

Paper CD05

The Role of a Project Programmer within GSK

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ABSTRACT

Pressure to meet evolving external and regulatory requirements is greater than ever which has served to strengthen the importance of the role of the Clinical Programmer across the Pharmaceutical Industry. Complex data capture and reporting for clinical research to meet increasing regulatory demands continues to expand, challenging the technical requirements for successful project execution.

Over the past couple of years, GSKs Clinical programmers have had to adapt to these growing complexities and demands, resulting in the need for stronger technical, operational and strategic leaders that can influence at the project level, define both clinical data and submission strategy and be leaders of exquisite delivery.

In this paper, we discuss the journey that GSK is currently on to support evolution of the clinical programmer role. We will describe our experience with creating a formal Project Programmer role; setting clear expectations for staff, our approach to capability development and we'll share some of the challenges faced in implementing and embedding the role within our organization.

INTRODUCTION

A standalone Clinical Programming department at GSK was formed in 2013 to support the evolving regulatory requirements and technical expertise required to deliver clinical projects and regulatory submissions effectively. This resulted in elevating the Clinical Programming function to form a stronger, focused department that drives innovation, influences industry standards and contributes to industry wide solutions for increasing efficiencies in data delivery. The formation of Clinical Programming provided opportunity and a springboard for programmers to achieve greater aspirations of working in closer partnership with key matrix colleagues and become exceptional technical, operational and strategic leaders of delivery with a voice at the project level.

The Situation

The Project Programmer role for many years has been a key role for the successful delivery of a clinical project. Although programmers have been performing this role in the background, it's rarely been executed at the true project level and thus there has been little recognition of the critical role programmers play in the successful delivery of project level execution in a comparable manner to the Project Statistician.

Historical organisational structure served to suppress the influence of programmers at the strategic and project-level, particularly when contained within a predominantly statistics-run function, even reporting to managers from a statistical background. This traditional hierarchy hampered visibility and encouraged programmers to function "*in the shadow of the statistician*". In addition, it prevented programmers from having the confidence to step up at project level discussions, particularly where their technical expertise should have been leveraged to drive exquisite project delivery (efficient, high quality and cost-effective).

Evolution of the Clinical Programmer

Evolving regulatory demands to meet submission requirements has put increasing pressure on data collection, data analysis and submission deliverables. Resulting in the need for a new kind of clinical programmer, one that can not only effectively execute analysis and reporting deliverables but one who is better positioned to influence and drive the overall data strategy for a compound. Leaders of exquisite delivery, ensuring consistency, compliance to regulatory standards and innovative technical solutions to meet regulatory challenges.

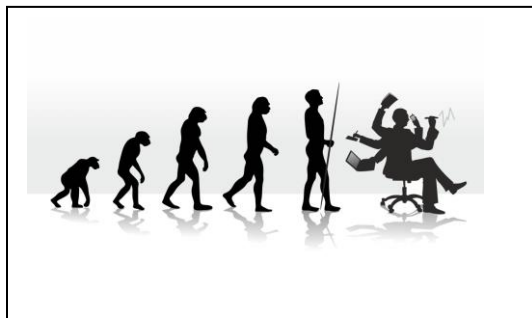


Figure 1: Evolution of the Clinical Programmer

Study Lead Programmer vs Project Programmer

The role of the Project Programmer differs from a Study Lead Programmer, who is responsible for a study within a compound, accountable for the operational activities and data delivery for a single study. The definition of the Project Programmer role is a clinical programmer accountable for leading programming strategy to deliver at the asset level, responsible for multiple studies or an indication for a compound. The Project Programmer is usually assigned when a compound has achieved the “commit to medicine development” milestone i.e. usually from phase 2 onwards and will sit on the project team representing the programming function.

THE FORMALISATION OF THE PROJECT PROGRAMMER ROLE

One of the fundamental areas that supported this initiative was the endorsement of a formal Project Programmer role from senior leaders within GSK's Statistics, Programming and Data Sciences function. A team of established programmers, sponsored by the Clinical Programming Leadership Team (CP LT), collectively shared their experiences of leading projects to understand common responsibilities and inconsistencies across the various therapeutic areas. The CP LT then set the vision and direction of travel for achieving the future vision for the Project Programmer role.

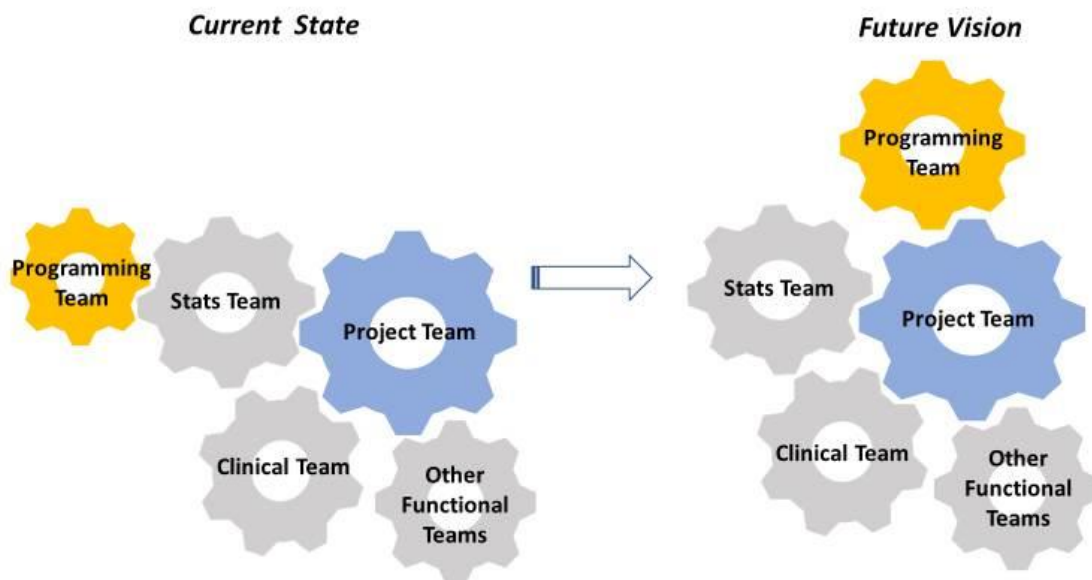


Figure 2: Current and future state

The Project Programmer Survey:

To enable the team to get an understanding of the existing awareness of the Project Programmer role a baseline survey was conducted prior to the formalisation of the role. A short questionnaire was sent to all key functional areas that interact with a Project Programmer (Target audience: Statistics, Programming, Data Management, Data standards, Clinical and Regulatory).

Survey Key findings:

- 220 people across the various functions responded to the survey
- 50% of survey responders were aware of their Project Programmer
- Data Management, Clinical Development and Data acquisition had low awareness of the role

The survey identified several areas where further education was needed for specific functions (e.g. Data Management) as well as additional training and guidance required to support programmers to increase contributions, influence and visibility on project teams.

Two major deliverables identified to support the Project Programmer role because of the survey were:

- 1) **A Project Programmer Role Specification/Expectations Document** to ensure alignment of expectations and consistency in application across the Clinical Programming function.
- 2) **A Project Programmer Training and Development Curriculum**, facilitating capability development tailored to individual need. This supports opportunities to strengthen leadership skills, grow as technical leaders, develop project management skills and to effectively influence within senior matrix environments and manage key stakeholders.

Through the survey and the various mechanisms put in place to support the Project Programmer role, it became very clear that a project level programmer was in demand and the benefits were well-defined and understood. However, it underlined that there was some way to go in terms of successfully embedding the role. A second survey is planned for one year on, to measure progress.

Project Programmer Role Expectations

This section provides details on the responsibilities and expectations of a Project Programmer collated through departmental discussions which identified common themes across therapy areas.

Major considerations included

- expectations of a Project Programmer from the functional teams that they would interact with, and
- ensuring that Project Programmers can perform at the asset level in partnership with the Project Statistician (not via the statistician)

Key areas of accountability were identified, these are detailed below:

1) Leadership and Accountability of Project data strategy and asset submission strategy

- Define and lead the data and delivery strategy for the asset, ensuring that a consistent approach is taken for individual studies within a compound or indication.
- Define the data components of the submission strategy, define additional key components required in addition to the standard data delivery to support a regulatory submission.
- Drive compliance to data reporting standards, ensure company and industry standards are adhered to consistently across a study including adoption of a new standard and assessing impact on reported and upcoming studies.

- Implement agreed data integration across the asset, gain project team agreement on the integration or pooling of data, retrospective harmonisation of industry standards where necessary and assessing impact on resource, time and budget.
- Author relevant regulatory documents to agree an overall submission strategy. Lead the Study Data Standardisation Plan for an asset, engaging with the relevant project team members, e.g. regulatory to ensure alignment.

2) Excellence in Project Management

- Overall programming accountability for the delivery of data and results across the project, responsible for timely and quality deliverables to the project team, including scheduling of data deliveries for dry-runs, interims and safety reviews as well as the final reporting.
- Accurately forecast resource and lead budgeting requirements for planned and unplanned deliveries, understanding budget impact and gaining approval of budget where additional resource is required.
- Proactively manage CRO relationships to ensure high-quality deliverables, primary point of contact for the CRO, driving oversight, negotiating deliverable timings, incorporating reviews, leading after action reviews and escalation as necessary to effectively manage and develop the CRO partnership.

3) Networking and Influencing

- Drive project level communications for excellence in delivery in partnership with statistics (not via statistics), representing the programming function. Proactively lead discussions associated with data delivery at the project level. Justifying a seat at project level meetings, actively communicate impact to project level decisions and highlight any project risk.
- Proactively connect discussions across the project team to ensure alignment, representing the voice of programming across the various functions, ability to effectively articulate downstream impact e.g. where additional data deliveries are required to support internal or external review, effectively communicating these to data management to ensure minimal impact on the programming team.
- Champion solutions to maximise efficiencies and overcome challenges.
- Effective stakeholder management appropriately targeted depending on the audience e.g. timeline / resource impacts and proposed solution to address.
- Influencing and reviewing RAP content to ensure consistency across a project.

Implementation / Embedding:

The aspiration is to have a Project Programmer for all projects, however, this is still work in progress. Currently, Project Programmers have been assigned to high priority assets based on existing experienced staff and key talent.

Training material formalizing the role for Clinical Programming and Project Teams was put in place, outlining expectations, including the value that this role is anticipated to bring in leading execution of project delivery. The material was tailored depending on target audience and delivered at various departmental meetings and forums.

A Project Programmer forum has been initiated to provide a platform to discuss, share and grow the Project Programmer role into an effective, highly functional, valued role to ensure strong leadership, efficiency and consistency on project delivery.

Progress with embedding the role and the support framework around it will continue to be monitored through a second survey in conjunction with feedback from the project teams.

BENEFITS

The formalization of the Project Programmer role has numerous benefits both in data delivery execution as well as providing opportunities to enhance the base skills of a clinical programmer from SAS programmers to exceptional technical leaders. Some of the expected benefits include:

- ✓ Recognition of the value the programming function brings in the execution of a project or submission
- ✓ Consistency maintained across a project to ensure efficiencies are leveraged from study to study
- ✓ Clear accountability of project level activities for programmers
- ✓ The assignment of a Project Programmer role at an early stage of development ensures a solid foundation and effective execution of programming activities for the life cycle of a project
- ✓ To explore career development opportunities for aspiring Project Programmers to grow into effective leaders
- ✓ Opportunity to assign lead programmers earlier to drive efficiencies at the study level e.g. at design stage to shape data/vendor specs, mappings, schedule of SDTM dataset deliveries etc. to leverage learnings across the project

The Project Programmer role allows programmers to represent the clinical programming department effectively to influence and drive project reporting deliverables and data submission level activities.

The role allows the project team to see programmers leading the technical execution and driving the data submission strategy at a project level. It also allows programmers to gain a greater understanding of the 'bigger picture' in terms of the role various functions play in clinical trial delivery and gives them the opportunity to influence cross functional teams at the project level. The Project Programmer role provides a defined career path for all programmers within GSK to aspire to.

CHALLENGES

Implementation of a new process or role within a large organisation comes with its challenges. For the Project Programmer role, this has been particularly difficult due to the historical arrangement of the programming function at GSK. However, the formation of Clinical Programming as a separate function, gives the department a unique opportunity to establish itself in delivering the project data strategy.

- Ensuring the Project Programmer role is fully embraced within the statistics and programming lines before communicating to other functions. There is an important partnership between statisticians and programmers which is critical in the successful execution of a study let alone at a project level. This was managed by ensuring stats leaders understood the value that clinical programmers will bring in this partnership, setting clear accountabilities between the two roles and expectations of a Project Programmer performing at its best.
- Awareness of the role outside of the statistics and programming function. This continues to be more challenging as historically functions outside of statistics and programming have channeled their requests via the statistician, this requires greater education and support from the established leaders within the programming function.
- Resistance to change, the nature of many programmers is a preference to program and input into technical solutions. This role is not to replace the role for programmers that want to remain as technical problem solvers, it is to create a pathway for those programmers that want experience in other areas. This is where communication / training is key to ensure staff feel supported.
- Identifying staff with the appropriate level of experience and skill to assign into the Project Programmer role for key projects. This is a journey that is going to take time to achieve at the desired level.

CONCLUSION

What worked well

- ✓ Endorsement of the role from senior leaders, the role is supported from the top down
- ✓ Talent Review and line management to support the development of aspiring Project Programmers by ensuring development plans are appropriately targeted for individual development
- ✓ Well-defined accountabilities of the Project Programmer role, providing a clear direction of the expectations
- ✓ Experienced team of programmers performing at a project level to drive the development of material and training
- ✓ Baseline survey to establish the initial gaps, this provided the foundation to build expectations for the role and develop appropriate training
- ✓ Communication and training to ensure staff felt supported

The purpose of the Project Programmer initiative was to formalize the role and to provide established clinical programmers the recognition of the vital role programming play in leading project delivery. The role provides clear accountabilities for the overall leadership of programming deliverables and data delivery execution. In addition, it offers the opportunities to branch into CRO management, resourcing/budgeting and project management. With the introduction of a more formal role and effective embedding of the role, it is anticipated that the visibility of programmers within the project team will be increased and lead to greater awareness of the vital contributions made by Project Programmers and study level programmers from an early development stage through to submission.

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