

No Regrets: Hiring for the Long Term in Statistical Programming

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ABSTRACT

Recruiting statistical programmers for lead positions who can be subject matter experts, plan work and direct teams is a formidable task. Finding the right combination of programming experience, clinical development knowledge, and leadership can prove to be elusive. After finding candidates, making the accurate decision to hire might be indefinable. In a widely quoted study on recruiting by the Recruiting Roundtable, 50% of hires are regretted either by the employer or by the new employee within just six months.¹ With the average number of work days to fill an opening being 58 days for companies >5000 employees², can a pharmaceutical company better its odds in making the right selection over just flipping a coin?

Improving ones odds means creating a better assessment process for both the company and the candidate. The company must assess whether a candidate meets minimum qualifications, has the capability to perform the job, and fits into the business' culture. To accomplish this task for statistical programming, the hiring process needs to assess six capability categories: Programming, Clinical Development, Leadership, Delivery Skills, Functional Technology, and Communication. Through use of coordinated questions at specific screenings stages, a company is better able to assess a candidate's capabilities while providing better insight to the candidate regarding job expectations and company culture. This paper will present the selection process being implemented to significantly reduce the chances of regret at a large pharmaceutical company delivering a late stage portfolio.

TO HIRE OR NOT TO HIRE?

Job interviews are a strange event in human interaction. It is a courtship between two people eager to fill a need: a manager looking to fill an open position and a candidate looking for change, be it job, company, or career. Each person in the endeavor wants to say "yes". The manager wants to end their search so they can get back to their real job. The candidate wants to end their search so they can start their new business life. If all parties involved want the same outcome and want it quickly, then why do companies with more than 5000 employees take up to 58 business days to fill an opening?

The reason may be that the hiring process and interview methodology used is not conducive for a quick, positive outcome. If one performs an internet search on hiring, one will undoubtedly come across a study by the Recruiting Roundtable that touts 50% of hires are regretted within six months, either by the employer or the employee. The research explains that there are three main reasons for this failure in making a good hire:

1. Allowing the candidate to describe themselves instead of having the candidate demonstrate what they can do.
2. Having a selection process that is either not consistent or not evidenced based.
3. Not providing sufficient information to the candidate about what the job is really like.

Other studies indicate 46% of resumes have false information³ and the internet is full of blogs debating whether one actually should lie in an interview. But it is not just the candidate at fault. One study found that 40% of new hires felt they received less than accurate information about a new job. In fact, over 60% of new hires were unhappy because they felt the company misled them during the hiring process.⁴

The decision process for most permanent staff hiring across the business landscape is similar: review resumes, conduct phone screens, invite successful candidates to an in-depth interview, then make a decision to offer. If the process is similar across industries, then why is the failure rate so high? Does your company have a similar rate of regret? If so, then what part of the process is not working?

The authors examined their department's hiring and interviewing process and concluded that it was at risk of meeting the issues stated by the Recruiting Roundtable. Namely, the interviewing practice:

- Relied heavily on leadership related STAR questions (situation, task, action, result) instead of concentrating on what the candidate could really do for the department.
- Did not have a harmonized selection process nor agreed set of questions targeting the needs of the department.
- Presumed the candidate knew what the job entailed instead of enlightening the candidate about the job's duties.

The authors devised a new interview methodology in order to rectify this situation in their department. There had to be a more efficient and effective way to identify potential candidates who could lead the statistical programming for projects.

INTERVIEWING PROCESS

Think about your company's hiring process and interview methodology. Are your interview questions focused too much on having the candidate sell themselves to you? Do you have an established set of interview questions that are consistently asked of every candidate? Is each question targeted toward a specific attribute or skill related to the job? Would the candidate be able to walk straight from the interview to a desk and have a good idea of the job expectations and tasks? Does your interview technique substantiate conclusions that a candidate's performance in their current job equates to success in a different job?

If you are answering "no" to these questions, then your company's interviewing process may be to blame if your company or your new hires are experiencing a high rate of regret. The entire hiring process must be a series in maximizing the assessment of a candidate. At the core, does the candidate meet the minimum qualifications of the job such as education and experience? If that core is met, then is the candidate capable of doing the job? That is, do they know the systems and applications, have the relevant knowledge, or demonstrate the aptitude to develop these capabilities? Then, comes a piece often missed by both companies and candidates: will the candidate fit into the business culture? There is no quicker way for a new hire to regret their hiring than to find out their new department's business culture runs contrary to their morals, ethics, or work expectations. Likewise, a company should consider the likelihood that a candidate may require performance development or become a team distraction regardless of whether they meet all the requirements and capabilities.

The authors posit that a company can improve its hiring process and interview technique to avoid high rates of regret particularly when hiring clinical statistical programmers. Improvements to the process involve three steps:

1. Identify key capabilities
2. Target specific questions to substantiate the existence of these capabilities
3. Use consistent questions to allow consistent assessments across all candidates

The first step is identifying the capabilities, qualities, and knowledge one needs in a high performing employee in one's department. After indentifying these attributes, the next step is to develop specific questions to find evidence of these capabilities. Interview time is short especially during the screening process. Thus, every question is critical in making an accurate assessment of a candidate. For this reason, managers should avoid asking spontaneous questions. Instead, use a harmonized script that allows one to assess multiple candidates using the same criteria.

The hiring process starts with reviewing resumes. Statistical programming jobs are highly sought after positions, thus hiring managers receive a volume of resumes to review. How does one review these resumes quickly yet effectively? The authors identified the act of reviewing resumes as the first risk in assessing candidates. Are your hiring managers harmonized in their search criteria? Misalignment can cause quality candidates to be passed over while lesser quality candidates to advance. The adjustment to be made is to establish minimum criteria for candidates that match the minimum targeted capabilities since the primary goal of a resume review is to filter out candidates that clearly do not have the capabilities to do the job. The following set of four criteria can be used to filter candidate resumes:

- Statistical programming experience
- Clinical development experience
- Knowledge of CDISC
- Leadership experience

Candidates who meet the above criteria then proceed to the phone screen stage. The company's phone screen process could be an even higher risk than the resume review. If there is no set list of questions, hiring managers are left asking impulsive and unplanned questions which make it difficult to compare candidates. This is particularly true if the hiring managers are not aligned on the key capabilities they are seeking. For example, one manager may be concentrating on coding expertise while another might be concentrating on project management experience. Establishing a set list of questions allows hiring managers to focus on verifying the minimum targeted capabilities. Candidates are asked to talk about their statistical programming experience, the projects they have worked on in clinical development, and how they are using CDISC in their deliverables. Candidates also are queried on their experience directing teams and major deliverables. In addition to meeting the minimum requirements, hiring managers now explore whether a candidate could actually do the job as well as whether the candidate would fit the company culture? If there is much doubt in a candidate meeting either of these two, then a candidate does not progress.

A candidate that successfully passes the phone screen progresses to the in-depth interview where the company does a thorough assessment of their capabilities. Years ago, this assessment would have been a battery of SAS® programming tests to check a candidate's coding and logic skills. The demand of statistical programmers has changed over the years, and now pharmaceutical companies seek a different type of statistical programmer.

WHAT PHARMA WANTS

There are lots of job advertisements seeking statistical programmers to work in clinical development. But recruiting statistical programmers for lead positions is not an easy task. Pharmaceutical companies no longer seek candidates with only SAS programming skills or even programmers with just clinical development knowledge. Due to outsourcing models and operating cost reductions, pharmaceutical companies want statistical programmers who can also be subject matter experts, plan work, and direct teams.

In Sascha Ahrweiler's 2014 PhUSE paper, "Managing the Change – Evolving from Statistical Programmers to Clinical Data Scientists", Ahrweiler presents the evolution of the statistical programmer into the "Clinical Data Scientist".⁵ Although the capabilities outlined by Ahrweiler could make good statistical programmer, they are not necessarily capabilities that the authors are looking for. Capabilities such as advanced computing, visualization, and emphasis on statistics are better suited for a newer area within pharmaceutical companies often referred to as informatics or advanced analytics. Programmers in such groups analyze and interpret data applying computational tools to a scientific problem such as modeling, trial design, and real world evidence.

Instead, the authors' needs concentrate less on statistics and advanced computational ability and seek statistical programmers who have clinical data flow expertise. Such statistical programmers are proficient in the flow of data from collection (SDTM) to analysis (ADaM) to output to deliver this data and output to internal and external stakeholders. Internal stakeholders are statisticians, physicians and clinical data scientists, while external stakeholders are regulatory agencies, key opinion leaders, and academic research organizations. These statistical programmers would take ownership of this data flow including building the strategy and overseeing its execution. They partner with the clinical team to bring clinical data to life and be stewards of this data during the drug's clinical life cycle.

To find such programmers, what capabilities should one be looking for? The answer is to look at the same capabilities pharmaceutical companies want when assessing a Contract Research Organization (CRO). Since it is the CRO employees that comprise the company's capabilities, it is a matter of projecting these capabilities to the individual level. The authors identified six necessary capabilities in each of our high performing CROs and in our statistical programmers. Therefore the authors sought interview questions to substantiate the following capabilities in candidates:

- Programming
- Clinical Development Experience
- Leadership
- Delivery Skills
- Functional Technology
- Communication

To avoid the three interviewing pitfalls noted earlier, interviews need to provoke evidence generating answers, answers that can best demonstrate what a candidate can do for the company. Avoid confirmatory questions such as "do you" or "have you" and utilize questions that require personal evidence or insight such as "tell me", "why is", or

“how do you”. Scenarios questions are a great interview technique for they not only allow a company to probe how a candidate would react in real world situations (i.e. demonstrate what the candidate can really do), but they also provide the candidate with a window into the job's expectations (i.e. what the job is really like). The authors also advise setting the interview order to keep capability questions grouped together. That is, group questions about a specific capability within the same section of the interview. For example, ask programming questions within the Programming section, while asking delivery skill questions in the Delivery Skills section. Since candidates usually are nervous during interviews, this arrangement of questions allows the candidate to focus on that capability and provide more thoughtful evidence of that capability instead of the first example or thought that jumps into their head.

PROGRAMMING

The purpose of this section is to evaluate the candidate's statistical programming capability as it applies to clinical trials and submissions. Many companies focus their efforts primarily on this section, evaluating the candidate by using a series of SAS programming tests. While this method of substantiating a candidate's SAS skills would be appropriate for a SAS coder's job, a verification of the candidate's work experience may suffice for lead statistical programming positions that pharmaceutical companies seek. Pharmaceutical outsourcing models have moved the day-to-day SAS coding activities to off shore groups. The result is many lead programmers at larger pharmaceutical companies spend less than half their time actually programming. Lead programmers need sufficient knowledge to perform quality assurance of these off shore groups and vendor deliverables: reviewing code, writing code for validation, and creating specifications. Instead of barraging the candidate with SAS questions and tests, questions should target the following skills within this capability:

- Sufficient knowledge of SAS to do the job
- Delivers CDISC conforming data
- Demonstrates application of programming standards
- Knows processes to produce quality deliverables
- Willingness to learn new skills and share knowledge

Since SAS typically is not a programming language learned in a college classroom, one can learn a lot about a candidate by asking how they learned SAS? What PROCs do they use to merge data, calculate statistical results, and create tables? What programming standards do they think most programmers violate? It is these types of questions that provide insight into how a candidate actually uses SAS. Instead of asking a candidate to name SDTM domain names, ask them which domains are difficult to program? Then, add a scenario such as showing how they would review code from an off shore group or asking the candidate to explain the programming life cycle as if you were a newly contracted CRO delivering a study.

CLINICAL DEVELOPMENT

Clinical development assesses a candidate's knowledge of the clinical development life cycle. It distinguishes statistical programmers who work in banking or insurance from those using protocols, statistical analysis plans and case report forms for their specifications. A statistical programmer adds value to a pharmaceutical company through their understanding of the clinical process, knowing expectations of regulatory agencies, and being able to bring data to life from the clinical database. In today's pharmaceutical company, statistical programmers add value by determining whether the company should spend millions of dollars converting legacy data to SDTM or by flagging that the investigator sponsored study with excellent results might not be submission ready.

To assess whether a candidate has this capability, a company needs target the following qualities:

- Demonstrates knowledge of the clinical development lifecycle
- Experience and interpretation of submission ready standards and knowledge of submission requirements is aligned with the company's expectations
- Understanding of functions and roles beyond statistics and programming
- Creates and interprets clinical trial specifications for data and output
- Actively participates in industry conferences and groups
- Understands the context of the data

Each company uses its own operating model, terminology, and process, thus do not expect candidates to understand your company's specific lexicon or department responsibilities and deliverables. What is consistent across companies is the generic, industry process of drug development (Phase I – Phase IV) along with roles and

responsibilities for physicians, statisticians, and regulatory representatives in that process. Questions should probe into what level of involvement and interaction the candidate has had in this process. Has the candidate led the programming contributions or did they follow orders? Does the candidate understand the purpose behind the deliverables that statistical programming creates? How does the candidate stay current in their industry knowledge? A suggested scenario question would be a typical interaction with a physician or a request from a regulatory agency.

LEADERSHIP

This capability assesses leadership in regards to statistical programming in the pharmaceutical industry in leading people, projects, processes and thinking. Basically, leadership capability differentiates those who can successfully direct work from those who need instructions provided to them. It is the difference between a programmer actively contributing and influencing in clinical teams to formulate clinical strategy from one who is given instructions by the clinical team. Leadership is being able to recognize inefficient processes and change them. It understands that a customer knows what they want but may not know what they need.

There are various theories on qualities of leadership. For statistical programming at a pharmaceutical company, leadership comes down to the following qualities:

- Represents programming in team meetings
- Identifies critical issues and thinks more broadly than their role
- Uses insight to challenge and adapt current approaches or ways of doing things
- Displays good integrity and ethical values
- Understands a customer's changing needs
- Partners with the customer in decisions made

Leadership is not project management. Often, there is confusion that programmers need more project management training when actually they need training to develop leadership skills. Leadership skills establish one's ability to drive performance, act decisively, collaborate with others, think strategically, develop a team, and be customer focused all while performing one's job with integrity. Asking questions that evoke a STAR response (situation, task, action, and result) is an optimal method to achieve insight on a candidate's leadership. The candidate is able to provide situations and their responses to them to demonstrate how their team succeeded due to their actions. Sample questions might include asking about the candidate's own programming vision and what they have done to achieve it?

DELIVERY SKILL

Delivery skills are a candidate's ability to apply and adapt relevant project management techniques to clinical programming processes and/or system development. Delivery skills are more than just being adept at project management. To lead a team to deliver projects and studies successfully, a candidate also must have expertise of the clinical data flow process. That is, what are the needs of the stakeholders, and how to efficiently and effectively manage tasks and deliverables so that the customer gets what they need on time and of quality while limiting undue resource consumption. When assessing delivery skills for statistical programming, one should consider the following attributes:

- Coordinates and produces various aspects of clinical studies or development projects
- Integrates data from multiple input sources
- Interacts with multiple customers and providers
- Well defined approach to issue management
- Makes effective decisions and can do so in the absence of complete information and when under pressure
- Knowledge of common clinical and programming procedures, processes, and working instructions

At the core, a candidate must know the basic delivery plan of a study and perhaps a submission as well. What is the scope of work, who is the stakeholder, what needs to be in place before the task begins? Each of these is essential to determine resource estimates, costs, and timelines. What does the candidate do to track progress or evaluate success of their team? Issues are bound to arise during the activity, thus how does the candidate log and track issue resolution? Depending on a company's needs, one may need to evaluate the candidate's experience managing or overseeing multiple deliverables, studies, or projects at the same time. Recommended scenario questions include responding to a typical stakeholder challenge or asking them to prioritize a given list of tasks.

FUNCTIONAL TECHNOLOGY

A decade ago at AstraZeneca, it was common for a statistical programmer to need only SAS knowledge since SAS was the primary application used to delivery clinical databases and output. Today, other technologies have entered the forum such as R for statistical analyses, electronic data capture applications such as RAVE®, and visualization software such as Spotfire®. Thus, statistical programmers now need more tools in their skill set than just being able to code using UNIX and Windows SAS. In examining a candidate's functional technology capability, one must consider the following:

- Used programming technology solutions that are compatible with the company's needs
- Has infrastructure to support the programming function when working remotely
- Understands approaches for ensuring appropriate access to data and output
- Experience with various programming technologies and platforms

Depending on the needs of the company, one may choose to formally test the working knowledge of these other technologies. A question about familiarity with CDISC validation applications has growing importance now that FDA issued their new electronic data submission guidance. A number of statistical programmers now work remotely, thus practicing data privacy and confidentiality has also become important and should be investigated.

COMMUNICATION

The interview practice talked about in this paper does not include specific questions to assess communication skills. Rather, the interview itself allows the company to assess a candidate's skill:

- Ability to convey thoughts and intentions in a clear, logical, and concise manner
- Ability to listen to customer's needs to gain understanding of requirements

At AstraZeneca, it was common for statistical programmers to receive their work from the statistician. Programmers often were viewed as a support group, thus they were not invited to clinical strategy meetings or to regulatory interactions with health authorities. With the FDA embracing CDISC data collection standards and more pharmaceutical companies outsourcing their direct programming activities, companies are now looking to their internal statistical programmers to lead teams and provide expertise in the data needs of health authorities. This change in skill need is increasing the demand for good communication skills. A company must know whether the candidate has the ability to represent programming in cross-functional meetings or even in meetings with health authorities.

CONCLUSION

The authors implemented this new hiring process and interviewing technique in late 2013. Since 2013, the department has reviewed and processed over 200 resumes, conducted over 50 phone screens, and interviewed over 30 candidates. The quality of candidates reaching the in-depth interview are significantly higher than before the process change, and now the rate limiting factor in the hiring process is the candidate's availability for the in-depth interview. The new hiring process had an immediate positive impact on the department's reputation by increasing the value successful candidates are providing to the clinical business. Programmers hired since implementation are seen by clinical teams as being key contributors and are driving the data submission strategies for their products. They are writing the dataset section in briefing documents and being invited to meetings with the FDA. According to new employees, the new interview process prepared them for the kinds of questions, strategies, and pressure that come with owning the statistical programming deliverables of a global product.

The hiring process is a key touch point in the health of a company and a statistical programming department. Management chooses how much to invest in the process. As indicated by a number of studies, management's choices on hiring have led to decisions that could be decided by flipping a coin. Statistical programming departments can significantly increase their odds by determining the specific capabilities they need in successful employees, and then tailor their interviewing questions to better assess and identify these qualities in candidates. Performing these quality candidate assessments is the key to obtaining no regrets when hiring for the long term in statistical programming.

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ACKNOWLEDGMENTS

The authors wish to acknowledge William Turner for his guidance and challenge to develop a long term employment solution in elevating the statistical programming department's reputation, quality, and overall contribution value to clinical development.

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