ABSTRACT

Clinical trial data processing is a critically important element of new drug development. This paper discusses an information system built with SAS. It frees managers from some of daily routings to just collect on-going projects' status information. It also act as a desktop time management tool for all the employee involved in the project. With SAS's rich capability, the system provides the managers with useful tools to perform analysis for the business process. This is one of significant advantage for such SAS based system over other over-the-shelf scheduling and project management software.

INTRODUCTION

The development of a new drug is a highly regulated process. This process includes several phases of safety and efficacy testing in order to meet stringent government requirements. In average, a success drug development process lasting 8 years and costing 300 million dollars. Companies are increasingly adopting measures to lower the cost by shorten the development cycle and improving the efficiency in the operation.

Clinical trial data processing often serves as the last major step before company filing the new drug application with FDA. Because drug company have already invested over hundred million dollars for a new drug just to reach this stage, 'on-time delivery' often is the ultimate goal which set up by upper management of drug company.

Due to the complexity of the process, management is an overwhelming task. Manager often need monitor the progress of projects sometime over a hundred clinical protocols across different drugs. For each protocol, the tasks are collaborate efforts of database administrators, data reviewers, SAS programmers, and statisticians. Thus, for management at such department(s), a good way of tracking and planning is essential.

SYSTEM DESIGN

The goal this system want to reach consists two closely related parts: project tracking and project planning.

Successful project management requires constant vigilance: finding out how much was actually accomplished and what remains to be done. Because of the complicated nature of process, there are a lot of factors can cause delay. Project tracking plays a major role of monitoring a project as it progresses. As work begins on the project, the current status of each activities are incorporated into the system. The input of updated status data is carry out by each individual involved in the project. The system refines the project schedule base on updated processes information. It includes modify the network diagram, revise critical path, reallocate resources to resolve conflicts. In some sense, most of 'fine-tunings' are taken place here. On the other hand, the system also designed to make information variable to the individual involved in the project. So every project team member can see the progress. They can better communicate each other and coordinate their efforts.

SAS/OR is the key ingredient of this system. The heart project management capability lies in Proc CPM - the Critical Path Method scheduling procedure. It takes activity precedence, time, and resource constraints and working day information to determines a feasible schedule for the project with the shortest completion time possible. Other two important features in project management - project network diagram and Gantt chart (schedule bar chart) are taken care by Proc NETDRAW and Proc GANTT.

When a good project tracking is in place, that is the time to utilize the tracking data to carry out project planning. The system refines the project schedule base on updated processes information. It includes modify the network diagram, revise critical path, reallocate resources to resolve conflicts. In some sense, most of 'fine-tunings' are taken place here. On the other hand, the system also designed to make information variable to the individual involved in the project. So every project team member can see the progress. They can better communicate each other and coordinate their efforts.

The whole system is integrate with SAS/AF Frame entry. It greatly shortened the time for prototype development. The user interface was designed to
make it easy for all the system users. Graphical icons and control objects such as push button, drop down list boxes, and navigation arrows were used wherever possible. SAS/SHARE is used to allow multiple users access the centrally stored the data. This concurrent access provides one of stand-out feature comparing to other off-the-shelf project management software.

DATA FLOW

Determined by source, data can be categorized into two parts. One is master data set. It is stored when system has been set up. Another part is acquired when project team member reporting project status.

The master data set can come previous business process data, even might not in SAS data format. It includes:

- Activity data which contains all activity information, such as task name, duration, resource requirements, successors, time constraints, and so on. It also includes project related information, for examples, project characteristics (total patient number, trial duration, case report form (CRF) total page number, and data table number, etc.)

- Resources data which contains resources availability levels and dates for resource used by activities in the project, along with the specification of type of each resource, information about working day and individual assigned to the project.

End-user reporting data mainly contains updated activity data - activity status, actual duration of tasks, and reasons which cause the delay.

Data from two sources combined through necessary data manipulation, then feed to Proc CPM. The output from CPM consists of schedule and resource usage data. After further manipulation, Proc NETDRAW and GANTT take the output from CPM to produce network diagram and schedule chart.

SYSTEM DESCRIPTION

The first screen is 'log on'. When a user log on, he or she is given a level of access, which is dictate by a prestores lookup table. The system can be broken down into three modules. They are 'reporting', 'management' and 'system administration'. Each module is represented by a push button in main menu. (see Figure 1).

First module is called as 'Reporting'. It is designed to allow each project team member to report project status. It also serves as a communication center to inform everyone involved in the project with up-to-date project status.

Figure 2 is the flowchart for the reporting module. In this module, each project team member can updated project's status. The system choose the activities assigned to the user according to lookup tables. For an example, when a statistician want to input the latest information (the bottom node in Figure 2), system will provide the current activities only assigned
to him and for the project the statistician chosen. Input screen uses radio boxes for multiple choice type questionnaire. For an example, it asks user to choose box of 'yes' or 'no' for the question if one specific activity has complete or not.

This module not only collects the progress data but also provides progress information to the project team. It is important for the project to move ahead smoothly when collaborative efforts are needed. Any member can see his or her own activities' timelines and also see the progress of activities ahead of his or her. Figure 3 provides the schedule for the whole project. The option of timenow is used in Proc Gantt to mark the current date. (the vertical line in schedule bar chart).

For the screen shown in Figure 5, There is overview of the progress for one therapeutic area. Managers can have a clear picture of what is going on in this area. The screen used a dynamic graphic object to show the projects' Gantt chart. Depends on what therapeutic area manager has chosen in the drop down list, after the push button 'done' was clicked, the required project profile will appear on the screen.

Management module's flow is illustrated in Figure 4. The module have two major paths along the line of functionality - tracking and planning. Within tracking (node of 'monitoring'), managers can either tracking the situation for specific task category for the information about individual's workload and performance, or choose to monitor the progress of the projects as a whole (see Figure 4).

The next figure is part of project planning. It is a review of resource utilization. In a new drug development there are lot of different endpoints need to be addressed separately. So often the case many parallel studies are planned. Due to the similarity among those studies, management can develop some kind of benchmark. It is even possible for managers to modeling the situation. Figure 7 provided histogram of standardized time spent for a group of parallel projects. The purpose is providing management a tool set to further benefit from the data this system has collected.
Figure 7  Standardized Time Spent on Project

Focus on the objective of management at department, the approach of this system is try to have minimum impact on daily operation at start. And then gradually enrich the system's capability. It is important to have the flexibility of expanding the system to accommodate more sophisticated analysis features such as decision. As increasingly using executive information system (EIS) in the industry, the system should be easy to be integrated into higher level management system.

The module of system administration is designed for the purpose of setting up new project, closing out the completed study and change the personnel information, etc.

NOTES

This system is based on the assumption of relative fixed step sequence in the whole process. Because most of companies has their process flow documented in standard operation procedure (SOP). Also, a self-adapted work flow system requires that the information about activity relationship of each step be recorded. Such ad-hoc system is good for business re-engineering process, but away form the scope of a daily department level project management system. On the other hand, if main objective is emphasis on process re-engineering or decision analysis, you either need provide related data source or have end-user to input extra data.

CONCLUSION

The system presented in this paper is a prototype, with the intention of showing that SAS can be used in not only simple project tracking but complicated project management and business process analysis as well. Our experience also prove that SAS/AF and SAS/OR are extremely powerful tools which gives application programmers the ability to develop simple, 'user friendly' systems to perform variety of project management tasks.

REFERENCES


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