How to find the best MDR solution for your organization

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ABSTRACT

Are you satisfied with the current Metadata Repository (MDR) solution strategy at your organization? Are you looking for a more efficient, beneficial MDR platform or to be more educated on the crucial factors of MDR solution?

Metadata Repository (MDR) has become essential for Life Sciences industries to store and manage standards (e.g., CDISC and company specific standards) and terminologies. However, many of organizations are struggling with current Metadata Repository (MDR) solutions because of version controls of standards, instabilities within systems, resistance of study teams and other issues.

The paper will elucidate common challenges, concerns and typical user complications encountered during the MDR selection and implementation process. The paper will demonstrate various solutions to these frequent issues. The paper will also introduce some variables to consider in MDR selection process – defining the business objectives of MDR solution, Proof of Concept (POC) and evaluation of MDR functionalities of different solution. The paper will introduce good practices to MDR implementation processes, including System Development Life Cycle (SDLC) and integration of MDR with in-house systems (e.g., SAS® and EDC) and change management.

THE INTRODUCTION OF MDR

MDR is metadata repository. It is the system that develops, stores and governs the metadata. It also provides work flows of how metadata could be developed, managed and governed. It can also manage the users such as requestors, developers and approvers. By granting the proper access to users, MDR helps the organizations to manage and govern most important assets – metadata.

WHY MDR?

The emergence of standards requires the organization to manage standards metadata. Using MDR, the organizations can manage standards metadata systematically and in organized matters. MDR can manage the followings:

- Industry standards - CDISC, CT, HL7, MedDRA, WHO Drug
- Company specific standards – codelists, value metadata
- Machine readable transform metadata
- Version controls
- Work flows
- Users (e.g., requestors, developers, approvers)

MDR SELECTION PROCESS

Defining business objective of MDR

The first thing that organizations need to define in MDR selection process is defining the objectives of MDR. The most common business objectives of MDR could be the followings.

- Regulatory compliance
- Management of standards
- Developing company specific standards
- Version controls of standards
- Standards governance process
- Standards metadata driven clinical trial artefacts development – SDTM, ADaM and TFL
- End to End standards driven process from protocol, data collection, SDTM, ADaM, reporting, analysis to submission

Proof of Concept (PoC)

Before buying a car, we usually do test drive. Testing driving helps us to understand about the car and service. It plays a major role on our buying decisions. MDR is a big investment for the organization, so PoC is strongly recommended before MDR solution selection. The organization needs to check the followings during PoC.

- MDR capability
- Hands-on MDR testing by users
- Real time testing
- Real time data
- Vendor service and its business domain knowledge

Evaluation of MDR

Before selecting the final MDR solution, the organization needs to compare the original business objectives with the capabilities of MDR choices. If MDR choices do not satisfy all the business requirements, the organizations need to ask MDR vendors to add or prioritize the business requirements then select the best MDR solution based on organizations' priorities. To select best MDR solution, the organization also need to consider the followings.

- MDR technology
- Business domain knowledges in CDISC standards and pharmaceutical drug development process
- System integration
- After services
- Cost vs value

MDR SOLUTION IMPLEMENTATION

MDR solution implementation is complex process. It will involve a lot of stakeholders such as IT, standards team, programmers, statisticians, data managers and many more. MDR implementation requires the followings.

- System Development Life Cycle
- Prototyping
- Integration with other in-house systems
- Standards knowledge / team building
- Change management

System Development Life Cycle (SDLC)

SDLC can help the organizations to implement MDR into their IT premises. The organization can use either waterfall or agile approaches, but it is strongly recommended to use agile approaches in MDR implementation. Standards keeps improving and evolving, so agile approaches will be more appropriate in SDLC of MDR. The waterfall approach is not appropriate for ongoing changing of requirements.

Prototyping

A picture is worth a thousand word. A good prototype is worth a thousand pictures. It is strongly recommended to build MDR prototype before a full implementation. Prototyping is basically building quick, small scale MDR system. The prototyping of MDR can help the organization in the following ways.

- Evaluate quickly and redefine in a series of quick iteration.
- Implements the quick, iterative approach rather than a full, long implementation
- Get a quick feedback and apply.
- Helps the organization to resolve little critical problems one by one.
- Helps built-to-learn mindsets.

Integration with other in-house systems

The greatest benefit of MDR is standards metadata exchange with other systems. So, MDR system should have data exchange tools such as REST API, so MDR can feeds standards metadata to other system. This will lead standards-driven end to end clinical trial drug develop process as shown in Figure ***1***.

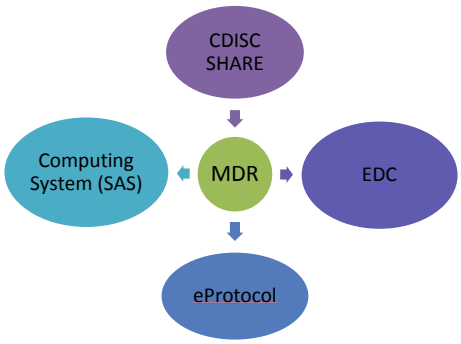

Figure 1- Integration of MDR with other systems

Standards knowledge / team building

MDR solutions is not only about MDR system. It starts from standards team who develops, stores and manages

standards, so it is very critical to build the standards team along with MDR system implementation. The organization also needs to build standards knowledge to keep up with the demands and futures of standards evolvement and regulatory requirement to use MDR effectively.

Change Management

One of the most difficult part in MDR implementation across organizations could be a change management. According to a statistic, 70% of all change initiatives fail mainly because of negative attitudes and unproductive management behavior. Most of people do not want to change. Probably, most programmers and statisticians might not welcome MDR solution, but be happy with excel spreadsheet. We recommend the following change management practices for MDR implementation.

1. Create a shared business objective. Both leadership and users should participate in creating the business objective of MDR strategy.
2. Engage and communicate across the organization. It is strongly recommended to communicate MDR implementation plan early and engage all the stakeholders early. Most of stakeholders should be engaged in MDR selection process as well.
3. Support the team. The organization should provide adequate trainings for MDR. It can't expect the users to switch from excel to MDR over night. The transition requires trainings and times.

CONCLUSION

MDR will bring a lot of promises such as standards driven E2E drug development process. In order to utilize a full potential of MDR, the organization should understand their own business objectives, select the MDR solution that fits the organization objectives, and implement MDR in a way that it serves the users and the business objectives.

REFERENCES

ACKNOWLEDGMENTS

We would like to thank Clindata Insight teams for their feedback, inputs and review.

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