

## Monitoring Quality, Time and Costs of Clinical Trial Programming Projects using SAS®

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### ABSTRACT

Effective management of the Quality, Time and Costs (QTC) of programming activities entails a collective collaboration between statisticians and programming teams. In order to manage a portfolio of studies, there is always a necessity of having a close monitoring of the progress by the management. This ensures that the projects are delivered with a great control over QTC. To manage the projects, data is collected for tracking (programming trackers), operation (resource projections), finance (baseline costs and continuing costs) and quality (issues trackers). Project dashboards can be built with SAS GRAPH® using the operational data with risk metrics built around the project progress. This paper will describe how SAS® can help in monitoring project progress in a simple and yet, elegant way in order to keep your projects on track and have a better understanding of the implications of QTC on a real time basis.

### INTRODUCTION

The core principles of project management are to define, plan, organize and monitor projects and SAS Programming deliverables management embraces all these core principles just like other projects. However, due to the complexity of the number of outputs to be produced by the teams, it can get difficult to effectively manage and monitor studies on real time basis.

Programming managers employ different techniques to gauge the health of a project(s) and as the number of projects increase, time can be a limited resource for the management to have an effective oversight and help project leads. Also, a lot of time and energy is required in order to completely understand all the details and to address the risks of a project. As a result, it is not uncommon for programming managers to take subjective judgment in managing the risks.

The focus of this paper is to provide some insight in order to mine the data from the project management tools and have a centralized mechanism to monitor the progress of studies. This would ensure that the QTC of programming activities are monitored in a real time basis and appropriate steps can be taken to mitigate the identified risks. With a combination of Microsoft Excel and SAS® GRAPH, we could develop data capture and visualization tools to monitor the projects and build dashboards to review the projects from the highest level (e.g. Program managers) to the lowest level (e.g., leads). Also, collaborating with Statisticians in building the metrics for the success of the projects should be acquired to ensure a system of two-way communication is in place.

### PROJECT SETUP FOR PROJECT MANAGEMENT DATA

Development of strategy and effective planning is a key for successful execution of any project. Project areas need to be setup based on a cross functional effort between Statistician and Programming Team including Managers, Leads, and Programmers. The following items can be taken into consideration and collective decisions need to be made in regards to identifying key metrics for the dashboards and data to be collected.

- a. Programming Deliverable – Data Management Listings, Data Imports, SDTM Mapping, SDTM Programming Development and Validation, ADaM Specifications, TLF Shells, ADaM Programming and Validation, TLF Programming and Validation and other adhoc Deliverables
- b. Resources : Name, Dates Active in the Project – Start and End date
- c. Baseline Assumptions – Baseline data for the programming deliverables based on the timelines: Completion Date, Review Date and Percent of Completion by Milestones, Actual Estimated Time
- d. Deliverable Status: a percent of completion or Coded list of values for each SAS programs
- e. Quality Trackers: Quality Issues documentation in sync with the Operational items. Data can be collected for Specifications Issues, Data Issues, Programming Errors
- f. Financial Trackers can be tied directly to the operational trackers- Budgeted hours and real time utilization.

Figure 1 displays Schematic representation of process for dashboard creation.

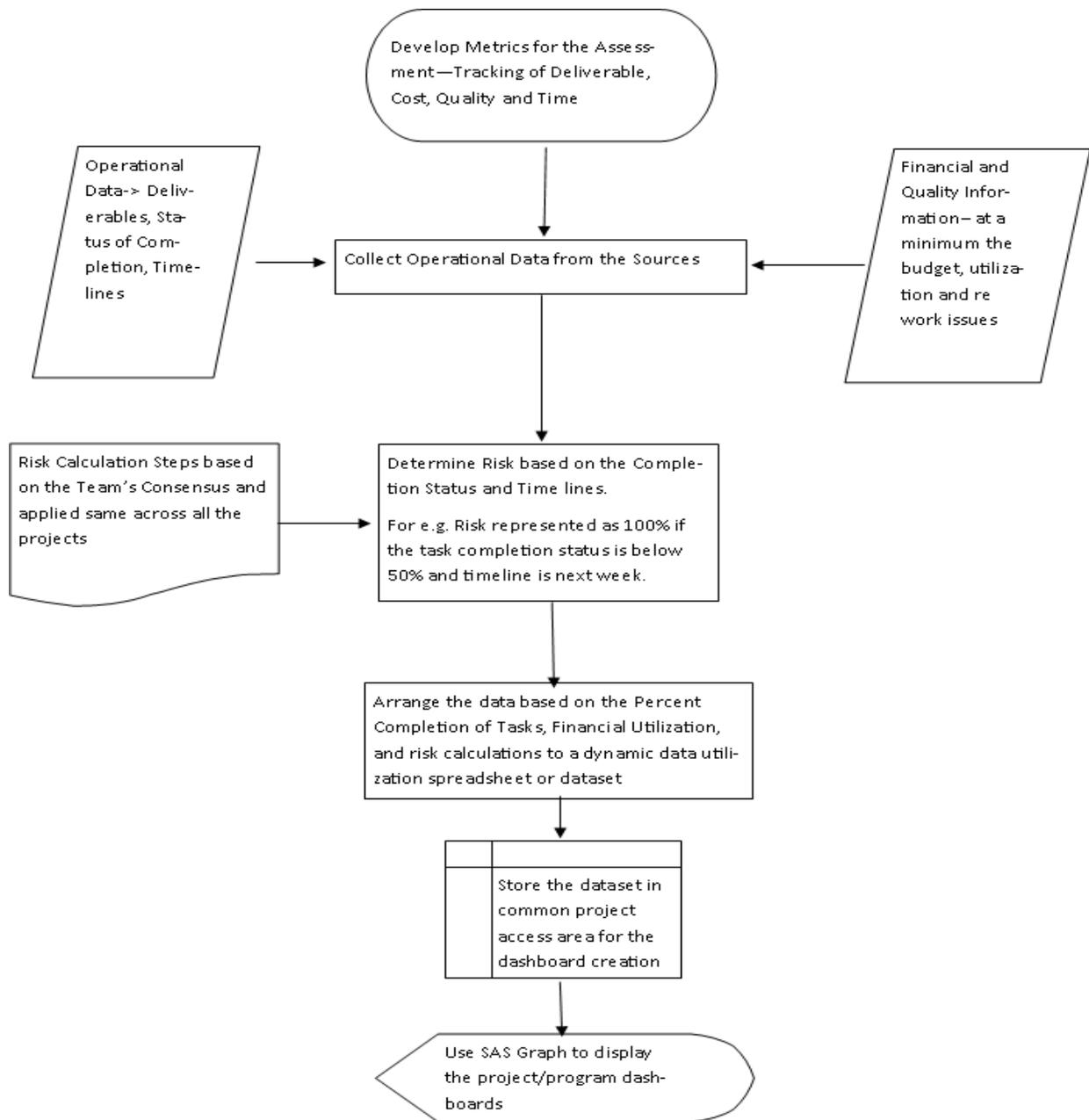


Figure 1. Flow Chart of Development Process for Dashboards

## RISK ASSESSMENT

For the purpose of this paper, six hypothetical projects have been simulated for creation of the program dashboard. Risk was defined as a classification variable with 25, 75 and 100 values. For risk estimations, different levels of complexities can be introduced. It can take into account the effects of time, quality, and finance on the project. For the simplicity purposes, risk has been defined as:

1. 100= if Days for Completion is less than 7 days and completion less than 75%
2. 50= if Days for Completion is between 7 and 30 days and completion less than 50%
3. 25= if Days for Completion is greater than 30 days and completion less than 25%

where Days for Completion = Current Date - Baseline Timeline Date.

Table presented below illustrates the final dataset that would be required for the generation of the programming dashboard.

Deliverable	%Budget Used	Risk	Completion Status	Project
ADaM	40	25	22.5	101
Listings	25	25	5.5	101
SDTM	65	50	13.5	101
Tables	50	25	2.1	101
ADaM	60	75	10	102
Listings	70	50	15	102
SDTM	90	75	20	102
Tables	10	100	25	102
Listings	30	25	30	103
SDTM	20	40	30	103
Tables	50	25	60	104
ADaM	30	25	40	104
Listings	25	25	50	104
SDTM	80	25	90	104
Tables	50	25	30	105
ADaM	40	25	40	105
Listings	25	25	50	105
SDTM	65	50	20	105
SDTM	65	50	40	106
ADaM	0	0	0	106

Once the data from all the projects is collated, dataset is prepared for the Dashboard creation. An example of dashboard is presented in Figure 2 in which six projects have been used for demonstration purposes. Risk lines are plotted in red indicating the financial risk and in blue indicating the risk for deliverable completion. The dashboard presented would give a holistic view of projects at one time. Further drill downs for the detailed programming issues, financial information or specific items can be added to the dashboards. Dashboards are programmed using SAS GRAPH® /SDGESIGN which can be linked to the data reference and comes handy with the project review meetings and risk escalation.

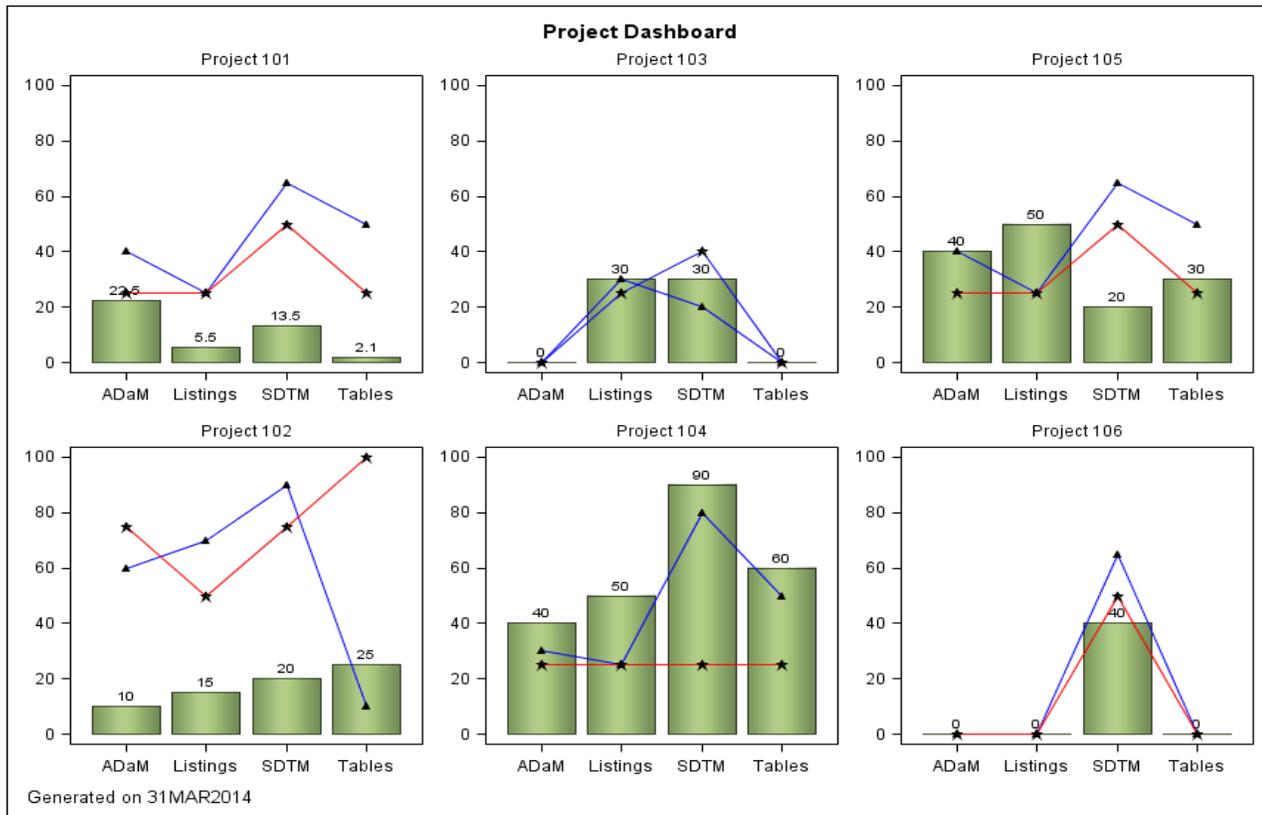


Figure 2: Sample Program Dashboard

## CONCLUSION

The technique presented in this paper would be a helpful tool for the management and programmers to get a snapshot of the status of projects. It is a simple yet, elegant tool that can be setup with minimal effort as well as additional tools in order to produce the metrics that would aid a transparent and real time view of projects and a better understanding of the associated risks.

## CONTACT INFORMATION

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