

Paper SP02

Project Programmer @GSK...the journey continues!!!

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ABSTRACT

The role of the Clinical Programmer continues to evolve and adapt due to increased pressure from regulatory demands; novel technology and growing complexities resulting in the need for stronger technical; operational and strategic leaders who can influence at the project level.

The journey to implement and embed the PP role within our industry is in its next phase of execution in our organization. Clinical Programming at GSK has laid out a broad vision for PPs to be leaders of Biostatistics operational excellence; driving strategic programming execution throughout the lifecycle of an asset.

In this paper, we present some of the tangible aspects of the journey thus far; these include the elevation of the role expectations; strengthening the training curriculum; developing a communication strategy that embeds our role; creating a fit-for-purpose resourcing tool; and finally establishing a formal stakeholder management framework to enhance our engagement with stakeholders.

INTRODUCTION

Since the launch of the Project Programmer (PP) role in Clinical Programming department at GSK more than a year ago, there has been an increase in the recognition of the role both within and outside of the department. However, there was still a significant gap between how the programmers viewed and how their stakeholders viewed this role. Moreover, it was apparent that many of the PPs were looking for practical, proven and consistent tools and methodologies that would help them deliver to their accountabilities. To realize the vision of the Clinical Programming department which very much depended on the success of the PPs, the leadership team endorsed the formation of a PP relaunch team. This team was entrusted with the responsibility to define the enhanced role expectations of a PP, to develop tools and techniques to further strengthen and embed the role, and to provide guidance and training to current and aspiring PPs. Meaningful metrics are also being defined to help increase the adoption of the tools and practices as well as to help gauge their effectiveness. The ultimate goal of the organization is the continuing development of the PPs and further embedding of the PP role in the clinical development arena.

PROJECT PROGRAMMER ROLE

The PPs are the drug development team's primary point of contact within Clinical Programming and are responsible for operational analysis data and results delivery for an entire project. While this role comes with a set of core expectations, the specific area(s) of focus for a PP at a given time varies based on the phase, complexity and the breadth of the project.

The role of a PP differs from that of an Indication Lead or a Study Lead Programmer. The Indication Lead Programmer is responsible for an indication, formulation or regimen, and as such there could be multiple indication leads working in the project. The Study Lead Programmer is responsible for a study within the project and is accountable for the operational activities and data delivery at the study level.

ACCOUNTABILITIES OF A PROJECT PROGRAMMER

The elevation of the role of a PP comes with enhanced expectations. PPs are expected to take on the leadership and accountability of the clinical programming project deliverables across the nine facets below.

- Lead and define the data (including submission) strategy for the project by defining all the data components; gaining agreement and implementing agreed data integration; influencing and reviewing the development of Statistical Analysis Plan content and operationalizing the data deliveries throughout the lifecycle of the project.
- Accurately forecast the Biostatistics budget and Clinical Programming resource needs for both planned and unplanned deliverables by leading scope development; proactively planning for internal resources; and managing CRO contracts, change orders and invoices.
- Effectively manage the stakeholders through targeted engagement; collaborative decision making; proactive communication of useful information and feedback; timely escalation of issues; and building alliances and relationships.
- Exemplify technical leadership by championing solutions to overcome challenges; leading the development of Study Data Standardization Plan; serving as subject matter experts; and authoring other regulatory documents.
- Demonstrate excellence in project management by assessing resource, time and budget, and managing the constraints; scheduling and delivering quality data packages; effective meeting management; and demonstrating business acumen.
- Embed rigor and discipline to ensure compliance to data reporting standards and industry guidelines; retrospective harmonization to these standards; and adoption of evolving standards.
- Champion solutions to drive consistency across a project and to increase efficiency by leveraging existing programming code; close collaboration with Study Lead Programmers, by proactive planning.
- Proactively manage and lead CRO relationships to ensure high quality deliverables by project level governance; serving as a point of contact for CRO; driving development of oversight plan; negotiating deliverable timings; and effectively managing and enhancing the CRO relationship.
- Influencing and networking at the project level by leading discussions associated with data delivery; articulating downstream impact to project level decisions; gaining alignment on issues and solutions; and justifying a seat at the project level meetings.

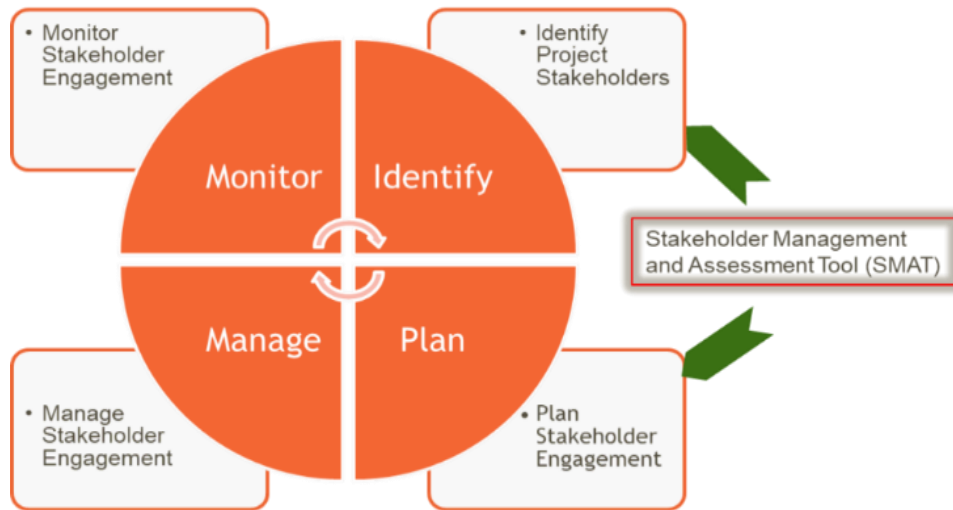
ENABLING TOOLS AND TECHNIQUES

With the clearly defined and well understood role expectations, the next logical step was to provide the PPs with targeted and practical tools and techniques, that would enable them to deliver to their accountabilities with rigour, consistency and efficiency.

STAKEHOLDER MANAGEMENT

To realize the broad vision laid out for the PPs, and to enable them to step up to this new role, it was critical that we established a formal stakeholder management framework which the PPs could leverage to better engage with their stakeholders.

We used the Project Management principles to plan this framework, and created an Excel-based tool (stakeholder Management and Assessment Tool or SMAT) for execution. SMAT was designed as a tool to develop relationships with stakeholders in a 1-to-1 setting, and not as part of a team meeting.



The four phases of Project Stakeholder Management are illustrated below.

IDENTIFY PROJECT STAKEHOLDERS

We listed all the stakeholders that the PPs are currently interfacing with. This included colleagues from cross functional groups, team members within Biostatistics, and the Biostatistics Leadership Team.

We reviewed this list and identified the key stakeholders that we felt had the most influence on our role. These included the Medicine Development Lead, R&D Project Manager, Regulatory Submissions Lead, Project Statistician, Project Data Manager, Study Lead Programmer, and Therapeutic Area Heads in Statistics and Programming among others.

The SMAT tool was populated with these stakeholders along with their functional area.

PLAN STAKEHOLDER ENGAGEMENT

The next phase involved defining the mutual expectations between the PP, and each of their stakeholders. We developed expectations that the PPs will have of their stakeholders, and likewise the expectations the stakeholders will hold of the PPs. By clearly identifying these, we wanted to send a consistent message across all projects. The expectations were not designed to be prescriptive, but rather served as a guidance to enable engagement. Additionally, for each stakeholder in the tool, we identified the ideal timing to begin stakeholder engagement.

MANAGE STAKEHOLDER ENGAGEMENT

The PPs were tasked to customize this tool for their projects and meet with their stakeholders to informally discuss the mutual expectations. Additionally, they were advised to agree on the frequency of their future meetings with stakeholders at their initial meeting to ensure they maintained those relationships. Once they have had an opportunity to meet with their stakeholders a few times, they were asked to assess them on three criteria:

- How much “power” the stakeholder has in influencing the PP role, and the value it brings to the project team on a scale of Very High to Very Low?
- How much “interest” the stakeholder has in influencing the PP role, and the value it brings to the project team on a scale of Very High to Very Low?
- How would they describe the stakeholder’s association with their role, and the value it brings to the project team? They would pick one among these five options: Advocate, Follower, Indifferent, Blocker, or Opponent.

The goal for the future is to develop specific steps a PP can take to manage a stakeholder based on information gathered from this assessment, and a survey to be administered to the stakeholders. Ultimately, the end goal is to ensure most of the stakeholders are and remain advocates for our role.

MONITOR STAKEHOLDER ENGAGEMENT

Stakeholder engagement is an ongoing process and it is important for the PPs and the programming leadership team to understand how effective we are in this process and how well the stakeholder management practice is embedded in the organization. Therefore, we have started the work to develop measures or key performance indicators to help us gain that understanding, and it is also our plan to further improve the framework based on the metrics and feedback. Additional details are provided in the KPI section.

BENEFITS OF STAKEHOLDER MANAGEMENT FRAMEWORK

There are several benefits to establishing this framework, and these are illustrated below.



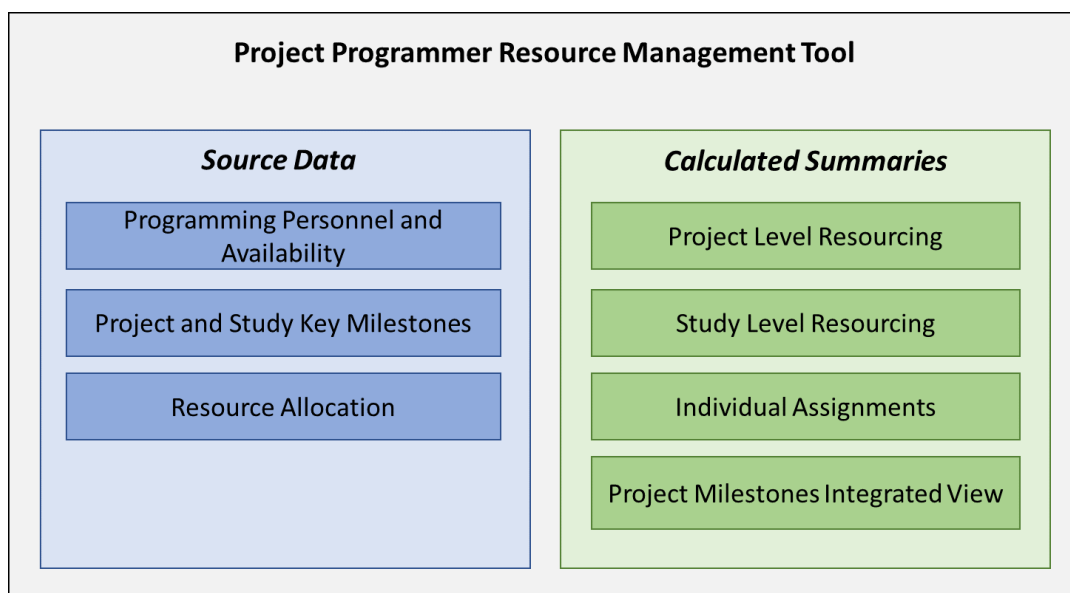
RESOURCE MANAGEMENT

One of the key responsibilities of a PP is resource management. This requires the PPs to have a clear and complete picture of the resources available to them; a solid and up-to-date understanding of the current and upcoming work; and effective methods to forecast project resourcing needs as well as identifying potential gaps

To assist the PPs with these activities and to ensure overall standardization and consistency across the entire Clinical Programming organization, a practical and fit-for-purpose resourcing tool was developed based on PP requirements with ideas taken from some of the existing framework.

This Excel-based internally developed resourcing tool can be used to track and proactively manage:

- Overall availability of programming resources
- Key study and reporting effort milestones for the project
- Demand of resources based on study and reporting effort
- Allocation of resources and tracking of assignments by individuals
- Utilization level of individuals
- Gaps or surpluses between demand and supply of resources



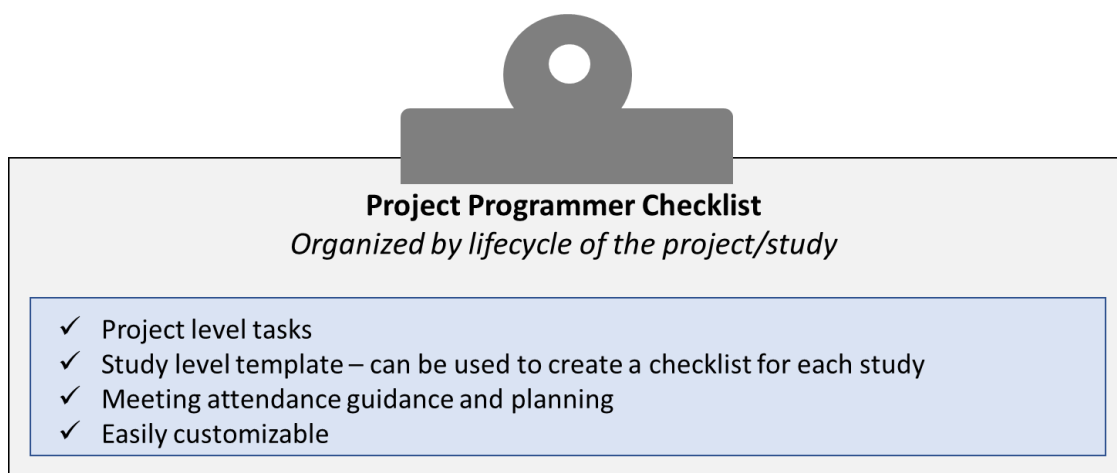
In addition to the standard functionality, we also built flexibility into the tool so PPs are able to track their projects at various work package levels (e.g., study, reporting effort) and also resourcing levels (e.g., team vs. individuals). They can easily add other custom summaries using native Excel functions. Having a standard tool with a uniform structure also allows summary-level information to be easily produced, such as overall resourcing supply and demand by therapeutic area.

Finally, like any planning and management tool, the usefulness of the tool depends on the quality of the data and timeliness of updates. The PPs are accountable for maintaining the accuracy and currency of the information such as when there is a change to project timeline or personnel, and they can delegate the monthly updates to the respective study lead programmers if they wish.

A key challenge in this tool was how to accurately project the number of programmers needed for a study or reporting effort. There was a desire to have a standard and consistent methodology for all PPs. However, we also acknowledged the fact that there were many factors that would impact the level of resources needed, such as therapeutic area, phase, and study design. The team felt that an algorithm that took these various factors into account was needed to make the resourcing tool more useful. At the same time this resourcing tool was developed, there was an R&D-wide initiative at GSK to revamp and also standardize the way we did enterprise-wide resource management. We are currently working in tandem with this larger effort to ensure we are completely aligned with other functional areas without creating silos and duplication of efforts.

PROJECT CHECKLIST

As the role indicates, the PP is accountable for the programming deliverables at the project level, so, it is important for the PP to have a clear understanding of the duties they need to perform and when. This Checklist serves as a guidance for PPs to fulfil their role as a PP, and to map the role specifications to actionable tasks and deliverables. It is not intended as an exhaustive list, and not all items will apply to one's project.



The Checklist encompasses the project end to end, spanning from project set-up to close-out. It contains high-level tasks for the entire project as well as those specific to each study within the project. Some examples of the project-level activities during Project Set-up phase are “Initiate creation of stakeholder Map and set up regular meetings with key stakeholders” and “Discuss resourcing strategy (to include programming) with project team”. For each study, during the Study Maintenance phase, there are tasks like “Periodic check of QC record “ and “For outsources studies, approve invoices in a timely manner“.

One of the very useful feature of the Checklist is the planning of meeting attendance for the PP. During the lifecycle of a project, there can be many meetings (both project and study-level) where programming representation is required. However, to maximize productivity and effectiveness, the PP’s attendance is not always necessary. It is the accountability of the PP to determine which meetings and when it is most appropriate for them to attend. To assist with this decision, the Checklist provides general guidance on the recommended multi-disciplinary team meetings that the PP should attend. Increasing the visibility of the PP with the project team is an important aspect of the PP journey, and having a strong and impactful presence at key meetings is critical to the success of the role. This is also the reason for the inclusion of meeting behaviours and expectations in our training program.

Depending on the specific needs or situations of the project, the Checklist is easily customizable, and is a living document that is meant to assist in both planning and retrospective inspection of PP responsibilities.

CAPABILITY DEVELOPMENT

ROLE-BASED TRAINING FRAMEWORK

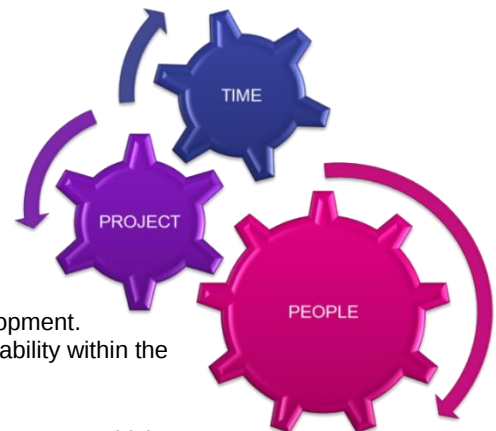
A training curriculum was specifically developed to enhance the business and leadership skills of PPs, and to support their development to become leaders of operational excellence. The curriculum focuses on three key aspects of development - time, project, and people management, and is a mix of mandatory and “just in time” training.

Some examples of courses in the curriculum are:

- Time Management: Energy 4 Performance and Delegating
- People Management: Influencing and Negotiating
- Project Management: Meeting Management and Decision Making

Since our PPs have varying levels of experience and possess different leadership strengths, they are expected to identify and complete the courses that are based on their self-assessment and will support their personal development. By having this curriculum in place, we are able to track development and capability within the department.

The rollout of the tools was accompanied by a mandatory training for the current PPs, which significantly enhanced the effectiveness and relevance of the information communicated to them.



EMBEDDING STRATEGIES

With the relaunch efforts including the tools and methods deployment, the team was able to reignite the excitement and reinforce the criticality of the PP role. In addition to training current PPs on the new tools, the key to retainment of knowledge and sustained embedding and growth is the ongoing practice and application of the training materials. It is also important to have a community that acts as a support structure that both encourages and nourishes the continuing growth of our PPs.

WORKPLACE/FAQ TRACKER

To facilitate timely communication and dynamic exchange within the PP community and with our stakeholders, a group was created on Workplace (the enterprise-wide employee engagement platform at GSK) for the PP community. The Workplace group is primarily for current and aspiring PPs, to get answers to their questions, share best practices, and help each other succeed. We also use this open group to educate others outside the PP community about this important role and the value we deliver to drug development. Many of the questions asked here are added to the Frequently Asked Questions list that is published and updated on a regular basis.

INTERNAL FORUMS

In addition to the online collaboration platform, we also hold monthly PP Forums where again, both current and aspiring PPs can get together to share relevant information that helps us grow and thrive as successful PPs. We discuss what we learned (lessons and pitfalls, best practices, as well as success stories), teach each other new tools and techniques, and inform everyone of process changes that impact our role. The current focus of the PP Forum is largely around the introduction and adoption of the newly developed and deployed framework and tools. As the adoption continues, our plan is to shift the focus to practical application and PPs sharing real-life experience of leveraging one or more of these tools.

EXTERNAL ENGAGEMENT

To achieve success in the PP role, not only is it important for the PP to understand and perform their role well, it is also important for the PP's stakeholders and team members from other functions to understand and embrace the PP expectations. Each PP is expected to communicate their role clearly and succinctly to their key stakeholders so everyone has an appreciation of the PP's unique value-add as well as what they all can do to help the PP deliver their accountabilities. To that end, we created a standard communication pack which the PPs can use with their teams and stakeholders. Some PPs have decided to partner with the Project Statisticians to deliver this material since there is often confusion from those external to Biostatistics, of how Project Statistician's remit differs from that of the PP.

KEY PERFORMANCE INDICATORS

We are developing KPIs to measure both the adoption and the success of this initiative. Measuring adoption provides information on whether PPs are leveraging the training, tools and strategies in place. Measuring success on the other hand provides information on the impact the PP is having on the project teams and their cross functional stakeholders.

MEASURING ADOPTION

The KPIs in this category capture and measure compliance with the following. We are putting in place a process to track these on a regular basis.

- Are individual performance and development objectives of PPs aligned with the Clinical Programming vision?
- Are PPs leveraging the tools and techniques in place to engage, and develop strong working relationships with their stakeholders?
- Are PPs utilizing the tools in place to lead their projects efficiently and effectively?
- Are PPs embracing the training curriculum to enhance their competency?

MEASURING SUCCESS

It is critical to measure the success of this initiative and the impact the PP role is having on the cross functional drug development team.

- We intend to create a survey to collect feedback from all the stakeholders identified in SMAT across all projects. The survey will be designed and administered this year to better understand the perspective of the stakeholders, including

how well it aligns with the PP's assessment of their stakeholders and how it has changed as a result of the PP relaunch initiative. New strategies will be devised to continue to engage with the stakeholders with an eventual goal to ensure that most of the stakeholders are and will remain advocates for our role.

- Enabling tools and techniques, and embedding strategies were created to support the PP's development, and we will continue to look for ways to enhance these. We know the role is successful when most PPs realize the value of this framework, fully embrace it, and leverage it in their daily work, and ultimately establish themselves as strong partners from Biostatistics.

WHAT'S NEXT

This initiative had tremendous success in 2019, and we aim to continue this momentum into 2020. We have several actions planned this year. These include:

- Deploy and track KPIs
- Develop additional tools to build capabilities
- Devise strategies to further embed the role in the organization
- Define the accountabilities of Study Lead Programmer, and expand the training, tools and techniques to them.
- Strengthen engagement at forums and on Workplace.

CONCLUSION

Clinical Programming function plays a key role in enabling expeditious, cost-effective and high-quality delivery of clinical trials reporting and regulatory submissions. As leaders of programming, Project Programmers can and should have a strong presence in helping the project and study teams shape resourcing, data and execution strategies.

Although we started our efforts to formalize and enhance the PP role at GSK more than a year ago, our journey continues as we persevere in highlighting this role and helping our veteran and new PPs in successfully fulfilling the expectations. We knew this would not be an overnight change, but rather a sustained endeavour that required focus, persistence, and teamwork. We fully believe that by equipping our PPs with the fundamentals (concrete and specific role expectations), job-enabling fit for purpose tools (e.g., SMAT, resource management), and comprehensive capability development framework, along with our ongoing efforts to assist and embed, we can and will realize our Project Programmer vision - Leaders of Biostatistics operational excellence, driving strategic programming execution throughout the lifecycle of an asset.

REFERENCES

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