

Being a Lead Programmer in a CRO : Is it any better or worse than in a Pharma Company ?

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ABSTRACT

Despite us working on producing the same basic deliverables there can be differences in the role of the Lead Programmer depending on whether you work for a Pharma company or a CRO. This paper investigates, from the perspective of personal experience, the different tasks and interactions that each can be expected to deal with and attempts to highlight some areas where we can learn from each other and become more effective Lead Programmers. Some of the areas that will be discussed are the types of clinical trials which are worked on, processes which are followed, interactions with internal and external parties, financial responsibility, differences in geographical interactions, the role of each in outsourced work, remuneration packages and maintaining a work life balance.

INTRODUCTION

Although job titles can be the same for lead programmers working in pharmaceutical companies and CROs (principal programmer, project programmer etc) there can be differences in both job descriptions and the reality of what each role involves.

From a personal perspective this paper will look at some of the differences and explain why they exist and how understanding them will help us all especially those wishing to move into a lead role in future, as well as those who are involved in working with lead counterparts from pharmaceutical or CRO companies as part of outsourcing projects.

OVERVIEW OF RESPONSIBILITIES

In general the main role of a lead programmer in both types of company is to lead teams in reporting clinical trials. This involves principally the production and validation of derived datasets and tables, listings and figures (TLFs) programming.

Although individual pharmaceutical companies have varying outsourcing strategies in my experience there is a tendency for more critical trials or those relating to more strategically important therapeutic areas to be dealt with in-house.

In addition to standard TLF reporting on individual trials, certain key parts of the process, in particular those related to submissions to regulatory authorities, tend to be dealt with by pharmaceutical companies in-house. This includes tasks such as pooled analyses (ISS/ISE), and electronic submissions (eSUBs). In certain cases a conversion of data structure is required for legacy studies in order to ensure all data is pooled in a standard structure. This task tends to be outsourced to CROs more than other tasks as part of the submission process. However with the recent move towards industry standard data structures in the form of CDISC this task may be less required in the future.

Several companies have recognized the value of the creation of generic macros either for use regardless of therapeutic area (e.g. safety macros) or those that are therapeutic area specific (e.g. efficacy macros).

In my experience there are fewer lead programmers leading teams in creating generic macros or reporting systems in CROs than at pharmaceutical companies as it can be more difficult to standardize in CROs as you are often working with a wider range of specifications originating from different clients.

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PROCESSES FOLLOWED

In general, most CROs I've worked for have slightly more detailed and numerous SOPs than pharma companies. The reason for this is that CROs' SOPs are often under close scrutiny from different clients and auditors so there is more need to have the processes followed clearly identified.

Both types of company often have an SOP that addresses validation and qc of report objects produced by statistical programmers.

In general a lot of companies have now moved to double programming particularly for derived datasets and there does not seem to be a significant difference in the validation strategies of CROs versus pharma companies.

INTERACTIONS WITH OTHER FUNCTIONS AND EXTERNAL PARTIES :

In pharma companies different functions can tend to be located in different parts of buildings, sometimes different buildings and sometimes even in different countries. This provides challenges for working effectively together and puts an emphasis on communication and teamwork.

In CROs there is perhaps more of a tendency for entire study teams to be located quite closely together and this can make effective team working and issue resolution a little more effective and immediate.

As mentioned previously lead programmers in pharma companies tend to work more often than their CRO counterparts on deliverables which form part of a regulatory submission. As part of this work there can often be more tendency for them to interact with regulatory affairs as well as the FDA or any other regulator. Interactions with the FDA often revolve around electronic submissions and providing datasets (raw and analysis) in a structure usable by the FDA in order to carry out their own exploration and /or analysis of the data.

In some cases there can be requests for executable SAS dataset creation programs and reporting programs to be provided,

Other functions which lead programmers can often interact are with project managers. I have not observed a large difference in this regard but if anything CROs will as standard offer the services of a project manager in most request for proposals and as such there can be perhaps slightly more of a tendency to interact with them within a CRO.

FINANCIAL / BUDGETARY RESPONSIBILITY

In most pharma companies unless you are head of department or even a higher grade then in general you do not have extensive budgetary responsibility. The exception would be for outsourced work where you may be involved in vendor selection for work orders. In addition you would also be expected to review change orders generated as a result of work deemed by the CRO to be out of scope.

In contrast in CROs lead programmers are often involved in project finances from the proposal stage providing input to the budgets and business development proposals . If a particular task or reporting of a study is then won , it is often the CRO lead programmer who will review the number of hours (and associated monetary spend) against the value in the budget to try to ensure that the department / company are being profitable. If any work is undertaken which is different to the task list in the original work order, then that should be raised to the project manager as out of scope work which necessitates a change order.

In addition, two potential elements of a CRO's lead programmer's responsibilities (particularly those who are line managers), which are not required by pharma lead programmers are to track utilization rates and realization rates of programmers.

These are defined as :

Utilization = (Number of hours on billable project work / Total Contracted hours) x 100

Example :

Programmer A works 30 hours on project tasks in a certain week.

Utilization = $30/37.5 \times 100 = 80 \%$

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Depending on the grade of a particular programmer then they are likely to have different target utilization rates. For example junior programmers will be expected to be working on client's work a large proportion of their time (>90%) whereas a manager or a lead programmer will have other non-billable responsibilities such as recruitment, business development, managing staff etc which will mean that their target rates will be significantly lower.

Realization = (time or value in budget / actual time or amount spent) x 100

Example : If the reporting of study X has a budget (amount costed to client) of £100,000 (2000 hours) but in completing this task 3000 hours (£150,000 equivalent) has been spent then :

Realization = (100,000/150,000) x 100 = 66.67%

It would be the objective of a CRO lead programmer to ideally achieve a realization rate of close to 100% . If greater than 100% is achieved then the team has been more efficient and cost effective than the original budget projected.

If a realization rate of <100% is achieved then the team has not performed the work efficiently relative to the budget and they have effectively been spending time for which the company will not be paid. If this overspend is due to out of scope work having been performed this should be raised as a change order to rectify this, though ideally out of scope tasks should be discussed with the customer in advance of work being performed.

COMPOSITION OF TEAMS BEING LED

In general pharmaceutical companies seem to have greater financial backing than that of CROs. Partially as a result of this their resourcing strategy can often consist of having a mixture of permanent and contract staff to allow for peaks and troughs in workload. Due to the cost of contract programmers, resourcing at CROs can seem much more carefully controlled and Lead Programmers there will often lead teams made up exclusively of permanent programmers.

In addition as programming teams in CROs are often working on standalone studies lead programmers tend to lead programming teams of approximately 2-5 programmers. In pharmaceutical companies teams tend to be working on a group of studies for the same compound or regulatory submissions and as such teams can often be larger. In that case you may have a lead programmer who is responsible overall for the programming activities for that compound but other lead programmers reporting to him/her may take on leading individual tasks/studies.

RESOURCING

In general it has been my experience that in CROs more precise resource estimates are required from lead programmers than in pharma companies. In most cases this can be determined quite easily from the budget or work order /contract using benchmarks which CROs apply to most projects to estimate the time required for each task. For example a CRO may deem that the main programming of a derived dataset will take 10 hours.

In pharma companies however resource estimates tend to be a little more approximate and as the project proceeds if there are any issues with meeting timelines then often the lead programmer will request more resource. Due to the financial colut of these companies they often approve whatever resource (or materials) that are required in order to meet the timelines/quality expectations. This is particularly true as projects get closer to filing.

GEOGRAPHICAL INTERACTIONS

Both pharmaceutical companies and CROs often have offices based through out the globe but there will be far fewer of these offices which have statistical programming operations working from them.

In general lead programmers lead teams who are based in the same country as themselves. However with increasing flexible working, lead programmers can often lead teams who are made up of programmers who work in the office and/or work from their home. This means that the emphasis on communication is even more critical than before.

In addition there are instances where both types of company have teams who may be split across countries. Some pharmaceutical companies have developed tendencies to split their main programming and validation across regions to take into account potential cost savings. Certain CROs are also following this approach where they have the capability in countries such as India, Eastern Europe and China. Due to the strictly controlled costs associated with contractors and careful control and planning of resourcing at CROs, they can also work more globally in general when resourcing projects.

OUTSOURCING WORK FROM PHARMACEUTICAL COMPANIES

When pharmaceutical companies make a strategic decision to outsource work there is often the need still for an in-

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house lead programmer to oversee the work carried out by the CRO to resolve any issues (e.g. ambiguity in requirements etc) and help to ensure that the quality of the work being undertaken is to the required standard. In this case lead programmers from the pharma company can often project manage the activities of the CRO's programming team as well as the lead programmer from the CRO. As part of the client-customer relationship the reverse is never true.

REMUNERATION PACKAGES AND INCENTIVES

There has tended to be a myth that lead programmers (and programmers in general) are paid less in CROs than pharma companies. In terms of basic salary I don't believe this to be true but when other benefits are factored in this may become more true in some cases. For example pharma companies tend to pay out larger performance related bonuses and often offer employees larger pension contributions and health care packages, though some CROs do compensate with higher basic pay.

NON-PROJECT RELATED WORK / INITIATIVES

As a result of there being pressure to maintain high utilization rates (% of time that is billable to the customer) then non project related work within CROs can often take a back seat. However for CROs more senior programmers do have more time made available so would contribute to activities such as interviewing prospective candidates and process improvements. They would also have lower targets if they have significant line management responsibilities.

WORKING CONDITIONS

Flexible working policies (location, hours)

As mentioned beforehand programmers including leads do tend to be able to benefit from flexible working policies (in relation to being able to work from home) and I don't believe there are huge differences whether one works for a pharma company or a CRO.

Working hours

Although there is not a huge difference the standard contractual hours for pharmaceutical companies tend to be 37.5 hours (7.5 hours per day Monday to Friday). Several CROs have similar contractual hours although there can be a tendency for this to be 40 hours per week.

However in some cases the contracts for lead programmers (and in some cases all levels) are worded in such a way that the hours vary according to business needs (i.e. in excess of the minimum can be required if needed).

The main area where there can be a difference in the hours worked is when timelines are looming and there is the need for either paid or in some cases unpaid overtime.

This tends to occur more regularly within CROs as there is an expectation from management that timelines will be met at all costs to try to increase the chance of receiving repeat business from that particular client. However, I would recognize that long hours can also be required at pharma companies e.g. at submission time.

CONCLUSION

Although it is often perceived that there are many differences between programmers' roles in CRO versus pharma this can often come from people who have not worked in both. In my experience the differences are not as many as one might expect.

That said the differences observed tend to be in the types of trials that are worked on, managing financial aspects of projects, providing resource estimates and finally the amount of time that is spent on non-project related work.

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I would say that depending in experience the opportunities and rewards can be exciting and attractive respectively regardless of the company you work for. As with many jobs what you get out of each often depends on how much you are willing to put in.

ACKNOWLEDGMENTS

Thanks are due for input and review comments received from Louise Webber, Associate Director of Statistical Programming Europe, i3 Statprobe as well as the section chairs for the professional development stream of PhUSE, John Moone and Kathryn Wright.

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