Master Data Management in Life Sciences Organizations
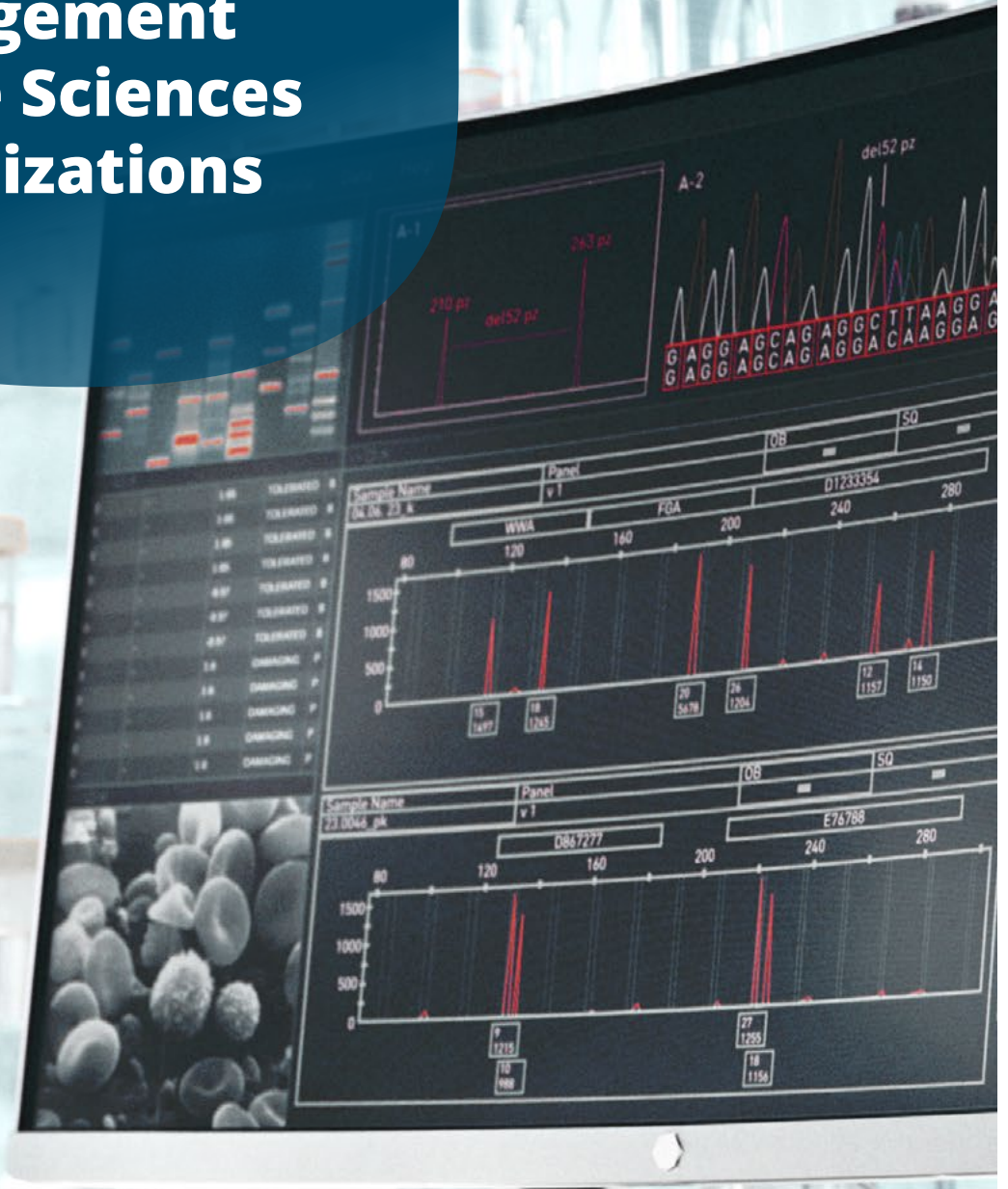
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Content

Introduction

Life sciences organizations are increasingly realizing that numerous business misunderstandings and misinterpretations about their data are happening across their organization. Therefore, the need for getting their data under control is more desirable than ever.

A common understanding of data is critical for effective system integrations as well as the successful implementation of unified platforms. As more organizations consider using emerging technologies, such as artificial intelligence (AI) and machine learning (ML) tools, the criticality will grow.

This common understanding must persist across systems and processes as well as throughout the value chain for teams to get the most from their data. For example, looming industry standards such as the Identification of Medicinal Products (IDMP) are motivating life sciences teams to pro-actively look across their organization and across data lifecycles to reach a common understanding.

The discrepancies in understanding can often be attributed to information silos and the implementation of departmental point solutions. When companies choose to transition to a unified platform, they often unearth discrepancies among systems that must be addressed prior to implementation. Increased data quality and governance can be achieved by defining a single source of truth as well as clear roles and responsi-bilities. Ultimately, this will ensure better patient safety and improved data-driven insights during drug development.

Defining Master Data Management

Master Data Management (MDM) is defined as *"a technology-enabled discipline in which business and IT work together to ensure the uniformity, accuracy, stewardship, semantic consistency and accountability of the enterprise's official shared master data assets."* [1] This definition captures the multi-dimensional nature of data while highlighting the complex challenge of achieving a common understanding. Emerging technologies are unlocking the data-rich workflows needed to take historic data and apply it to new questions and applications. This approach is changing the way organizations view and value data – from utilizing data for the optimization of current business processes to strategically transforming the business of the life sciences organization. The ways in which organizations capture and manage data assets are fundamental to the success of this approach, emphasizing the importance of *Findable, Accessible, Interoperable and Reusable* (FAIR[2]) data implementation.

1 www.gartner.com/en/information-technology/glossary/master-data-management-mdm
2 www.nature.com/articles/sdata201618

Figure 1. Unlock the potential of data through MDM – the business benefits.

Efficient & effective decision-making

Performance improvements

Growth acceleration

Digital transformation

Business Benefits of Master Data Management

In addition to solving the challenges of siloed, duplicated, and misaligned data across the enterprise, MDM is an enabler of multiple business benefits *(figure 1)*. Standardizing data within and across organizations facilitates automated connectivity, management and sharing of data.

Performance Improvements
A trusted view of critical data and reduced data errors enable optimized performance, thereby facilitating seamless data flow across systems and business areas as well as allowing global access to interoperable scientific and operational data.

Efficient & Effective Decision-Making
With high quality (master) data and better resilience of data usage, more accurate reporting and analytics are ensured. This enables data-driven insights in trial planning, execution and reporting as well as reduces the risk and increases the confidence in decision-making.

Growth Acceleration
When a single source of truth in data is achieved, a better understanding of the data, and thereby the products, is enabled. This leads to a better foundation for establishing an early pipeline based on precision medicine, ultimately resulting in faster time to market and reduced costs.

Digital Transformation
MDM establishes the foundation for efficient and effective digital transformation. With the improved data quality and ability to embrace new data from both internal and external sources as a result of sustainable MDM, the organization has a solid foundation for utilizing advanced technologies and data usage, such as advanced analytics, AI, Internet of Things (IoT), data simulations and more.

Potential Implementation Challenges
MDM initiatives come in all shapes and sizes. Sometimes they falter because the criticality of an organization's data quality is not fully understood, or it is handled in the background by day-to-day data firefighting heroes who manually solve it – this is time that is not evident to top management or is difficult to measure. MDM eliminates the need for reactive data quality issue solving and enables an organization to proactively manage data quality, which is critical for facilitating informed decision making and is foundational to creating a data-driven culture.

Scope can also be a concern when addressing cross-functional data. Who owns the data, who needs the data, the number of stakeholders and the amount of leadership support can all impact the progress and pace of an MDM initiative. Some of these issues can be addressed through organizational change management (OCM), but they still require time and attention. Business stakeholders should participate in setting the right metrics and business KPIs to ensure benefit realization and success. If the metrics are not connected to business outcomes, they will not drive business accountability and, ultimately, success.

Data is a strategic business asset and should be owned by the relevant Line of Business – and not in IT or by IT systems – and should be treated as such. It is important to articulate the broader value of a successful MDM initiative to all stakeholders as well as the specific benefits that are relevant to the overall MDM goals.

Implementing Master Data Management

Most life sciences organizations understand the value of their data and now have MDM on their data agenda. As these organizations begin to look at MDM, they must assess what they currently have and determine where they want to go.

There are three general components to an MDM initiative; the scope, timing and depth of detail will be different for each organization and will be driven by their unique goals.

Setting the Direction
Teams must first develop their unique data vision and strategy. This forward-looking content will guide efforts and define the scope of the MDM initiative. It establishes high-level ambitions and goals, assesses the current capabilities, and identifies the capability gaps. The vision and strategy generally articulate what is needed for the organization to make progress towards their overall MDM goals.

Modelling the Organization
Next, the team should turn their attention to designing a data governance framework. The framework should document the roles and responsibilities of governance bodies, define the common terminology or vocabularies as well as identify the data governance KPIs. This will be closely tied to an analysis of all the current data processes and lifecycles, which should include details of the systems, processes, owners, rules, and quality criteria for data which are ultimately captured in a data catalogue.

A data catalog is a detailed inventory of the organization's data assets and relevant stakeholders, and it is an integral element of an MDM framework and implementation. The data catalog ensures transparency and having one source of truth regarding the data assets in an organization.

The enterprise-wide availability of the data catalogue is essential and can vary from being supported by off-the-shelf MDM solutions to being presented on an organization's intranet. Regardless, the publication of the data catalogue depends on the organization's maturity, the systems being used and the scope of the MDM initiative.

Defining the Architecture
Data architecture is another foundational element of an effective MDM implementation. It includes data models, data and information policies, rules and standards that an organization uses to manage data and its flow through the organization's systems.

Data models are visual representations of an enterprise's data elements and the connections between them. By helping to define and structure data in the context of relevant business processes, models support the development of effective information systems. They enable business and technical resources to collaboratively decide how data will be stored, accessed, shared, updated and leveraged across an organization.

Finally, the technology stack represents an inventory of all the systems being used to achieve the MDM goals. This may include an MDM solution and multiple data lakes or data hubs.

MDM Use Cases

There are several use cases that illustrate the interesting opportunities that an MDM implementation can bring to life sciences organizations. As more organizations travel down the path of MDM and data governance, the foundation is built to reap the true benefits of the business use cases as exemplified below.

Optimizing Clinical Trial Conduct
MDM efforts in clinical trials and associated processes can facilitate investigator and site selection. Using performance and operational data, sponsors can effectively select and onboard the correct and most competent sites and investigators. Once onboarded, they can gain greater value from the investigator and site relationship by using metrics such as compliance, enrolment and retention rates as well as data management performance in order to rapidly identify the need for additional training and support. Similarly, leveraging broader data assets can assist in the identification and selection of the most suitable patients for a clinical trial, enhancing study start-up activities and helping to target the right patient populations more efficiently.

Enhancing Time to Market
FAIR data supports the reuse of data from research through drug development and commercialization, enabling faster, data-driven decision making. This allows product teams to set the right metrics to evaluate clinical endpoints and make informed decisions before spending money. Teams can use data standards such as IDMP to fully standardize product data, beyond the traditional boundaries of the Regulatory department to include discovery, manufacturing and more. This holistic approach strategically positions the organization to embrace important data trends such as real-world data and real-world evidence (RWD/RWE) that are changing how products are developed.

Getting the Most from a Unified Platform
Many life sciences organizations are moving towards or have already implemented a unified platform, spanning different business areas, which support broader collaboration and data sharing. A strong MDM foundation enables these teams to get more from their technology investment. The unified platform promises the potential to eliminate system, department, site and country information silos and streamline end-to-end processes. However, a seamless data flow and automated business processes cannot be achieved without standardizing data across R&D. MDM is often included in such cross-functional projects as an essential and foundational workstream. The number of legacy systems, maturity of the organization, number of external data partners, current data governance models and the organization's understanding of their own data will dictate the scope of the MDM component of such projects.

Conclusion

The idea of truly understanding the data, its pedigree and its context can be complex and potentially overwhelming. However, MDM holds the key to unlocking improved decision-making and increased efficiencies that impact the entire organization as well as the way data is collected and managed throughout its entire lifecycle. MDM continuously ensures that teams collect and maintain data assets with a common understanding as it moves throughout the organization's systems and processes.

It encourages the use of data visualizations and reports that bring new and potentially earlier insights to teams to make better, more efficient decisions. In this manner, it adds significant value throughout the enterprise and continues to create new opportunities to improve processes and reduce the time and costs.

About NNIT's MDM Services

NNIT offers a range of MDM advisory and implementation services that are based on a robust MDM framework. Our extensive cross-functional life sciences experience and data expertise inform our holistic approach in developing, implementing, and maintaining a successful data vision and strategy.

Using this framework, we help life sciences organizations move towards a common understanding of their data, implement sustainable data governance strategies as well as effectively use their data to support quicker and better decisions.

We help clients articulate the scope of the project, assess their unique needs, develop priority workstreams that align with their data goals and recognize the value of MDM. NNIT's MDM services enable life sciences teams to leverage data assets in new, more meaningful ways.

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About NNIT

NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it was our own. And of course, we meet the industry's strictest regulatory requirements. We apply the latest advances in technology to make our clients' software, business processes and communication more effective.

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