

Pain of Your Back(up) or Efficient Resourcing of Back-up Solutions for Programming Leads

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ABSTRACT

There are a number of possibilities to provide continuity of processes in a programming team set-up with one lead programmer being the only team member exposed to interactions with other stakeholders and responsible for oversight of all the activities when this person is unavailable temporarily or permanently. A role of an early-assigned back-up is considered. Apart from decreasing the vulnerability to unexpected situations, this allows consultations and peer review of decisions and strategy. In this paper, several scenarios for a back-up lead programmer selection are discussed in terms of cost-benefit ratio.

INTRODUCTION

With growing requirements, both business and regulatory driven, one can notice the workload for programmers in clinical studies tends to grow, and as industry timelines continue on an aggressive trend, one could often see the programming teams growing in size as well. This increases the workload and importance of programming leads, who may then spend most of their time managing their project and liaising with other stakeholders (e.g. timelines and resource planning) rather than focusing on actual programming tasks. Such discussions with other stakeholders are often delicate and can be challenging. Thus conflicts and (hopefully) compromises are unavoidable. While all these are regulated by standard operating procedures, these will never cover 100% of the issues, and many key decisions are often found only in meeting minutes or emails.

The programming lead may often be the only person aware of the overall progress and challenges facing programming. The lead may have teams of programmers assigned to his/her project, of whose abilities they know very well. While various documented appraisal schemes exist across the industry, they will never be as reliable as real-life experience of working with an individual programmer.

As important as they are, the programming leads are still human beings, subject to a number of scenarios that might cause the programming team to require a back-up like honeymoons, illnesses, big lottery wins, injuries, promotions, or even job change. Some such events cannot be planned upfront and while there would be acceptable rationale for such events, the business impact of them can be massive, and it can have a negative impact on project timelines.

ASSUMPTIONS

To avoid misunderstanding, some definitions are provided below.

DELIVERY

A general term describing what the programming team is expected to deliver at a pre-defined time-point. This can include datasets, tables, figures and listings, as well as other documents.

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DOCUMENTATION

A variety of documents driving the delivery work, both regulatory required as well as used for internal team communication, including, but not limited to Statistical Analysis Plan (SAP), Protocol, Case Report Forms (CRF), emails, and meeting minutes. There can also be special forms of common reference documentation like files with links to or copies of meeting minutes, key emails, SAP, etc., created with tools like Zim, OneNote, or zNotes.

STAKEHOLDERS

This is the most general group and can virtually include anyone interacting with the programming team. This would usually include data managers, biostatisticians, clinicians, and medical writers; but can also include regulatory colleagues, sales, and/or marketing representatives, depending on multiple factors. The level of interaction will vary between deliverables as well as within a deliverable on subsequent stages. Some of these interactions may be difficult to foresee.

MANAGEMENT

This is a general term for a person or people accountable for resourcing programming teams. The management setup will not be considered in this article and it is assumed they are interested in providing high quality and on-time deliveries with the minimum required resources.

STATISTICAL PROGRAMMER (SP)

Programmer with understanding of clinical development environment: they would be trained in ICH GCP and other requirements. A SP can be assigned a variety of tasks in a programming team and their participation can range from creating or debugging small fragments of code to leading entire deliveries (when they perform the role of Programming Lead).

PROGRAMMING LEAD (PL)

Programming team consists of at least two Statistical Programmers. Normally at the beginning of the project, a programming lead would be assigned so it is clear who holds ultimate responsibility for the programming work. This person will have an overview of the entire delivery, in terms of both input and output. PL maintains communication with the stakeholders and is also responsible for the review of various documents and ensures that the programming work is documented. The overview and planning of milestones is also within the PL's responsibilities. They are in the best position to assess the impact of resource assignment with regards to timelines and quality of the delivery.

CANDIDATES

NO BACK-UP

Let us consider the scenario of no back-up. There is only a PL and his team, with individual programmers focused on their part of their work. As a team may have ten or even twenty programmers, this can mean each individual programmer knows a small part of the delivery very well and have no overview of the entire delivery. Furthermore, they are often isolated from the interaction with other stakeholders, learning only about their tasks assigned by PL. Management would not be aware of all the details of the work within the delivery that a new PL needs to know.

Now suppose the PL is suddenly unavailable. Depending on the legal and cultural background, the probability of such situation may differ, however should never be neglected. People can have an acute illness or an accident, rendering them unable to work. They are often able to leave the job without notice. They may also be assigned to other tasks, which are so urgent and absorbing, that they are completely unavailable for their previous team.

Assuming documentation of the delivery is complete and comprehensive, it is possible for any qualified programmer to review the documentation and talk to programmers for "some time" before fully taking over the role of the lead. This "some time" will probably be lost – the programmers need guidance from the PL on regular basis. Instead, they will need to spend their time explaining relation between documents, programs, decisions, assignment and progress of tasks up to date. A number of possible alternatives are considered below.

HIGHER-LEVEL BACK-UP

In this scenario, the duties of the PL are assumed by a person higher in hierarchy. This would be either the PL's line manager or someone responsible for a spectrum of deliveries (usually responsible for consistency, etc.). Depending on the day-to-day level of collaboration, this approach would have advantages and disadvantages. This is a good solution if there are not too many deliveries supervised by or too many PLs reporting to the Higher-Level Back-up. Otherwise the Higher-Level Back-up is immediately overloaded with work should he/she have to take the duties of a PL over. This is because it is not cost effective to keep a higher level person available for standing in for the PL. If it actually is the case, this would be a very reasonable way of resource usage. The Higher-Level Back-ups follow the development in all deliveries and in the course of their duties are always in a position to take over.

There is however one major drawback to such a setup. When more than one PL is unavailable at the same time, the Higher-Level Back-up may easily be overwhelmed. In turn, they may reduce their attention towards other tasks and the absence of PL in one delivery influences multiple other deliveries that require support from the Higher-Level Back-up.

PEER BACK-UP

Another possibility is to have a Programming Lead of another analysis pre-assigned to potentially replace the PL.

The benefits here are that the back-up is used to these kinds of responsibilities and should be aware of all the processes. Unfortunately, such back-up would already have duties of their own, thus may lead to overloading with work in many circumstances.

TEAM MEMBER BACK-UP

In this setup, one of the statistical programmers assumes the back-up responsibility. The selection of the suitable candidate should be based on a number of factors. The choice of the back-up must be reasonable for other SPs in the team to avoid frictions. The candidate must have a good understanding of the processes within the organization. Furthermore, good communication and time-management skills, as well as fluency with understanding, reviewing, and creating documentation are required. All these skills and abilities may prove critical in terms of both quality and resourcing of the delivery. The benefit of such a solution is that it is easily scalable and this is the only solution considered here that may still work if all the PLs are gone at the same time (e.g. if you want to have a one day training, discussion, or team building event including all the PLs). Still it takes a candidate with abilities which a regular programmer may not have to be available within the team.

BACK-UP ENGAGEMENT

A number of actions or processes possible in preparation for unavailability of PL are considered below.

DESIGNATION

The author considers this as the minimum companies should strive for. It should be clear, either from the established procedures or from internal communication, who is designated to replace the PL if required. This allows the nominee to at least ask the critical questions while the PL is still available. Furthermore, the selected person can object the designation while there is still time to discuss and consider other potential candidates. Once the back-up selection is finalized, the selected person can at least get prepared for the role, mentally at the least, if no other effort is possible considering resource limitations and time constraints.

The benefit comes immediately and only at the moment of transition. The slower the organization in decision-making process, the more beneficial it is to assign the back-up before any need arises: the responsible person can start taking duties over right away. However, it does not solve any of the problems discussed above in the "No Back-up" subsection. Any designee should insist on the time required to prepare for this role and a hand-over before and after any substitution should be formalized.

This level of engagement makes sense only for back-ups who are experienced in leading programming teams themselves. They need to be aware where and how to look for information, how to communicate with SPs and stakeholders, and ultimately how to successfully deliver what is required. Obviously, it requires a well-standardized environment, so that the volume of delivery-specific documentation to take over is not overwhelming.

PROGRESS AWARENESS

Progress awareness is keeping in touch with the progress of work and its status by the nominated back-up. This would include receiving key emails forwarded by PL or otherwise, and information on key developments and decisions. While it does require some continuous effort and attention from the back-up, taking such steps helps avoiding confusion at the moment of hand-over.

Engagement on this level has all the advantages of the previous one ("Designation"). Furthermore, the back-up is aware at least of critical issues and milestones to be reached; can quickly identify responsible persons to reach out to for additional details, actions, or decisions. This comes at the expense of prior time investment while the PL is still available.

The author expects it would take an extremely responsible and dedicated person to follow communication with little or no time allotted for this or to even maintain motivation. For environments where the need for back-up replacing the PL is unlikely, it may be considered as training for a future PL. A mentor (preferably the current PL) would explain and/or verify the correct understanding of the work, communication, and documentation flow towards delivery. Another approach would be with an inexperienced PL having their mentor performing duties as back-up while supervising them. This level of engagement still requires a well-standardized environment, so that the volume of delivery-specific documentation to take over is not overwhelming.

INVOLVEMENT

The back-up is engaged in virtually all activities by PL, which should also include taking over some of the PL's ongoing duties. The extent of back-up involvement is agreed between PL, back-up, and the management.

The back-up participates in meetings both within and outside the team. The PL and back-up can alternate duties of drafting the agenda, minutes, or even the very participation or leading in some of the meetings. Standing in for the PL for some of the meetings allow greater flexibility for the team and for the PL. Furthermore, the back-up may maintain common reference documentation. These duties should not be considered only as administrative burden, but rather an opportunity to get a clear view and understanding of the current situation.

The back-up is engaged in program development tracking, makes sure the progress is regularly and correctly documented. Liaising with SPs who seem or happen to fail to follow established practices can also take some burden of the PL. The PL can resolve any conflicts if they arise in the process.

Another area open for back-up involvement is resource planning. The back-up and PL can share experience they have with strengths, weaknesses, and development potential in SPs. While the author believes PL should be the driver of resourcing, the back-up should be aware of all the reasons and aims foreseen in the resource plans, potential challenges as well as consider scenarios for reaching critical milestones on time.

Furthermore, the back-up may be expected to challenge ideas and decisions of the PL, create and/or review documentation for the delivery, or even manage parts of the delivery.

Engagement on this level has all the advantages of the previous one ("Progress Awareness"). Furthermore, by getting the back-up to act, the interest in the delivery is fuelled, and the team can easily benefit from the experience of the back-up. Thus, the time investment prior to any crisis situation is not lost, if the PL finalizes the delivery with no absences whatsoever. The team gains leadership validation.

This level of engagement can be tailored to the current development stage of the back-up and abilities of PL. It also ensures a smooth transition of PL duties; also allowing the back-up to develop skills required from a PL gradually in the process if necessary.

LEADERSHIP DUO

In this setup the distinction between PL and the back-up is formal. They form a partnership sharing duties, discussing decisions and guiding SPs on daily basis. As they share their duties in leading the work, it may be that they are able to perform some programming, thus decreasing the burden on resource consumption. This scenario is most resilient against sudden

unavailability of the PL, but, like most close-knitted relationships, requires people with a well-fitting personality and a team-oriented attitude. This may also be considered an intermediate stage of duties transition between PL and back-up as discussed in “Involvement” subsection above. However, in such scenario this would be a temporary status. It should allow preventing tensions due to personality differences from building up.

CONCLUSION

All organizations have to balance between a rigid structure that helps limiting scale of chaos in daily life, and elasticity, which helps avoiding chaos in unordinary circumstances. The author believes that every organization should have sound procedures enforcing automatic assignment of back-ups for PL, well in advance of taking over. These procedures should also specify the level of engagement of the back-up. Still, some elasticity is needed to adapt to the resources available. These adaptations should be recognized up-front and before any crisis arises. Organizations should also consider engagement of team members in back-up responsibilities throughout the work on a delivery as an opportunity for them to grow. Unless unordinary circumstances arise, such set-up offers best cost-effect ratio.

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