

Implementing a Meta data Repository (MDR) using Functional Service Provider (FSP) how does it work?

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ABSTRACT

The sponsor created its Excel® SDTM Metadata and started contributing to development of an MDR. Implementation was a huge amount of work that feasibly could not be covered in a short time by the sponsor. They needed a consolidated team, specialised in SDTM and with the capacity to understand the potential of the MDR tool.

The first challenge for the FSP was being familiarised with a new tool, an SDTM+ sponsor philosophy and understanding the impact and scope of each change. Transition of internal knowledge to the FSP was the key at the beginning of the implementation. Simultaneous familiarisation with new processes then governance had to be defined for the MDR tool users and reviewers. JIRA® Software was there as fundamental to help with process and issue management. Shortly the first study was in, exciting and challenging. We will share our experiences, obstacles and solutions.

INTRODUCTION

The sponsor developed an SDTM+ library, a centralized metadata model, for the storage of all study data within their clinical data warehouse. This SDTM+ library has been used since July 2015 and at the moment includes the following main components:

- SDTM+ metadata
- SDTM+ user guide
- SDTM+ Standard CRF Library

The SDTM+ metadata is administered within an MDR tool.

The sponsor approach is to outsource both trial conduct and the creation of CDISC SDTM+ datasets, and keep maintenance and governance of the data standards in-house.

Chiltern was selected as an external FSP to maintain the SDTM+ standard library and review key deliverables in SDTM+ format (mainly CRF, Trial Design Domains (TDD), and metadata structure). As part of this maintenance Chiltern were requested to keep track of each task (maintenance/review request). This was accomplished with the use of JIRA® Software.

A team of Clinical Programmers with experience in SDTM was immediately put in place. Our first challenge was to become familiar with the MDR tool, to understand how its elements were related, what was the impact of a change to the metadata within the tool, or a change to the CRF library. We also needed to become familiar with the sponsor SDTM+ library and comprehend what the '+' was.

We received appropriate training and, most valuable, a transfer of knowledge from the sponsor.

The next step was to identify where, during the conduct of a trial, we step in. The implementation of the MDR tool added new processes and modified existing ones within the sponsor organization, governance had to be defined for the tool users and reviewers. This needed to take into account that within the MDR tool there is a role defined for both a developer and an administrator.

Chiltern created new high level and task specific process flow charts. These were cross functional flow charts for Chiltern Clinical Programmers as standards reviewers and developers/administrators of the MDR tool, as well as the sponsor Clinical Data Project Managers (CDPMs), and Standards Manager. These were developed and then implemented in JIRA®.

But how much does one study deviate from the standard? Thanks to JIRA® reports we could compile all tasks requested per study, and track the number of changes/updates that were implemented with each new version of metadata released.

In this paper we will share our experiences, obstacles and solutions.

FAMILIARIZATION

The first challenge was to become familiar with the sponsor MDR tool and with the SDTM+ sponsor philosophy. Therefore after a kick off meeting the sponsor scheduled a series of training that were performed approximately every two weeks. Each of them described a purpose, a list of participants and a goal to be accomplished.

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In the first training session, **Sponsor SDTM+ library**, we were introduced to the SDTM+ metadata and CRF libraries, and to the related documentation.

- SDTM+ metadata library (with SDTM+ user and administrator guide)
- Standard CRF library (with CRF library user guide)

The above-mentioned documentation is aimed at two audiences, the user, and the administrator for both libraries. The user, who needs to design a study CRF with associated SDTM+ metadata, and the administrator, who is responsible for the maintenance of the library.

The standard data model or SDTM+ metadata was created originally in Excel®, then loaded and managed in an MDR tool. The main purpose is to provide a centralised metadata model for the storage of all study data within the sponsor clinical data warehouse.

Figure 1 - SDTM+ library

Domain	Description	DB Requirement	Library Requirement	Custodian	Class	Structure	Purpose
AE	Adverse Events	Mandatory	FDA Expected	No	Events	One record per adverse event per subject	Tabulation STUDYID,U
BE	Biospecimen Events	Optional		Yes	Events	One record per instance per biospecimen event per bios	Tabulation STUDYID,U
CE	Clinical Events	Optional		No	Events	One record per event per subject	Tabulation STUDYID,U
DS	Disposition	Mandatory	FDA Expected	No	Events	One record per disposition status or protocol milestone	Tabulation STUDYID,U
DV	Protocol Deviations	Mandatory		No	Events	One record per protocol deviation per subject	Tabulation STUDYID,U
HO	Healthcare Encounters	Optional		No	Events	One record per healthcare encounter per subject	Tabulation STUDYID,U
MH	Medical History	Mandatory		No	Events	One record per medical history event per subject	Tabulation STUDYID,U

The standard CRF library is a Microsoft Excel® file containing all sponsor's standard CRF pages. Below shows an example. Note that the last section outlined in red is marked as optional, and optional text is marked in pink.

Figure 2- CRF page example

[DM]	[SUPPDM]	Demography	SITEID	SUBJID
		Visit Name	VISIT	
Country Identifier		<i>Pre-print this if only a single country is being used, or provide a list of country codes in which the study is being conducted.</i>		
	COUNTRY			
Date of Birth		Age		Years
	Day Month Year	AGEU	AGE	
	BRTHDTC			
Sex	SEX	<i>Age field has to be used CML Y if regulatory Authorities/Requirements do not accept the full date of birth for data privacy reason.</i>		
Male				
Female				
Ethnicity	ETHNIC			
Hispanic/Latino				
Not Hispanic/Latino				

The macros in the file allow the creation of study specific CRF. This file is used to create the SDTM+ standard CRF library, but also the mock-up CRF (*), and to validate a study CRF created by a third party.

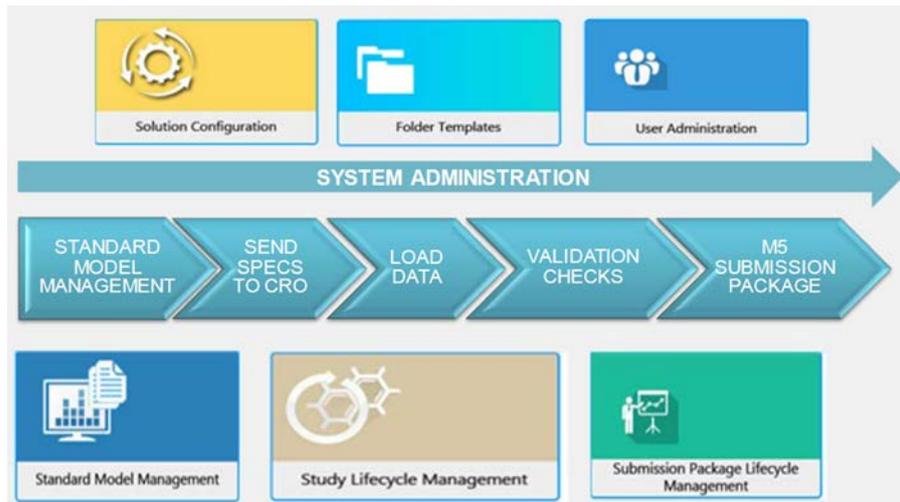
The user who generates a study CRF, can select from the SDTM+ CRF library only the forms needed, generate page numbers, keep or delete optional fields, show or hide SDTM annotations and finally use the macros to create a PDF version.

In a second training session we received an **Introduction to the MDR tool**. We were introduced to the MDR tool, and its components. We were also trained on how to manage the SDTM+ library within the MDR tool. This provided the team with the skills to perform library or administrator tasks.

* Mock-up CRF: the first draft version of a CRF sent to a CRO to help them in the design of an eCRF. It might be slightly different to the final eCRF, some changes due to DM system limitations might need to be implemented.

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Figure 3 - MDR tool, global overview



The tool stores a standard model (SDTM+) and allows users to generate specifications based on the standard model to provide to third party CROs. It can perform compliance checks of deliverables from CROs against specifications, and can generate the submission package (structured as M5 folders with ISS, ISE and TLFs).

Our training was focused on the Standard Model Management module, in which we are responsible for maintaining the standard model, developing new objects or updating existent ones.

Finally to refine the library processes around the MDR we participated in the **SDTM+ MDR tool process workshop**. Following this workshop, we were able to define processes that can be rolled out to broader Chiltern team and end user sponsor study leads (CDPMs).

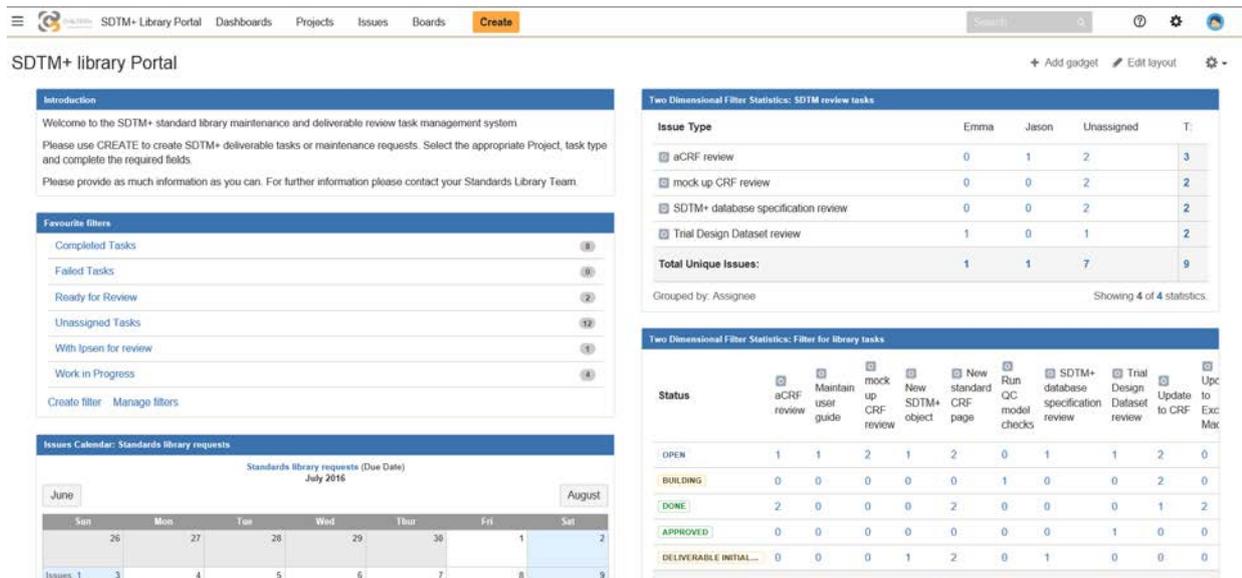
Later on training and a pilot practice were organised by Chiltern in which the tool chosen to track the individual tasks was introduced. This combination of training and practice prepared the sponsor study leads to use the JIRA® task management system.

JIRA® Software is cloud based and supplied by Atlassian® as an 'off the shelf' system. The software is used to track tasks associated with library maintenance and the review of SDTM+ study deliverables.

JIRA® (core) is a workflow management system that can be customised to suit required needs. Each requested task added in JIRA® can transition through customised workflows. Different roles can be defined to perform the transitions. As the task changes status an email notification is sent, and there is the ability to watch tasks.

The figure below shows a general view of JIRA®, which can be customised. Once a task is created there will be a developer and a QCer, times are defined and the task can be followed while it transitions from one status to the next.

Figure 4 - JIRA® functionality



Finally, a **JIRA® pilot practice** was in place for a period of approximately 4 weeks, to allow the sponsor standards team to pilot and test the JIRA® Software for task management. After this period of time some small adjustments and refining were done to the tracking tool, based on needs for a production environment.

The MDR tool was new for the sponsor too, therefore the last training was addressed to both sponsor and Chiltern teams to test the MDR system. We all followed the **Sponsor MDR tool pilot practice**.

TRANSITION OF INTERNAL KNOWLEDGE TO THE FSP

For a two month period Chiltern worked hand in hand with the sponsor SDTM Specialist. We worked together through each obstacle we found and we were mentored through our first reviews.

The sponsor SDTM Specialist was the main contact point between the users of the standards (CDPMs) and our team of Chiltern Library Analysts (CLA) who maintained the standards. Thanks to this approach at the start we could focus on specific discussions, regarding the SDTM+ metadata, the CRF library or TDD and the use of the MDR tool, without knowing the specific study details.

Each new annotation made into the CRF library, each new controlled terminology term, or each variable added into the metadata was discussed up front, and the elements impacted were defined.

All of the CLA's changes were checked and validated by the sponsor SDTM Specialist and approved by the sponsor Standards Manager.

Soon the sponsor gained trust and CLA's gained self-confidence, which had a direct positive impact on efficiency.

During this period we experienced most of the tasks associated with managing and updating the sponsor SDTM+ library and the review of SDTM+ study deliverables. This helped us to define our own processes and responsibilities within Chiltern.

In an SDTM+ environment, with SDTM metadata being updated frequently and the '+' being under familiarization, the transition of internal knowledge was crucial for both teams. Little by little decision making processes were put in place, and tasks and steps were specified within in a flow chart.

We knew what we had to do and we were certain we could fulfil the sponsor's expectations.

IMPACT AND SCOPE OF EACH CHANGE

The SDTM+ library has the following elements:

- SDTM+ Metadata
- SDTM+ User Guide
- SDTM+ Standard CRF Library

The **SDTM+ Metadata** structure of the model follows the philosophy of define.xml Version 2.0 and is broken down into the following sections:

- Dataset Level
- Variable Level
- Controlled Terminology

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- Value Level Metadata
- Computational Algorithm
- External Dictionary
- Standard Unit-Conversion Factors

These sections are all related within the tool, following SDTM structure. For example, if a variable has associated controlled terminology (CT), then the CT should also be present in the metadata, and so on. The tool includes validation checks to evaluate the consistency of these relationships.

The **SDTM+ User Guide** describes the SDTM+ model and defines how it should be used, with illustrative examples where necessary. To avoid redundancy, this document only describes rules not already covered by CDISC SDTM IG.

The **SDTM+ Standard CRF Library**, as mentioned previously, is an Excel® file including all standard CRF pages from which the metadata is built and maintained within the MDR tool. This means that if a variable is present on one standard CRF page, the page number will be linked to the variable in the tool. And vice versa, if a variable is present in the metadata with its origin being CRF, a CRF page should be available in the standard CRF library.

Within the MDR tool together with the main metadata components the latest version of related documents like annotated CRF and SDTM+ User Guide are included. Each related document might be affected by a change in the metadata or CRF library due to a new study request, e.g. a new variable.

The relationships between the standard documents like the CRF library, or user guides need to be maintained manually. Therefore before any change is made to the metadata or the CRF library there is a need to evaluate what could be affected, which related document is impacted, and how. If the impact is large, more than one related document could be affected, and the more time it will take for the update to be available to the end user. So any change or update that requires a change in one or more related documents will take that much longer than a change with no repercussions.

Within each user guide there is a 'Change control' section where all changes are tracked in a table including Document version, Section, Change, Author and Date.

There are no automated relationships between the CRF library and the SDTM+ metadata. Consistency of the common elements have to be done and maintained manually.

Each SDTM+ user or administrator guide are Word® files, examples included in these guides are taken as a print screen from the metadata or from the CRF library. Therefore any update to a CRF standard page or to the metadata might have an impact in one or more sections of the user or administrator guide.

With each new version of the SDTM+ library, an end user will get an updated version of the metadata, CRF library and related documents. Including the metadata in Excel®, empty xpt files per SDTM domain and associated define files.

GOVERNANCE

The sponsor outsource the trial conduct and the creation of CDISC SDTM+ for all trials, whereas the development and governance of the sponsor data standards are kept in-house.

As mentioned before Chiltern is responsible for the maintenance of the standard SDTM+ library:

- Maintain CRF library, updating/creating elements, including the associated user guide.
- Maintain the SDTM+ metadata, updating/creating objects, including the associated user guide.
- Performing impact analysis when a new versions of CDISC SDTM or CT is available.

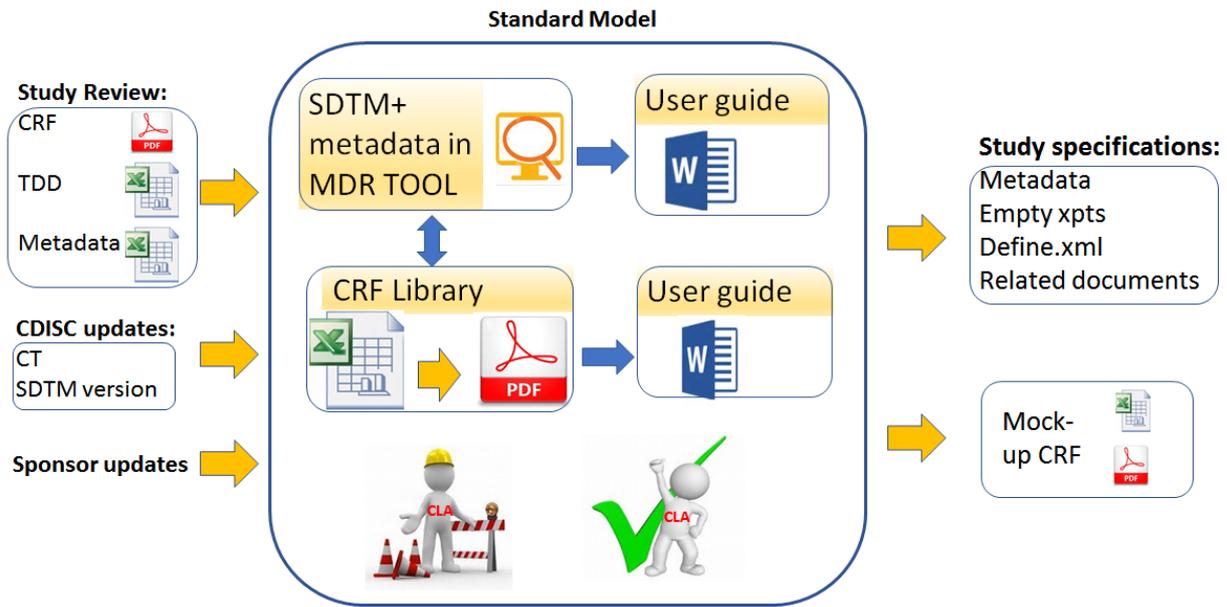
Also responsible for the review of key deliverables in SDTM+ format as detailed below:

- Reviewing mock-up CRFs
- Reviewing annotated aCRF/CRF in SDTM+ format
- Reviewing trial design datasets in SDTM+
- Reviewing data base specifications in SDTM+

This outsourcing process is under the responsibility of the sponsor standard manager.

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Figure 5 - Global overview of SDTM+ maintenance

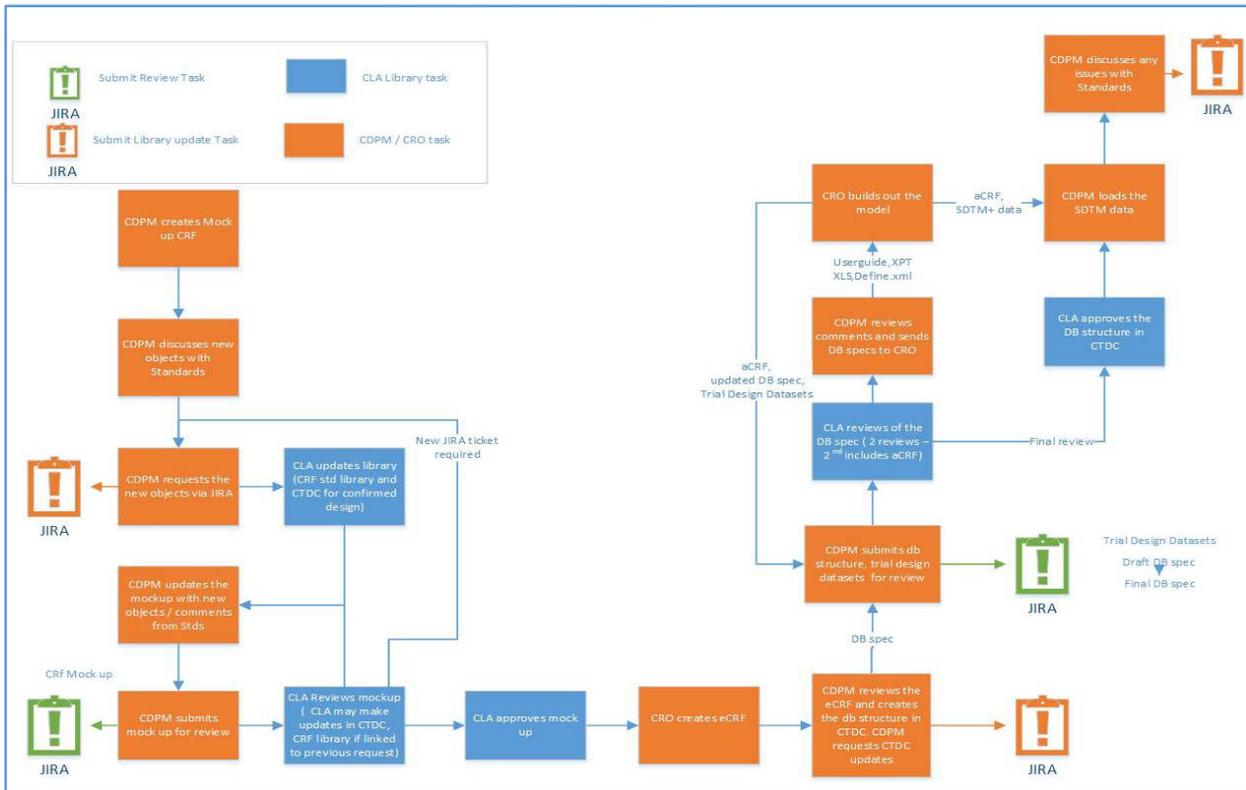


Each sponsor request is tracked into JIRA® the collaborative tracking system.

From the standard model, maintained in the MDR tool, study trial structures are built by the CDPMs by selecting objects from the SDTM+ library to create the study level metadata. These data base structures (specifications) will be sent to the CROs. Later on the data from clinical trials, provided by CROs will be loaded by the CDPM into the MDR tool in SDTM+ format for validation.

Due to the introduction of the MDR tool to the CDPMs, processes were redefined but no definite general flow chart for the review of deliverables was available. After a workshop with CDPMs and several discussions, Chiltern proposed a high level Study Deliverable Review workflow. In which JIRA® requests were introduced to provide an overview of how JIRA® interacts with the MDR tool status.

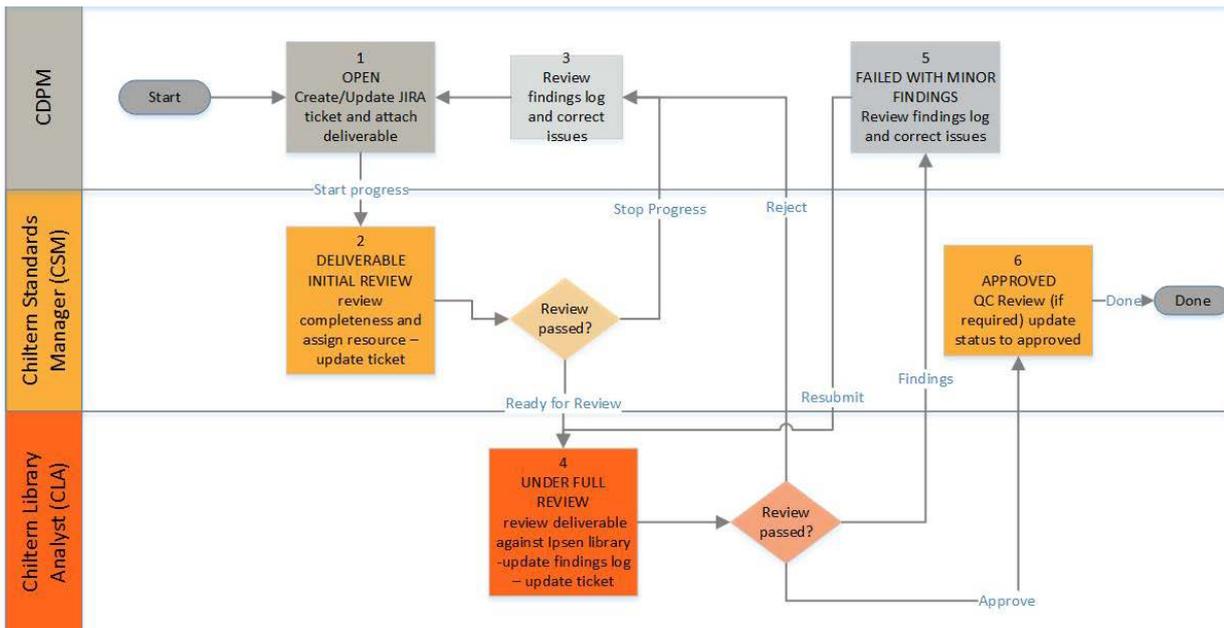
Figure 6 - High level Study Deliverable Review workflow



The purpose of showing the above flowchart is not to discuss each step in detail but rather to see the level of complexity and how simplified our latest version was, shown in the last figure of this section.

From this first interpretation on how review tasks were done at the sponsor and after the introduction of the MDR tool and JIRA®, all possible CLA tasks were defined. A list of CLA tasks was created and its specific flow chart. Within each flow chart the different roles that could possibly interact depending of the type of tasks were included. See an example in the figure below.

Figure 7 - Example of standard workflow for study deliverable review tasks.

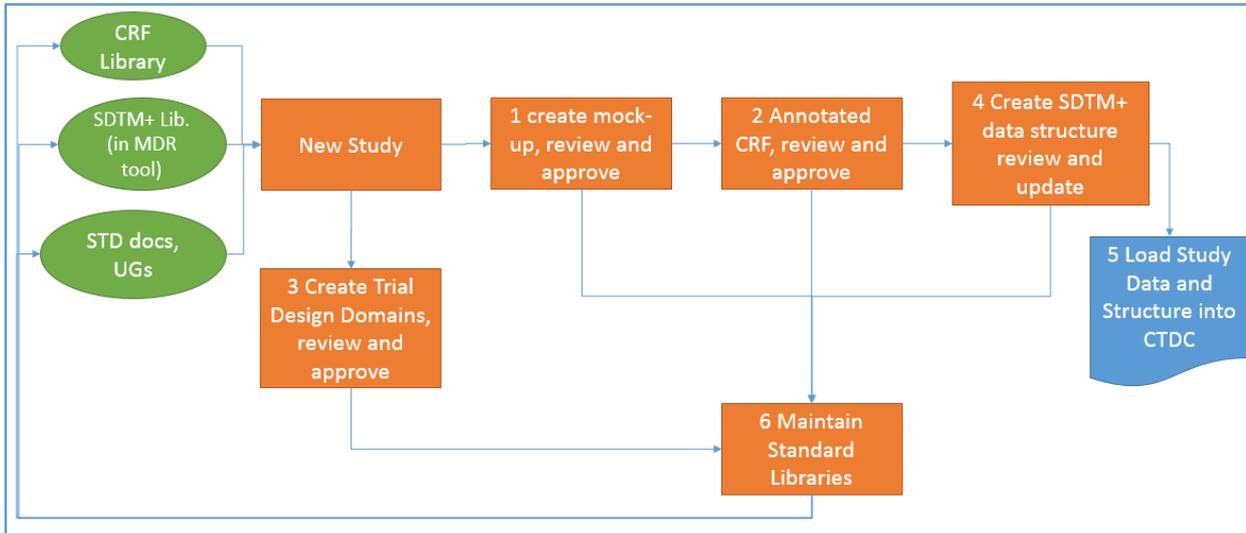


The first list of tasks was based on initial discussions around the project, prior to any real experience with the MDR tool. As we gained more experience with JIRA® and the MDR tool we were able to make some improvements.

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Finally after a diligent review and study of how each tasks was related, we managed to simplify the sets of CLA's tasks into a general flow chart. From which each basic element could expand into a more detailed flow chart, with specific tasks per role.

Figure 8 - CLA tasks, general flow chart



A good understanding of our tasks, its relationships and interoperability with other roles makes us conscious of the impact of our decisions.

USE OF JIRA® SOFTWARE

The JIRA® based system, was tailored to meet the requirements of the SDTM+ library project. It was used to track all related task communication. The system interface is quite intuitive and very little extra information is needed to start working on it.

We started defining our two main tasks as two different 'projects' within JIRA®:

- Standard Library Requests (SLR) - Library updates (including MDR tool and CRF)
- SDTM+ Deliverable Review (SDR) - Study Deliverable Reviews

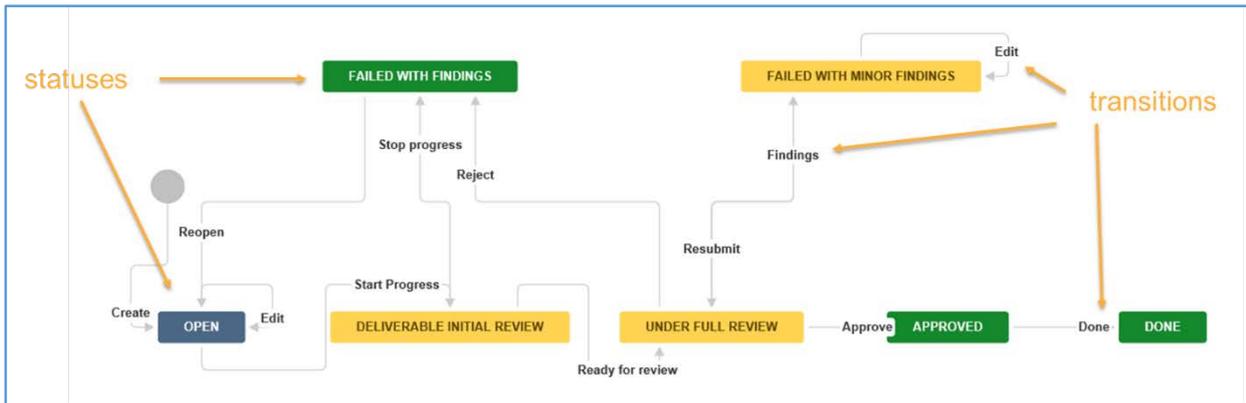
And three different types of users have been setup, with access dependent on the role assigned

- Chiltern Librarians
- Sponsor Standards
- Users (CDPMs)

Within this system we have the ability to implement our customised workflows, the ones specific to each CLA task, discussed and defined in the previous section of this document. Therefore within each flowchart each issue (CLA task) is transitioned through its respective workflow. The system also gives the ability to control roles that can perform those transitions.

JIRA® sends e-mail notification when the tasks change status, and it is possible to 'watch' tasks, which means that you will be notified of every status change of the tasks or new comment added.

Figure 9 - JIRA® flow chart



When opening a task there is a link to its workflow, in which the actual status of the task is coloured. The statuses are classified in colours as 'To Do' (blue), 'In Progress' (orange/yellow), 'Done' (green). Also by positioning the mouse on the transitions the complete line is coloured and shows clearly which tasks are linked. This graphic overview of the flowcharts at any time helps the users to be familiarised with the processes but also clarifies which step is next.

One of the basic JIRA® functionalities is the Dashboard, it can be customised for each user's needs. The content of the tool can be filtered by any element that is present like study number, type of task, project, role, statuses, etc. See figure 4 as an example.

When creating a task the amount of fields available will depend on the type of issue/CLA task. See below an example, note that in the comment field can attach files and as many comments as needed can be added to an issue.

Figure 50 - Sample of an entry screen

Finally a report in csv or Excel® format can be created from the complete list or one of the filters already customised for a particular dashboard. See example in figure 11.

FIRST STUDY, THEORY VERSUS REALITY

We anticipated minimal updates for each study but in reality this became bigger than expected.

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In a period of ten months we have worked on more than 350 JIRA® tickets related to changes to the SDTM+ and CRF libraries, with each ticket involving one or more change requests. We implemented 25 updates to user guides, and reviewed 14 studies.

To give an idea the average study requires from 1 to 15 changes, but we had a couple of studies that required more than 50 changes. See an example report from JIRA®, filtered on one study number.

In the figure below you can see the different types of updates. Normally reported by the CDPMs but also added by the CLA due to related documents impacted by the changes originally requested.

Figure 61 - JIRA® report one study

Issue Type	Issue Key	Issue ID	Summary	Assignee	Reporter	Priority	Status	Resolution	Created	Due Date	QC	Study ID
mock up CRF review	SDR-95	17201	001 - Cabozantinib PASS - CRF Mock	CLA3	CDPM1	High	Done		12/12/2016 19:02	13/12/2016 00:00	admin1	999-777-001
New SDTM+ object	SLR-300	15510	Need for a new variable FTPT	CLA1	CDPM4	Medium	Done	Done	18/01/2017 10:40	27/01/2017 00:00	admin	999-777-001
New SDTM+ object	SLR-301	15511	Need for new VLM : QNAM EQ GRO	CLA1	CDPM4	Medium	Done	Done	23/02/2017 15:06	28/02/2017 00:00	admin	999-777-001
New SDTM+ object	SLR-333	16600	Need for a code Average of 3	CLA1	CDPM4	Medium	Review failed with f		23/02/2017 15:36	28/02/2017 00:00	admin	999-777-001
SDTM+ Full DB spec review	SDR-93	17103	Please approve DB Specs	CLA1	CDPM4	High	Done	Done	28/02/2017 12:36	02/03/2017 00:00	admin	999-777-001
Trial Design Dataset review	SDR-96	17302	FR01072-001	CLA3	CDPM4	Medium	Done	Done	30/03/2017 11:47	30/03/2017 23:00	admin	999-777-001
Update to Codelist	SLR-112	12211	Codelist Unit, mA value: Synonym t	CLA1	CDPM4	High	Approved		12/04/2017 15:03	18/04/2017 23:00		999-777-001
Update to Codelist	SLR-213	13800	Need for a Immunogenicity Specim	CLA1	CDPM4	Medium	Done	Done	26/05/2017 10:27	30/05/2017 23:00	admin	999-777-001
Update to Codelist	SLR-306	15800	Need for creation of missing metad	CLA3	CDPM5	Medium	Failed with Minor F		24/04/2017 11:26	27/04/2017 23:00		999-777-001
Update to Codelist	SLR-374	17900	Please create new codes for UNIT	CLA1	CDPM5	Medium	Done	Done	08/08/2017 09:31	15/08/2017 00:00	CLA2	999-777-001
Update to Codelist	SLR-460	19639	Please update codelist FASCAT (se	CLA1	CDPM5	Medium	Done	Done	08/08/2017 09:36	15/08/2017 00:00	CLA2	999-777-001
Update to SDTM+ metadata	SLR-459	19638	Please create few items for domai	CLA1	CDPM12	Medium	Failed with Minor F		14/04/2017 15:20	27/04/2017 23:00		999-777-001
Update to SDTM+ metadata	SLR-452	19631	Add domain SC to CTDC and add res	CLA3	CLA3	Medium	Open		07/08/2017 14:10			999-777-001
Update to SDTM+ metadata	SLR-453	19632	Add FATESTCD needed for RCC Hist	CLA3	CLA3	Medium	Building		07/08/2017 14:24		admin	999-777-001
Update to SDTM+ metadata	SLR-454	19633	Add categories for PR/FAPR/CM/EX	CLA2	CLA3	Medium	Done	Done	07/08/2017 14:43		CLA1	999-777-001
Update to SDTM+ metadata	SLR-455	19634	Add needed updates to HO/SUPPH	CLA3	CLA3	Medium	Done	Done	07/08/2017 15:01		admin	999-777-001
Update to SDTM+ metadata	SLR-456	19635	Add variable EXDOSFRQ to EX and C	CLA2	CLA3	Medium	Done	Done	07/08/2017 15:07		admin	999-777-001
Update to SDTM+ metadata	SLR-457	19636	Add QNAMs for SUPPPR and SUPPCI	CLA2	CLA3	Medium	Done	Done	07/08/2017 15:14		admin	999-777-001

Weekly meetings with the sponsor were set up from the beginning, we discussed progress, timelines, uncertainties, procedures, etc. We were able to confirm or clarify information received during the trainings, discuss possible improvements and clarify requests.

The best approach is accomplished when the CLA and CDPM work as a team from the Kick-Off meeting of the study. Many CRF design questions can be addressed earlier thus reducing the timelines to the final eCRF and limiting the amount of review rounds.

CLA decisions clearly explained and on time can be easily implemented, reduces re-work and improves communication between CDPM and CROs.

What is feasible and what are the limitations are not always clear from both sides, the secret is a good communication.

WHAT IS NEXT?

There is always room for improvements. We are currently working on the updates needed to the SDTM+ library due to the latest version of CDISC controlled Terminology. We made an impact analysis comparing the current controlled terminology stored within the MDR tool and the current CDISC CT published on 2017-06-30. Our goal is to have these checks in place to make the task much quicker for future CT release updates.

The analysis attempted to programmatically identify terms that needed to be updated in order to migrate the SDTM+ library CT to the latest version. However, much of the activity involved manual review with manual updates. In the meantime we needed to continue with the updates to the current terminology for new studies.

Our start point was the CDISC CT official list of changes:

- Add new CDISC Synonym
- Add new term to existing codelist
- Add new term to new codelist
- Addition of new codelist
- Remove CDISC Synonym
- Remove term entirely from codelist
- Remove term from retired codelist
- Retire codelist
- Update CDISC Definition
- Update CDISC Submission Value
- Update NCI Preferred Term

Checks were created to address all of the above, but some additional manual checks were needed to address values that were moved for example. Or when CDISC CT changes involved two of our key variables, for example a change

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that involves both codelist code and submission value. And last but not least the sponsor custom CT values that might be present in a CDISC CT new version but with a slightly different text but similar interpretation.

Another question that is being working on is: Can we relate the elements from the two libraries CRF and SDTM+ automatically? And from that can we then somehow automate the QC of study specific CRFs?

CONCLUSION

Standard and related documentation in place helped to gain rapidly a good understanding of what was available and how was it maintained. The combination of training and practice was a key for a fast familiarization. This complemented with a transition of knowledge from the sponsor to the FSP, had a positive impact in efficiency and trust. Decision making processes were put in place, and tasks and steps were specified in a flow chart.

The SDTM+ library has two main elements, the SDTM+ metadata and the CRF library with its respective user guide. The SDTM+ metadata is split in different sections which are related based on the SDTM structure. These relationships are checked within the MDR tool. But there are also relationships defined between the two libraries which are not automatically checked. Consistency between the related elements of these libraries should be maintained manually. Therefore an evaluation of what is impacted needs to be done before something is changed.

Within each publish of the SDTM+ metadata the MDR tool compiles the two last versions of the libraries and the related documents, all of them ready for an end user. The package includes SDTM+ metadata with associated user guide, CRF library and the user guide, empty xpts of all SDTM domains, and Define files. The SDTM+ model is then available as a set of documents and not an isolated metadata.

Providing valid standards and clear user guides for the sponsor is a need due that the trial conduct and the creation of CDISC SDTM+ for all trials, is outsourced by the sponsor. Although the sponsor is responsible of the development and governance of their own data standards.

Working with an MDR tool keeps things aligned, the study cannot be conducted if it does not follow the SDTM+ metadata. Although there are some gaps to fill in.

A clear list of Chiltern responsibilities was defined by the sponsor, which can be summarised in maintenance and validation of SDTM+ metadata, aCRF/CRF in SDTM+, and Trial design datasets in SDTM+. Each of these tasks or any sponsor request is tracked into JIRA the collaborative tracking system. Finally these activities are under the responsibility of the sponsor standard manager.

The introduction of the MDR tool causes that CDPM's processes were redefined including the participation of Chiltern. After a workshop and several discussions Chiltern proposed a high level Study Deliverable Review workflow, introducing JIRA and its interaction with the MDR tool.

From a first complicated diagram, all possible CLA tasks were defined with its specific flow chart. And shortly after a conscious review of how each task was related, we managed to simplify the sets of CLA's tasks into a general workflow. Within which each element can be broken down to the last detail within a specific tasks with its respective role.

The use of FSP helps to test what is not working properly from an outsider point of view, as user, developer and admin. The FSP experience implementing SDTM in other environments also brings questions and ideas on what to improve or how. It was very helpful to have standard documentation in place, although at each study we found either a small clarification was needed or a complete section should be added or changed.

We value the use of JIRA an intuitive and easy to use tracking tool, it can be customised to specific tasks and roles. Also allows us to evaluate the amount of work done by study, per period of time and so on. We can specify the amount of changes in each new version published. If any change needs more clarification the responsible CLA who performed the change and the QCer are linked to the issue or task.

We understand the impact of our decisions, we try to automate and ensure consistency in each task, and keep ourselves constantly looking for possible improvements.

REFERENCES

There are no references due that the information in this paper is based on internal documentation from the Sponsor and from Chiltern, which are not public.

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