



Master Data Management

A Life Sciences
Industry Perspective



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Data-based Decision Making

Life sciences companies face a challenging industry environment – one characterized by lackluster pipelines, increased regulatory constraints, patent cliffs, and a need to constrain costs. Failing to adapt to the changing environment is not an option. As such, these companies look to adjust their business models by making the necessary changes to regain traction. As with any industry, decision makers look for some rational course to guide the decisions they make. Where do they look for what they need? In their data, of course. Life sciences companies are heavily dependent on accurate and reliable data to make informed business decisions. Such decisions could alter the company's strategic course; give rise to two former industry competitors merging; result in a promising new compound being in-licensed; lead to product divisions being bought or sold-off; or even progress or halt clinical trials.

Often companies are known to have silo-based applications where much of their data is found to be duplicated. The fit-for-purpose applications housing the data serve their business purpose, but in turn create other data-related problems. As you might imagine missing, incomplete, and duplicate data can be costly for a company when it is used as the basis for a company's decision. Although data is often found in multiple versions across disparate sources, there exists a solution to address the many challenges created by data in this situation - Master Data Management (MDM). Master Data Management consolidates data into accurate lists of data which serve as a single point of reference by utilizing a combination of tools, processes, governance, policies and standards. The resultant data is referred to as Master Data. Data which can undergo this process exist as different types of entities such as products, customers, employees, suppliers, etc. MDM can process data found across multiple system architectures, platforms and applications, and allow for sharing of consistent and accurate data within a department, division and more importantly across an enterprise.

The Inner Workings of MDM

Getting to consistent and accurate data entails identifying the entities along with their sources and metadata. This information is then used to model the master data by identifying information such as hierarchies and relationships. In essence, data modeling takes data and applies structure and organization to it such that it can be readily processed by a database. This task takes time, but is worth the effort as it helps to identify processes and how data flows. Tools import this information and begin the process of cleansing the data by completing tasks such as consolidating duplicates, creating source maps, and matching and merging, for example. Clean, consistent, and accurate data helps ensure quality data are available for those who need it when they need it.

It should be noted that getting the data clean is only half of the equation. Keeping it clean is the other half. Maintaining clean data is facilitated by incorporating, in part, Data Stewards and Data Governance into the MDM process. Data Governance provides authority and control over the management of data through the use of processes, methods, technology, and Data Stewards (among other possible governance representatives). It provides decision rights to data-related circumstances, identifies the decision-tree of

responses, and more. With Data Governance in place, one can be confident and rest assured that the data is of high quality and can be trusted. Data Stewards help ensure that the processes, methods, standards, etc. put in place through governance are upheld. They are considered the go-to person for data-related inquiries and matters as they intimately understand the data and the associated processes. With this being said, Data Stewards should represent the business, not IT. Likewise, MDM should not be considered an IT project, yet an IT solution used to address business problems and questions, and make informed decisions.

MDM Deployment Options

As organizations look to address business problems by improving the quality of their data with Master Data Management, the details of deployment will need to be thought through. Solutions can be deployed across an enterprise or within a functional area. Functional area MDM solutions are deployed to a functional area to meet their specific business needs. While this type of deployment offers a fit-for-purpose solution which can be completed for less costs and in less time than an enterprise solution, it does come with downsides such as the need to modify solutions when the business needs change, and the need to reconcile data that is shared with other systems. Historically, large companies deployed enterprise-wide solutions. An enterprise MDM solution provides that single version of the truth across all systems. Although costlier and a longer deployment timeframe, the long term benefits of increased productivity and organizational efficiency make it well worth the investment for some companies.

Another deployment consideration is whether the solution will be implemented on premise or in the cloud. Vendors with the largest collective share of the MDM market have traditional on premise solutions, although solutions in the cloud have become available for those who prefer that option. On premise deployment can be characterized as lengthy and costly (due to one-time implementation costs, ongoing maintenance costs of both hardware and software, and likely customization and upgrade costs). Because of the immense human and financial resources consumed, on premise solutions may not be a rational course of action for an entire enterprise already dealing with cost pressures and dwindling profits. A cloud-based solution would seem to be a logical choice, right?! Well, ironically enough some companies choose not to place their enterprise master data in a cloud due to perceived security risks.

Cloud-based implementations, unlike on premise, are faster, require no infrastructure to maintain, consists of browser-based accessibility and security, are scalable, economically worthwhile, easy to implement, and flexible for business changes. On premise implementation can take upwards of a year to complete, while cloud-based implementation can take only weeks. One great feature of cloud-based solutions is that upgrades are typically a part of the solution package. Also, as mobile device use in the field by sales force reps increase, cloud-based implementations will allow for integration of the MDM solution with mobile devices.

Prior to beginning any MDM program, the business goals or problems that will be addressed should be clear, and a sponsor of this endeavor should exist. Although an enterprise solution might be best to help resolve the issues with data-silos, a solution that takes a phased approach where MDM is deployed in a certain area first might be a logical path forward for some life sciences companies. This approach begins

the process of addressing the data issues impacting decision-making by starting small, but with an eye to a larger enterprise-wide solution. A phased approach will enable the company to see incremental improvements and realize some benefits more quickly as they attempt to adjust to increased pressures of the industry.

Practical Uses for MDM in the Life Sciences Industry

Master Data Management is used in multiple industries - banking, retail, government, healthcare, and life sciences to name a few. If we zoom in on the life sciences industry, we'll see that there are very practical ways in which companies are benefiting from its use. Take mergers and acquisitions (M&A), for example. The current state of the life sciences industry is one of consolidation. In an effort to address dwindling revenues due to patent cliffs and less than optimal drug development pipelines, companies look to M&As as a sort of a tourniquet. Data integration is a critical task that must be taken during an M&A through use of business processes, rules, and data standards applied to the data of the acquired company. During a merger or acquisition, MDM solutions can help companies integrate data across the two formerly separate enterprises in an effort to provide reliable and consistent data which will inform critical business decisions in a time of what might be considered tremendous flux.

The life sciences industry is also characterized by ever tightening regulations. Let's look at another example – compliance with the Physician Payment Sunshine Act. This is a law enacted in 2010 designed to increase the transparency of financial payments between life sciences companies and health care providers (HCP). Physicians and life sciences companies must work together. That's a given. The hope for this Act is that it will bring to light any conflicts of interests and deter any unethical behavior. A major challenge with compliance to this law is tracking the expenses against other expenses particularly since HCP payments and benefits can be captured in multiple systems. Having a single point reference that tracks and reports this information across the enterprise is crucial to being compliant. When life sciences companies want to know the accurate financial payments they've made to HCPs, they can readily turn to their MDM solution with confidence for the answer, and remain compliant with the Sunshine Act.

Life sciences companies have supply chain data that is dispersed across multiple business units and across multiple geographic locations. For finished products or even supplies (in the case of clinical trials, for example), an accurate view into the current inventory is key to operational efficiency. Some common issues faced with managing clinical supplies for trials include, limited view into the supply chain, demand fluctuations, and packaging and labeling changes to support randomized or blinded studies. Companies need the systems in place to effectively manage the clinical trial supplies. Drug needs to be at the site and ready for dosing subjects, and the trials need not experience drug outages. Master Data Management can help life sciences companies with visibility across the clinical supply chain, thus, creating efficiencies between the life science company and their partnering CROs as the MDM solution provides a single version of truth.

In keeping with the theme of clinical trials, let's turn now to clinical trial data. Clinical trials are a key component of the drug development process. Data across multiple trials must be aggregated to make sense of it for decision making. Massive amounts of data are collected as a part of clinical trials posing a challenge of managing it all. Other challenges with clinical trials data include, disparate sources existing for storing clinical trial data, legacy clinical trial data which is not readily accessible, minimized ease with which to perform analyses and glean understanding, and inefficient oversight of clinical trials.

Clinical data management aims to ensure that data generated from clinical trials is reliable, high-quality, and statistically sound. A sound technology solution, such as an MDM solution, can help companies more effectively manage their compound data and clinical trial data, and provide a consistent and consolidated view of data to support study start-up and execution; thus, expediting go no-go decisions. They can, for example, assess sites for enrollment performance and, if necessary, make more timely decisions in cases of poor site performance. Also, access to accurate and real-time data can lead to better compliance as regulatory reports can be generated more readily, and responses to regulatory inquiries can be addressed quickly.

One last example to consider in the life sciences industry exists with product recalls by medical device companies. FDA regulations regarding recalls mandate manufacturers contact all users of the device being recalled. Inaccurate or incomplete customer data housed in different systems poses a huge challenge with device recall compliance. This results in costly consequences as companies take exhaustive measures in order to reach all the users. Medical device companies can benefit from MDM solutions aiding their need to maintain regulatory compliance through the generation and maintenance of accurate customer data.

How Pharmica Can Help Your Organization *Get Better*...Data

By now you've gained an understanding of Master Data Management, and specifically, how the life sciences industry is benefiting from its use. To begin your company's journey with Master Data Management and reaping the benefits of such, here's how Pharmica Consulting can help. Pharmica offers service options in the following areas:

- **MDM Strategy Development:** We work with our clients to ensure that the strategy and the primary business objectives are aligned. The strategy aids the organization in discerning its specific needs (i.e. why Master Data Management is necessary), determine the capabilities an MDM solution should contain, etc.
- **Data Modeling:** Our team of IT experts will define data models that map entity relationships to improve data accuracy, and determine what architecture is required.
- **Data Integration and Management:** Our team of IT experts will leverage appropriate processes and tools to collect and consolidate data from disparate sources into a central repository, and conduct a cleansing of the data to generate that single version of the truth data.

- **Data Governance and Stewardship:** We work with our clients to devise mechanisms to manage their data and maintain the quality of it. This process entails identifying the roles, responsibilities, and associated processes.
- **Data Analytics:** We help our clients understand how to leverage data for decision-making using visualization tools.

Master Data Management is a journey and often clients benefit from the use of consultants to correctly set up their program, obtain quick wins, and ensure long term success of the project. If you have any questions about MDM and how to apply it to the life sciences industry, we would like to hear from you or attend Pharmica's MDM conference.