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How to keep the project on budget in the clinical trial study

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ABSTRACT

If a SAS® programmer is responsible for the budget of a clinical trial study in the biometric department, he or she will need to watch and keep the project on budget throughout the study. The paper is intended for those who are interested in budgeting in the biometric department. It will discuss the reasons and ramifications for going over budget during the study such as an incorrect budget, improper resourcing, poor execution, incorrect deliverables and miscommunication. The paper will also discuss the ways to reduce the costs and save a budget. The paper will be based on CDISC clinical trial setting.

INTRODUCTION OF BUDGET

The project budget is the estimate of time, money and resources required to complete a project. It is largely based on the number of deliverables required, the duration of the project and an accurate assessment of the resources. However, a budget is meant to be an estimate, so the precision of this estimation becomes very important. In order to provide a more accurate estimate, the critical budget items should be identified for the project.

INTRODUCTION OF BIOMETRICS BUDGETTING IN CLINICAL TRIAL STUDY

The biometric budgeting in clinical trial study is based on the tasks in the contract. In order to understand how budgeting works in clinical trial study, a SAS programmer should know what the budget items are in the contract. Usually, the biometric budget is based on the following items or tasks

- The creation of a Statistical Analysis Plan (SAP) and Mock Up Tables
- The number of SDTM and ADaM
- The number of Tables, Listings and Graphs
- The frequency of deliverables

A SAS programmer might need to consider the followings in the budget as well.

- The creation of Define document(xml and pdf) for SDTM and ADaM
- The application of Controlled Terminology
- CDISC compliance check (e.g. OpenCDISC checks on SDTM or ADaM)
- The number of project meeting with clients
- The number of Data Transfer(external and internal)
- The number of Data Reconciliation (e.g. LAB and IVRS)
- Coding (e.g. Who Drug and MedDRA)
- Programming support to other department such as data management
- Ad hoc reports
- Inflation rate

EXAMPLE OF PROJECT BUDGET TEMPLATE

Budgeting can be easily done with the help of a budget template. Below is an example of a simple project template of clinical trial study. The below example contains only three tasks – SDTM, ADaM and TFL, but usually, the budget template is more complicated. For example, it could contain other tasks like ones mentioned above (e.g. SAS, Mock Up Tables or Define documents). For a simple calculation, the rate of programmer is set to $100 per hour and "Hours for each task" is set to 20 hours. However, there could be more than one rate such as one for Senior Programmers and another for Junior Programmers. The budget template could also include unique TFL and non-unique TFL; usually, each is assigned a different number of hours to complete.

Number	Task	Hours for each task	Total Hours	Programmer Rate ($/hr)	Total Rate ($)
30	SDTM	10	300	100	30,000
20	ADaM	10	200	100	20,000
100	TFL	10	1,000	100	100,000
	Total		1,500		150,000

As seen above, the scope of the project is 30 SDTM, 20 ADaM and 100 TFL. At the specified programmer rate of $100/hr, the total estimated budget for above project is $150,000.

According to the budget template, the biometric department can reduce the budget in two ways:

- Increase the programming efficiency, so the hours for each task are less than 10 hours.
- Decrease rate of programmers by using offshore resources assuming that offshore resources are as good as onshore resources.

For example, if the company can save about 20% either in "Hours for each task" or "Programmer Rate", the company can save about $30,000 in the total budget.

REASONS FOR GOING OVER BUDGET

The following may be the main reasons for going over budget.

- Incorrect budget from the beginning
- Improper resourcing
- Poor execution
- Incorrect deliverables
- Miscommunication

INCORRECT BUDGET IN THE CONTRACT

The contract is a project agreement with sponsors. The program leader needs to make sure that what is expected from biometric department should match what is written in the contract. The program leader should start with the correct budget; if the contract does not match the budget, the project will definitely go over the budget. In order to start with the correct budget, the program leader also needs to provide the precise estimates for the contract. In a typical setting, it is almost impossible to estimate the exact number of the deliverables for the client. The program leader can first provide the estimates as close to the final number and monitor the deliverables through the project and inform the clients of any differences.

IMPROPER RESOURCING

Proper resourcing requires the following:

- Proper experience level of programmers to the assigned works.
- Resources have or have access to appropriate training.
- Correct number of programmers during the assigned period.

Appropriate programmer assignments are critical to project success. For example, if a programmer does not have much knowledge on ADaM, but he is assigned to an ADaM project without the proper training and mentorship, he or she will not be able to finish the assignments in time and will take a much longer time to finish ADaM datasets compared to ones with ADaM knowledge.

There are occasions when the resources for a project require additional training. If a task is given to a programmer who has not received proper training, he or she will not be able to finish the assignments on time and will also spend more time to finish the projects. Therefore, if a programmer requires proper training, it should be provided before the project starts.

The size of the team will depend on the projects and the expected project duration, but in order for the team to finish the projects on budget, the team should consist of the optimal number of programmers. More programmers may require more training and an increased learning curve for the assigned project. An insufficient number of programmers faces the risk that the project won't be finished in time. If possible, it is the best for the programmers to be assigned to one project for a long period of time rather than frequently moving resources from one project to another project. Whenever a programmer is assigned to a new project, he or she will have some type of learning curve for the new assignment.

Below is an example of how programmer resourcing could be done. Please note that "Hours for each task" is an arbitrary number. These hours will vary with each company. Also note that for the purpose of simple calculation, each task includes both development and validation time and there is no distinction made among the level of programmers (i.e., Senior or Junior programmers).

Number	Task	Hours for each task	Total Hours
30	SDTM	10	300
20	ADaM	10	200
100	TFL	10	1,000
	Total		1,500

As seen above, the project is estimated at 1500 hours for the programming task. Two different scenarios will be shown below.

First, let us say that we need to finish the project within two and half months, about 10 weeks. We assume that each programmer contributes about 30 hours per week. So, mathematically, each programmer contributes about 300 hours over 10 weeks. In order to finish the project within two and a half months, the project requires about 5 programmers for 10 weeks.

Another scenario is that we assign 3 programmers to the project. So, assuming that each programmer can provide 30 hours in a week on this project, 3 programmers can contribute about 90 hours in a week. So, 3 programmers will be able to finish the project in about 16 to 17 weeks.

If the program leader understands the logic behind resourcing and applies it to the project, the project will have the optimal number of personnel. If the project has more personnel than needed, the project is more likely to go over budget. On the other hand, if the project is understaffed, the project could be in danger of not meeting the timeline. Therefore, it is critical to have the optimal number of programmers assigned to the project.

POOR EXECUTION

Even with the proper resources and a well-funded budget, if the team does not have a well-defined plan and does not carry out the project well, the project will definitely go over budget. A poorly-executed project always cost more compared to a well-executed project, so it is critical how the team leader runs the project.

INCORRECT DELIVERABLES

It is always better to get things right the first time. If the deliverables do not meet the expectation of the clients, first of all, the team looks bad and secondly,if the team needs to provide additional deliverables, additional costs for time and resources will be incurred. Below is an example of the costs associated with resending the deliverables without any program changes. For a simple calculation, “Hours for each task” is set to 0.5 hours, which includes the time for both the development and validation.

Number	Task	Hours for each task	Total Hours	Programmer Rate ($/hr)	Total Rate ($)
30	SDTM	0.5	15	100	1,500
20	ADaM	0.5	10	100	1,000
100	TFL	0.5	50	100	5,000
	Total		65		6,500

As seen above, the process of resending costs a lot of money. It is always better to get it right at the first time.

MISCOMMUNICATION

There are two kinds of miscommunication – external miscommunication with the clients and internally within the project team. Miscommunication can lead to incorrect deliverables, which leads to unsatisfied clients. Effective communication always saves time and resources. It will keep all the related parties in the same loop and help the team to work as one unit. In order to communicate effectively, the program leader needs to do the following:

- Have a regular project meeting with the clients and with the team.
- Communicate the process and current status of the projects.
- Communicate the issues or concerns early.

HOW TO SAVE A BUDGET

So far we have discussed about what could cause the project to go over the budget. There are also many ways to save resources and times, eventually saving a budget.

- Clear understanding of the projects and contracts
- Detailed planning for the projects and proper execution of plans.
- Proper resources (e.g., keeping the same programmers in the similar studies, proper allocation of works)
- Efficiency in programming. (e.g., the proper usage of macros and generic codes)
- Effective communication – internally and externally.
- Regular budget monitoring – The team needs to monitor the budget on regular basis. For example, if 60% of the budget was spent, 60% of tasks should be done. If there is a big discrepancy between budget spent and tasks done, the team needs to investigate what caused this and what needs to change.

- Keeping accurate records of out-of-scope work. Usually, if there is a big discrepancy between budget spent and tasks done, there could be some out-of-scope works. The team leader needs to communicate the out-of-scope works with the project manager.

REVIEW OF BUDGET MANAGEMENT AFTER STUDY

It is really important to review the budget right after study completion. The team needs to find out from review process whether the team can improve the project process and cost management for future studies. The review can consist of the following items.

- Review the task time spent in the study. If the company has a system that allows all programmers to document their time by task, the project team can analyze how much time was actually spent on each task, so the team can find out actual time or costs spent on each task.
- Review the contract and the deliverables.
- Review the current project management process.
- Gather similar projects' historical data and analyze them.

CONCLUSION

On the surface, it seems like managing the budget is not a programmer's job. For most companies, helping to manage the budget is not even part of the programmer's responsibilities. There may be a misconception that a SAS programmer, even a programmer lead, does not know much about how a budget works since he or she is deeply immersed in the statistical programming of the study. However, SAS programmers can be the perfect partners for helping to manage the budget for a clinical trial. The SAS programmers are the ones who are working on the project on a daily basis and who know every detail about the project. So, we can provide more accurate estimation and feedback about the budget if we understand more about how the budget works. The managing of a clinical trial budget is somewhat similar to programming. It is calculated, organized, planned and followed. Even though the budget is not a programmer's primary job, SAS programmers will derive great benefit if we understand how the budget works in the clinical trial. Furthermore, if we understand the budget, we can help with the budget throughout the project.

CONTACT INFORMATION

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