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Data Standards Governance

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ABSTRACT

The adoption of MDRs by pharmaceutical and bio-technology companies enable them to collaborate and re-use data, but they also present challenges with respect to the internal harmonization. Metadata harmonization and management is not a one-shot project. Instead it should be a progressive organizational improvement that requires associated metadata governance processes, which should be supported by MDRs. Furthermore, to make sure that it's not the organizations that have to adapt to an MDR system but the other way around, MDRs should support flexible configuration of these governance processes. In this demo you will see a prototype of a Standards Governance module by BDLS, supporting integration with Library Management features such as the workspace and versioning, as well as a configurable workflow.

INTRODUCTION

Data Standards are used by pharmaceutical and bio-technology companies for two main reasons. First, because they necessary for submission to regulatory authorities, and second, because they are useful for streamlining work and enabling collaboration and re-use of data. Despite industry standards being increasingly in place and adopted, these companies usually have organizational standards, which often pre-date the industry ones, and normally enrich or adapt the industry standards to the reality of the organization. Furthermore, the rate of publishing of new industry standards has been steadily rising over recent years, especially regarding new Therapeutic Area standards and controlled terminology. These reasons are the main drivers for organizations to adopt MDRs, as well as to put in place governance processes, in order to be able to appropriately manage their data standards. Typically there is a team in the organization that will own these process and provide the data standards to be used by the rest of the organization.

GOVERNANCE THROUGH CHANGE REQUESTS

The data standards governance team is typically the main end user of the organization's MDR. They are the *librarians* that create, modify and publish the organization's data standards libraries to be considered by Global Data Managers (GDMs) in the set-up of clinical trial data collection and by Statisticians while planning for the statistical analysis.

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Figure 1 - Library Management User Interface

BDLS has implemented an MDR with features that enable managing organization standards, part of a module named Library Management (LM). The module implements the *library* concept as a collection of metadata to be used together, and allows to visualize metadata at 5 levels: Domain, Variable, Value-Level, Code List and Code Value metadata, as depicted in Figure 1. It also supports metadata standards used at different moments of the clinical trial, CDASH, SDTM and ADaM, as well as the traceability links between them. The metadata objects in the LM module can be checked out and edited by the organization's librarians in their personal workspace but need to be validated before the changes become effective in the library. All changes to the library are version-controlled, meaning that LM keeps all versions of metadata objects that were at some point in time in the library. This enables "time-travel" in the library - checking a library's metadata at given point in time.

New Change Request

State: Request new content Next action: Approved

Owner: Joao Goncalves Start date: 17-08-2016

Assignee Group: Due Date: 19-08-2016

Assignee*: Joao Goncalves Priority: Medium

Library*: BDLS_SDTM

Description*: please insert Description

Relation for change*: please insert Relation for change

Subject*: please insert Subject

Figure 2 - New Content Change Request

Q Search Create Change Request With Selection

Filtering

Text

Status

- ☒ Approved
- ☒ Deferred: Later
- ☒ In Progress
- ☒ Initial (Draft)
- ☒ Initial (Submitted)
- ☒ Completed
- ☒ Rejected
- ☐ Closed

Involvement

- ☒ All Requests
- ☐ My Requests
- ☐ Assigned to me

Type

- ☒ Request new content
- ☒ Request content change

Drag a column header here and drop it to group by that column.

	CR#	Status	Owner	Assignee	Create Time	Due Time	
☐	52501	Approved	jgoncalves	jgoncalves	17-Aug-2016	19-Aug-2016	Edit
☐	52514	Initial (Submitted)	jgoncalves	jgoncalves	17-Aug-2016	19-Aug-2016	Edit

Figure 3 - Change Request Search & Filtering

With the use of organizational data standards, *librarians* are bound to get requests to change those standards from the users of data standards (typically GDMs and Statisticians). These change requests are usually prompted by the need to comply with newly published industry standards or by requirements specific to some studies. They can be captured and managed using documents and a process or, more interestingly, using a change request tracking tool, either a generic pre-existing one or one integrated in the MDR.

BDLS has implemented change request tracking in the MDR through the Standards Governance module (SG). It is possible for GDMs and other users of data standards to create change requests requesting new metadata or changes to existing metadata, as shown in Figure 2. The requester can also describe the change as well as the rationale for it and finally submit it for evaluation. The standards team is then responsible for following up the request, by interacting with the requestor for more information or by moving the request to implementation phase. Users can at any time check the progress of change requests by searching for them using free text, the state and type of requests as well as that user's involvement in the request, as depicted in Figure 3.

CONFIGURABLE PROCESS WORKFLOWS

It is of key importance that with the adoption of an MDR that supports change requests the organization is not forced to adopt a specific change request process. Similarly to generic change request tracking tool, MDRs that support change requests should support configurable workflows and fields. The system must adapt to the organization, not the other way around.

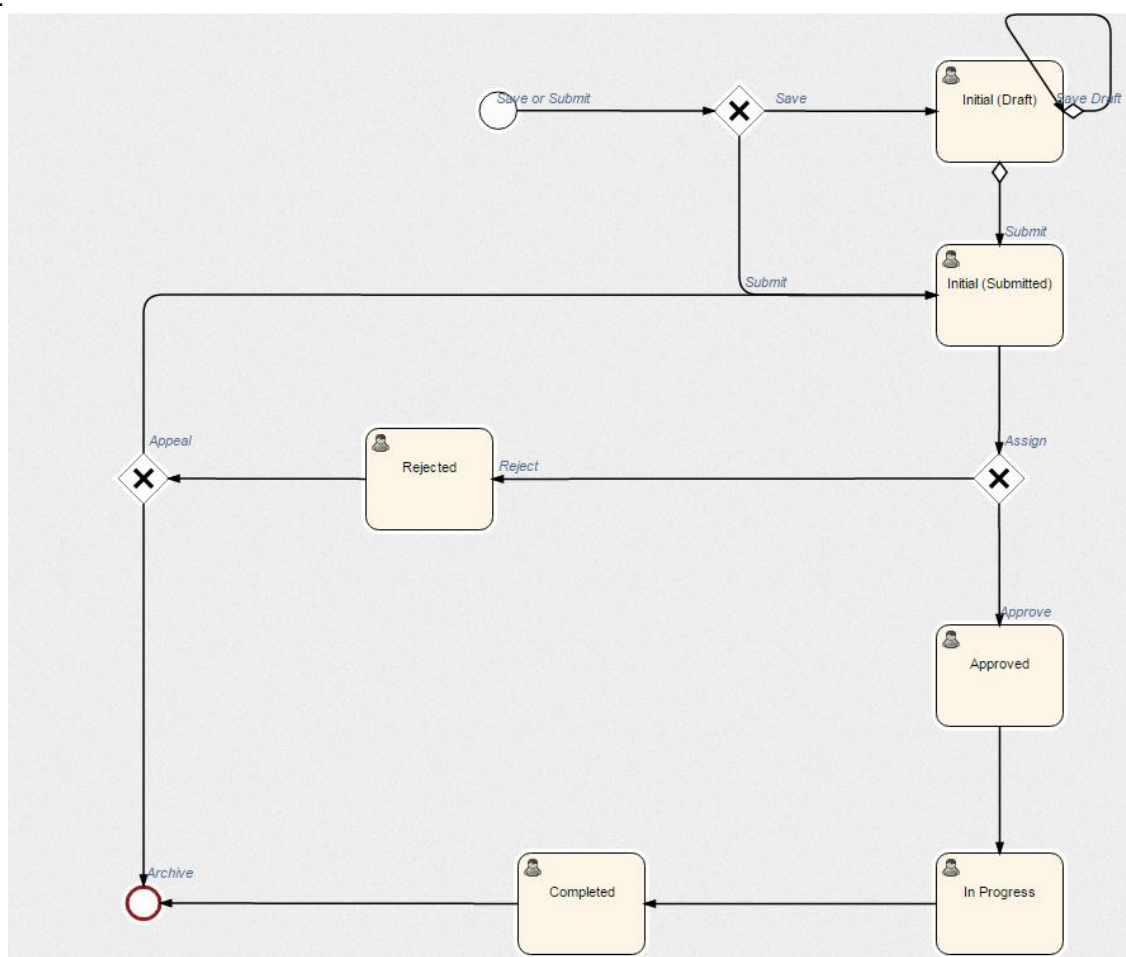


Figure 4 - Default Workflow for Content Change

Having this in mind, BDLS's Standards Governance (SG) module implementation integrates with a third-party open source workflow engine. The workflow engine was chosen because it has an active development community and supports process specifications using the Business Process Model and Notation (BPMN) 2.0 standard. Using the workflow engine it's possible to design new change request processes or change the default ones (new content or content change), as seen in Figure 4. Process design includes adding states in the workflow, adding specific fields for each workflow step, and specify which fields are mandatory. The SG module dynamically adapts to the configured workflows, showing any new processes, states and fields in the MDR UI.

INTEGRATION WITH LIBRARY MANAGEMENT

Being the team responsible for publishing data standards for a large organization is not an easy task. The pressure to deliver on time a large quantity of consistent standards can be troublesome, especially at a moment in which industry standards are being released at a quick pace. Therefore, the biggest argument in favour of having change request management functionalities in the MDR instead of relying in a generic change request tracking tool is the possibility of integrating those with metadata management functionalities, significantly easing the librarians' work.

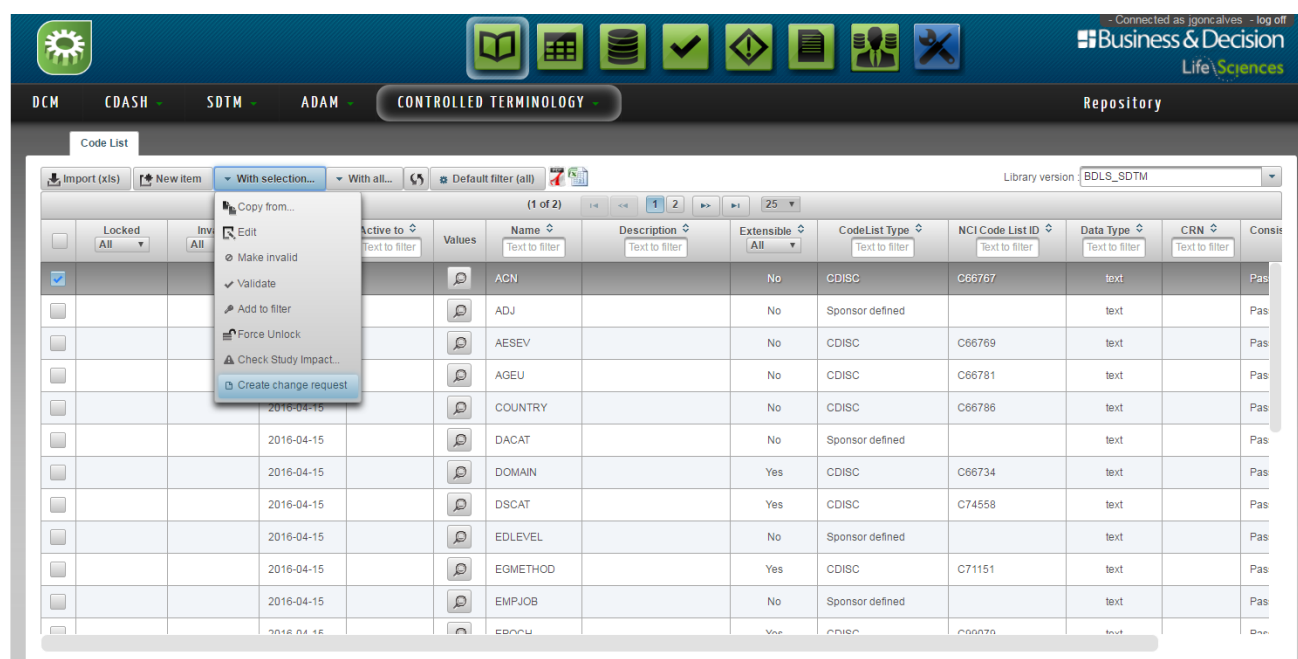


Figure 5 - Create Change Request from Object in LM

The screenshot shows the 'New Change Request' form. The form has a 'State' field set to 'Request content change' and a 'Next action' field set to 'Complete information and submit'. The form includes fields for 'Owner' (Joao Goncalves), 'Assignee Group' (Joao Goncalves), 'Assignee' (Joao Goncalves), 'Start date' (17-08-2016), 'Due Date' (19-08-2016), 'Priority' (Medium), 'Library' (BDLS_SD TM), 'Linked Objects' (Code List ACN, 2016-04-15 - 2999-12-31), 'Subject' (please insert Subject), 'Description' (please insert Description), and 'Rationale' (please insert Rationale). The 'Create change request' option from Figure 5 is selected, and the 'Linked Objects' field shows 'Code List ACN, 2016-04-15 - 2999-12-31'.

Figure 6 - Content Change Request with Linked Object

At BDLS we decided to create the SG module as part of the MDR due to the benefits of an integration with the LM module. A key feature of this integration is the possibility to initiate change requests directly from LM based on the selected metadata objects, as seen in Figure 5. When a request is created in this situation the targeted objects become automatically associated

with the request, easing tracking, impact assessment and metadata visualization while evaluating change requests (see Figure 6).

Change request linked to metadata objects have a number of additional capabilities. One of them is the automatic check-out of objects linked to a change request into the workspace of the person assigned to implement that change. This will prevent another librarian to take action on objects being targeted by a change request implementation, and this will be visible while browsing the standards in LM. Finally, after the change is implemented and the impacted objects are promoted back into the library, the new version of that object will be associated to the change request that originated it, keeping documentation of the changes in the MDR, as depicted in Figure 7.

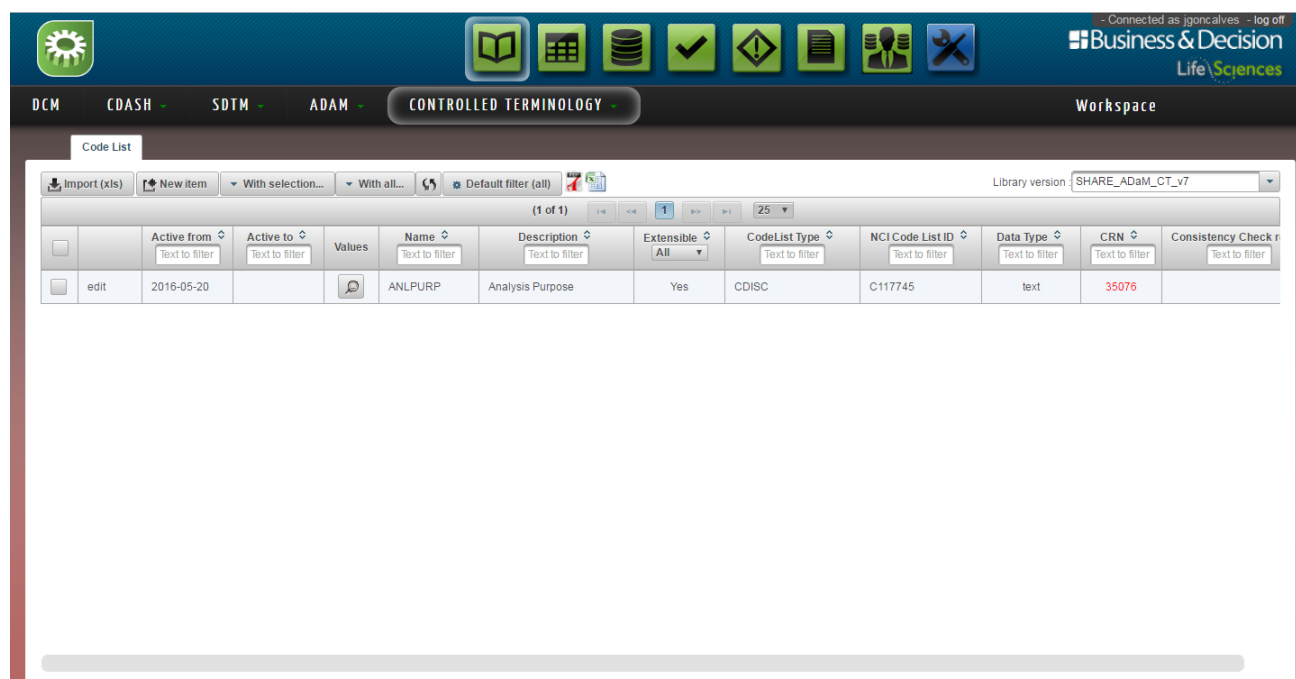


Figure 7 - Change Request number associated to LM Object

CONCLUSION

The management of data standards is a task of critical importance in the current moment of the industry. The volume of data standards that are being published by the industry and adopted by organizations cannot hamper the execution of clinical trials. More support tools for the data standards teams are needed, but unless they are integrated and streamline the work, there is a significant risk that more tools won't solve the problem, simply. Moreover, as the coverage and history of data standards grows, it will be important to keep track of standards changes and the reasons for those changes.

For these reasons BDLs invested in internally developing the Standards Governance module described in this paper. With it we acquired the necessary information to implement similar functionality in a new MDR solution, or integrating with an existing MDR.

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