PhUSE 2016

Paper PD07

Desired Competencies for Speed and Efficiency (in the Drug Approval Process)

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ABSTRACT

The stakeholders would like to emphasize in areas such as pooling strategies, data standards, supporting software, programming techniques, statistics, and regulatory requirements, etc. early on in their projects. Along this process, the focus would be to standardize, automatize, design trials, and utilize the data/ code to become effective. If the efficiencies with outcomes are met as planned, it would result in a deliverable with less time to complete the task. But is it that straightforward to achieve speed and efficiency on everything that we work on?

Typically resources have a variety of - functional and technical skills; coding preferences; personality and communication styles; etc. Taking that into consideration, in this paper I will list the required skills/ areas and emphasize few competencies within each of them, which could be considered as the key elements in working towards the penultimate goal of fast track to drug approval through speed and efficiency.

DISCLAIMER

This paper represents my own personal opinions. By figuring out these guidelines the "hard way", I have been able to learn and progress in my career quite well. Below suggestions do not guarantee success, nor are they officially sanctioned by the company where I am presently working or at any company where I have previously worked.[1]

INTRODUCTION

Every individual has a style when it comes to working on their professional development, certainly it's challenging, but as well rewarding to get the experience. Apparently, it doesn't stop there, the more crucial and important undertaking would be to focus on spending the time to develop and cultivate the much needed skills. In addition, it's imperative to make the next step as a habit, that is, individual's morale and motivation which could be maintained high by contributing towards the team and deliverables.

Throughout this paper, I will be presenting the competencies that could be considered as the key elements in executing below summarized skills/ areas within their critical procedural steps. The industry examples within each of the competencies would be focusing on a statistical SAS® programmer as the resource.

- Scope of Work
  - Business Acumen
  - Planning
- Prioritization
  - Organizing
  - Timely Decision Making
- Interpersonal Skills
  - Effective Communication (Verbal and Written)
  - Interpersonal Savvy
- Mentoring and Coaching
  - Managing and Measuring Work
  - Understanding and Directing Others

SCOPE OF WORK

BUSINESS ACUMEN

In order for a resource to be effective, s/he should work towards becoming a subject matter expert (SME) in their function, unless the individual is fortunate enough to realize their potential/ interests early in their career. As these individuals have been dedicated to a function, it's perceptible for them to have limited exposure outside of their function, therefore might not be knowledgeable enough to understand the policies, trends, technology, and information affecting his/ her business and organization.

These inexperienced resources need to get informed and understand how businesses work and should be aware of how strategies/ tactics work in the marketplace. As they might have been pigeon-holed within their function for multiple years, they should get ready for a new perspective and try getting close to the customers outside of their respective function. These individuals should clearly understand the integration points with other functions like – data management, biostatistics, clinical, statistical programming, and medical writing, etc. If we take the example of a SAS programmer from statistical programming function, it would help in realizing the importance of why tables have to be generated with quality after analyzing the data received from the data management group. So upon delivering these outputs by programmers to statisticians/ clinicians for review, and once approved, they are put together by medical writers in the clinical study reports for submitting to the respective agencies. Although most of the leaders are aware of the process outlined above; however, I would like to emphasize for those who are individual contributors that they should also know how their businesses work while trying to meet either client and/ or organization's expectations.

PLANNING

An integral part to build a business or team would be to understand the specifications, scope of work, and budget/ finance. Then, estimate the need to plan and prepare by establishing goals and objectives, scope out difficulties, plan for task completion, develop schedules, and do roadblock management. Also, it is critical to envision the structure and process flow.

So what does it mean for someone who is a statistical SAS® programmer? - Upon receiving the protocol and statistical analysis plan (SAP) for a clinical study, the programmer should understand the list of tables (LoT) also called as table of contents (ToC) and then from that LoT try to figure out the number of units (unique vs. replicates) against the benchmarks to estimate the work hours needed to complete the assignment of generating the outputs. Additionally, the programmer should take into consideration of other tasks like extracting and converting the raw data into derived datasets, which would be utilized by the macros to generate the tables for clinical study report. Once the difficulty of these tasks and projects are scoped out, the programmer should be able to manage the work efficiently by prioritizing and then signing up for those tasks.

PRIORITIZATION

ORGANIZING

As the scope of work is determined, now it's about organizing to find and arrange the time available by first understanding the – budget, material, support, training, etc. Despite appropriate advance planning, if the desired results are not accomplished, it could very well be due to any of the following: Inexperience to bargain and manage time efficiently; Lack of delegation for big projects; Unaware of how to manage multiple tracks for complex tasks; Rely too much on self; May scramble at the last minute and have to work long hours to finish.

To orchestrate multiple activities at once to accomplish a goal, the individual should be able to use time effectively and efficiently. In my opinion, the resource should assess and sign-up for a task that matches their capacity. In statistical programming world, it would mean to complete the required macros efficiently to generate derived datasets and tables of high quality.

TIMELY DECISION MAKING

With the information we have around the scope of work and our planning to organize the time, it's important to make decisions in a timely manner in order to not lose on time to complete the work, which generates revenue for certain organizations.

Under tight deadlines and pressure, sometimes the limited or incomplete information we get from the specifications is what we have to rely on to make a quick decision to get the work done. For example, after looking at the SAP or study protocol, the resource shouldn't scramble to get started on the new work. If this individual is conservative, cautious, or a procrastinator to make a quick decision, it would most certainly delay in completing the task on time with some compromise to the quality, which would hurt the productivity expected of this resource.

INTERPERSONAL SKILLS

EFECTIVE COMMUNICATION (VERBAL AND WRITTEN)

In life sciences industry like most others, it has become conventional to work in a distributed office environment that includes full-time remote commuters (i.e. working from home), which brings to the surface on heavy importance for effective verbal and written communication. Therefore, the resource should be able to write clearly and succinctly in a variety of communication settings and styles. Also, be effective in a variety of formal presentation settings: one-on-one, small and large groups, with peers, and bosses.

With teams comprising of resources across the globe and possibly the manager remotely working from home, it's imperative for the individual to be effective on the phone and via emails in communicating study related issues (e.g. datasets, tables, graphs, etc.) and any other difficult topics (e.g. performance, input, feedback, conflict, etc.).

INTERPERSONAL SAVVY

An effective resource relates well to all kinds of people – up, down, and sideways, inside and outside of the organization. S/he should take the time and energy to build relationships with manager and colleagues by exercising the listening skills and making an effort to be approachable. This would certainly help in building the appropriate rapport with the team and also might take it to the next level of building constructive and effective relationships.

For most tasks in the statistical SAS® programming world, we typically have a production (source) programmer to write macros to generate the required analysis datasets and also write additional programs to generate the outputs based of these analysis datasets. For this work, before the outputs are delivered to internal or external clients, it's validated by independent programmers from scratch to conduct quality check on everything performed. All of this might involve lot of back and forth communication of issues between production and validation programmer, which could lead to conflict in thoughts and approaches. When the resource is approachable, these programmers would reach out without hesitation to provide direct feedback/ input.

MENTORING AND COACHING

MANAGING AND MEASURING WORK

A good resource is adept at how to marshal the act of balancing the time and cost. To acquire that skill and be proficient in doing so, s/he should clearly - assign themselves appropriately with the responsibility for tasks and decisions; set clear objectives and measure the work assigned; monitor the process and progress with being able to measure the results; and as required seek work-in-progress feedback from the manager/ leader and/ or from the team for effective empowerment and engagement on the tasks/ projects.

When a task like creating derived datasets or programming macros to generate reports (i.e. tables, listings, and figures, etc.) are assigned to the statistical SAS® programmer, it's critical to communicate the benchmarks which makes it possible to measure the work done by the associate. When the manager is clear on goals, in this case, the number of derived datasets or outputs generated, s/he would be able to track the metrics and discuss the outcome with their staff. After initial discussions around work allocation, if expectations were misunderstood by this resource (a direct report), the manager should be flexible to utilize the most recent metrics in providing effective feedback on how to align with the expectations and therefore engage this resource in accomplishing the goal-setting effort.

UNDERSTANDING AND DIRECTING OTHERS

Good management consists in showing the staff especially the intermediate people on how to perform and complete the assignments like exceptional performers. So how would the leader bring out the best in a person? – By taking time to understand the strengths and weakness of their staff and with a clear communication that would maintain the two-way dialogue on the work and results. Upon which, the manager would establish a clear direction by distributing the workload appropriately and setting the goals and objectives.

The manager or leader should spend the time with the resource (for example a statistical SAS® programmer), and during 1:1's gauge their background and professional experience to see what assignment would the programmer be more comfortable in getting started with the team. For example, one of the most commonly desired interests of a programmer would be to work on complicated hands on programming to develop the macros. Since the manager is now aware of the associate's interest to work on a particular area, s/he should look for an assignment like developing standardized macros for the whole compound (clinical study trial/ program) and have the resource work on such a team.

CONCLUSION

In today's world, to build a strong and productive resource is a challenge, and then to develop and cultivate them by periodically recognizing and rewarding their effort is a huge undertaking. With that said, it is extremely rewarding to work on the professional development and be part of a highly functioning team.

Hopefully, by working towards the competencies introduced in this paper, every individual will acquire the skill set to timely implement the above material in executing the procedural steps to retain their expertise, which would help towards the much required goal to fast track the drug approval through speed and efficiency.

REFERENCES

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