Paper DS08

Implementing a Metadata Repository Solution - A User Story

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ABSTRACT

With a Metadata Repository (MDR) solution increasingly seen as an essential aspect of a clinical development infrastructure, what are the important points to consider when an organization makes the decision to implement such a solution? This paper will take a practical look at the implementation process and provide practical insight to that process from both a customer and a software vendor perspective.

We'll look at the responsibilities and expectations of the customer and software vendor, project team considerations including, who needs to be involved, what skills and experience are required, and project sponsorship. Project prerequisites and scope, effective communication strategy, and out of the box functionality vs customer specific customization will be analyzed. We'll contrast pre-project expectations with actual experience and highlight those points deemed critical to the success of an MDR Implementation project.

INTRODUCTION

The modern day clinical trial is becoming increasingly complex, no longer reliant on data collected via case report forms (CRF). Multiple sources, and/or streams of data, are now commonplace as the science of the clinical investigation is becoming more sophisticated. New data sources and streams include: Omics data, wearable devices, specialty lab data, imaging data, companion diagnostics, healthcare data, real world evidence, disease and patient registries, to name a few. These sources must be integrated into the clinical development life-cycle as efficiently and seamlessly as possible to keep both clinical development costs in check and clinical development timelines nimble.

Companies that have chosen to invest in an MDR are generally looking for a solution that can replace a simple metadata management process driven by spreadsheets. A robust metadata management system, alongside a system to manage data definitions and specifications, will provide capabilities to address broader clinical development life-cycle efficiency and quality goals. Standards play an important role in both the quality and efficiency of clinical trial operations. By harnessing comprehensive and well-defined data standards, organizations can automate standardized and repeatable aspects of the clinical data life-cycle[1] allowing clinical development staff to focus their knowledge and experience on the novel and value-added aspects of a clinical trial.

The implementation of an MDR is a major undertaking and there are many factors to a successful implementation. This paper intends to provide valuable insight that will offer guidance for organizations entering into an MDR implementation project. The scope will cover, principles of an MDR, what it is, and what it can do. It will address the complexities of integration of an MDR with other clinical development systems which positions the MDR as the single source of truth for data definitions and specification. We will highlight points that functional units within a clinical development organization need to consider, because an MDR implementation cannot be successful without process redesign.

PROJECT SPONSORSHIP

An MDR project should be a Clinical Development Organization project with representation from all functions engaged in the clinical development life-cycle. It should not be a Data Management and IT responsibility only. With that in mind, project sponsorship must be at the executive management level and ideally tied to a Clinical Development incentive goal. Executive level sponsorship is essential to secure appropriate funding, scope, and timeline commitments. Executive level sponsorship also sets expectations and reinforces commitment to the project for the entire Clinical Development Organization. A successful MDR project is often a multiyear commitment, particularly if the project scope is defined as Protocol-to-Study-Report. This encompasses the full clinical development life-cycle and is often tied to broader operational efficiency or continuous improvement goals across the R&D Enterprise. A sponsoring IT organization is critical to ensure proper technical analysis and IT provisioning are in place from project inception.

Lesson: Clinical Development Executive Leadership and extended team sponsorship is essential.

PROJECT LEADERSHIP

The ideal customer project lead should have detailed knowledge of the clinical development business, including an understanding of the day-to-day workings of each functional unit, as well as knowledge of the IT infrastructure into which the MDR will be integrated. The project lead will have a dedicated IT resource to support the project through the implementation process, engaging IT analysts and additional specialists as required. The project lead will have a good network of contacts within the Clinical Development Organization and be able to identify key allies and functional area champions, or functional stakeholders, to help drive the project forward.

The vendor project lead must be the single point of contact for the customer and be able to translate business requirements to functional system requirements. A customer new to the product will get up to speed slowly, therefore the vendor needs to provide a sandbox environment to support orientation and education on product capabilities. To avoid problems during the implementation process, the vendor should share best practices and pitfalls learned with other customers. A configurable MDR system can accommodate most of the requirements a customer defines but that doesn't mean it should. For example, within a typical MDR configuration, maximizing functionality of the data to support legacy processes may correspondingly impact system performance and ongoing maintenance.

Customer and vendor project leads must facilitate the engagement of subject matter experts, from both organizations, at the appropriate points during the project. Key stakeholders and any functional group that will work with the MDR must be engaged throughout the project. Later changes to assumptions made early in the project will have major implications downstream, late changes can be avoided by ensuring early and cross-functional engagement.

Lesson: Stakeholders and key Clinical Development personnel must be engaged early and must be engaged often. Project team personnel must be given sufficient time to contribute fully and effectively to successfully implement project objectives.

PROJECT PLANNING

As with any project clear planning upfront helps avoid complications later in the project. The project can be broken out into a number of major deliverables, each requiring varying degrees of commitment, effort and resources (see Figure 1). Many of the activities will run in parallel and some of the activities are discussed within this section of the paper. Ownership of specific project deliverables will be clearly defined as either the vendor or customer responsibility. It is important to demonstrate progress at specific points during the implementation and an agile development methodology with clearly defined sprints will allow incremental value to be delivered during the implementation. Agile methodologies for implementing the requirements provide significant advantage over the traditional waterfall approach. Requirements are bundled into several well-defined sprints to implement the prioritized list, composed of configuration activities and product enhancements. Sprints are typically a few weeks in length to quickly implement a "minimum viable product" based on the latest set of prioritized requirements.
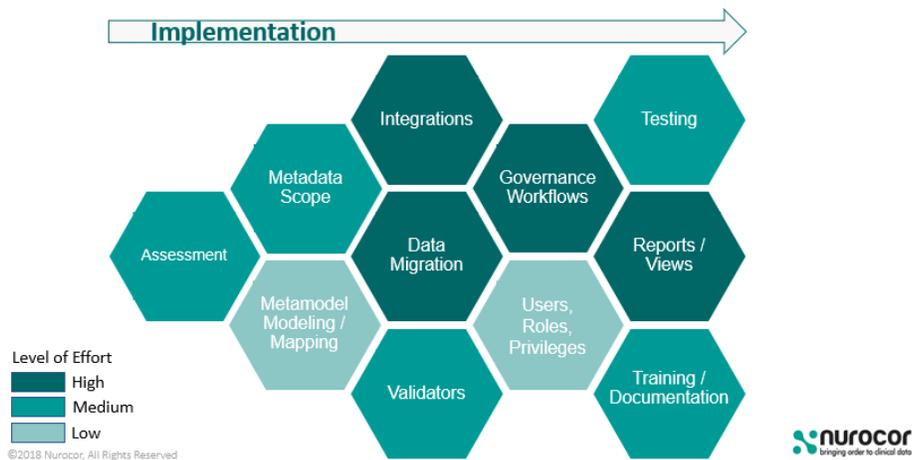

Figure 1: High Level Generic Project Schedule with Level of Effort Categorization

PROJECT REQUIREMENTS & SCOPE

A prerequisite to setting a manageable project scope is a robust set of customer requirements. The assumption on the vendor side is that a customer will have a solid and comprehensive set of requirements. The project should include a thorough assessment process where the vendor gains a full understanding of requirements, clarifying them with the customer from an implementation perspective and then providing best practice recommendations for satisfying the requirements. The customer must have a solid business analytical strategy laid out in advance that all members of the implementation team buy in to and agree to operate by. Requirements should be prioritized to enable the project scope to drive value for the customer.

The vendor needs to acknowledge that the customer will go through a learning curve as they become familiar with the MDR, its role in the organization, and how it integrates into existing clinical development processes. It is important to consider the impact on existing processes and/or the need to develop new processes around the use of the MDR and the enhanced content it holds.

As the project progresses the customer may identify new opportunities or revise original requirements due to a better understanding of the product and capabilities. Requirements gathering may then evolve to a more iterative process in the early stages of the engagement. It is therefore essential that the vendor provides sufficient orientation to the product upfront to allow a good evaluation of requirements. This can be a careful balancing act as any delay or ambiguity upfront will potentially cause delays later in the project. The vendor can help guide the customer through this process if they are given full access to process documents, data specifications, and subject matter experts, early in the project. Access to comprehensive and real metadata, that represents the full scope of metadata the MDR will house, is essential for defining a robust model for the metadata (metamodel). A full understanding of the clinical trials ecosphere is important including the EDC system and the defined process of trial data input, storage and mapping in support of downstream analysis and reporting.

On the customer side, one of the challenges is to ensure that key project personnel have sufficient time and availability to contribute to the project. This requires that management of project team personnel recognize their time commitment as an essential responsibility and dedicate a sufficient percentage of time to the project. Project team participation should not be an additional responsibility on top of the primary job. Based on experience, it is critical to distribute responsibility across a wide array of resources. Although the project lead may also serve as an SME, separate resources leading activities such as requirements finalization, testing, training and change management, should be identified and placed into lead or work stream coordinator roles. These are in addition to the array of IT professionals required to configure, install and thereafter manage the system.

A high percentage of requirements can be agreed upon upfront during an assessment phase, but new requirements may emerge, or existing requirements may be refined throughout the project. For example, the customer may have high level requirements at the beginning of the project, not discernable as such by the vendor. As the project progresses, additional details may come to light as the initial release of the system is used by the customer. Finally, as detailed user acceptance testing (UAT) is performed by the customer final refinements of the requirements may be required.

Lesson: The vendor and customer realize that finalizing robust requirements may be an iterative process. Full and detailed analysis in the assessment phase can and should reduce this along with the right number of experienced personnel providing SME input.

SYSTEM INTEGRATIONS

System integrations provide an opportunity for significant value to be realized from the MDR. Metadata can be served from the single point of truth to multiple systems. This ensures that common definitions across systems remain consistent. Systems integration is one of the more complex aspects of an MDR implementation. Timeline estimates should take into account the dynamics of working with other project teams, schedules and resources' commitments. This can often lead to additional time. Multiple integrations can compound the integration process often requiring cross-system coordination of requirements and resources. To be successful both vendors must be engaged in the solution, the customer must set expectations clearly, the vendors must agree on the technical aspects of the project, ensure resources are made available for the project (people and technology), and that timelines are agreed to. It will likely be necessary for vendors to set up sandbox instances of their products to support integrations development.

DATA MIGRATION

Data migration is the process of loading the company's metadata into the MDR in the agreed upon format and sequence. This can be a complex task depending upon model differences from original baseline data or

spreadsheets. The process can become involved when transforming metadata into a load format for automated loading. Depending on the extent of metadata additional resources may be necessary to support the loading. In the case of one vendor, a utility was developed to automate the loading of a large volume of data. The customer must have access to IT development staff able to develop additional supporting utilities and tools.

PROJECT EXECUTION
Once requirements and scope have been agreed upon and the assessment phase is complete the project moves to an execution phase. As mentioned several times already, strong project management is an aspect essential in this phase and communication becomes a critical feature at this point.

COMMUNICATION
It is important for all implementation project members to speak and understand the same language. Concepts and terminology used in the project should be clearly defined. It is important for the vendor to clearly explain uncommon or product specific terms to avoid any misinterpretation or potential confusion. It is not unusual for the vendor and customer to speak using the same words but actually mean something completely different. Validation of assumptions is critical; demonstration examples are a valuable mechanism for challenging assumptions and ensuring a common understanding.

Weekly project status meetings provide the mechanism for tracking progress and raising questions for broad project level input and escalating issues that may delay or derail the project. Meeting attendees must have authority for making decisions or ability to identify the path to overcome obstacles. Project managers will employ tools for monitoring issues and actions and tracking to resolution.

One of the most important aspects of communication is providing updates to the clinical development community that will ultimately be affected by the implementation of an MDR, either as users of the system or consumers of the content. Communication should be regular and repetitive. Research has shown that effective messaging requires seven repetitions before action is taken by the recipient[2]. Early engagement avoids later disappointment, so communicating early and often is a good way to engage future users of the system. New or unforeseen challenges may come to light during Q&A sessions. If challenges present themselves, clinical development staff can begin thinking about possible process impacts or improvements.

An effective communications strategy may include multiple elements. Email, newsletters, awareness sessions and forums, training, and website support may all be required depending upon the enterprise. For example, a large Pharmaceutical Company may operate globally with supporting teams placed throughout the world. Getting an organization ready must be well thought through with the comprehensive but realistic strategy.

SYSTEM INTEGRATIONS
System integrations require the customer to provide strong project management, but the vendors must take responsibility for delivering the agreed upon solution, within the specified timelines. Vendors must align on expectations around resources and commit to project timelines drawn up with the customer. Slippage by either vendor may have serious implications for the overall project timeline. It is important to engage business users to provide acceptance testing of the solution whilst in the development stages. This will ensure that the solution is fit for purpose but also that feedback is provided at a time when vendor resources are still available to make any necessary adjustments.

Integration with an EDC system is one of the most common and important integrations with the MDR. Each EDC system has its own idiosyncrasies that need to be considered when defining the best integration pathway. One common discussion point is which system is the source of truth for a metadata specification, particularly when study level metadata is housed in the MDR. A good MDR can capture all of the attributes required to operationally build an EDC study and that study specification can be pushed to the EDC system via various processes, automated or manual. Some companies chose to manage the global library standard within the MDR and utilize the EDC system to manage study specifications where the standard metadata is manipulated for study use. This approach makes assigning the source of truth a little more difficult, but business process can help the customer manage that complexity.

SYSTEM INTERFACE
Metadata curators, staff that utilize a metadata repository every day to develop metadata become familiar with the product and system interface easily. Occasional users that interact with the MDR are generally business users, who use the MDR to query a reference or review a particular standard or are likely to be study team members putting together draft specifications for a new study. Those users require an interface for viewing metadata in a way they

are familiar with. An MDR solution must be able to present metadata in a familiar format such as an annotated CRF, Define.XML, tabular report format or via a simple business focused interface.

AUTOMATION

With the MDR nearing implementation, Pfizer can now consider automation of processes that otherwise can be resource intense and potentially impact quality such as the regular and automated import of controlled terminology.

GOVERNANCE OF CHANGE

The MDR should support change allowing the enterprise to govern meta-data evolution through effective version management and change governance. Pfizer's governance process is dependent upon various TA and Global team's ability to review change, authorize, deny and prioritize implementation of requests in a timely manner. This is managed via another ticketing system and in the process of integration, required further integrations to the systems providing program and study detail. This combined with an interweaving of business process added complexity both technically and logically through changes in business process.

CONCLUSION

Lesson one: Do not consider an MDR project as solely the responsibility of Data Management and the IT functions. A well-defined MDR implementation strategy recognizes the needs of all functions within the clinical development organization. Accordingly, the implementation project must engage representatives for all functions within a clinical development organization to ensure needs are met and to challenge assumptions. A successful implementation project is a partnership between the vendor and the customer, both sides need to take time to listen to and understand the other. The vendor must be able to speak to the customer from a business process perspective. The ideal vendor partner has the technical expertise and a solid business knowledge of the clinical development process. From a customer perspective the implementation project is sponsored by senior management and there is a recognition that business process may need to evolve in order to make full use of an MDR. The degree to which the organization is ready or willing to do that will vary from company to company. The successful organizations are those that have already accepted the necessity for change.

REFERENCES

[1] How a Metadata Repository can Facilitate Automated Data Collection Processes, Judith Goud
[2] It's Not Nagging: Repetition is Effective Communication, Marton Jojarth

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Thanks to Dan Ringenbach for the project planning graphic and providing input during the development of this paper.

RECOMMENDED READING

Recommended reading lists go after your acknowledgments. This section is not required.

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