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The Evolving Role of Project Programmer in The Next 3-5 Years

Vinay Gupta, BioNTech SE, Mainz, Germany
Manas Rout, BioNTech US, Cambridge, US

ABSTRACT

Clinical trials are becoming more complicated, driven by extensive global studies, increasing demands from regulatory agencies, and the introduction of new technologies. Everyone from individual contributors to team leaders and managers requires the combination of project management and programming skills at their best. After sizeable experience in the industry, most statistical programmers aspire to become a 'Project Programmer' and get into the act of 'managing the project and people.' However, the project programming is much more than just technical up-skilling. Project programmers need to know that there is much more that we need to skill on; technology, project management, and stakeholder relationships are just three aspects. A project programmer must also define the problems and issues and uncover solutions through collaboration. We will share an overview of what the role of a Project programmer will need and should focus on and the required skills, including vendor management. We will also look into the methodologies, tools, and technologies that a project programmer should adopt to the changing times.

INTRODUCTION

Whether in a Clinical Research Organization (“CRO”) or a sponsor environment, the effective management of resources is critical for effective project delivery. With various responsibilities, project programmers must continuously update their technical skills and keep abreast of the industry and regulatory trends affecting their roles. It's vital that the modern project programmer is adaptable and invests in personal development. Depending on the team size, a specific function and responsibility may exist for a project programmer to assign tasks, forecast peaks and troughs of work, and manage the delivery of the work. Within a sponsor, it could involve working with outside vendors or within a CRO acting as governance and liaison with sponsors. Not least, we must invest time in the continued development of those soft skills of communication, project management, leadership, and mentoring, which are increasingly important in the day-to-day lives of today's project programmers. These essential qualities/pillars would guide a project programmer as to how these should be used. We will discuss in this paper some of the key ones:

- Project Management
- Programming technology
- Communication
- Innovation
- Training/Mentoring and
- Vendor Oversight

These skills and techniques will be needed to evolve the role of a Project programmer in the upcoming years.

PROJECT MANAGEMENT – METHODOLOGY

According to the PMBOK (Project Management Body of Knowledge) Guide, there are 5 phases to it, starting from initiation to closure, including planning, execution, and monitoring. The future of project management is bright. There remains strong demand for people to deliver change. The Project Management Institute (“PMI”) says that by 2027 employers will need nearly 88 million people in project-related roles. The global market for project managers is increasing. The role of the project manager has long been shifting away from someone who can tick off tasks as complete on a Gantt chart and towards a strategic leadership role to drive change in an organization.

Let's talk about the mythologies in Project Management. We have different methodologies, and I will talk about a couple of them here: the Waterfall and the Agile method.

Waterfall Methodology

The waterfall methodology is the grandfather of project management strategies. It is synonymous with adjectives such as linear and sequential since the movement flows in one direction, like a waterfall. In waterfall project management, each development stage must be completed before moving on to the next step. For example, in clinical trials moving from SAP/SPECS to SDTM, then to ADAM, etc., in a sequence.
The notable downside of this methodology is that many projects miss their deadline. If even one stage is delayed, it

has a trickle-down effect on the whole project. On top of that, making any necessary changes is difficult and time-consuming, and delaying testing until the end of development means that if a problem is found, it's not easy to fix - further postponing the release.

Agile Methodology:
Agile methodology is the smarter and most used one, crushing the significant project steps into shorter sprints. With agile, the idea is to start small, iterate, and pivot until you reach a good product. Agile is a more flexible project management approach focused on continually improving the product. In an agile framework, content for localization is moved around in smaller boxes, and the localization team can either work embedded in the sprint (rare) or as a subsequent step at the end of the sprint. It requires planning, execution, review, rinses, and repeat. Daily scrums, weekly sprint review meetings, and burn-up/drop-down charts can be used for multiple RE/Activities or tasks simultaneously, and IA/CSR/IB/DSUR of different studies can be made on a priority based.

PROJECT MANAGEMENT – TOOLS

PMI defines project management as the "application of knowledge, skills, tools, and techniques to project activities to meet the project requirements." It involves Expertise in scope, time, cost, quality, risk management, communications, and stakeholder management, among other areas. Project management tools are the project manager's answer to managing projects. There are a lot of project management software tools out there. The tools help for better display and visualization charts for monitoring purposes and can be run on multiple projects simultaneously. Different Project Management tools in market-Monday.com, Jira, Zoho projects, Trello, Kissflow project, etc., are a few popular tools that can be used for tracking and monitoring the progress. Monitoring progress through various tracking mechanisms ensures successful clinical trial execution from recruitment through retention and follow-up.

Project management is critical to ensure that the clinical trials are set up, enrolled, conducted, and reported on time and within budget. At any given time, the project manager shuffles plates and tries not to drop one. By using these tools, the data can be automated, and there will be no need to fill numerous templates or trackers such as the time tracker, vacation tracker, allocation tracker, activity tracker, study tracker, escalation tracker, DM tracker, ad-hoc analysis tracker, programmer comments or validators comments, etc., Tools help project managers to maintain an overview in the complex set of clinical trials.

We all have these practices in place, and many use them. Project management will not be time-consuming in the future, the process will be streamlined across therapeutic areas and teams, and the best practices will be used. With the upcoming framework, everyone will speak the same language, use the same tools, look at the same information, and have the process efficiently harmonized. Subsequently, in the future, project management will be streamlined across therapeutic areas and across teams to support their role.

PROGRAMMING TECHNOLOGY

Improving efficiency is essential in statistical programming within CROs and sponsor environments. In some roles, statistical programmers may be specifically tasked with identifying areas where efficiencies can be gained and improving processes. This can involve the development of macros and utility programs and evaluate and introduce new technologies, including visualization tools. Here under the programming technology, we will cover parts of languages (R/SAS/Python), visualization software (Tableau/Spotfire/BI), and internal tools (company specific).

The industry is seeking better alternative Technology & Tools that are sustainable and can provide optimal solutions to address Industry challenges effectively. Looking at the current industry trends, R usage is less than 10% in activities related to Pharma Regulatory Submissions at this juncture. However, R is extensively used in public health projects, healthcare economics, exploratory/scientific analysis, trend identification, generation of Plots/Graphs, specific Stat analysis, and machine learning. R is not widely used for CDISC (SDTM, ADaM) dataset creation. The R language is being used in Adhoc/expletory quick analysis for statistics and programming, internal validation, and analysis. Even Informal reports where the formal table is not needed are being done using R. FDA is now allowing to use of R to an extent. Despite these bottlenecks, R is doubtlessly creating its own (larger by the day) niche in the pharmaceutical industry.

Let us know why R has many benefits over SAS:

Cost-Effectiveness:

Python and R are both open-source languages and are free to download. SAS is commercial software. It is priced in a higher segment and still beyond reach for the majority of professionals (in individual ability)

Graphical Capabilities:

In the case of graphical capabilities, Python gives tough competition to R with the help of graphical packages such as Visby and Matplotlib. But it is still complex compared to R. R has the best graphical capabilities because of the packages like Lattice, ggplot, RGIS, etc. R produces a dynamic and interactive graphic interface.

Community & Customer Support:

As Python and R are open-source languages, there is no technical support for any issues. Although there are various significant online communities, you can get great help for any problems, or the company itself can help build a support team. On the other hand, SAS has dedicated customer service in addition to the community. Therefore, it is possible to reach out to them if any issues with some other technical challenges or setup come up.

Coming to data visualization tools implementing a data visualization tool does require an up-front investment in time and resources. However, the gains in efficiency throughout the clinical trial life cycle produce long-term operational benefits such as:

1) Identifying the trends and getting a better understanding of data visually
2) Understanding the Randomization pattern and checking for bias 1:1 or 1:2
3) Check for Outliers in any lab values or other values of interest
4) It can also support risk mitigations and risk identification by checking data entry issues by site level and identifying the challenge
5) Supports check stratification impact and subgroup analysis checks
6) Site-level analytics – such as identification of no. SAEs, deaths, any triggers, and can help the site to educate

There are several advanced business intelligence platforms available. Microsoft Power BI, for example, is a powerful, customizable platform that provides visual interpretations similar to Tableau but also aligns with Office 365. Power BI features regulatory-compliant security and permissions, as well. Power BI can proactively identify and manage study risks in compliance with the ICH E6 GCP guidance when used in clinical trials. It simplifies the ability to make data-driven decisions, spot trends, and identify ways to improve clinical trial efficiency and effectiveness. Although we have had these tools in place for a long, what is lacking is the applications in statistical programming –how they can be used to achieve more remarkable results and ease the programming, data interpretation, user experience, play with data, view it, make decisions, and interpret it like a data scientist.

Lastly, the Company specific tools we need to constantly update our knowledge about advances in the industry enhancements by understanding the trends and the Expertise and best practices. We need to bring all tools and technologies together for better enhancements.

COMMUNICATION

"*One should not aim at being possibly understood but aim at being impossible to misunderstand*." (Quintilian)
Clinical trials are inherently collaborative between many different teams; therefore, communication skills are essential. There are various aspects of efficient communication, such as cross-functional collaboration, cross-project support, transparency, review, and feedback. Poor communication in clinical trials may have a negative impact, including stress, possible conflicts between clinical research professionals, and a breakdown in relationships. Other negative effects of poor communication are unmet expectations (ineffectiveness), wasted time because work is inefficient and must be re-done, non-compliance, and possible invalidation of data. Communication that is free of assumptions is one of the characteristics of excellent communication. It is essential to listen, ask questions to ensure understanding of the task, agree on what needs to be done and confirm the agreement. Communication is a two-way process that requires mutual understanding.

One of the most critical skills is the ability to communicate among various cross-functional teams, whether within the company, such as data management, or at a vendor, such as a central lab or a CRO. Communication from the beginning is vital. As soon as we have selected a CRO, the clinical project manager who leads the study goes over the task order, indicating the CRO services, line by line with all of the functions involved — biostatistics, data management, regulatory, drug safety, clinical supplies — so that everyone in the company and the CRO is entirely aware of the expectations and deliverables, avoiding unnecessary change orders. Thus, one of the most essential tools in creating a collaborative environment is building a cross-functional culture. Developing a deeper understanding of what different departments and co-workers do can increase respect and open lines of communication. Collaboration between these teams is crucial to understand the complete picture of the study.

Further, ideal communication should be transparent. Transparency makes it easy for respective departments and team members to understand what actions have been completed and which steps need to be taken. It implies openness and accountability. Sharing the complete picture with timelines and priority to the team about the upcoming activities and tasks and also helping the team to develop their skills, making them understand the priorities, and making them comfortable to ask questions and give suggestions.

Another factor for effective communication is providing review or feedback. Feedback is personalized information based on direct observation crafted and delivered so receivers can use it to achieve their best potential. In the medical setting, feedback (or lack thereof) extends beyond self-improvement and ultimately impacts patient care.

TRAINING AND MENTORING

Being a project programmer, mentoring and training is an integral part. Training and mentoring can be categorized into four key aspects: therapeutics expertise, CDISC expertise, tools and technology, and leadership skills.

Under therapeutic expertise say, if we are talking about ONCOLOGY as a therapeutic area, the project programmer should provide a mentor; all the participants in the clinical trial involved should have an understanding of all the terminologies such as PFS, OS, CR, RECIST, DCR, ORR, Types of tumors such as solid, blood and the sub categories and different indications such as for solid tumor - NSCLC, SCLC, BC, for Blood cancer – SLL (Small Lymphocytic Lymphoma)/CLL (Chronic Lymphocytic Leukemia), understanding the data which may be specific to the therapeutic area, novel trial designs and novel endpoints, etc.

Training in data standards is essential for efficient trial process and successful data submissions: CDISC datasets help regulatory agencies to review them with transparent and standardized clinical trial data. When data is poorly organized or not easily interpretable, this can cause pushback from regulatory authorities or delays in the drug development process, with valuable time spent organizing and making sense of the data. CDISC data standards provide sponsors efficiency in structuring their raw data in alignment with globally accepted and required standards for successful data submissions. The project programmer should expertise their team in all three major data standards: SEND for nonclinical data, SDTM for clinical data, and ADaM for analysis-ready data.

Learning further tools and technologies supports in improving processes and better validation techniques: As discussed in previous sections, tools and technology play a vital role in clinical research. Proper change management is needed to keep up with new tools and processes—upskilling and the will to adapt. For example, statistical programming has meant, in many cases, SAS programming. However, as other languages gain popularity, programmers need to expand their skill set and learn more programming languages. Also, working with more dynamic programming languages will require the programmer to come up with better validation techniques to test new features that have not yet been validated. So, programmers also need good validation skills to validate programming packages successfully.

It has long been presumed that programmers are more introverted and numbers-focused. While this may be true, it does not need to be the primary way programmers are to be described. Programmers can be both leaders and educators in their fields of work. To be a successful leader, one must strive to be a proficient listener and communicator. Before maximizing the skills of those around them, one must understand the strengths and needs of those on their team. A good leader will strive to build strong relationships within the team. As the leader, it is best to figure out the personalities and traits of those on your team and identify any concerns. This task will continue throughout the study and allow to implement methods to steer the team and research in a more healthy and productive direction. For example, while a statistician may help with a program, the completion of the programming still falls on the programming team. The same is true if a programmer is helping to troubleshoot a statistical method; ultimately, the person responsible for the statistical approach will be the statistician. In the end, those on the team must know their roles and responsibilities as well as the roles and responsibilities of the rest of the team.

INNOVATION

The role of the project programmer is not for today but for tomorrow. They are never satisfied with the status quo and painstakingly try to identify areas of improvement. They define programming and reporting standards, pilot new processes to develop efficient study/project management, participate in novel initiatives (both internal and external) to help to set potential future standards, SOPs & ways of working, and develop functional and personal competencies – again, just the beginning. In short, project programmers innovate and define the future of programming efficiencies, processes, methodologies, their role, and the role of clinical programming as a function – the possibilities are endless.

The pharmaceutical industry as a whole is suffering from the twin challenges of lack of innovation on the one hand and cost containment on the other. In this climate, it's imperative that the industry continually improves and brings new drugs to patients faster. The statistical programmer has a vital role to play in this paradigm. It's critical for statistical programmers, whether in a CRO or biopharma environment, to have a mindset geared to process innovation and improvement- do things faster and more efficiently while maintaining the highest ethical and quality standards. By developing strong knowledge and understanding of your organization's current processes and keeping up to speed with industry trends, technologies, and approaches, the statistical programmer can play an essential role in streamlining the path to regulatory approval.

VENDOR OVERSIGHT

Project programmer working in a sponsor environment is expected to have a clear understanding of working with the outside organization (i.e., CRO), warrants the need to be trained on SOPs related to vendor oversight, and is expected to be very well versed with the process, roles, and responsibilities to plan, manage and review the statistical deliverables delivered by external or partners to the biometrics function of a sponsor.

As the deliverables can be a wide range of requests from medical, clinical, pharmacovigilance, and regulatory involving the safety of the patients and efficacy of the product candidate, it's of utmost importance to lay out proper risk-based planning in collaboration with the appropriate stakeholders (i.e., Bio-stat Lead, DM lead, Medical, etc.).
Project Programmer is ultimately accountable for the quality of all statistical programming deliverables and must review and approve:

- SDTM specifications, metadata, define package (including the annotated case report form, reviewers guide, and SAS transport files), and compliance check report.
- ADaM specifications, metadata, define package (including the reviewer's guide and SAS transport files), and compliance check report.
- Programming activities - ensure the review/validation for all outputs (SDTM, ADaM, TLFS, etc.) is accurate, complete, timely, and compliant.

The project programmer, along with the Bio-Stat lead, is responsible for all statistical activities and accountable for conducting and documenting the weekly/bi-weekly/monthly study status meetings, also expected to document all key data issues and notes to file after a snapshot for a milestone deliverable. Tracking KPIs, quality-related concerns, and discussing lessons learned with CROs after key deliverables becomes a key to the success of the partnership with the sponsor.

CONCLUSION

With such a variety of responsibilities, it's critical that the modern project programmer is adaptable and invests in personal development. In addition, modern project programmer needs to continuously update their technical skills and keep abreast of the industry and regulatory trends affecting our roles. Not least, a project programmer must invest time in the continued development of those soft skills of communication, project management, and leadership, which are increasingly important in today's project programmers' day-to-day lives.

The role of the project programmer has evolved over the past and will continue to evolve. The prior sections described how a changing landscape had yielded new trends impacting clinical trials and the subsequent skills required to be successful project programmers in the new environment. As a result, project management skills need to evolve from statistical programming to project leadership and management. The project programmer must focus on several techniques and dimensions to thrive in the new clinical trial environment. There is no "silver bullet" that a project programmer needs to use to ensure that a project will meet all of its commitments. Instead, it combines constant diligence (project management) and consultative skills (project leadership) and uses them effectively in the appropriate situation.
As long as people are open to change in this rapidly evolving environment and as long as they are engaged in their personal development and are willing to act out of their comfort zone, the abovementioned aspects will help project programmers evolve to the next level.

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CONTACT INFORMATION

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

Manas Rout
BioNTech US
40 Erie Street, Cambridge, MA, 02139
Manas.Rout@biontech.us

Vinay Gupta
BioNTech SE
An der Goldgrube 12, 55131 Mainz, Germany
Vinay.Gupta@biontech.de