

Is your library a success: manage and measure conformance across partners and projects

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ABSTRACT

The creation of a standards library is only the first step in the process of implementing standards within your organization. Being able to monitor how your library is being used is critical to having a library that meets stakeholder needs. Measuring conformance is not just about "policing" how well teams are complying with your standards, it is also crucial for having a robust library that can grow with your organization. A library is successful if people are using it, and using it appropriately.

This paper describes a solution that facilitates better collaboration between partners and supports continuous process improvement by minimizing the risk that your library is not being used appropriately and allowing for the objective measurement of the use of your library across projects and across partners. These metrics can then be used to improve conformance such as identifying areas for process improvements or training needs.

INTRODUCTION

There are two key components to maintaining a successful library of data standards. The first is to make it easy for end users to implement the standards correctly (or conversely, make it difficult or impossible for them to not use them correctly). The second is to monitor the use of the library and use this understand objectively how the library is being used and identify areas for improvement. This paper will briefly describe a solution that includes both of these key components, and take a closer look at how conformance data may be used to identify where to concentrate governance and training efforts.

A data standards library is not a static entity. There is often a lot of focus on defining content and also how to govern that content so that updates and additions are managed in a controlled manner, but there is rarely an organized, data-driven approach to where these efforts can be most effective.

In the early stages of rolling out a data standards library, there is not usually any historical information available regarding what metadata are most commonly used in studies. Without a formal way to track the metadata across studies, there is no way to target where the majority of the work should be spent. Anyone who has been involved in defining standards within an organization has undoubtedly had difficult conversations about what is absolutely necessary and what has been included in studies historically (although no one can remember why that items was added). Once you have your initial library defined, you now have the capability to start collecting that data and making better informed decisions on future releases of standards within your organization.

THE TOOLS

The key to having data-driven process improvement is (obviously) having the data. The solution that is used by the authors to accomplish this several key features as shown in Figure 1:

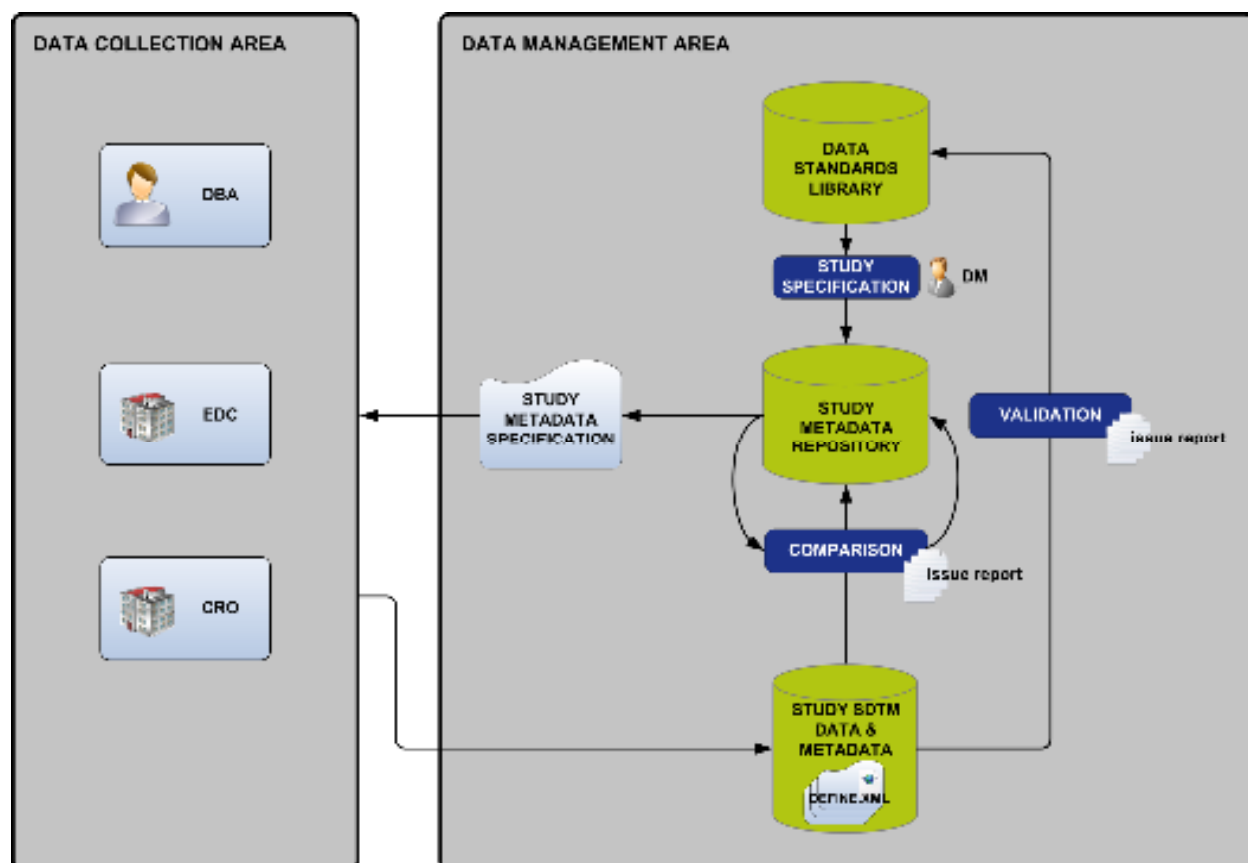


Figure 1: Overview of Data Standards and Study Specification platform

To eliminate the possibility for users to deviate from the data standards, the platform includes an interface for defining study-level metadata via selecting directly from the appropriate libraries. These study-level metadata can then be provided to internal or external partners to use when defining the data collection and tabulation (SDTM) datasets.

In addition, the platform includes an interface for checking the deliverables from these partners against the study-level specifications, as well as against any version of the data standards.

The features of this platform that are critical to the topic of this paper are:

- A metadata repository containing all the data standards library objects
- An interface for selecting which library objects are used by a study along with storing these study-specific metadata in their own repository.
- The capability to compare data and metadata provided by an internal or external partner to either the full library of objects or the study-specific metadata
- A repository for the output of these conformance checks that includes details such as the date the issue was first identified and when it was resolved, the library object that it relates to, and the study in which the issue was found as shown in Figure 2.

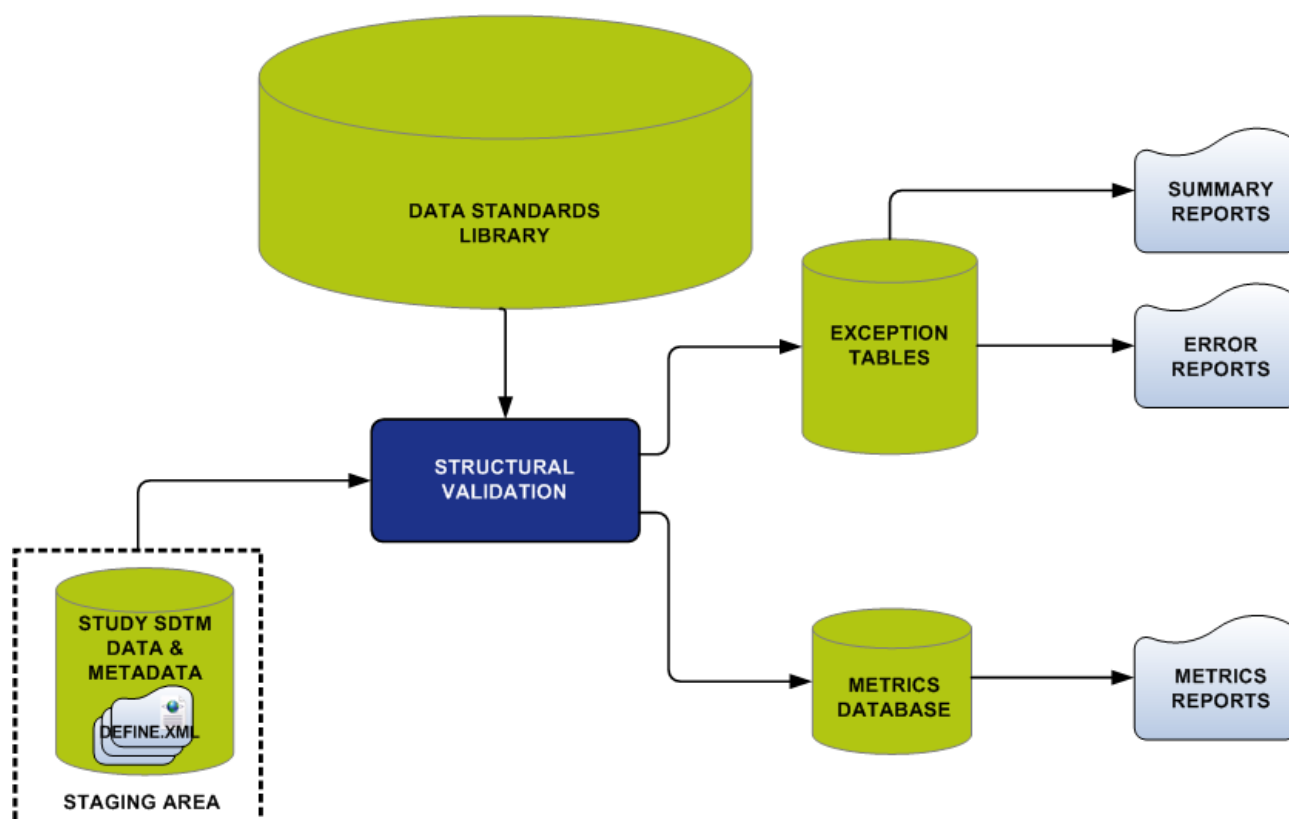


Figure 2: Overview of Data Standards Issue Management

Using the data in this issue management database is where we will focus now.

THE ANALYSES

There are several reports and analyses that can be done and we will discuss just a few.

TRENDS IN WHICH LIBRARY OBJECTS HAVE THE MOST ISSUES

This provides a starting point for process improvements. By identifying the most problematic library objects, you can investigate what the root cause may be. It is possible that it could be solved through better training of end users on the proper use of the library. Perhaps there are improvements that can be made to the standards to make it more user-friendly. Until you can identify these objects in a quantifiable way, you may end up spending lots of time on improvements that are not necessary. Tracking these trends over time provides objective feedback on whether the training or process improvement was successful.

FREQUENCY OF USAGE FOR LIBRARY OBJECTS

Initial creation of data standards libraries tends to fall into two groups. One approach is too strict and does not include sufficient content to cover complex trials, while the other approach attempts to include so much variability that there is little standardization in the end. The best approach is somewhere in the middle. If you can track which library objects have been used and how often, you will be better prepared to concentrate efforts on enhancements that will have the best impact. When prioritizing updates to the data standards library, historical information on the usage of similar types of library objects can help identify which new library objects are the most critical to add first and the lesser-used types can be a lower priority update.

TIME TO RESOLVE AN ISSUE

By knowing when an issue was first identified and added to the Issue Management database and knowing when it was resolved allows for performance metrics of internal and external partners to be assessed.

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TRENDS ACROSS PROJECTS

Are there issues that seem to appear more frequently in cardiovascular studies than other therapeutic areas? Maybe the library is working very well for Phase I studies but there are more issues with compliance on Phase II?

TRENDS ACROSS TEAMS OR PARTNERS

Does there seem to be an increase in the number of issues found when a particular vendor is used? Are there some teams that struggle with properly implementing the standards that perhaps could benefit from additional training? By analyzing the frequency of overall issues, you can define reasonable performance metrics that your partners will be expected to meet. Frequency of specific types of issues can be used to provide targeted and specific feedback to your partners on where improvements are needed. It also provides an objective comparison of how well a partner is complying with the requirements provided to them.

CONCLUSION

Conformance checks that compare study data and metadata to your library can generate valuable information for streamlining and improving the compliance with your standards. To accomplish this, the output from the conformance checks must be stored in a repository to allow for tracking the resolution of any issues that are identified. To avoid unnecessary overhead on team members, it should be possible to easily close issues programmatically when they no longer are identified by the conformance checks.

Using the data available in this issue management repository, as proposed in this paper, is far better than relying on anecdotal feedback on how easy or difficult it is to use the data standards or how well or poorly a partner is complying with requests.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

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