

PhUSE 2016

Paper PD03

Why programmers make the best functional leads: do statisticians really know best?

Tom Ward, PPD, Cambridge, UK

ABSTRACT

There has been a lot of discussion recently about the future of programming in the pharmaceutical industry. It often appears there is an expectation for programmers to progress in a more specialist and technical direction while statisticians often appear favoured for the Biostats functional lead role. Isn't a strong programming background just as valuable in this position? When taking on my first study as a functional lead I had to justify my assignment to the sponsor. Having a programmer as the functional lead may be new to the industry but is a possible route of personal development at PPD. Over the course of that study I learnt what I can do to make sure that being a programmer does not impact on the study and will actually benefit it. I hope to be able to pass on this advice and empower programmers to break convention and take up functional lead positions.

INTRODUCTION

When you look at the role of a programmer across the industry it is often the case that the majority of their time is spent programming. In order to progress as a programmer one can progress in a more specialist and technical direction or as a Lead Programmer (LP). Across the industry, process and job position structure can vary, especially between CRO and Pharma. Hence, I will go on to explain the terms and my assumptions on which this paper is based. Within a study team, the LP is responsible for managing the programming team and ensuring the deliverables are created as required. This position usually sits below and reports into the Biostats Functional lead (or Biostats & Programming Project Lead, BPL), a position often held by an experienced statistician. The BPL is responsible for budgeting and forecasting for the Biostats and Programming resource throughout a study. The BPL typically reports to the project manager and has direct client contact. The Lead Statistician (LS) works alongside the LP and is responsible for writing the SAP and randomization schedule (if required) and statistical review of deliverables. Depending on experience they may also cover some of the LP duties. They also report into the BPL.

The initial scope of this paper is to explore the reasons why a programmer is equally capable of filling this position as a statistician. I also discuss why programmers hold lower responsibility at study level.

In addition, I hope this paper will empower programmers to take more ownership for the study, to become more accountable and to put themselves forward for these functional lead positions. I also want to draw on my personal experience to outline the benefits having a programmer as a BPL can bring to the study and the company. It is clear, from discussing the ideas for this paper with former colleagues and acquaintances that the points I raise are also widespread in their experiences.

DIFFERENT ROUTES IN, DIFFERENT PATHWAYS UP

Not all programmers are made equal. Even from my desk I can see programmers who live to re-program anything and everything they can get their hands on and/or studied computer sciences at University, sitting alongside programmers with a degree in statistics. At the other end of the spectrum there are people, myself included, whose childhood experience of computers was limited to the odd game of solitaire when it was raining too hard to build forts in the garden, or we were just too tired to play more than 7 hours of football in a day. While writing this paper I have heard of programmers with degrees as varied as tree surgery and zoology along with more typical medical sciences degrees. As well as these different experiences, people also have different aspirations and career goals. Many may want to continue to develop their programming skills and move into technical expert/ Principal Programmer positions. Because of the position I am now in and the career aspirations I have, my Professional Development Review goals do not relate to improving my programming skills. They are tailored towards improving my emotional intelligence and gaining study leadership and management experience.

NOT 'JUST' A PROGRAMMER

PhUSE 2016

During the development of this paper, it became evident that SOPs often specify a statistician should complete tasks which programmers are not only capable of, but often better equipped to complete. Tasks such as TLF shells creation, dataset programming specifications and derived dataset review all require strong study and industry knowledge and understanding of the protocol and the study endpoints. The easy, but often lazy assumption is that a statistics background would be essential to the complete understanding of these tasks. The reality is that although most studies contain some form of inferential statistics, the majority of outputs will require straightforward descriptive statistics which any statistical programmer can accomplish. It is hard to say whether such SOPs led to programmers being reluctant to take on these tasks, or whether programmers avoiding these tasks lead to the wording of the procedures.

While writing this paper I have heard of situations where a programmer will program exactly what a dataset specification defines, even if it is clearly contrary to the SAP/ Protocol because it is not their "job" to challenge the statisticians understanding. In some companies it is also common for a programmer to request updates to a spec to be made by a statistician, rather than being able to make updates themselves. Both of these situations result in a lack of ownership of their work, and also lead to further lack of empowerment of programmers to take on such responsibilities. This is clearly not a helpful situation for the study in terms of efficiency, budget or quality. As I mentioned in my introduction, programmers can come from all walks of life and a huge variety of degrees. A programmer with a statistics degree could take on more of these tasks that a statistician would normally cover. This can benefit both the study and the individual programmer. It is important that when assigning tasks, the skills of the team members are considered.

I was recently the LP on a study where there were a number of efficacy outputs which were assigned to Biostatisticians. Some of these relied upon complex models where support from the LS was vital for these outputs to be created accurately. However, the majority of the programming could easily have been implemented by programmers, even though they were defined in the efficacy portion of the SAP. In hindsight, delegating these tasks to programmers and challenging them to work beyond their comfort zone would have enabled them to gain confidence in their ability, and apply to future studies.

At PPD, the full job title of a programmer is "Programmer Analyst". The "Analyst" part is important because it alludes to the fact that more is expected than just writing code. The programmer analyst must have good understanding of the study and be able to question the data or the results of the analysis. They must be able to work with autonomy, make decisions, and be accountable. When you look at those requirements, plus the obvious ability to program and understand the processes surrounding programming, being able to write or update a dataset specification and create a set of TLF shells should not be too much of a departure. These documents rarely contain complex statistics, and when they do, these often minor sections can be delegated to someone with greater statistics knowledge. It might be easier to re-allocate responsibility to the statistician and avoid this kind of work, and in many cases SOPs actually back this up, but it might actually be in your own interest to take on these tasks. Having a programmer take responsibility for tasks which clearly affect the programming should be good for the health of the study. If you rely on someone who has less, or even no programming experience, there are likely to be more updates required once programming activities begin with inconsistencies or issues that a programmer may have spotted.

PROGRAMMERS IN THE BPL ROLE

I was at a wedding recently where the father of the bride was discussing his daughters achievements. He was proud to say that she was a project manager working closely with a team of programmers, and it showed excellent communication and personal skills because programmers are a tough bunch to work with. You can spot an outgoing programmer, he suggested, because they look at your shoes when you are having a conversation with them, rather than their own. This may be the case for some, but it is certainly not the case for everyone.

Qualities needed to be a good BPL are similar to a number of other management positions, not just in our industry, but across business. In a world where everything is presented as a "top 10 ways to...", any list relating to management skills will feature "communication" near the top. Communication is fundamental in that it is a requirement for so many other important skills such as delegating tasks, passing on information and motivating your team. By communicating well, you can share your vision and empower your team. Good communication is also vital to allow tactful and concise communication with the client or external study team. Despite the story I just told, communication isn't a skill that eludes a whole function. It is true that some programmers communicate better than others, just as it is true that the opportunity to lead motivates some while terrifying others. The same is true in any walk of life, and the person fulfilling the BPL role should be selected based on their ability to lead rather than their job title.

PhUSE 2016

Having said this, you might think I am suggesting that anyone can be a good BPL as long as they 'talk a good game'. However, there is also a significant need for the BPL to have a sound technical knowledge of the work Biostats and Programming do. On a recent "speed-dating" meeting with a team of financial analysts, the most commonly asked question was "what do you actually do?", and I have had similar discussions with my study PMs. The PM has responsibility for the overall study progress and budget, but it is vital that they can rely upon the information provided to them by BPL. The BPL needs to be able to discuss the tasks the Biostats and Programming team are undertaking and must raise and discuss any issues or concerns clearly and concisely, either with the PM or directly with the client. A programmer or statistician in a BPL role is in a perfect position to do this and if required, can bring the LS or LP, respectively, in to discuss any specific concerns. Involving an experienced programmer or statistician in discussions at this level can bring great improvements in the progress of the study and the relationship with the client.

PROGRAMMER VS STATISTICIAN

Having discussed why experience of the department should be a pre-requisite, I would like to discuss the benefits a programmer may be able to offer in the BPL role relative to a statistician. When you compare the key skills required to be a good programmer and a good leader, there are a number of similarities. Writing a good program is not just a case of throwing a load of code at a page and hoping it runs. It requires critical analysis of the required result and planning to consider the most efficient route. These skills can make the difference between a logical and efficient program that other programmers can easily pick up later in the study, and one that becomes bulky and over complicated. Much of a programmer's work involves debugging or updating existing code requiring logical and analytical thinking and problem solving, along with risk management to consider the pros and cons of different options. A programmer will also often be working across multiple studies concurrently, and so the ability to manage their time and weigh up priorities is essential to be a valued programmer. All of these skills are directly transferable to being a BPL as long as it can be combined with that all important communication.

All studies are different and there are definitely examples where complex statistics modelling forms a large portion of the work and where a Statistical BPL has clear benefits. However, in my experience, I would suggest that the number of "simple" tables, listings and figures requiring no more than summary statistics significantly outweighs the number of outputs requiring statistics modelling so a programmer BPL should still be considered. Other tasks the BPL may be accountable for are DM validation listings, SDTM mapping and derived dataset programming featuring no statistics modelling. For all of these tasks, if the BPL is a statistician with little or no programming experience they will have to rely heavily on the LP. In terms of the number of Biostats & Programming hours budgeted for a study, the number of hours for programming tasks is far higher than those requiring statistics knowledge so again, having strong technical programming experience can only be of benefit to the success of the study.

Before the statistics endpoints can even be considered, there are hundreds or thousands of hours for programming tasks. What is understood to be a programming task versus a DM task will likely vary between different companies but generally, programming DM data validation listings, missing pages reports, database extracts and external data imports all contribute significantly to our study budget. Even once we have a set of accurate data, the mapping of raw data into SDTM or other forms of post-processed data is another complex programming task. During this early stage of the study, which could go on for years, an experienced programmer can help maintain a good relationship between the team and the client (both internal and external) by showing technical understanding and the ability to discuss the progress of the study. Another benefit of opening up the BPL role to more programmers is that it will allow more junior programmers to take on the LP position. The BPL is then able to maintain good knowledge of progress of programming activities while mentoring the LP. This can create a clear pathway of development from early on in a programmer's career. Also, by encouraging programmers to take on the types of tasks I have discussed above it will release more of a statistician's time and allow them to consider the use of more advanced statistical methods that might benefit a study.

MAKING THE MOVE

As I have alluded to already, even simple studies do have some statistics requirement and as such, it can be a concern to the client that by having a BPL with no statistics experience, risk of reduced quality could be introduced. It is important, as it is when assembling any study team, to consider the individual strengths of people in each position to mitigate this risk and ensure the correct people are available to the study at the right time. In my first assignment as a BPL the client was concerned that because I was not a statistician I would not be able to fulfil the role. It was important that I was able to reassure the client that the study team had been assembled to ensure we were able to manage their trial effectively.

As a programmer it is easy, and often essential, to delegate the statistics portion of the study to the LS, and you need need to be able to depend on their experience and knowledge. However, it is important to remember that, while

PhUSE 2016

delegating this work, the BPL still holds accountability for the deliverable. In my first study as a BPL I initially took a more relaxed approach, but as we moved closer to the first delivery I felt the need to get more involved and take more responsibility as the client often wanted to discuss progress. Although not qualified to review the statistical analysis myself, I wanted to make sure I understood the outputs and could be involved in discussions relating to the analysis database. I made sure that within the team we resourced experienced statisticians to complete the quality review and senior statistics review to ensure the analysis was delivered to the expected quality. The level of involvement needed will vary between studies depending on the experience of the rest of your team. The LS on the study I was working on was relatively inexperienced, but we protected the study by ensuring the Senior Statistical Reviewer could compensate for this and take a hands-on role. Ideally the Senior Reviewer would be able to mentor the LS in this scenario so that the experience can be passed down while support in study decisions is provided. The delegation of these tasks ensured confidence in our independent review of deliverables. This team layout allowed me to learn from the experience within the team and grow more confident in making decisions for the efficacy outputs. When building a team it is good to consider the study budget and consider if it allows for more than one member of the team to attend client meetings. This will often be the case anyway but the benefits of additional roles being assigned should be weighed up against the need for more people to attend meetings.

When moving from being a study programmer into a leadership position, I found it helpful to honestly evaluate my skillset and areas that I could improve. I discovered I could improve on emotional skills like empathy and tools to motivate team members but this could equally include technical understanding or communication. By evaluating your strengths and weaknesses you can learn where you and your study team might need more support and also aid your personal development. Becoming more self-aware and improving on the areas identified can help you gain the trust of the project manager and your client in addition to the rest of your team. I have recently used SWOT analysis to identify my personal strengths and weaknesses and I believe this would be a good method to review the makeup of a study team and ensure all required skills are present.

A good study programmer will be a problem solver and will enjoy the challenge of fixing bugs or completing a programming task. When moving into a leadership it is often a difficult habit to break but it is important to delegate tasks well. One of the first lessons I learnt when leading a team is that even if you are confident you could do the task quicker than one of the more junior members of your team, the BPLs time is more valuable when used to lead the study. It is also important to consider the skills you have within your team. For example, by resourcing programmers to create and review specifications or do the majority of the programming you can leave more time for your statistician resource to work on more complex statistical analysis. Proactivity is required to plan the tasks and resources to do this well.

HOW DOES IT BENEFIT MY COMPANY?

As well as targeting the programmer with this paper I think it is also important to consider how allowing programmers to progress in this direction can benefit the employer. By giving their programmers the opportunity to progress into functional lead positions, this will encourage and motivate employees to buy in to the company. It is no secret that a successful company relies upon good staff retention. If a company spends time and resources training and developing programmers, but then has limited opportunity for growth, there is a risk that they will become demotivated. Without motivation, this could potentially reduce productivity of the team and also risk staff deciding to leave. Personally, I see career advancement as one of the main differences between contract and permanent SAS programming positions and it is important that companies can offer this if they wish to employ and retain permanent staff rather than relying upon contractors for their programming expertise. At PPD, personal development is taken very seriously and employees are encouraged to improve their skills both technically and inter-personally. I've had the opportunity to choose the direction of my career path based on my strengths while at PPD, and moving into the BPL role has made the key difference to me to feel more motivated and engaged.

As well as the effect on the individual programmer you are giving the opportunity to, you are also opening up more opportunities for junior programmers. With a programmer in the BPL role it is possible to give a more junior programmer the chance to work in the LP position, knowing that there is greater oversight and back-up for their activities. With a statistician as the BPL, there is the risk that, with an inexperienced LP, programming activities could be problematic or review steps be missed.

CONCLUSION

My career goals and aspirations are tailored towards developing in a management directions and away from the generally accepted technical programming pathway. This is a path that PPD supports and encourages and I believe this opportunity can motivate me and other like-minded programmers. I have also discussed how a motivated and empowered programmer in a lead role can benefit their employer and their study teams. I think it is important to make the most of the individual skills we have rather than just base study roles on the job titles we have. Once

PhUSE 2016

programmers start taking responsibility for more of the individual tasks I have discussed previously, it is easy to see how their skills and knowledge can allow them to become an integral members of a study team and a successful BPL. The inherent skills required to become a good programmer are often transferable and can place the programmer well in lead positions. Their success can also be of benefit to the study and the company.

Looking back, in hindsight, at my first study as a BPL, there are a number of lessons I have learnt, as discussed in this paper, which I hope to carry forward into future studies. The skills and knowledge required to build and lead a strong study team can help make the progression of a programmer a success rather than a risk.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Tom Ward
PPD
Granta Park
Great Abington
Cambridgeshire/ CB21 6GQ
Work Phone: 01223 374910
Email: tom.ward@ppdi.com

Brand and product names are trademarks of their respective companies.