

You are the Concierge – a CDISC compliant project management tool on SDD

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Background

Time is so precious during submission. So many things are happening in such a short period of time. There is definitely a lot workload on the study leads' shoulder where tons of time is spent on tracking the delivery status and checking the completion against study timeline.

This poster is to demonstrate a high-quality tracking and CDISC compliant reporting system for a sample Clinical Study Report (CSR) submission.

Objective

The objective is to increase the efficiency and quality of the output delivery process, while decreasing the overall time of submission.

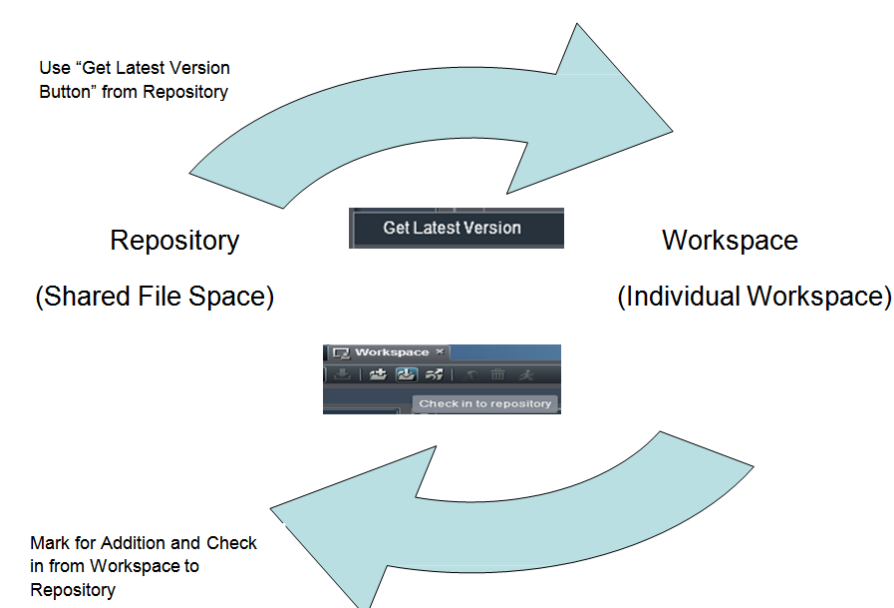
An Excel tracker will serve as info center backed up with JAVA tools grabbing document status including latest modified timing, upstream/downstream document status, traffic lighting OPenCDISC report status, and other features SAS® Drug Development (SDD) allows administrator users to monitor such as scheduled batch jobs.

A time management sheet on this Excel will also track the programming team delivery hours and link to Microsoft Projector as an estimation of study timeline.

Introduction

We designed this tracking system based on SAS® Drug Development (SDD). SDD is a centralized, controlled and compliance-enabling platform where each user is setup with a private workspace and the team has a shared repository space where the final delivery outputs will be checked out.

Fig 1. Repository-Workspace Check in/out workflow (Lobby-Room)



I would use the metaphor of a hotel in this case: the workspace is a private “room” where users can sit comfortably with no disturbance and enjoy the freedom and security of private space. Repository is more like a “hotel lobby” where our study lead will be the concierge diligently taking care of each guest, traffic of “luggage” and update the team when “dinner is ready”, also known as the time when the latest raw data comes in.

Moreover, SDD displays document information such as the last modifier, last modified time, version, signature and if the workspace is synchronized with repository. We will discuss later in the tracker design and JAVA part how these columns were collected and analyzed.

Fig 2. SDD document information display in repository:

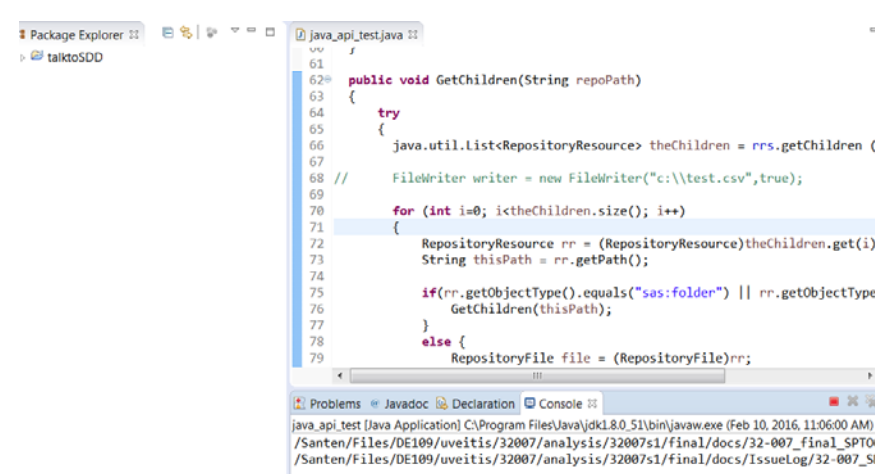
Modified By	Date Modified	Signed	Repository Version	Workspace Status
Helen Shi	Jan 22, 2016 10:13 AM		1.0	

Centralized Design

Status information is collected and summarized by JAVA, then a SAS program will read in the status report of repository documents and update the tracker with:

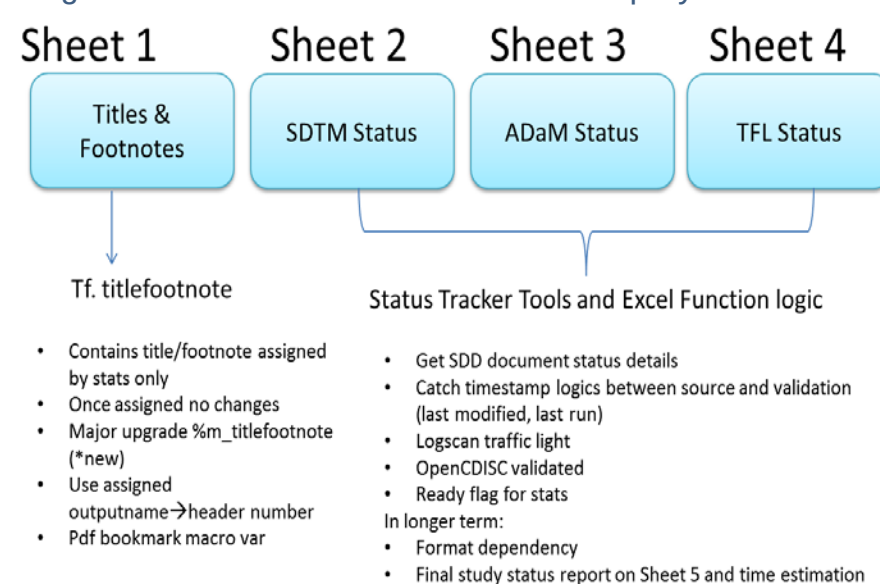
- Timestamp (last modified, last run) of:
 - o Source and validation program.
 - o Upstream documents (served as input of the program such as raw data or macros).
 - o Downstream documents (usually the outputs, status of report, e.g. Logscan report and OpenCDISC validator report etc.)
- Logic check: traffic lighting OpenCDISC validation result for each domain and Logscan pass/no pass.

Fig 3. JAVA talking to SDD (eclipse interface)



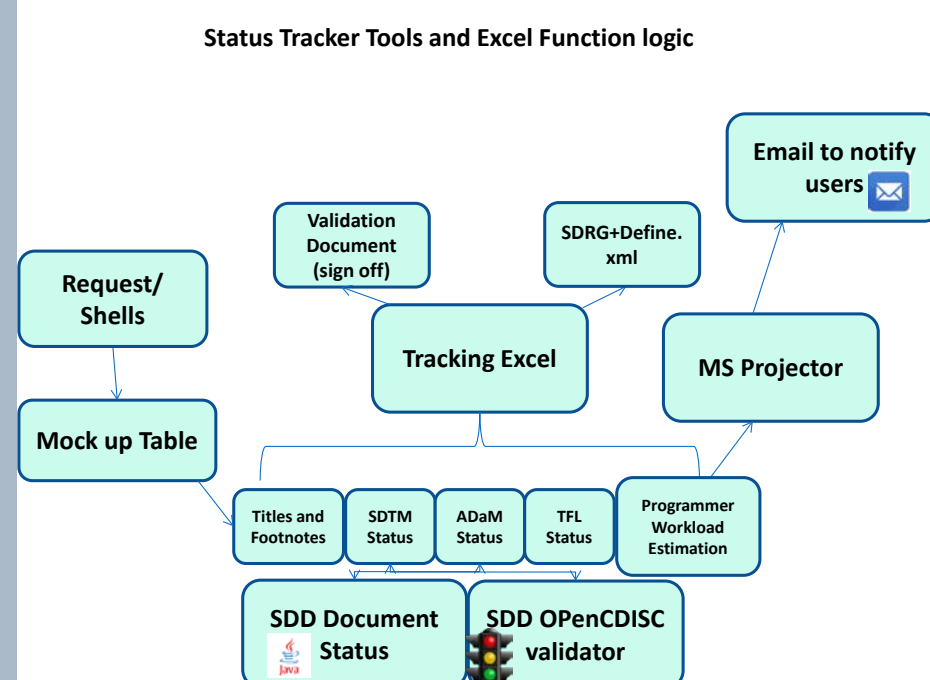
Programmers can build algorithms to the tracker by comparing timestamps against each other. A few simple examples would be: Output document should be always updated later than the input document. Or log file being modified always no later than the program itself. This also makes sure all ADaM programs run on the correct version of SDTM datasets. Just imagine how much hassles it will save during the rush time of delivery.

Fig 4. SDD document information display:



Map of the “Hotel Lobby”

Fig 5. SDD document information display:



Study Timeline on Sheet 5

At a study milestone, the study lead would usually want to check the status of one delivery. How many tasks left on the table? Any bottleneck issues? Is the task load assigned correctly and if a specific programmer needs help?

The 5th sheet helps estimate the hours each programmer spent on the categories of programming. It helps each team member to use his or her full strength and help out each other when necessary.

Fig 6. Sheet 5: Time estimation is based on the Task Assignments from Status Tracking Sheets

[illegible]

Comparing this sheet to the study timeline, study lead can quick get an idea of the completion status and how much time needed for specific task. If a triggering algorithm is built in when certain task is left behind and in danger of meeting timeline, the team will be able to receive alert emails from Microsoft Project.

Expanded Use on Projects

Besides reflecting the status of a delivery and help with resource allocation, this tracking tool is planned be used in ad-hoc production tracking and delivering sample trial reports when there are existing templates available.

The projected auto-generation feature will make it easy to group certain outputs together and generate sample exploratory deliverables. Statisticians/ad-hoc requestors will be able to review a sample delivery with draft stamping during the study.

We will expand further in document monitoring and documentation using this tool with:

- Scheduled data refreshing
- Randomization file lock-up
- Supplemental source data import and archiving
- Validation Documentation
- Hard coding memos
- TMF archiving

For auditing purpose and review, there might be many things to do down the road for a clear look at study Issue tracking and documentation.

Contact Information

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