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Clinical SAS® Programming: Analysis and Mitigation of Risk

Parag Shiralkar, eClinical Solutions, A Division of Eliassen Group

ABSTRACT

SAS® programming is an important function of clinical reporting work in pharmaceutical industry. Despite importance of SAS® programming in clinical reporting work, several factors at various levels of organization impact the productivity of programming as a 'business function'. These factors originate from the dynamics within an organization and the dynamics of the industry and often develop various types of risks in programming projects. While managing programming projects, project managers often need to deal with such risks. Most of the time such risks impact directly on the product delivered by the programming services. In some cases such impact is clearly visible financially through time and money lost in fixing the errors or in dealing with less priority work.

This study explores factors which may cause deviation of risk from the perceived risk by the project managers working on SAS® programming projects. Analysis of such deviation of risk and the 'management' experience of project managers can provide valuable findings about how project managers working on clinical SAS® programming projects should be mentored and should be prepared for risk mitigation.

INTRODUCTION

Role of SAS® Programming in clinical reporting environment is often attributed to meeting the reporting needs of the clinical team working on a clinical protocol or on a drug submission. Such reporting needs often include development of reports, graphs, queries, and datasets for submissions as well as for ad-hoc reporting requests. While perceiving SAS® programming as a function of an organization, primary objective of such function is to meet the clinical reporting needs in a qualitative and cost effective manner. Management can meet reporting needs in a qualitative manner by ensuring availability of appropriate reporting environment and skilled and experienced SAS® programmers. Meeting such needs in a cost effective manner may not always be easy because of uncertainties and risks associated with the clinical trial. The approach in this paper suggests macroscopic analysis of SAS® programming function and focusing on reporting needs as a product delivered to customers.

This paper reviews sources of risk faced by SAS® programming function and discusses possible ways to mitigate such risk. It is recommended that management should follow the practice to train and mentor the SAS® programming project managers for proper project planning, analysis, and risk mitigation. In order to assist the management in such efforts, this paper conducted a study to evaluate relation of risk perceived and risk faced by the project managers working on clinical SAS® programming projects. The causes of risk deviation are explored in detail in order to provide better insight of project planning. This study also analyzes the management and programming experience of SAS® programming project managers against the risk deviations experienced by such project managers.

SOURCES OF RISK AND RISK MITIGATION

When programming function or team does not meet the reporting needs in a qualitative and or cost effective manner, then such product delivery can be considered as a result of improperly mitigated risk by the management. In other words the sources of risk can be attributed to all the factors which pose obstacle to the programming team in meeting the reporting needs in cost effective, timely, and qualitative manner. While considering clinical trial reporting as a 'project', sources of risk can be broadly categorized in terms of logistic, technical, trial specific, business, and financial factors. Further explanation of each of these factors is given below:

- Logistic factors: Most of the factors in this categorization relate to the programming project logistics. This includes project planning, task scheduling, resource planning and management, team management, communication.
- Trial specific: Factors in this categorization mostly focus on issues originating from the trial management. Such issues include changes in trial analysis, number of submissions, planning of trial project activities, trial reporting complexity, and patient recruitments.
- Technical: This is one of the most frequently ignored sources of risk. Factors in this area include technical and information technology infrastructure including functioning of communication or e-mail servers, operating systems, clinical reporting systems, and that of database management systems and servers.

- Finance Issues: Resource planning and management is often dictated by available or allocated finances to the project. Any changes in the assigned budget or any imposed budget constraint can result into inability of programming function to meet the reporting needs in cost effective and qualitative ways.
- Business issues: These issues include management's decision regarding continuation of trial, changes in operating procedures, methods, and policies, and number of regulatory reviews requested by regulatory authorities.

Mitigation of risk: With growing work load and work pressure, often management identifies project managers for managing programming projects by evaluating the programming experience of such personnel. Quite often programming project managers may not be completely familiar with the sources of risks discussed above. At the same time management does not have enough time to ensure that programming project managers are in fact aware of these sources of risk. So, in such situations, whenever the risks are realized during the project progression, 'dealing with the situation' is the most common approach to deal with the risks. Although in most cases such approach works out very well and programming project managers can ensure proper delivery of the reporting needs, such approach often results into lot of stress on programmers as well as programming project managers. Such stress can be realized in terms of long working hours, and short turnaround time to meet the reporting needs. As a proactive approach to mitigate such risk, programming project managers often consider the logistic factors primarily in terms of the clinical trial project timelines and amount of deliverables associated with each submission of the trial. Despite such proactive and reactive approaches to deal with the risk, quite often the risk turns the project delivery in to a disaster. Such results clearly underscore the need of strong proactive measures for sound project planning. Succeeding sections of this paper discuss a review of completed clinical trial reporting projects. The lessons learnt from this study can help management deal with the risk planning, and risk mitigation in a proactive manner.

RESEARCH METHODOLOGY

It is assumed that each project manager working on SAS® programming projects in clinical reporting environment carries out some sort of risk assessment and analysis before the trial start-up and during the period of trial. Deviation in product quality or cost occurs when such perceived risk significantly differs from the actual risk faced by programming project work. Further, such possible deviation of risk may occur because of varied degree of clinical SAS® programming and management experience of project managers. It is important to asses how such management experience of programming project managers contributes to risk analysis. Based on these factors, the objectives of this study are:

1) To asses if actual risk faced by clinical SAS® programming project managers during the project life significantly differs from the risk forecasted or perceived by such managers prior to start of or during the time span of project.
2) To analyze influence of management and programming experience of project managers on the risk assessment capabilities.

DATA COLLECTION AND ANALYSIS

This study considered programming tasks associated with 18 clinical trials. Most of the trials in considerations include phase-IIa, phase-IIb, and phase-IIIa, with some exceptions of phase-IIIB, and phase-IV trials. All these trials were completed in the time span of 8 months to 1.5 years. These trials were assigned to five different project managers. During the time span of the trial, these project managers handled few other trials apart from the trials in the consideration of this study. Several factors based on which the project managers planned for resources, evaluated, and assigned the resources and planned the programming activities are considered as a basis for risk perceived by the project managers. The risk faced by each project in terms of various uncertainties is closely monitored during the time span of the project. The risk faced and risk perceived is recorded in terms of three point scale indicating low, medium, and high risk associated with each factor of risk. For each project under consideration, such risk is recorded for following sub-factors associated with principle factors under consideration:
Technical Factors: Performance of clinical reporting system, performance of operating and e-mail servers, performance of database servers, scheduled and unplanned maintenance of servers and systems.
Trial Specific Factors: Cross study programming efficiency, changes in trial analyses, delay in patient recruitment, trial complexity.
Logistic Factors: Resource planning and management, knowledge of resources, resource turnover anticipation and turnover realized, team dynamics and communication, and project activities delay.
Business Factors: Changes in operating procedures, changes in reporting method and processes, decisions about trial continuity.
Financial Factors: Budget planned vs needed, and decisions about continuity of budgeted funds.

After measuring the risk in terms of three point scale, average of such quantified measurement (one point- low risk, two points- medium risk, and three points- high risk) is taken at the level of each project and major causes of deviation of risk faced vs risk perceived are evaluated. The resulting data is shown below.

Summarized Results- Risk Experienced, Perceived, and Management Experience			
Project Code	**Perceived Risk**	**Experienced Risk**	**Causes of Deviation**
PR-1	2	2.13	Technical issues, less cross study efficiency, Issues with resource management.
PR-2	2	2.064	Upgrades of systems
PR-3	2	1.832	Changes in trial analysis, delay in patient recruitment.
PR-4	2	1.996	Delay in patient recruitment, business decision to stop the study.
PR-5	2.02	2.032	Lack of cross study efficiency, changes in trial analysis.
PR-6	2	2.198	Team dynamics, issues with resource management, lack of cross study efficiency.
PR-7	2	2.632	Upgrades of reporting system, delay in patient recruitment, changes in reporting requirements, imposed budget constraints, excessive regulatory queries
PR-8	2	2.2974	Additional submission requirements, additional analysis requirements
PR-9	2	2.032	Changes in trial reporting requirements, fluctuations in resource requirements.
PR-10	2	2.032	Additional requirements for deliverables, changes in reporting requirements.
PR-11	2	2	Minimal deviation.
PR-12	2	2.36	Changes in trial reporting, communication issues, changes in budget availability, new rolled out processes, lot of regulatory requests.
PR-13	2	2.232	Trial complexity, lack of cross study efficiency, fluctuations in trial requirements resulting into changes in resource demand
PR-14	2	2	Business decision to stop the study
PR-15	2	2.3	Resource planning issues, changes in budget availability
PR-16	2	2.3	Changes in budget, issues with resource management
PR-17	2	2.26	Decision to hold the trial, fluctuations in resource requirements
PR-18	2	2.28	Delay in patient recruitment, delay in trial activities, decision to hold on to the trial.

Note: Risk rating range 1 to 3, 1 indicates low risk and 3 indicates high risk

From this data, it is evident that most of the project managers perceived intermediate risk associated with each project and factored that risk in while planning for project activities. However, as shown in the data, the risk faced by each project varied because of several uncontrollable factors. From the data it appeared that the risk faced is higher than the risk perceived. The null hypothesis here is:
H_0: There is no significant difference between the risk perceived by programming project managers and the risk faced by the programming projects
Ha: Risk faced by programming projects is different from the risk perceived by programming project managers.

Results from two sided t-test indicate t-statistics value of -3.70 and t –critical value for two tail test as 2.109. Corresponding P-value is 0.0017. At 0.05 significance level, we reject the null hypothesis and conclude that risk faced by programming project significantly differs from the risk perceived.

In most of the cases the causes of risk deviation were related to factors which were beyond the control of programming management and project mangers mitigated such risk faced by taking appropriate actions. Some of the trial planning factor such as ‘delay in patient recruitment’ or decision to stop the trial can impact the project level resource management. However, factors such as ‘expected’ delays in project activities or lack of cross study efficiency or complex trial design/analysis can certainly be factored in while developing the project plan. Resource planning and management is another major source of risk. Meeting resourcing demands by ensuring timely supply of skilled programming resource is often a challenging task. Because of changes in trial analysis requirements, often assigned resources remain unutilized or can get over-utilized affecting the overall productivity of the programming function. Risk associated with unanticipated turnover of resource can be minimized if the management has a sound

knowledge transfer and knowledge retention plan. In order to reduce the impact of resource management on project productivity, it is important to revalidate the resource requirements periodically over the time span of the project. Although complexity of trial analysis and reporting plays a critical role in meeting the programming deliverables, it is important to note that the causes of risk deviation vary considerably in different projects. As stated earlier, since the projects considered in this study are managed by five different project managers, it would be interesting to see how different project managers perceived the risk based on their experiences.

For further analysis, the risk deviation is computed as a difference between the experienced or realized risk and the perceived risk. Then the mean percentage risk deviation associated with each project manager is analyzed against the experience of project manager. The resulting data is shown below:

Summary of Risk Results and Experience of Project Managers

Project Manager	Projects Managed	Management experience (years)	Mean Percent risk deviation	Primary Causes of Risk Deviation
A	PR1-PR6	2	1.93%	Less cross study efficiency, delay in patient recruitment, changes in trial analysis, technical issues.
B	PR7, PR8	1.5	23.23%	Resource management issue, Imposed budget constraints, Team dynamics, excessive regulatory queries, Additional submission and analysis requirements.
C	PR9-PR11	1.5	1.06%	Changes in reporting requirements.
D	PR12-PR15	3	11.15%	Resourcing issues, budget issues, lot of regulatory requests, and communication issues.
E	PR16-PR18	3	14%	Budget issues, communication issues. Business decisions to stop the trial.

Note: Risk deviation is computed as a difference between realized risk and perceived risk. Mean percent deviation is calculated by taking an average of risk deviation of all the projects under the same project manager and then by analyzing the percentage of such value.

Although this data seemed to be insufficient to draw any statistically significant conclusion, it can give valuable information in terms of why certain project managers experienced significant risk deviation. From the analysis and review of these projects and project management, here are some important findings:

- Project managers with less management experience strictly follow the processes and have fresh perspective towards validation of processes during changes in business requirements. In some cases, their lack of management experience results into inaccurate resource estimations and inability to handle the team dynamics.
- Project managers with less management experience but lot of programming experience often get tempted to focus more on technical issues. This result into issues related to project planning and overall team management. However such project managers ensure that the quality of deliverables doesn't get impacted in any circumstances.
- Project managers with relatively more management experience often face project risks more in terms of business issues. A less likely area of project risks can be perceived in terms of team dynamics or unclear anticipation of resource turnover. If mentored properly, such project managers can do highly proactive project planning.

FINDINGS AND RECOMMENDATIONS

Above analysis and findings reveal that management of clinical SAS® programming project can pose different set of challenges depending on type of clinical trial reporting. Further the risk analysis, and analysis of such projects varies greatly depending on the experience of project managers. Risk estimation and project planning is always a very first proactive step towards risk mitigation. As stated in the consolidated data, most of the causes of risk or sources of risk deviation as observed in the projects under consideration of this study can lead the management to proactively plan for mitigation of such risk. First step of risk mitigation starts with appropriate delegation of project assignment to appropriate personnel. Most of the management and project logistic related sources of risk can be factored in proactively if we assign right project manager to the programming project. In general programming experience is a primary consideration in selecting the project manager. Asides this, management should consider different factors into account while selecting the project manager. Some of the recommendations in this regard are stated below

- Approach of a project manager towards programming: If programming project manager spends most of the time in dealing with programming issues, he or she won't have enough time to deal with the management issues. It is found that because of their programming background, often project managers get tempted to dive in to technical aspects of project. Before assigning any programming project, management should mentor the project managers about how much they should involve in programming aspects of the project and how much they should focus on programming issues.

- Team dynamics: Each programming project may pose different set of challenges. Depending on the nature of deliverables and on reporting needs, project manager should be capable to set up appropriate flow of communication with the programming team, communication of programmers with the clinical team, reporting of programming issues, and serve as a point of issue escalation resolution wherever applicable. Project manager should also be capable to distribute the work load among the team members appropriately and should empower the team members. Most of the issues related to team dynamics and communication can be minimized by mentoring the project managers on team management and communication.

- Past experience of project managers: Although its important that project managers need to have sufficient SAS® programming experience, asides that it is strongly recommended that project managers have some experience of managing team of programmers. Such management experience is a very important requirement and should be a major consideration for assignment of programming project. Management should also consider the project performance of manager on previously completed projects. Such performance should be evaluated in terms of cost, time, speed, and quality metrics. Such metrics can provide clear idea of how project manager has forecasted and mitigated the project risks in previously completed projects.

- Ability of manager to visualize a 'complete' picture: Programming project manager should have thorough knowledge of the drug development and clinical trial processes. Knowledge and understanding of project manager should not confine to the work of programming function. Management should mentor the project managers on drug development process and interdependencies of different business functions working together on clinical trial. Project managers can plan the project activities, budget, and resourcing requirements more accurately if they understand the risks associated with the operation of a whole trial. As found in the collected data, some projects were on hold because of delays in patient recruitment. The risk realized is in such case in terms of possibility of under-utilized programming resources. By taking such scenarios in to account, project managers should plan for optimum resource utilization.

- Cross functional communication: Project managers should understand importance of paying attention to such communication and to initiate such communication as and when required. Project manager should be capable to analyze the issues related to system or server upgrades, other specific maintenances related to information technology, and business decisions regarding program or trial continuity. Project managers should relate and analyze such issues with project timelines, and with planned resource utilization. After such analysis project managers should also be capable to analyze the impact of such issues on programming work and report the possible options to deal with such impact to management.

- Standardization of reporting processes: Changes in standard operating procedures, and regulatory requirements often impact on reporting processes. Further as a part of continuous improvement, most of the organizations often review and amend the reporting processes. Roll out of such processes can pose challenges related to learning curve. If such processes are getting rolled out during the project period, managers should develop plan of action on how project activities will follow such processes without impacting the project timelines or quality of project deliverables. In general project managers should demonstrate capabilities to develop, review, amend, and implement such plan of action on project activities. This can minimize the risk deviation significantly.

- Revalidation of assumptions: Allocation of resources and system infrastructure to any programming project is based on the assumptions about timelines and deliverables estimated in the beginning of the project. In order to avoid any risk of not adhering to those estimates, it is critical that project managers proactively revalidate the project timelines, deliverables, and resource requirements on a periodic basis by collaborating with the clinical team and with the management. Such revalidation and need based amendments of the assumption, and amendment of allocation of resources and infrastructure can help the management improve the productivity. As a regular exercise, management should conduct such reviews across all the programming projects.

- Maintaining thorough documentation: This is always a key in dealing with any project risk. In clinical reporting environment, documentation in terms of issues/decisions log, quality check reports, specification documentation, and other programming related documentation can serve as a basis for knowledge transfer, knowledge retention, and for audit trail. Despite realizing its importance, in some cases project managers keep the documentation but fail to enforce or implement the practice of documenting things thoroughly.

Management should implement a status check on documentation practices in order to deal with the project risks.

Depending on the nature of clinical programming projects, the practices and approaches of risk analysis and mitigation can vary. Most of the approaches suggested here are based on the number of projects evaluated as a part of this study. There could be several other considerations which can help management improve the productivity, plan for project activities and analyze and mitigate risk. Such considerations can be highly dependent on individual organization structure, policies, and overall culture of an organization.

CONCLUSION

There is a lot of emphasis on reduction of cycle time associated with each stage of drug development program. With resource turnover, changes in organization strategies and policies, such efforts of cycle time reduction often pose risk on individual projects of different business functions. As a part of continuous improvement when management takes measures like streamlining the processes, standardization initiatives, and budget reduction for programming projects, such steps can not provide desired output if project managers managing the programming projects are adequately mentored for risk analysis and mitigation. By monitoring the programming projects and by analyzing the collected data, this study provided important recommendations for better project management and for effectively analyzing the project risks. Most of the factors discussed in this study indicate proactive measures for risk mitigation. Lessons learnt from this study also underscore the importance of selection of appropriate project manager and importance of mentoring the project managers for programming project management. Considering the fact that SAS® programming project management in clinical reporting environment can pose to different set of challenges, this study recommended methods to effectively manage such projects. Management can explore some of these stated factors by relating those to the policies and procedures of their organization.

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CONTACT INFORMATION

Your comments and questions are valued and are encouraged. Author can be contacted at pshiralkar@eliassen.com or at pcshiralkar@gmail.com