



In addition to this, the complexity of study designs, the current regulatory requirements to implement CDISC data standards (Study Data Standards for Regulatory Submissions Position Statement, 2013), and development/validation efforts towards all programming deliverables are requiring larger programming teams.

A typical late stage clinical study could necessitate a programming team of 8 to 12 full-time resources. Further yet another layer of complexity is the trending phenomenon of the blended programming team consisting of permanent employees and contingent or contract workers (Grudzinski, 2012). Technology has also allowed the emergence of virtual Statistical Programming teams with remote workers spread across different locations and time zones within and outside the US (Polus, 2015).

All of these facets mentioned above of today's programming team factor into the quality, timeliness and cost statistical programming projects, and if not managed tactfully could be negatively impacted.

Traditionally, statistical programming teams have a Lead Programmer who is responsible for monitoring progress of the programming tasks and to ensure quality of the deliverables. He/she has to direct and distribute programming activities to the study team and becomes responsible for the management both technical and non-technical aspects of the project. As a matter of fact, with the trending anatomy of statistical programming teams, broadening scope of statistical programming activities, and cost cutting measures, there's a need for increasing focus on managing the non-technical aspects such as communication, forecasting and tracking of needed personnel and hours.



**Figure 2. The various tasks and responsibilities of the Lead Programmer. Lead Programmer Needs Help!**

The lead programmer can be easily overwhelmed by all of these multitasking expectations and responsibilities. In view of this, we are introducing a new and necessary role to the Statistical Programming team-the programming Project Manager (PM).

In the world of the CRO or niche vendor providing statistical programming services on multiple projects particularly, the management of other essential yet non-technical aspects of the project is done better by a dedicated resource separate from the Lead Programmer. The programming PM has global oversight

of a few different projects and works closely with the Lead Programmers for each project. Consequentially, the PM takes off other management burdens from the Lead Programmer that allow him/her to focus more on the technical aspects that directly affect the quality of deliverables. The value the programming Project Manager brings to the Statistical Programming team is two-pronged: 1) Increase efficiency and effectiveness; and 2) reduce risks.



**Figure 3. Programming Project Manager to the rescue! The tasks and responsibilities the Programming PM can help with.**

## THE CASE FOR A PROGRAMMING PROJECT MANAGER

First, it is important to distinguish the role of the Programming PM from the role of the Clinical Project Manager. The Clinical Project Manager, either at the Sponsor side or the CRO end is responsible for managing all aspects of a clinical trial, including the biometrics functions. However, the programming PM is distinctly focused on the planning, execution, controlling and closing of a statistical programming project; managing the project in tandem with a lead programmer.

## LEAD PROGRAMMER-PROGRAMMING PROJECT MANAGER PARTNERSHIP

In Table 1 below, we detail the responsibilities of both the lead programmer and programming PM in co-managing any statistical programming project over five main categories.

Lead Programmer	Programming Project Manager
<p><b>1. Project planning and resource allocation</b></p> <ul style="list-style-type: none"> <li>○ Assist in the development of project plan/timeline</li> <li>○ Participate in the review of CRF, protocol and SAP</li> <li>○ Study folder set-up</li> </ul>	<p><b>1. Project planning and resource allocation</b></p> <ul style="list-style-type: none"> <li>○ Develop project plan/timeline</li> <li>○ Estimates workload and resources as per project requirements</li> <li>○ Develop trackers needed for monitoring progress on task assignments</li> <li>○ Coordinate and lead team kick-off meeting to introduce the project scope, timeline and assignments</li> </ul>

Lead Programmer	Programming Project Manager
<p><b>2. Work assignments and teamwork coordination</b></p> <ul style="list-style-type: none"> <li>○ Technical and protocol knowledge-sharing with team</li> <li>○ Assign and track tasks on a daily basis</li> <li>○ Tracks technical issues raised and addresses potential issues proactively</li> </ul>	<p><b>2. Work assignments and teamwork coordination</b></p> <ul style="list-style-type: none"> <li>○ Track progress of assignments and deliverables</li> <li>○ Assess and address personnel productivity issues</li> <li>○ Coordinate and lead internal team meetings</li> <li>○ Foster team culture of good work ethic, accountability, and motivation</li> </ul>
<p><b>3. Communication and documentation</b></p> <ul style="list-style-type: none"> <li>○ Act as a Subject Matter Expert</li> <li>○ Acts as a liaison between the client, Statistician and programming team</li> </ul>	<p><b>3. Communication and documentation</b></p> <ul style="list-style-type: none"> <li>○ Develop a communication and issue escalation plan</li> <li>○ Document meeting minutes and project decisions</li> <li>○ Be the primary point of contact for the team with the client</li> <li>○ Provide project updates to the Sponsor and organizational management</li> <li>○ Escalate project issues and risks in a timely manner</li> </ul>
<p><b>4. Supervision of programming process</b></p> <ul style="list-style-type: none"> <li>○ Develop needed macros and/or tools in SAS® for data analysis and reporting</li> <li>○ Ensure adherence to process, programming standards and regulatory requirement</li> <li>○ Perform conformance and quality checks of deliverables</li> <li>○ Programming edit checks</li> <li>○ Hands-on programming of deliverables</li> </ul>	<p><b>4. Supervision of programming process</b></p> <p>***Programming PM has minimal to no role in the technical aspects of the project.</p>
<p><b>5. Monitoring of project personnel hours</b></p> <p>***Lead programmer has minimal to no responsibility in tracking hours expended on tasks.</p>	<p><b>5. Monitoring of project personnel hours</b></p> <ul style="list-style-type: none"> <li>○ Ensure efficient and effective utilization of hours. E.g. Daily status update tracker</li> </ul>

**Table 1. Responsibilities of Lead Programmer and Programming Project Manager**

**The Value the Programming Project Manager Adds to Project Oversight and Management**

1. **Risk management:** The current scope of statistical programming projects (complexity of project) and nature of programming teams (remote, virtual teams) introduced a number of risks that the programming PM can identify, assess and monitor and control.
2. **Project team coordination:** The work of the programming PM enhances team cohesiveness and direction, and also results in more careful and competent management of the team.
3. **Communication:** Lessening the burden of communication for the lead programmer leads to more accurate and timely communication, keeping all project stakeholders appropriately informed.
4. **Resource management:** Increased monitoring of project personnel hours by the programming PM helps in conserving resources in order to execute within budget.

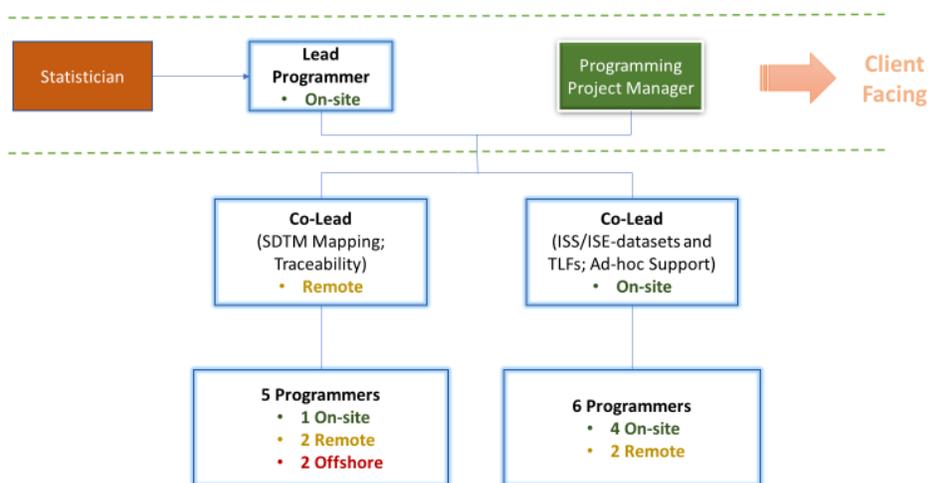
## CASE SCENARIO

As part of an NDA submission, a mid-sized pharmaceutical company (Sponsor) in the Oncology therapeutic space committed to submit to the FDA the following:

- Tabulation datasets in CDISC SDTM format for 8 Phase I-III studies.
- Integrated Summary of Efficacy (ISE) in CDISC ADaM format.
- Integrated Summary of Safety (ISS) in CDISC ADaM format.

Our company, as a biometrics niche vendor, was contracted to convert legacy data to SDTM and conduct traceability to original analysis datasets; program ISS and ISE ADaM datasets, and 280 ISS/ISE Tables, Listings and Figures. We would also be responsible for the generation of ad-hoc reports (Phase III and NDA submission support). NDA submission was targeted to be due to the FDA in 20 weeks from the start of work.

Figure 4 is a chart of the team we put together for the project based on our resource and timeline estimation. The lead programmer worked with the Statistician on all necessary statistical matters. Then in tandem with the programming PM, the lead programmer coordinated the flow of the project tasks in order to execute within a very tight timeline and budget.



**Figure 4. The Project Team**

### ***Characteristics of the project team requiring focused management***

The programming PM drew out risk profile of the programming team that included the following:

1. 29% of the programming team (4/14) had not worked together with this team before.
2. 50% of the programming team (7/14) worked remotely.
3. There were two offshore programmers with 10.5-hour time difference from the regular hours of operation of the Niche Vendor.
4. 36% of the team (5/14) were contract workers who did not have full access to the work environment, including company processes and systems.

As this team was largely virtual, over-communication was essential to mitigate the risks of programmer isolation, insufficient supervision, feedback and collaboration. Also, with team members working in

different time zones, work assignments had to be strategic, factoring in turn-around times, response times and task complexity. Delays and gaps in communication between team members in different time zones had to be carefully managed. Especially for off-shore programmers, task delegation had to be carefully planned on a continuous basis. For the contract hires, any issues or questions encountered due to their limited accessibility to the work environment had to be handled by the programming PM.

The programming PM developed and maintained a plan to manage these risks in order for project deliverables to be met with high quality, on time and within budget. Below are some of the management operations the PM deployed for effective management of the team:

- a. Maintaining a group Instant Messenger platform to enhance collaboration and cohesiveness.
- b. Daily stand-up meetings to track progress of task assignments, discuss/address issues raised, and escalate potential issues
- c. Maintaining programming assignment trackers with target and completion dates, running issue log, QC and Reviewer comments logs.
- d. Monitoring timesheets, daily updates from the team and setting weekly targets.

By having a dedicated programming Project Manager to relieve some burden off the Lead Programmer's management responsibility on this fast-paced project, the SDTM mapping and ISS programming was completed with high quality, on time and within budget. Oversight of the quality of deliverables by the lead programmer was enhanced. Communication flow with the Sponsor and within the team was enhanced. Team productivity was consistently high and time wastage was minimized.

## CONCLUSION

The challenges of the current trends of statistical programming activities and teams place a greater burden on management of analysis and reporting projects. This burden should not be carried by the lead programmer alone if project quality, timeliness and cost cannot be compromised. This is the premise for bringing in a programming Project Manager to increase team efficiency and reduce project risks.

The main impediment to having a dedicated programming Project Manager is the further cost of an additional resource. However, the programming PM's time is about 0.25FTE of the Lead Programmer's time on the project. Nonetheless, the value the PM brings, in improving efficiency and reducing risks for high stake statistical programming projects, justifies the cost of the added resource.

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