

Dual Roles: I'm not just a programmer!

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ABSTRACT

Any successful business will be able to hire and retain great employees. One critical component to retaining those employees is establishing a focus on professional development that originates with the company leadership. Contract research organizations (CROs) are no exception. One unique type of professional development occurring in our organization is the opportunity for dual roles, not only in management but in operational areas. When an employee has reached a senior role in his/her department, they may be interested in ways to transition into roles with more leadership potential and/or a demand for higher-level technical skills. The focus of this presentation will be on the ways statistical programmers can work in dual roles and expand their skill set, as well as support different operational groups and become involved at the onset of project planning.

INTRODUCTION

Employee retention is a concern for any business, and contract research organizations (CROs) are no exception. The most satisfied and hard-working employees are ones who feel challenged and supported in their professional development, which originates from company leadership and is propagated throughout the culture of the organization. In addition to increasing seniority within their department, statistical programmers can gain vital experience by working alongside other operational departments. Most data services CROs will have departments such as: Biostatistics, Statistical Programming, Data Management, Project Management, Business Development, Contracts/Proposals, Marketing, Finance, Human Resources, and Quality Assurance. This inter-department interaction can inspire statistical programmers who are interested in a broader career path. Also, statistical programmers may have education and experience that allows them to step into a part-time role in another department. The focus of this paper will be on the ways statistical programmers can work in dual roles and expand their skill set, as well as take on more leadership responsibilities, support different operational groups and increase involvement in upfront project planning, specifically in the clinical data services sector.

LEAD PROGRAMMER ROLE

The first step in the professional development of most statistical programmers, beyond technical skills, is assuming a lead programmer role on a project. Tasks for a lead programmer often include assignment of programming tasks to team members, keeping team members on task to meet deadlines, and responsibility for documentation completion. Often the lead programmer will work closely with the lead statistician and project manager and will need to communicate effectively with these colleagues, as well as, occasionally, the client. Senior-level programmers will typically be leading more than one study at any given time, so soft skills, such as time management, communication, problem solving, and flexibility, are important in this phase of a programmer's career development.

Lead programmers do not necessarily have to be senior programmers; in fact, junior or on-role programmers should practice leading studies to acquire the skills needed to progress to the senior level. Junior or on-role level programmers can practice the soft skills mentioned above by co-leading a study with a senior-level programmer, who would act as a mentor. The senior-level programmer can designate tasks to the junior or on-role level programmer and provide support by reviewing their work, having regular conversations about expectations, and answering project-related questions. Ultimately, the junior or on-role programmer should be able to lead a less complex study on their own, by practicing with the supervision of different senior programmers on different studies and developing their own leadership style.

SUPPORTING BUSINESS DEVELOPMENT

Beyond acting in the lead programmer role on projects, statistical programmers can become involved in supporting new business acquisition, through support of the Business Development, Proposals, and Marketing groups. In the statistical analysis portion of a project, a significant amount of work and hours involves statistical programming. Therefore, it can be valuable to have senior-level programmers work with the proposal group to give input on strategies and cost estimates and be involved in the planning stages of projects. For example, our organization has baseline estimates for the time needed to complete tasks such as SDTM dataset programming or table programming.

These baseline estimates are produced from a set of assumptions and are periodically revised based on the hours used on recent studies. If a senior-level programmer reviews a project proposal, along with perhaps the protocol of a study and/or a draft case report form (CRF), they could give feedback to the proposals team as to whether the current baseline estimates are sufficient for this specific project or if the time should be increased or decreased based on previous experiences with similar types of projects. This sort of insight comes from leading multiple types of studies, across different clinical phases and study drug/device indications, and using this previous experience to estimate how long (on average) a senior vs junior resource would spend on common tasks.

A senior-level programmer could also suggest a strategy for the most efficient way to program a statistical analysis. For instance, when asked how the statistical programming team would handle an ISS (Integrated Summary of Safety) submission, a senior level programmer could offer strategy suggestions for the best way to pool data that might not occur to the Business Development team member based off of pros and cons of previous experiences with ISS or ISE (Integrated Summary of Efficacy) projects.

Senior-level statistical programmers also can be the lead programmer or subject matter expert for some internal Research and Development (R&D) projects. In the case of data services, this could be a tool that harnesses the power of data analytics to help a client make decisions about the progress of a project, increase the efficiency of repetitive tasks, or find some hidden insights in a large data repository. Beyond the technical skills to develop such tools, the programmer is often requested to support Marketing and Business Development by giving presentations or demos to clients and developing content for brochures or other marketing material. The lead programmer or subject matter expert should be able to translate the technical aspects of such products into materials for a non-technical audience and be comfortable in a client-facing environment.

DUAL ROLES

One unique type of professional development occurring in our organization is the opportunity for dual roles, not only in management but in operational areas. Specifically, this paper is focused on two departments: Biostatistics and Project Management. We will discuss both the soft skills and technical skills that make these dual roles possible, as well as give personal examples of our successes and challenges.

PROGRAMMER TO BIOSTATISTICIAN

Statistical programmers with a strong statistics background and education may be interested in pursuing a study biostatistician role. In our organization, entry-level technical employees, with an education in statistics, often start their careers as statistical programmers. Many of them remain in the Statistical Programming department, but occasionally, we have employees that transition to a Biostatistics position. By working in a dual role, the programmer can gain experience and develop new skills, as well as benefit the company by taking on some of the workload in that department. In addition, certain technical knowledge and responsibility, such as coding a statistical model or filing study documentation, is often shared between the lead programmer and study biostatistician. Figure 1 shows the overlap between the roles.

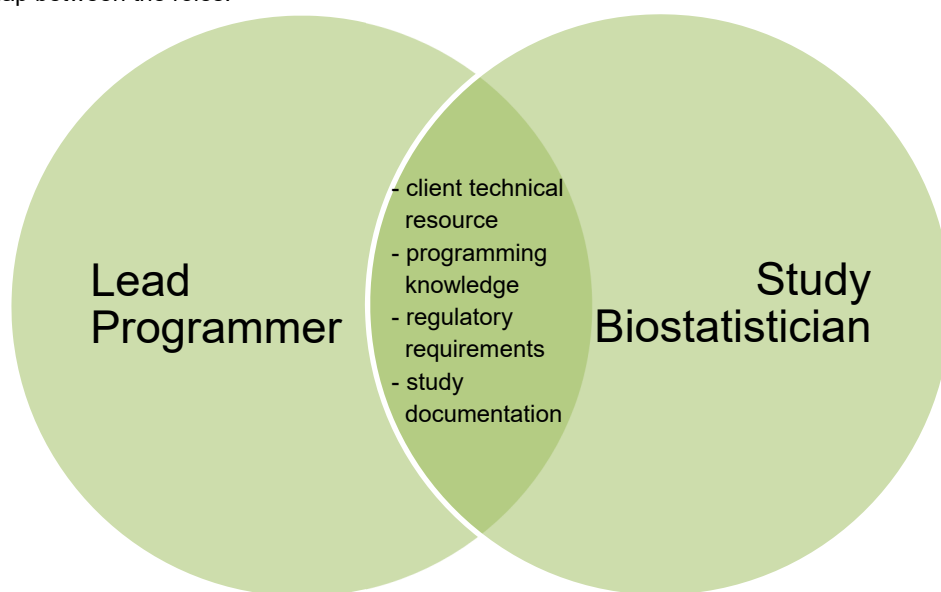


Figure 1: Venn diagram of role and responsibility of Lead Programmer vs Biostatistician.

Considering the clinical data services industry, a study biostatistician will work closely with the lead statistical programmer to perform the planned statistical analysis for a clinical study. Both parties must understand the goals of the study, to be sure the statistical analysis is aligned with the clinical study plan or protocol. The clinical study manager, or other study administrative personnel at the pharmaceutical or medical device company running the study, may not have the expertise to plan the statistical analysis or ensure the data standards for regulatory submission are met. It is the responsibility of both the lead programmer and biostatistician to be a technical resource for the client. They can give insight into what type of analysis is feasible, given the study design and how data is collected. Also, they should both have knowledge of regulatory requirements for submission of the data and statistical analysis and be able to play an active part in the submission process. We have found that having a statistical programming background can give unique insights into other aspects of operations, such as creating specifications for outputs or providing feedback on CDISC standards to a study sponsor.

AUTHOR'S PERSONAL EXPERIENCES

My experience as a statistical programmer has helped in my transition to a role in biostatistics in several ways. Specifically, it has allowed me to hone some of the requisite skills for biostatisticians, which include both technical knowledge and effective communication.

Technical knowledge of statistics generally comes from formal education and training. However, understanding the programming process is a great asset for developing specifications for statistical analyses (e.g. Statistical Analysis Plan or SAP). I know the layouts for standard tables within our company and how they can be produced using general programming macros. I also have knowledge of the programming challenges involved in combining and harmonizing data (e.g. in CDISC standards), which is useful for highlighting potential issues in protocol development and CRF design. Statistical Programming and Biostatistics also commonly share study documentation and standard working processes. My experience as a programmer is valuable in reviewing programming documentation, such as ADaM metadata or derived data specifications, which ultimately are the responsibility of the project biostatistician.

Biostatisticians and statistical programmers always work closely to produce a statistical analysis, which necessitates regular communication between departments. I have worked with most, if not all, colleagues in the Biostatistics department as a statistical programmer, so I feel comfortable asking for support on biostatistics topics. Also, since I have an advanced understanding of programming language and terminology, I can communicate additional details about the statistical analysis to the programming team, in terms of coding and execution. As a lead programmer, I've also had the unique experience of being heavily involved in client communication, for a large and complicated project. I'm confident that this experience has prepared me to communicate with clients moving forward, from a biostatistics perspective.

Something I find challenging about working in a dual role is separating the responsibilities of the role I am assigned on a project from the responsibilities of the other role. For example, I've been a lead programmer for several years and when I'm assigned as a biostatistician on a project, it's difficult to refrain from checking behind the lead programmer to make sure programming documentation is filed or that validation is documented properly. I personally have a difficult time letting go of responsibilities, so I've had to work on trusting the lead programmer to manage their own obligations while not taking that burden onto myself. One activity that helps with this issue is having a kick-off meeting between biostatistics and programming team members at the onset of the project to discuss our expectations and accountabilities.

PROGRAMMER TO PROJECT MANAGER

Statistical programmers with experience leading studies, supporting business development, and mentoring junior resources could have an interest in the project manager role. As a project manager, a statistical programmer could use the organizational skills related to managing a statistical programming team and expand those skills to learn how to manage all aspects of a biometrics project, from the onset of designing a CRF to the finalization of the Clinical Study Report for a project. While a lead statistical programmer will only occasionally be in contact with clients, a project manager is often the main point of contact. This means that a statistical programmer moving towards a project management role will need to expand their communication skills so that they can effectively manage communication with all team members internally and externally, regardless of their respective roles within the project. Figure 2 shows the overlap between the two roles.

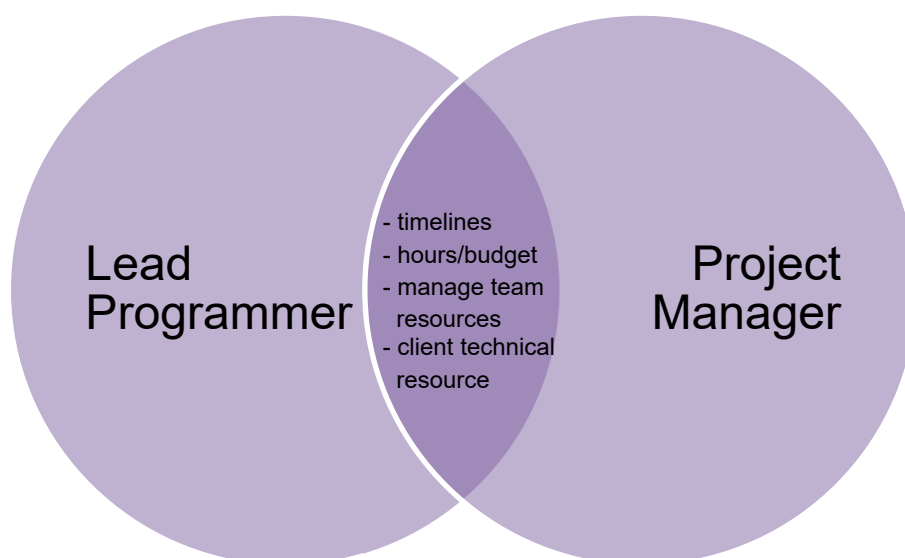


Figure 2: Venn diagram of role and responsibility of Lead Programmer vs Project Manager.

Project managers are also typically in charge of managing project timelines. This involves creating realistic timelines, communicating with all team members, and ensuring our team meets the timelines as agreed upon with the client. As a lead programmer, you are responsible for ensuring the programming team produces their deliverables on time. However, as the project manager, you are responsible for delivering all project components in a timely manner and must be aware of how delays to one component of the project will have an effect on other project deliverables. For example, if a project database does not lock as planned, then the timelines related to the statistical analysis will have to be delayed or adjusted accordingly. The project manager also needs to be aware that changing timelines for project work affects the availability of various resources, such as biostatisticians and statistical programmers. This could mean changing team members or outsourcing to contractors if the originally planned team members are unavailable at a later time.

As a lead programmer for a project, it is the lead's responsibility to manage the programming team to make sure that the time spent on the project does not take longer than the time allotted in the budget. This means monitoring the time logged during the project and following up with team members who seem to be struggling to complete their assigned tasks within the allotted time. This concept carries over to the project manager role as well. It is the project manager's responsibility to make sure that all team members, not just statistical programmers, keep their tasks within budget. If a task is larger in scope than originally planned or is more difficult than originally thought, then the project manager is responsible for updating the contract to take this extra complexity and time into account. However, if the project team is struggling to complete tasks on time, even though the scope and complexity are as expected, the project manager works with the functional leads to see what actions can be taken to improve project efficiency and keep tasks within budget as much as possible.

AUTHOR'S PERSONAL EXPERIENCES

As a project manager, I have found that my experience as a statistical programmer gives me the confidence to communicate with sponsors when they have questions about the feasibility of a new request that might be out of scope. This is because I can anticipate how much of an effort might be required from a statistical programmer or biostatistician to deliver the new request, or what would be a feasible timeline for producing this new work. In addition, I can answer sponsor questions related to CDISC documentation or questions about submitting data to regulatory authorities because of my experience with these activities from the statistical programming role.

My experience supporting the Director of Statistical Programming with managing proposals for new work has also helped my transition into the project management role. When looking at a proposal for statistical programming work, we estimate the time needed for tasks starting from baseline estimations for each type of task being included for a contract. As a senior-level statistical programmer, you are aware that the ADaM datasets will be more complex for an oncology study with a complex efficacy endpoint, and consequently, it is then estimated that more time is needed for programming those datasets. On the other hand, a project where only safety data is summarized with similarly structured outputs might be considered less complex and less time would be needed to complete those tasks. This experience as a statistical programmer helps me as a project manager to better estimate how long tasks might take for certain projects and to allocate resources for this work accordingly. For example, if I know that a study uses

questionnaire data related to epilepsy, I might request a lead programmer resource who I know has experience deriving that type of questionnaire data because we worked on a similar study together as programmers.

An aspect of the dual statistical programmer/project manager role that has been challenging for me has been managing my time so that both statistical programming tasks and project manager tasks are split evenly throughout a normal workday. There are times, when a project has statistical programming deliverables with an upcoming due date, when my role as a lead programmer may require more than 50% of my time. I have found that in this situation, the best approach is to be honest with your colleagues when multiple projects have conflicting priorities so that you can ask for support from your coworkers in order to manage ongoing tasks. In this situation, I was able to ask another project manager within our group to manage the communication with a sponsor and our other functional leads related to concerns about locking a database for a few weeks while I managed the complicated delivery for my project where I was the lead programmer.

CONCLUSION

It may often appear to senior-level statistical programmers that they do not have the opportunity to communicate with clients or take on larger responsibilities beyond their own department. However, statistical programmers who are ready to take the next step in their career should take the time to fully assess the skills they have gained from leading projects and evaluate if those skills can be translated into a new or different role. With this knowledge, they can explore alternative career options, such as we have illustrated at CROS NT through the implementation of dual role positions. These dual roles provide the unique opportunity to foster a cross-disciplinary experience, improve communication/leadership skills, and bring valuable insights to project teams.

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