized structure, standards, and processes* are in place. By doing so, you will alleviate the need for remediation exercises in the future.

"Data Governance is not worth it if we cannot quantify the value to be realized"

Companies sometimes get caught in the trap of trying to attach a quantifiable number to the value of data governance. Evaluating the value of data governance in the same vein as one might evaluate expansion into a new product line is a flawed approach. There is tremendous potential value in the wealth of available data that biopharma organizations already possess. Unfortunately, many organizations are often unable to leverage that data and optimize its value due to lack of data governance.

Organizations in comparable regulated industries do not attempt to attach a numerical value to having accurate, reliable, and secure data. The strategic *value of data assets is inherently understood*, and their curation and protection are expected, not merely a "nice

to have." The life sciences industry needs to shift its mindset, as shareholders, patients, and regulators not only expect, but also demand that data is governed properly. You cannot attach a number to the value of doing things the right way, but the cost of doing things the wrong way and exposing the company to reputational risk could be catastrophic.

Essential Components of Data Governance

While there is no one size fits all data governance prescriptive plan, at ResultWorks, we believe there are several principles and themes that are essential to any data governance program's success.

Clearly Understand the Challenges at Hand

In order to effectively address data quality and governance issues, there must first be a clear understanding of the types of challenges that exist. In many cases, the current state landscape isn't captured or summarized in a digestible way, making it difficult to secure buy-in to move forward. Until data quality issues are defined and categorized, it is very challenging to prioritize and address them.

Conducting a current state data governance assessment allows an organization to move from anecdotes to a common understanding of the issues. This can be an eye-opening evaluation as a light is shined on the overall

state of data quality, perhaps for the first time. The assessment should be performed at a level that meets the objective of identifying the key issues and themes so that the right approaches and solutions can be crafted to resolve them.

It is also crucial to gather a clear understanding of root causes, and to distinguish between issues that are systemic vs. those which are isolated incidents. The practice of root cause analysis not only applies to the current state assessment but should also be a staple of data governance as issues arise on an ongoing basis.

Employ a Right-Sized, Value-Based Approach

Depending on what the current state assessment uncovers, the prospect of addressing all data quality issues that exist may seem overwhelming. It's critical to identify the proper scope and priorities to focus on. Governance scope and activities should reflect a right-sized, value-based approach so that execution is pragmatic, and success is achievable.

When identifying scope and priority, it is important to consider:

- What categories of data are of most importance to stakeholders?
- Where are we exposed to the greatest data security, privacy, or compliance risks?
- What issues present the largest pain points and impact the greatest number of stakeholders?

- What issues result in expending the most time and effort investigating or resolving?
- Where are the opportunities for some quick wins?

Phasing in different data domains or business processes will enable teams to focus on tackling what's most important first and start delivering tangible results that people can see, touch, and feel. By doing so, momentum builds and stakeholders gain trust and confidence.

Strive for Continuous Improvement

The rollout of a data governance program is a significant milestone that enables the foundational framework and structure for an organization's journey. But achieving the ultimate objective of proactive and effective data governance is a long-distance journey, not a sprint.

A strong data governance program will ensure continuous improvement with an objective in perpetuity. Just as with all other areas of business, mistakes will be made, and lessons will be learned along the way. The key is to apply those lessons to refine and enhance your data governance standards and processes as the program evolves and matures. Establishing feedback mechanisms and metrics to measure and monitor the ongoing health of the data governance program is an essential aspect of ensuring continuous data quality improvement.

Building a Shift in Culture

Data governance has not historically been embedded within the culture of most life sciences organizations. As with any strategic objective, the commitment to achieving greater data quality must be driven from the top down. Leadership must ensure that accountability for data quality becomes an inherent part of the organizational culture. Data quality cannot be viewed as optional and done on a "best-effort basis." Instead, it must become an expectation as part of everyone's day-to-day responsibilities. Otherwise, there will never be enough energy to make it stick.

The preferred approach may vary by organization, but regardless of whether you decide to employ a "carrot" or a "stick" approach to driving conformance, strong change management will be needed. It's important to educate stakeholders and champion the cause to help everyone appreciate the need for data governance and understand the negative impact that results from poor data quality. In some cases, resources in the trenches may not fully be aware of downstream impacts and tend to think about the data they are generating as "my data."

Another needed shift in mindset that some may face is the heavy reliance on consensus-driven decision making. Driving for 100% consensus on every data governance decision is not a practical approach and can result in organizations stalling and churning on key

decisions needed to move forward. Individuals should be identified and empowered to make decisions that best serve the cross-functional interests as a whole, while objectively evaluating the perspectives of each impacted function. Without this type of framework, the amount of standardization, and thus the ability to leverage or re-use the data, will be limited.

These shifts in culture will happen over time not overnight. As perspectives evolve, the right behaviors are instilled, and the organizational mindset is shifted from that of "my data" to "our data."

Conclusion

Data governance may not be as exciting as artificial intelligence or machine learning, but it is a foundational ingredient to the data leverage that biopharma's desire. Only by applying data governance practices can the door be opened to even broader gains with the new technologies at our doorstep.

At ResultWorks, we believe data governance is an integral building block for innovation that all life sciences organizations, whether involved in emerging modalities such as CAR-T, or having a well-established portfolio with diverse product pipelines, should embrace. For those organizations in newly emerging areas, there is no time like the present. By establishing appropriate data governance programs early on, you will be able to avoid many of the headaches that so many others have already

encountered. For those organizations further along the maturity curve, it's never too late to ramp up your data governance efforts. There is simply too much at stake.

Now is the time to talk about the elephant in the room, dispel the red herrings, and put your organization on a path to proactive data governance that is tailored to best meet its needs. Only then will you be able to rely on your data to grow, scale, and apply technology and automation that will optimize both insights and innovation.

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For over 25 years, Astrix has been a market-leader in delivering innovative solutions through world class people, process, and technology that fundamentally improves scientific outcomes and quality of life everywhere. Founded by scientists to solve the unique challenges life sciences and other science-based business face, Astrix offers a growing array of strategic, technical, and staffing services designed to deliver value to clients across their organizations.

ResultWorks, an Astrix business, achieves success for our clients through skilled facilitation and exceptional management and leadership across Life Science domains from Research, Non-Clinical, Clinical Development, Regulatory Affairs, Safety, Manufacturing, and Pharmacovigilance. To learn more about how ResultWorks enables biopharmaceutical leaders' success, visit www.resultworksllc.com.

To learn the latest about how Astrix and ResultWorks are transforming the way science-based business succeed today, visit www.astrixinc.com or www.resultworksllc.com.

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