Building Effective Statistical Programming Teams for Clinical Trials

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ABSTRACT

In resourcing a team of statistical programmers for a clinical trial, management must consider many aspects. The dimensions to be considered are experience with the client, knowledge of therapeutic area, complexity of study, scope of deliverables, timeline, programming skill set, and availability of each team member. These dimensions must be ranked and project risks must be identified. This paper explores resourcing considerations and well as methods of team communication to keep the project on target with meeting milestones.

INTRODUCTION

Assigning resources to a team takes planning on the part of management. This paper outlines issues to be considered and thought processes involved when resourcing statistical programming teams for clinical trials.   This paper is written from the point of view of a contract research organization (CRO) that works with a variety of pharmaceutical and biotechnology sponsors.   However, many of the concepts are appropriate for organizations that keep statistical programming projects in-house as well.

The first task in building an effective team is to select the team members. Questions to assist you in selecting the project lead and contributing programmers are listed below. The skills required of the project lead could apply to all members of the team, however as the project lead usually has the most influence on the project's implementation, I have listed project lead and contributing programmer considerations separately.

PROJECT LEAD CONSIDERATIONS

WHO HAS PRIOR EXPERIENCE WITH THIS SPONSOR?

This is important because many clients have specific requirements for their data presentation plan in terms of font size, font type, file format, naming conventions for variables, etc. Sponsors also often have specific requirements for naming program files, creating analysis datasets, naming statistical displays, and writing SAS code. Sponsors do not appreciate having to break in a new programming team from a CRO that has worked with them previously. Sponsors value the institutional knowledge that working with a CRO as a partner can provide.

WHO HAS EXPERIENCE WITH THIS THERAPEUTIC AREA?

A project lead with therapeutic experience will be familiar with the deriving the efficacy endpoints. This will aid in making sure programming specifications are clear and accurate. A project lead with experience in the therapeutic area, will also be more effective working with other functional areas such as clinical data management and medical writing because they will have a good understanding of expected data values and co-morbidities which could influence these values such as expected verses treatment-related adverse events.

HOW MUCH COMMUNICATION WITH THE SPONSOR WILL BE REQUIRED?

Will the communication be via teleconferences, e-mail, face-to-face or a mix of these methods? If communication will be frequent, it is important for the project lead to have excellent written and verbal communication skills.

HOW MUCH COMMUNICATION WITH OTHER FUNCTIONAL DEPARTMENTS WILL BE REQUIRED?

If the team will be working directly with other functional departments, it is important for the project lead to have an understanding of work processes of these departments. Established working relationships with people in those departments also will be useful in working out any project glitches that may develop during the life of the study.

WHO HAS GOOD ORGANIZATIONAL SKILLS?

The project lead will need to have good organizational skills as they will interface with other functional departments and attend meetings or teleconferences with the sponsor. The project lead will need to communicate timeline changes and project strategies to the team so as to keep the project on track and assign appropriate tasks to team members. If risks to completing the project on time or within budget arise, the project lead will need to remedy the problem or create a new plan of action. A project lead must also keep management informed about the status of the project and know when to involve his or her supervisor in problem solving. A project lead that does not regularly communicate and monitor the activities of the team puts a project at risk for missing milestones and/or overrunning the project budget.

CONTRIBUTING PROGRAMMER CONSIDERATIONS

WHAT IS THE IDEAL NUMBER OF PROGRAMMERS WE NEED ON THE TEAM?
If the team is too large, communication can be a challenge and too many learning curves must be climbed. If the team is too small, programmers can get overwhelmed and fatigued, which can lead to errors and rework. For these reasons, the size of the team has a direct correlation to completing a quality product on time and within the budget allocated.

When determining the size of the team, it is often helpful to pay attention to the estimated number of unique displays. Producing each duplicate display will be in a fraction of the effort needed to create its unique counterpart. Thus, the unique displays become a project pacing item and aid in helping to decide the number of programmers needed. The size should allow enough flexibility to maintain requirements for independent validation of deliverables while letting programmers juggle competing priorities from other projects.

For FDA submission projects or other very large projects involving hundreds of statistical displays and complex integrated analysis datasets, we find having a larger team divided into safety and efficacy sub-teams works well. If the project requires it, we may break it down further and have teams assigned to clinical data streams such as laboratory or adverse event data.

ARE WE FOLLOWING OUR SOPS OR THE SPONSOR'S?
If you are required to follow the sponsor's SOPs, then you will need to allow each member time to train on them. If you have worked with this sponsor previously, you may not be able to pass this cost on to the sponsor as they will have expected you to have already been compensated for this effort.

HAVE WE DONE A PROJECT SIMILAR TO THIS BEFORE?
Perhaps we already have programs with similar logic flow and display layout that can be modified. Chances are that the project was done with the same sponsor much of the naming conventions, preferences for displaying statistics, confidence intervals, zero counts, and such will be the same.

HOW COMPLEX WILL THE PROGRAMMING BE?
You will need to take into account the study design, the inferential statistics that will be needed, the complexity of the analysis datasets, etc. For example, PK parameter calculations are more complex than adding some identifying information onto a physical exam dataset. Would macros to create a number of the displays be the best approach? Will there be masked and unmasked versions of the same display to be produced?

WHO WORKS BEST WITH WHOM?
While everyone should be able to work and play nicely together, the fact is that programmers are people and personality conflicts do occasionally happen. If the scope of work is large and the timeline is short, this may not the project you use to work out any relationship issues among the programming staff.

WHAT IS THE AVAILABILITY OF RESOURCES?
Chances are the ideal set of programmers will be already allocated to different projects. However, most programmers are comfortable with working on more than one project at a time. This is because there are natural lulls in project work as new data is being cleaned, subject enrollment changes, revised specifications are being approved, etc. The number of concurrent projects a programmer juggles will vary by individual and the scope of the individual projects. It is best to check on a programmer's availability with either the programmer's supervisor or directly with the programmer before assigning them to a new project.

WHAT ARE THE MOST IMPORTANT CONSIDERATIONS FOR THIS PROJECT?
I find the best way to answer this question is to ask myself "What would put this project most at risk?" For example, putting together a team of programmers with no familiarity of oncology terms for a Phase II breast cancer study would mean there would be no one familiar with calculating best overall response. This would put the project at risk for error. Therefore, experience with oncology trials should be one of my top considerations for this project.

METHODS OF TEAM COMMUNICATION
Any decisions that bear on the logic or analysis dataset variable derivation should be documented in the programming specifications. Communication to the entire team about timelines is best documented in a file stored in the project directory. This minimizes miss-communication and saves the project lead from answering the same question about milestone due dates and keeps the team members' e-mail inboxes less cluttered with project documentation.

TEAM MEETINGS
Depending on the scope of the project, we have found regular team meetings to be a quick way to coordinate work in a project. These meetings can be informal or formal with a set agenda. We have found that a 15 minute daily meeting to determine who will be responsible for what displays is helpful as we approach the delivery date. We can also use this time to stage the final statistical and cosmetic QC for a group of displays once validation is completed. For those project times when a great number of tasks are being completed at the same time, as brief meeting in the early morning and another in the late afternoon work well to keep all vested partners apprised of the project status.

WHY WERE THESE TEAM MEMBERS CHOSEN?
Most people what to know why they were assigned to a particular project over a different one. Why not share this information? This will make team members aware of their own and other team member's strengths.

ISSUES TRACKER
As programming begins, there are inevitably questions that need to be answered. Many times, the answers to these questions are important for the whole team to know. Microsoft Excel is a useful tool for creating a "Issues Tracker". Appropriate columns for the issues tracker might be the question/issue; reason it is important; the date the issue was posted; the name of the person posting the issue; the answer to the issue; the name of the person answering the issue; and the date of the answer.

ONLINE PROJECT MANAGEMENT TOOLS
At my company we have an online project management tool to keep track of each item in the statistical deliverable to the sponsor. All items in the deliverable have associated tasks that must be completed in order to produce a quality product. Programmers can be assigned or volunteer for a task. As a task is completed, the programmer indicates this in the online project management tool. This tool keeps all members of the project team aware of the project status without having to rely on email or other cumbersome methods of communication.

COMMUNICATE HOW MANAGEMENT WILL SUPPORT THE TEAM
The project team should know what decisions the team can make as individuals and as a team, on what decisions management need merely awareness, and what decisions need management approval. Communicating this to the team early on will mitigate project risks and save valuable time in completing the work.

CONCLUSION
Careful planning of the project team size and considering the skills needed for the project lead and contributing programmers by management, will go a long way to giving a statistical programming project an excellent start. Making use of communication tools and giving team members the authority to make some decisions on their own will help the project stay on target to meeting milestones within the budget allocated.

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