Deployment of SAS® Programming Contract Staff: Pathway to Sinkhole or Best Strategy for Programming Division?

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Abstract

In pharmaceutical industry various factors decide the budget associated with the SAS® programming service. These factors often relate to hiring policies, roles and responsibilities defined within the organization, and strategy defined by upper management as far as utilization of budget is concerned. Traditionally, SAS® programming is often considered as an 'allied' function supporting other 'main' functions like Statistics and data management. Considering these circumstances and substantial fluctuation in resourcing needs, programming division is often 'forced' to adopt a strategy of hiring contract staff. Contract staff deployment in SAS® programming often provides lot of benefits to the programming division. Such benefits are realized through co-employment risk reduction and no obligation for the division to keep the augmented contract staff on-board when project is over. At the same time, this strategy may back-fire the division if issues arise from recruitment, training, and retention of contract staff. If issues arise, it may jeopardize ability of programming division to complete their projects or meet project needs and may risk into loss of credibility as well.

This manuscript sheds light on the core aspects of contract staffing of SAS® programmers and discuss the risks and benefits of contract staffing of SAS® programmers. Through case studies this manuscript provides more informative discussion about things which procurement and programming departments should pay attention to while defining their strategy of hiring contract staff.

Introduction

Drug development process involves lot of data analysis and reporting. Although drug development is a long process, there are key milestones which warrant extensive data analysis and reporting. Drug development process proceeds through pre-clinical development, phase-I/proof of concept, full development, and post marketing research and development. Each phase involves analysis and reporting of data. Within each phase discussed above, numbers of clinical trials are conducted depending on drug development needs. Often the data analysis and reporting needs are dictated based on the milestones associated with the clinical trial progression. In typical pharmaceutical environment, there could be multiple clinical trials associated with one or more drugs progressing simultaneously. Each clinical trial involves reporting of collected and analyzed data. Such clinical reports are often in the form of tables, listings or graphs. Since clinical data reporting involves lot of general data analysis as well as statistical analysis, such 'analyzed data' is usually reported separately for ease of regulatory review. Mostly the clinical reports (tables, listings, and graphs) are developed from analyzed or analysis data. Clinical trial involves collection, reconciliation, and validation of clinical data during progression of trial. These tasks are conducted by data managers. Although data is collected and managed during the progression of trial, it is also analyzed and reported at same pace during trial progression. Such intermediate 'review of data' is important for decisions pertaining to patient safety and success of trial. Some of the important intermediate reviews of data during trial progression are as follows:

a) Blinded Data Review: Often referred and abbreviated as BDR. Such data review based on 'blinded data' is often conducted at different data 'cuts'. As an example, if the clinical trial reaches to a milestone where 5% of the clinical data is collected, then based on such 5% data cut, the sponsor may choose to do a blinded data review. Such blinded data reviews can be multiple in a long duration phase-III trial. In small duration phase-I trial, there might be only one blinded data review or there may not be a blinded data review at all. Obviously, open label trials will not have such review as the data is already un-blinded.

b) Safety review: These reviews are conducted to ensure that the drug exposure during clinical trial is not resulting into adverse events and abnormal findings in the patient population. Such safety reviews can be decided by clinical trial team of sponsor. The other safety reviews are triggered through the data safety monitoring board or data monitoring committee requests. Such data safety monitoring board is usually an independent third party assessing safety of drug during clinical trial.

c) Interim Analysis: This is a formal clinical data analysis conducted during the progression of trial. In large phase-III or long term Oncology trials, there could be more than one Interim analysis depending on trial data analysis needs. This event results into a thorough and formal analysis of collected clinical data during the

trial progression.

d) Abstract Submissions: During the progression of clinical trial, biostatisticians may require to present the result of trial data in the industry conferences. These types of abstract presentations happen frequently in case of epidemiology, Infectious disease, and vaccine trials. Also, such conferences are aimed to share the latest findings in industry and are often part of phase-IV or post marketing research and analysis.

e) Clinical study report: This is a final and conclusive reporting of data after the clinical database lock and after completion of trial. This involves comprehensive reporting of clinical data in terms of tables, listings, and graphs and such reports are part of the final clinical report developed by the medical writer.

Each of the above milestones requires extensive clinical and statistical programming. Obviously the programming resource need is governed by the above reporting needs related to the clinical trial milestones. There are other factors such as planned regulatory submission, regulatory response which require additional programming support for analysis and programming of data.

Resourcing Strategy

As discussed above reporting needs of clinical trial is a key factor in deciding the extent and timing of programming resource needs during the trial. Besides this, other major factors that come into play in deciding the resource needs are related to organization's in-house capabilities in terms of subject matter experts, reporting environment and other computational and logistic resources. Looking at all these aspects the management decides whether it is a best choice to in-source or outsource the programming work. In case of outsourcing the work, the organization still needs in-house staff to ensure that outsourcing partner is providing quality deliverables. Things get much more complicated when the organization chooses to in-source the programming services. The benefits of in-sourcing are often realized through close control on operations, resources, and governance of the work. Even in in-sourcing of programming work, organizations often face difficult situations in deciding whether they should hire a contract staff, or hire consultants, or hire full time staff. For further discussions of pros and cons of hiring a full time staff or contract staff, let's consider two distinct scenarios:

a) Sponsor has programming resource needs related to early development of a drug: Typically in such circumstances, the sponsor is conducting multiple phase-I trials. Time-span for such trials is usually anywhere between 6 months to 1 year. There are at least two deliverables requiring extensive programming with very fast turnaround requirements for programming deliverables (tables, listings, and graphs). One or two months prior to these deliverable milestones there is a rapid increase in programming resource needs. At the same time in remaining time of trial assigned programmers may not have enough work. These peaks and valleys could be off-set by assigning the programmer to another phase-I trial going on simultaneously. Another major risk factor that may come into play is related to stopping of trial because un-safe drug. If sponsor has such multiple drugs in their development pipeline, then it proves to be more appropriate to hire a full time dedicated programmer who can continue to work on multiple trials and build expertise. If the drug referred above is the only drug sponsor is working on, then it may be more appropriate to hire a contract staff.

b) Sponsor has programming resource need related to phase-III trial: In full development phase, sponsor may be conducting limited number of phase-III trials. Each such trial requires extensive data analysis related to efficacy reporting. After completion of trial, the regulatory submission needs subject matter expert who can do hands on programming and knows the data well. On the other hand the actual extensive SAS® coding can be done by some other programmer. In these circumstances, hiring a contract staff is usually a better option.

Above illustrations explain the resourcing strategy based on the trial reporting needs of a sponsor. Let's consider the pros and cons of hiring contract staff vs hiring a permanent employee. In general, majority of the risks and benefits associated with these options are fairly consistent with those of other industries. However, since clinical SAS® programming involves lot of learning of clinical data pertaining to specific drug or trial, contract staffing in SAS® programming can add more complexities as compared to contract staffing in other industries.

Contract Staffing vs Hiring Permanent Staff:

In general, contract staffing provides lot of benefits to sponsor pharmaceutical companies. As a sponsor, you are essentially hiring a SAS® programmer for a shorter and designated duration of time period by keeping the trial specific deliverable milestones in mind. This sound like you get the people whenever you need them and you don't take the employment burden of same staff when you don't need them! This helps the sponsor or clinical research organizations in following way:

a) Reduction of co-employment risk: Contract staff which is employed with you for a shorter designated duration is not considered as permanent staff. This means an organization is not obligated to provide lot of benefits which are otherwise offered to the permanent staff.

b) Work within budget constraints: The budget is utilized whenever you want it to be utilized and the manner in which you want it to be utilized as long as trial timelines hold true!

On the other hand benefits of having permanent staff includes getting complete control on staff's utilization and assignment and relatively long term commitment from the staff. These benefits come with a financial and employment burden on the organization. Although the benefits of contract staffing sound to be too good to believe, in general these benefits come with lot of risks. Some of the major risks associated with contract staffing are as follows:

a) Getting a programmer who is right fit to position: No matter how good is your interview process, there is always a risk that in real time work, the programmer who sounded very good in interviewing process may not be the right fit to job requirements. Since the role is on a contract basis, hiring manager does not get enough time to train and mentor the contract programmer.

b) Location constraints: As oppose to getting a permanent staff at certain location, getting a short term contract staff at certain location always poses lot of challenges. Such short term employment comes up with lot of background relocation and related logistics of a contract programmer. Many times hiring manager may get a right programmer but not at a desired location. Having a virtual team and getting a programmer working remotely and efficiently poses different set of challenges to hiring manager.

c) Turnover: Contract staffing always comes with a risk of turnover. Many times contract programmers look for full time or permanent employment and tend to move on with such opportunities. This results into disruption of project work. Even if contract programmer completes the work and leaves, he/she takes the knowledge of data acquired during the project duration. So, after completion of contract, losing the contract programmer is always a loss of intellectual capital.

d) Utilization limitation: Contract staff is always limited to work for 40 hours per week. When there is additional need as a result of peaks in work load, contract staff may not be receptive to such needs. In general, if the work consistently exceeds the expected work load, contract staff may ask for immediate compensation. Unlike permanent employee, contract staff needs to be handled in a different manner as far as utilization expectations are concerned.

Besides the above limitations, vendor relations and the whole sub-contracting in the business adds lot of complexities and pose challenges in retention of staff. Whereas the whole vendor management puts lot of burden on the contracts and outsourcing department, getting too many full time employees puts similar burden on human resources and other service staff within organization. With the above pros and cons of each type of staffing, it is obviously worth thinking for programming division to decide if they should continue to deploy contract staff. More importantly, the question is about getting the right mix of permanent employees and contract staff.

Factors to Consider Right Mix of Staff

SAS® Programming service in pharmaceutical industry witnessed lot of changes in past ten years. Ten years back, every organization used to work on their own data standards, and had their own ways of statistical reporting as dictated by biostatisticians. Since then there are major changes in the way pharmaceutical industry would work in drug development process. One of the major innovations that positively impacted the way industry works is the emergence, of CDISC and its adoption, and maturation by pharmaceutical industry. This resulted in consistency of collected, submitted, and analyzed data through CDASH, SDTM, and ADaM respectively. With standardization of data, obviously reporting standardization took place. This resulted in consistency in which the typical safety domain specific tables and listings are represented. To supplement this, regulatory authorities came up with industry

guidance which accelerated the new drug application (NDA) and drug approval processes. These changes in industry and 'open' knowledge of the way clinical data is collected, reported and analyzed enabled any professional with programming and analysis capabilities to 'learn' SAS® system, get acquainted with clinical trial processes and make a successful switch in their professional career. Similarly, professionals with data management, standards, and other capabilities could easily start working as a statistical programmer.

These major changes in pharmaceutical industry reduced the risks and drawbacks of hiring SAS® programming contract staff. The whole issue of knowledge retention and management with on-boarding of contract staff was less important with standardization of data and reporting macros. On the other hand sponsor companies could be in a better spot by hiring a well qualified contact SAS® programmer who is well aware of recent industry updates and latest updates in SAS® software. Typically, permanent employee would lag behind in getting such updated skill set because of his/her constant exposure to same environment. In this case, it appears as though hiring contract staff in SAS® programming is a correct strategy. However, the other aspect of drug development process is about having a strong knowledge of data and already built in SAS® programs to do reporting of such data. Subject matter experts having such knowledge must be on-board with the company for a longer period of time. Such subject matter experts (SMEs) are likely to be developed through full time employment only.

Based on above discussion the optimum strategy to decide mix of permanent employees and contract SAS® programming staff should be based on the need of subject matter experts and the extent to which the organization expects to get acquainted with the latest development in industry.

Staffing Models:

Based on the above discussion it is obvious that the sponsor and CROs need to decide the strategy of hiring right mix of full time vs contract staff. Based on the volume of work the organization may have, different staffing models can be deployed. Some of the staffing models are discussed below:

a) Blended on-site/Off-shore model: In this model, portion of programming staff works from off-shore and remaining portion works on-site or on-shore. The on-shore staff working in the same or similar time zone interacts with customers of business lines. Actual coding work gets deployed off-shore. Such work off-shore is usually done in low cost economic regions. This blended model provides lot of cost benefit but comes up with a risk of having virtual team.

b) Flexible staffing model: This model is more on the lines of consulting and results into utilization of vendor resources on 'need basis'. Although such model sounds very good option for client, vendor community faces tremendous challenges in terms of making right resources available at right time.

c) Functional Services model: This is a volume driven model in which sponsor or client provides bulk of work at a lesser cost to the specified vendors. This is a cost effective and efficient business model if the sponsor prefers to engage in long term partnerships with specific number of vendors.

Conclusion:

Contract staffing is essentially a flexible arrangement to meet the fluctuating resource demand needs at sponsor or CRO organizations. Clinical SAS® programming function poses unique set of challenges as far as effective deployment of contract staffing is concerned. Management needs to evaluate such challenges in terms of both technical and business perspectives before deciding the strategy of utilizing contract staff. Various factors discussed in this manuscript reflect the considerations management should give before choosing right mix of full time and contract staff. Moreover, the contract staff can work with the organization in various staffing model. Any sponsor or CRO need to carefully evaluate, and examine the pros and cons of each staffing model before choosing the right model for their current resourcing needs. Effectiveness of staffing strategy in programming function completely depends on how well thought the hiring and governance is conducted by the management of programming division.

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