

Paper SP03**Programmer to SME – Career Game Changer**

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ABSTRACT

Imagine an intersection in a Venn diagram, where one circle represents “Programming” and the other “Management” – the intersection is what we would call “Subject Matter Expert (SME)”. Subject matter experts are individuals, who are competent to perform the work hands-on as well as manage the work - gauging the complexity and time required, thus enabling effective study management. SMEs shoulder major risk in successful delivery and hence, have become popular touch points for the leadership or project managers in the recent times. Their work revolves around 3 major productivity targets: a) complexity of the task, b) resource/task allocation to individuals in the study team, c) quality and timeliness of the tasks/report objects delivered.

This paper will discuss few career-game changing scenarios and pointers to evolve from a programmer to an effective SME in today's programming world.

INTRODUCTION

There is an increasing shift in organizations moving towards lean management structures. “Each One their Own Boss” seems to be the most preferred trend of this generation of workforce. The kind of talent pool available is more interested in holding its technical streak while, limiting the need for full time managers. The role of SMEs has become very interesting for many people in the market today, owing to the fact, that it helps one stay loyal to basic technical stuff and yet have a part of their work profile into management of the technical aspects of the study.

WHO IS A SUBJECT MATTER EXPERT?

Subject matter expert is an individual with typically excellent know how of the programming aspects in a study. He/she is an individual who has experienced a wide gamut of work real-time in their career span and hence can relate to the complexity of the assignment/data quickly. A typical SME level programmer would have below professional qualifications:

- Experience in SAS programming for pharmaceutical projects demonstrated by a strong working knowledge of regulatory requirements relevant to statistical programming and reporting
- Skilled in project management including time management, planning, resource management, problem solving and project execution
- Ability to interface with different stakeholders across all levels, in cross functional environments, cultures and time zones
- Extensive knowledge of global clinical trials practices, procedures, and methodologies
- Exposure on International Council for Harmonization – Good Clinical Practices (ICH-GCP) guidelines and Code of Federal Regulations (CFR) Title 21, Part 11 that covers the management of electronic records, electronic signatures and computer system validation



Figure 1: Venn diagram the intersection between a SME, stakeholders and work responsibility

WHY SHOULD AN INDIVIDUAL CONSIDER BECOMING A SME?

SME role offers an individual to hold on to the technical aspect of the role which is their core strength. After years of programming, SME role offers exposure to manage delivery through effective resource allocation and timeline management. Crux of the matter is - they need not give up on their technical forte, yet perform tasks related to technical aspects of study management.

WHAT ARE THE KEY RESPONSIBILITIES OF AN EFFECTIVE SME?

MANAGE THE WORKFLOWS:

Clinical trial data analysis occurs in a defined and protocol driven manner. Each step has its importance and there is no scope of missing or reducing the steps in a process to ensure the desired outcome. Success of any process is in confirming to the steps involved systematically. However, such processes are sometimes faced with challenges of accommodating dynamic changes or updates to the data process.

SMEs are supposed to plan or accommodate for changes (dynamic or planned) keeping in mind the framework within which such changes must be inputted or accommodated.

Let us see this with an example below:

CASE STUDY: JOHN'S SUCCESSFUL WORKFLOW MANAGEMENT

Role: John – SME

Team Members: Mary, Cindy, Julia, Peter

Team Member Profile:

- John, Cindy, Peter – Sr. Programmers
- Mary & Julia – Jr. Programmers recently added to the study team.

Situation in hand:

Timeline for deliverable is 2 weeks. Cindy is on vacation for 1 week in this 2-week period. Peter, Mary and Julia are also involved in other studies. The study belongs to the therapeutic area (TA) where Peter has extensive experience. There is an anticipated update in the base dataset which will impact the report objects in the delivery.

Actions by John to make the deliverable a success:

- John discusses available hours with Peter, Mary & Julia in study meeting and shares the deliverable tracker
- John announces Peter as the study lead and makes who will oversee work assignment
- Peter assigns work with clear instructions to code to dynamically accommodate the last-minute anticipated changes and creates a tracker to mark the work status
- John works closely with Peter to maintain the documentation at all stages

Success story:

The last-minute updates are accommodated, and deliverable is sent successfully on time.

Below is the appreciation email from sponsor:

"Kudos the team on timely completion and accommodating the last-minute changes too! Great work John, Peter, Cindy, Mary and Julia!"

John identified the expert in his team and assigned what he/she will do best. John ensured workflow management and the end was a success story

SEEK CLARITY:

Picture this scenario. You ask your manager for more information to work on a report and she says, "make a logical assumption of the missing data and work it out!". This may be applicable in the general reporting context but in our domain, assumptions can sometimes lead to disasters. Hence, it is better to ask questions and get them clarified at an early stage than having your team or you re-do the entire set of activities later-on.

CASE STUDY: CHIP & FLORA – CLARITY LEADS TO SUCCESS!

Chip is a contractor to ABC Inc. Chip is working with a study team as a Sr. Programmer in a study spread of 3 months consisting of 171 report objects in total. While coding for the report objects assigned to him, Chip finds that the SAP and TLF shells are contradictory, the logic seems to be totally out of scope. He promptly reports it to Flora, his study lead and SME, Director of Programming at ABC Inc. Flora, although skeptical and not convinced about the remarks from a contractor, decides to have a deep look into the issue reported and concludes that the deliverables cannot be programmed based on assumption. She sends an email to the entire study team in the below lines:

Hello All,

We have found that the SAP and TLF shells are contradictory, the logic seems to be totally out of scope. We have written to the sponsor seeking clarity. All of you are requested to hold on to the work assigned w.r.t. this study until further information is received from the sponsor.

- Flora

Once clarity is received on the issue, the work resumes the normal and the deliverables are sent out in time and the customer sends huge appreciation for the team's prompt reporting and resolution mechanism.

Flora realizes that Chip's prompt reporting helped the organization save a lot of time and money and efforts on repeat work. Most of all, earning a good name for ABC Inc. with their customer. She sends out a nice appreciation email to Chip's managers and extends his contract for further term sighting great performance.

Here, we saw that seeking clarity when there is a need is extremely important and goes a long way in

- *Saving money and time*
- *Avoiding repeat work*
- *Developing productive and everlasting relations.*

BUILD RELATIONS:

We are human beings and not machines who work for 8 to 9 hours. SMEs function as a sandwich between programming team and the management. It is important for SMEs to develop trust-based relations encouraging open communications. The key is to establish teamwork, transparency and trust as the three founding pillars of the relations. Everything you do or is seen as an achievement is because of teamwork. The work should be carried out in such a way that everyone is aware of all the relevant information and decision-making process to ensure transparency and consistency in process implementation across. In an environment where each one receives credit for their work and there is transparency, the relations will naturally be trust-based and nurturing them would be easy.

CASE STUDY1: TASK ALLOCATION – WHO WILL DO WHAT?

Don is a SME.

Task in hand:

Dear Don,

Priorities for September 7th – 8th:

<i>Listing</i>	<i>76.2.1.2</i>	<i>Discontinued Patients (Randomized Population)</i>	<i>Unique</i>
<i>Table</i>	<i>24.1.1.8</i>	<i>Enrollment by study center and treatment group (Randomized population)</i>	<i>Unique</i>
<i>Table</i>	<i>D7</i>	<i>Disclosure of demography and other baseline characteristics (Full Analysis Set)</i>	<i>Repeat</i>
<i>Table</i>	<i>D8</i>	<i>Disclosure for Patient Disposition (Screened Population)</i>	<i>Repeat</i>

Below are the hours allocated to TLF programming:

Task	Hours per task
Table Programming - Unique	6
QC - Unique Table	3.5
Table Programming - Repeated	0.75
QC - Repeat Table	0.75
Figure Programming - Unique	6
QC - Unique Figure	0.75
Figure Programming - Repeated	2
QC - Repeat Figure	0.25
Listing Programming - Unique	2
Listing Programming - Repeated	1
QC - Listing	0.5

KR,
Flora

Team members available to Don:

2 senior programmers Tim and Cook - involved in other 2 studies with upcoming deliverables in 2 weeks' timeframe. 2 junior programmers – Susan and Bree and Don. Susan can do slightly complex assignments. Bree is on vacation 5th and 6th September.

Don's task allocation plan: (notes from his diary)

Allocate unique ones between Tim, Cook and self. Allocate the simple repeat report objects and slightly complex report object to Susan and remaining to Bree.

Have status calls daily, re-assign. Re-plan the delivery, if necessary, update the tracker for person responsible and task status.

Case Analysis:

Don plays with strength of his team members. This will help in developing a strong team in the longer spell of working relations. Each one will feel good about their success in the task assigned and completed by them. This will develop respectful rapport within the team members as well.

CASE STUDY 2: DEALING WITH EXPERIENCE

Mike and Tom are SMEs handling other studies and individual contributors for studies handled by SMEs – Carlos and Orson.

Below are 2 sample emails from Carlos and Orson regarding the task allocation/update:

Dear Mike,

Please open the study folder, refer the tracker.xls and update the table assigned as per new mock shells (v1.4) available in the documents folder of the study.

*Output to be saved in a separate folder dated today named **update 1.4***

Get back to me for any doubts.

*Thanks,
Orson*

Dear All,

We must complete the below tasks today.

@Tom – minor update – header and footer of 1.2.1.14

@Mike – 23.2.2.4.x series need footnote update to match shell

@Orson – open the study database and complete the listing 4.3.82. call me for any clarifications.

*Thanks,
Carlos*

Case Analysis:

Carlos plays by experience. He is not giving detailed instruction to his team members understanding the qualification, experience and profile of his team members. What we communicate is important. It is also how we communicate, which matters in building fruitful work relations.

On the contrary, Orson plays by the dictionary and is very detailed irrespective of experience. Mike is a SME level programmer. Mike need not be given such detailed instructions. Sometimes, such detailed emails can be perceived as undermining the other individual's capabilities and can impact the relations. Hence, we must be mindful of how we communicate as well.

CASE STUDY 3: THE GREAT WALL OF SME

CASE DESCRIPTION:



CASE ANALYSIS:

As a SME, we need to be aware that success is always about teamwork. At the time when we don't succeed, a SME's responsibility is to take the feedback and work on improvement for future. This is called leading from front. We also need to be aware that best of planning can be countered by:

- Team member non availability (sickness or personal emergency)
- System failure
- Time zone differences leading to increased TAT for small clarifications

ACCEPT CHANGE:

Change is the only constant. People in a study may change, some datasets may get updated and require re-work, if we keep our mind open, to anticipated as well as unanticipated changes, we will succeed in the role of SME and provide our stakeholders with delightful work experience.

CASE STUDY: SETTING THE RIGHT WAY TO CHANGE

Lynette a long time SME in a study team, is moving out of the team. She must transition her work to Gabrielle who is taking over her role in the study. Lynette is also moving to another team where Juanita (previous lead) is transitioning information about the study to her.

Lynette has a track record of maintaining the project documentation to the perfection. She also has made notes where different process has been followed based on customer requirements. This helps the incoming lead Gabrielle take over and handle the study deliverables with minimal impact. Lynette also documents and records the KT sessions to help Gabrielle for future reference.

In the new study which Lynette takes over from Juanita, she follows the same process. She makes notes and takes signature acknowledgement from Juanita on all the documentation. Lynette also records the KT sessions to capture the project nuances which were transitioned verbally to ensure, there is a back-up to refer in case of future doubts. Lynette is soon the favorite in her team for her clarity and approach. The client as well as the team members feel her as a long standing and a reliable team member who is in complete grip of her project.

Juanita, who is moving into senior management of the company, promptly reports Lynette's transition style and it is converted as a template for project transitions in the future for the organization. Lynette is awarded a bonus for her exceptional contribution in the knowledge transfer process of the organization.

Case Analysis:

Changes can come in many forms, be it – moving from a pet study and taking up a new study. Meticulous and disciplined approach is the only way to successfully embrace change. It is clearly seen in Lynette's case that her meticulous and "eye on the target" approach, makes her the expert SME. Lynette displays attributes of a professional who is highly accepting of change and challenges which come with it.

BEGINNER SME – RASCI MATRIX

RASCI matrix is a matrix which indicates the responsibility/accountability/support/consulted/informed roles with respect to tasks/activities.

- R – indicates the role who performs the task
- A – indicates the role, which is accountable for the task, basically the person is the signing off authority for the task
- S – indicates the role/s which support in the task completion
- C – indicates the role which is consulted for inputs to enable task completion
- I – indicates the role which is informed regarding the task progress or completion.

Apart from being responsible for the routine programming activities a SME performs activities towards customer management, delivery management and Compliance from an overall project perspective.

Below is the formal RASCI matrix sample for a beginner SME Programmer:

Task	Customer management			Delivery Management				Compliance		
Activities	Act as key contact for project deliverables	Respond to queries raised by regulators or sponsors	Enhance customer relations and trust levels	Review work package and create effort allocation schedule	Support and supervise programming team towards resolving issues	Communicate with project stakeholders	Attend /conduct meetings as needed	Adhere to guidelines and study documents – protocol etc, pertaining to the study	Develop processes to facilitate training and regulatory compliance	Create and maintain project related documentation
R	R	R			R	R	R	R	R	R
A	A	A						A	A	A
S			S	S						
C										
I										

CONCLUSION

Careers are not made; they are built. When we start our careers, often we are not clear on how we will progress. Typically, 4 to 5 years into a field, we learn our strengths, weakness, likes and dislikes. Evolving into the SME role in our career line can be a great one. It helps us be an integral part of study delivery and management without having to venture into the routine line management aspects. A programmer essentially enjoys and appreciates programming tasks because that is mind challenging and algorithmic. In conclusion, the best part of becoming a SME is, we can still program while we manage to some extent.

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