Paper DS14

Common-Sense Tips For Weaving Governance Into An MDR

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ABSTRACT

The industry is seeing an upsurge of sponsor organizations attempting to unite their standards governance with the technology that houses and manages their standards: a Metadata Repository (MDR). It is a project that varies according to the differences between sponsors regarding architecture, culture, process, and priorities.

- What are your existing governance pain points without an MDR?
- Are your user requirements for how governance functions in the tool thorough and testable?
- Are there legacy components of your governance that could be revamped or replaced?
- How will your clinical teams interact with the MDR?
- What are your key integration points across the clinical data architecture?

Having spent time in standards governance on three sides of the pharmaceutical industry - sponsor companies, contract research organizations, and software vendors - I intend to explore some helpful considerations and beneficial approaches to overlaying governance processes on top of MDR technology.

INTRODUCTION AND BACKGROUND

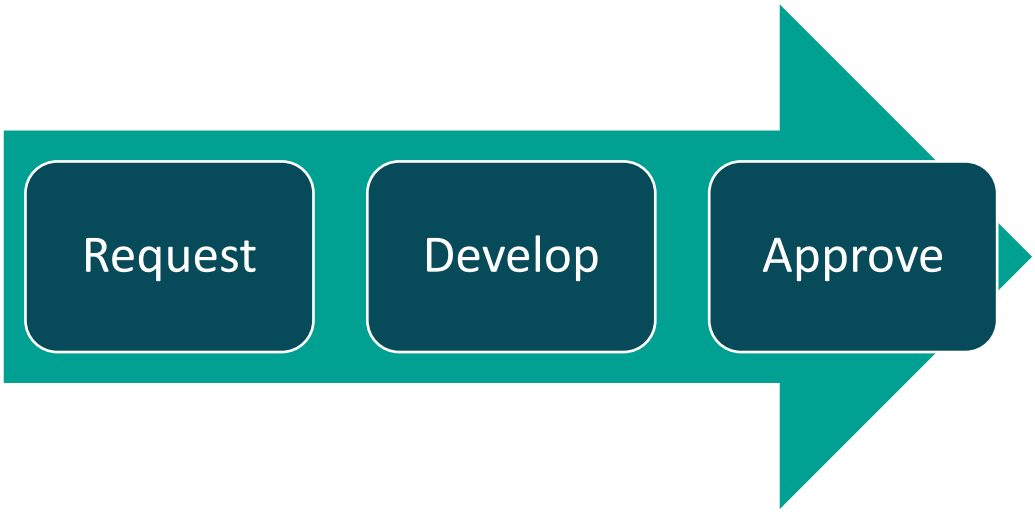
Standards governance groups are a key piece for adherence to the regulatory standards demanded of a sponsor's clinical trials, the methodology behind proving safety and efficacy of their medical therapy. They are also tasked with ensuring that standardization helps the sponsor deliver expeditious, successful submissions that result in faster time-to-market for their products.

While sponsor organizations vary in the resources for and the extent of activities that they ask of their standards governance group, in some form or another they are typically responsible for the following regarding clinical data standards:

- Oversight of standards, both industry and sponsor-specific

- Development of standards efficiently and consistently across the clinical trials organization
- Proper usage of standards that achieves efficiencies for shorter clinical data lifecycle

The governance groups utilize repeatable processes to perform an assortment of actions to fulfill their responsibilities to the sponsor organization. Each sponsor has their own priorities and focal points that determine the exact actions to be taken. However, at a high-level, they can be grouped into 3 basic governance steps:



- **Request** – Submission of a request to the Standards Group explaining the need for a new standard or revision to an existing one, including actions such as request triage, impact analysis, and escalation.
- **Develop** – Leveraging the decisions and information from the Request stage to tangibly create or modify the metadata that describes the standard, including actions such as metadata definition and peer review.
- **Approve** – The authorization of the request with a specific context and method for general consumption by the larger clinical organization, including actions such as promotion and export.

The other piece to the standards governance function within sponsor organizations is the MDR technology that handles the standards metadata. While there do exist MDR tools in the industry that are solely for housing and browsing of the metadata, for purposes of this paper we will be focused on the type of “Next Generation” MDR tools that incorporate governance workflows within the tool itself to allow standards teams to execute their processes in conjunction with the development of the standards metadata, all within one application. The centralized governance facilitated by this level of MDR begets adherence to standards across the organization, and thus consistent data meaning and easier integration of data for analysis and submission purposes.

Essentially, the MDR supports the standards governance team by putting the following instruments into their hands:

- **Oversight** - A centralized single source of truth for the standards and the ability to administer access to them based on group/role, in conjunction with the logging and tracking of change requests to those standards
- **Control** - Rigorous control of the standards metadata including logical relationships between metadata, impact analysis of changes, and auditable metadata demonstrating the who/where/when of changes
- **Workflow** - Prescribed electronic governance activities that efficiently move a request from submittal to approval while simultaneously providing meaningful metrics that display the performance of standards governance
- **Action** – At a study level, the capability to search, explore, and utilize the standards most appropriate for the trial, and the export of the standards metadata to the clinical systems

THE PAIN POINTS

All standards governance teams experience some challenges in their efforts. Differing priorities and unhealthy choices made within the clinical processes surrounding the clinical data flow provide some of the discomfort, while others are the unavoidable, natural dynamics of the never-ending "standards vs innovation" debate within all clinical organizations. Regardless of the source of the "pain point", sensible governance process design can help alleviate the pain of situations such as:

- Standards released "at risk" before approval, being only partially developed and vetted
- Limitation of the standards team to effectively prioritize and deliver approved standards due to the disconnect between the tracking of requests and the resulting developed metadata
- High rate of usage of "one-off" structures due to frequent clinical team insistence upon exceptions for their specific study
- Over-reliance on clinical process milestones such as First Patient In Date to drive the standards process, disregarding the length of time needed to develop the new or modified standards
- Misalignment of existing clinical execution processes with new standards development processes, such as the standards requests deadline scheduled after the testing for the eCRF build
- The use of an unstable draft protocol to determine standards requests, resulting in much re-work in the development of the standards

ANALYSIS AND DESIGN

At the beginning of any MDR implementation project, there is a thorough analysis and design phase that addresses everything from metadata modeling to data migration to integrations to governance workflows. The scope of this paper will specifically target the workflow component, and some considerations when attempting to overlay governance processes on top of MDR technology.

It cannot be overemphasized that getting the governance process right **before** implementing the software is a critical foundation towards effective standards governance within the tool. An honest and comprehensive evaluation into the existing governance processes is a must, because a simple yet purposeful, tool-agnostic design of the governance process enables the standards team to quickly incorporate the tool into their everyday practices and be up and running in no time. If the analysis of the governance is more cursory than complete, there is a high probability of the resulting workflow development to be full of disconnects and re-work.

Simple process design leads to efficient workflows. In my experience, too many standards governance groups attempt to complicate and overstretch their process in their zeal to fully utilize the functionality of the tool. However, this can lead to convoluted workflows that subsequently burden the standards team members. An example would be an implementation creating complex branching within the electronic workflows, only to discover that once implemented these additional handoffs strain their existing resources and add bottlenecks that weren't there prior to the MDR. Keep in mind that once the MDR is in place, there will soon be much experience gained within the tool to create a knowledge base from which the standards team can later refine/expand their use of the MDR workflows.

Analysis of the governance processes into the electronic workflows of an MDR provides an exceptional opportunity for process improvement. Not every single little existing governance task, activity, or responsibility needs to be incorporated as an electronic workflow within the MDR. There may also be issues of governance scope that affect the functioning of the team. For instance, perhaps the standards team is overwhelmed from the enormous number of requests heaped on the team without the level of resourcing needed to address it properly. The analysis and design associated with an MDR implementation is the perfect time to address this unmanageable workload by refining the scope of governance. This could be as simple as scaling down the number of details being governed for the eCRF builds to only the most important features of the eCRF, or as complex as allowing CDISC-knowledgeable programming resources to do the hands-on mapping of collection variables to SDTM.

The foundation for any software implementation is the advance compilation of business requirements. For an MDR implementation, this includes requirements that detail every task, action, and activity of the governance process that is needed to be included in the governance workflows in the tool. It cannot be stressed enough that these business requirements be drafted, reviewed, and approved well **before** the technical development starts. If these requirements are cobbled together on-the-fly at the same time as the technical development is occurring, there **will** be the inevitable misunderstandings, misalignment, and re-work of the developing workflows in the tool. Considerations of the following are just a sample of the types of requirements that are necessary up-front:

- Explicit information in the impact analysis that is critical for the standards team to determine if a requested change is warranted
- Detailed matrix of business roles vs system roles/permissions
- The exact nature of how a request will be escalated

- Decisions/actions/checklist that are needed to accurately route the request to the appropriate standards team member
- Critical governance metrics needed by the standards team to present to their leadership and the organization at large, not to mention the metadata in the MDR that the metrics are based on

There is a tendency to force as many customizations as possible into the MDR implementation while the opportunity for progress is there. In my experience, this often leads to loading more work effort (configurations, upgrades, etc.) into the implementation than is feasible considering the concrete nature of timelines usually associated with implementations. It is therefore advisable to evaluate customizations as they are revealed, placing them in a business necessary vs nice-to-haves set of lists. Educated prioritization and pressure-testing each "business necessary" item will undoubtedly make the implementation run more smoothly and productively.

MANAGING THE PROJECT

Once the MDR implementation is underway, managing the project will likely be a challenge given that an MDR is still a tool that is relatively unfamiliar to the IT organization, that more clinical business resources than normal will need to be involved, and that those clinical resources will need to participate heavily in the requirements, design, and testing. An approach, regardless of agile or waterfall methodology, that addresses and incorporates the following concerns will fare better in an MDR implementation:

- Firm commitment from the correct subject matter experts (SME) resources to do quick off-line review when required. While meetings are necessary to resolve issues among a group, individual off-line SME review is the key to keeping Develop-Review-Approve cycles as short as possible. To ensure this, obtaining commitment from the SME's leadership proves extremely valuable as well.
- Allow for some real-life use of tool by the people that will be using it day-to-day before making the final tweaks of the workflow customizations. Standards team resources might have listed requirements without the full breadth of experience to know how it will play out in practice. For instance, insisting upon email notifications at every juncture in the workflow often leads to a crippling number of notifications in one's Inbox, resulting in an agonizing signal-to-noise ratio there.
- Resist the temptation to incorporate every idea that surfaces beyond the development phase of the implementation. It is ok to build a list of "future enhancements" that can be implemented after Go-Live. In other words, don't put project timelines at major risk in order to build the entire world.
- The User Acceptance Testing (UAT) phase of the project is an important component of an MDR implementation, as the users not only have to learn a new tool, but they often also have to adopt a new mindset of managing metadata in an MDR rather than spreadsheets. Thus, it becomes essential that the users/SMEs be heavily involved in UAT well before it begins. They need to be the ones writing the UAT scenarios that spell out the day-to-day activities the MDR will be used for, reviewing the scripts that the technical script writers have

authored, and executing the scripts to ensure the user experience and expectations are appropriate.

CONCLUSION

MDR tools with governance workflows can provide a tremendous lift to a sponsor's standards team by centralizing and streamlining how the standards are accessed, defined, and managed. Timely turnaround for new requests and quick, reproducible application of standards in trial execution will breed a significant measure of trust by the clinical organization regarding standards, enabling collaborative rather than antagonistic interfaces with the clinical teams who can most benefit from the use of standards.

Considering this, the implementation project itself inexorably affects how the standards governance process is woven into the MDR workflows, thus affecting the outcomes with the clinical teams. Thorough analysis, proactive requirements, and engaged testing are but a few of the necessities for the implementation project execution to produce these positive impacts.

CONTACT INFORMATION

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