

Programmer to SME – Career Game Changer

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Authors Bio

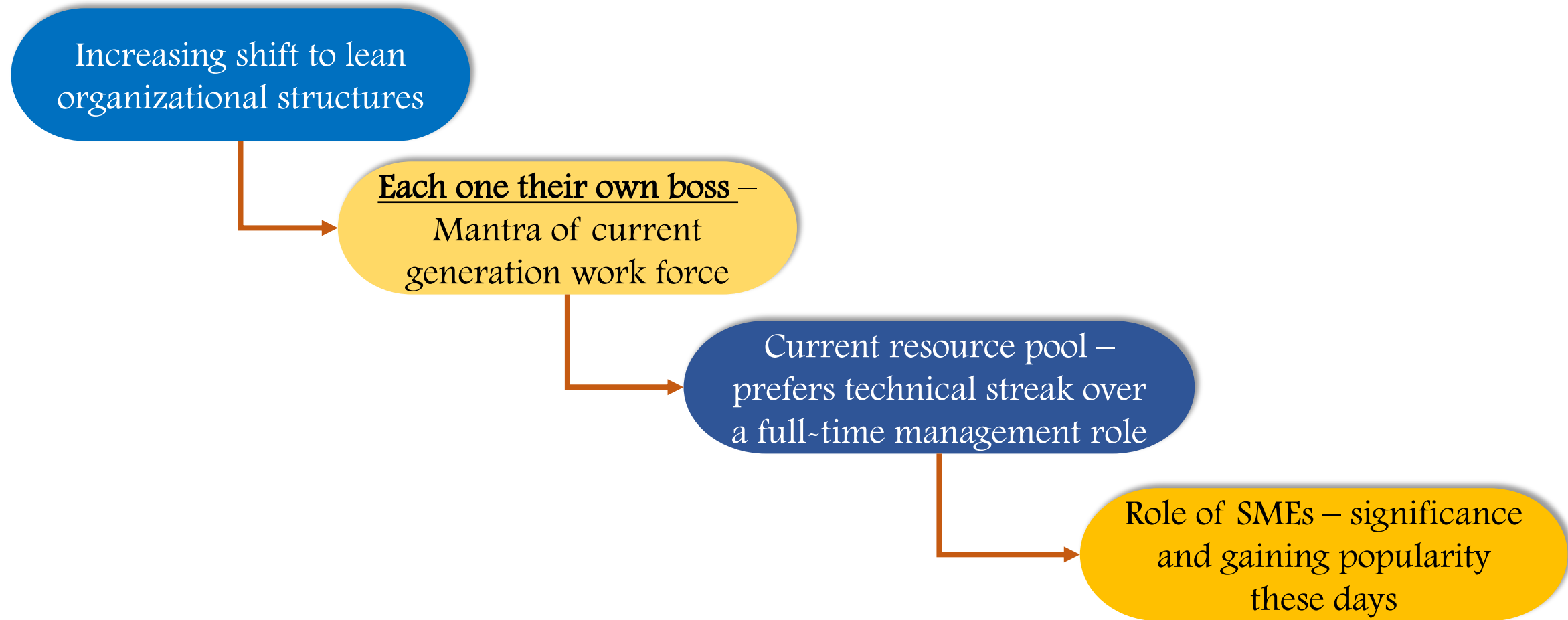


Divya Cetlur: Seasoned professional with over 8 years of experience in the field of human resource management in clinical domain. She holds a post graduate diploma in management and has done certification courses in transactional analysis and is a certified internal auditor for ISO processes. In her career span she has handled a gamut of HR management from recruitment, L&D, compensation to performance management and other aspects of employee life cycle management.

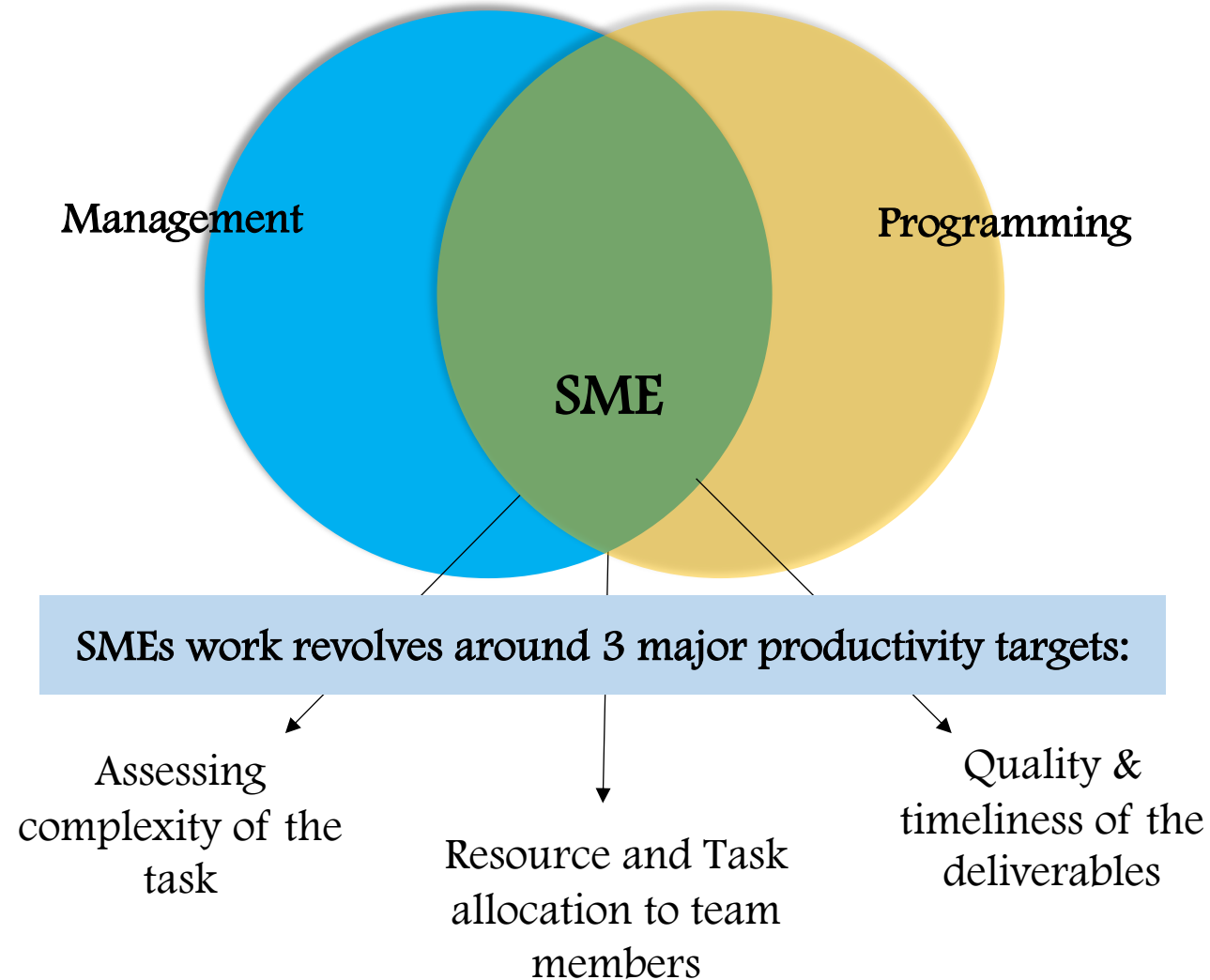


Charumathy Sreeraman: Charumathy alias Charu is a seasoned industry professional with over 9 years of experience. In her career span, she has worked on several complex studies across all the phases of clinical trials and in varied therapeutic areas including oncology, CNS, Dermatology. She is a pro in SDTM conversion and AdaM programming. Apart from being a qualified Chemical Engineer and a Masters in Biotechnology from the University of Manchester, UK, and a full time professional, she is also a daunting mother and homemaker. Her penchant to research on topics and constantly present papers in various industry level conferences such as ConSPIC, PharmaSUG, PhUSE have earned her the title of “Serial Paper Presenter” amongst her close circle.

Background



Background



Agenda

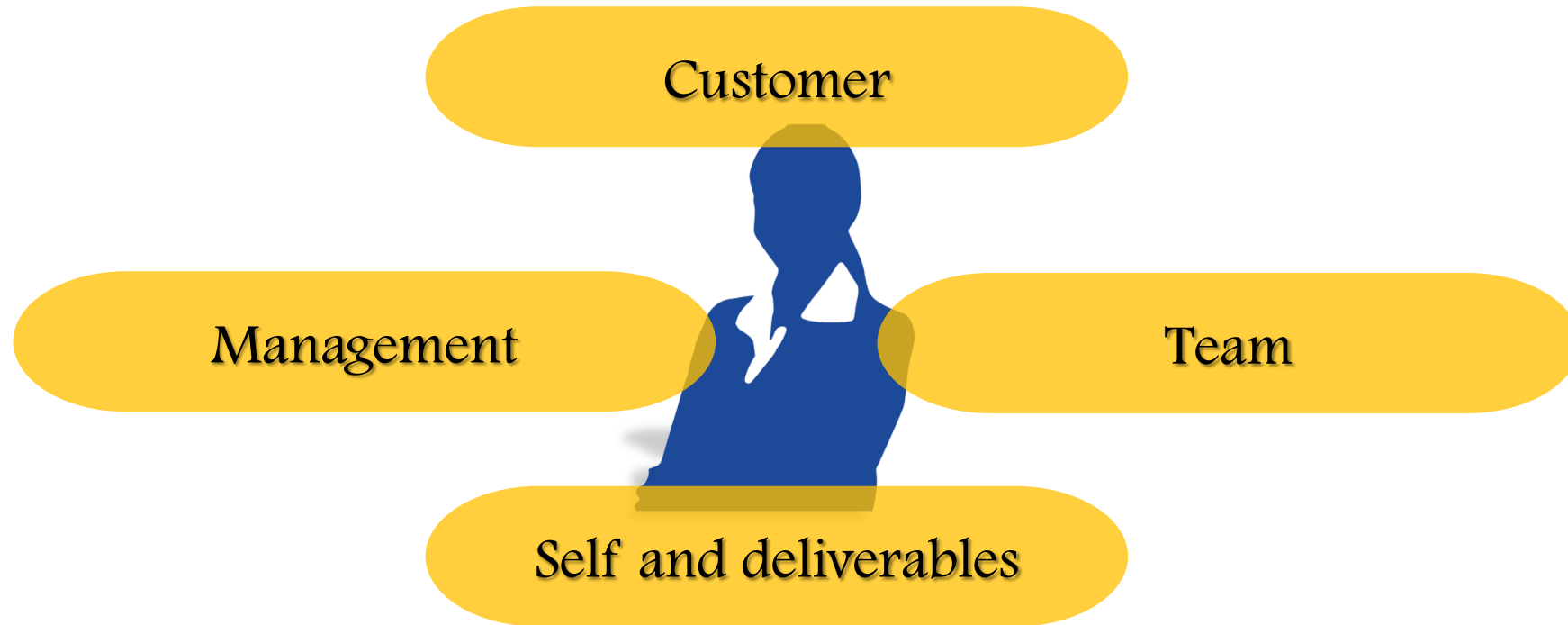
- Who is a SME?
- Why should an individual consider becoming a SME?
- What are the key responsibilities of an effective SME?
 - Manage workflows – case study explanation
 - Seek Clarity – case study explanation
 - Task allocation ~ cases explained
 - Accept change – case explanation
- What is RASCI Matrix?
- Our representation of a beginner SME Programmer's RASCI matrix
- Acknowledgement
- Conclusion
- Questions

Who is Subject Matter Expert?

- Experienced in SAS programming with strong knowledge of regulatory requirements relevant to statistical programming & reporting in pharmaceutical projects
- Skilled in project management including time management, planning, resource management, problem solving and project execution
- Stake holder management & possess cross cultural awareness
- Extensive knowledge of global clinical trials practices, procedures, and methodologies



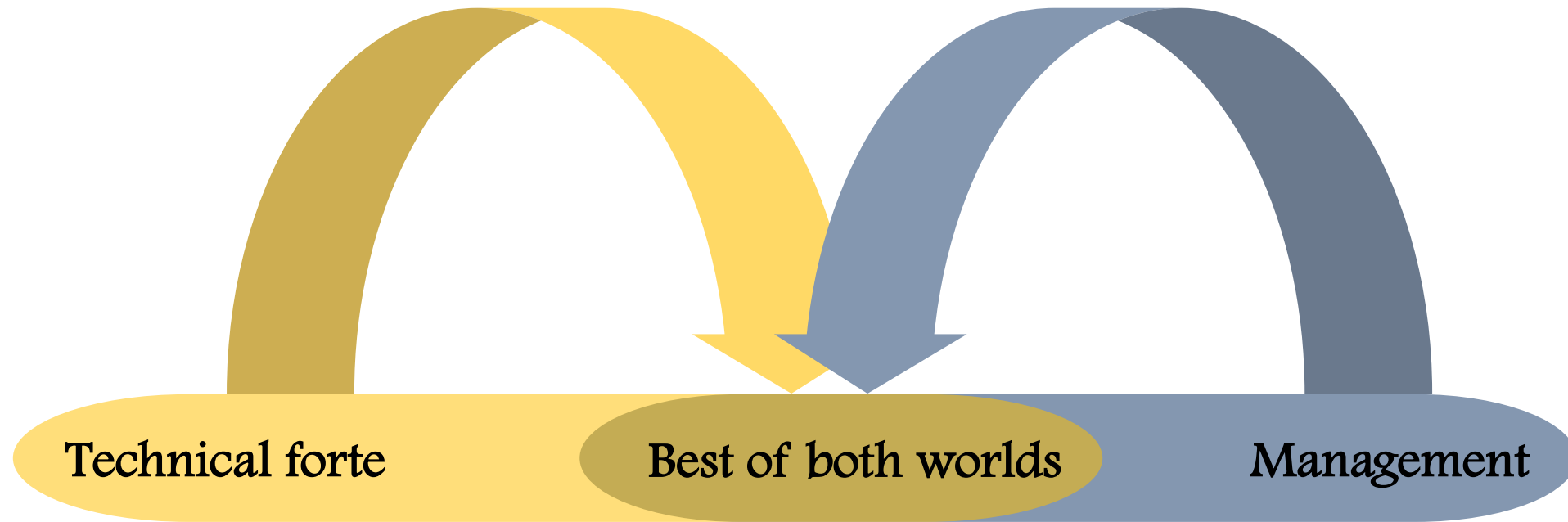
Who is Subject Matter Expert?



Subject matter experts stand at the cusp of customer, management, their team members and their own self and the deliverables which they are responsible for as individual contributors in other teams

All of it looks simple... Is it?

Why – become an SME?



We need not give up on their technical forte, yet perform tasks related to technical aspects of study management.

Key responsibilities of an effective SME



1. Manage the Workflows

Case Study:

John is SME having to handle a study deliverable with timeline of 2 weeks.

Team members – profile & availability:

- Cindy & Peter – Sr. Programmers,
- Mary & Julia – Jr. Programmers recently added to study team
- Cindy on planned vacation for 1 week in the 2-week period.
- Peter, Mary, Julia are involved in other studies as well
- Peter has extensive experience in the therapeutic area which happens to be the TA of this study

There is an anticipated update in the base dataset which will impact the report objects in the delivery

Actions by John:

- John discusses available hours with Peter, Mary & Julia in study meeting and shares the deliverable tracker
- John announces Peter as the study lead
- 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:

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!”

Key responsibilities of an effective SME



2. Seek Clarity

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 something amiss and reports it to Flora (SME & Study lead)



Chip

Hi Flora, The SAP and TLF shells are contradictory, the logic seems out of scope



Flora

Team,
Hold on to the tasks assigned as the SAP and TLF shells are contradictory. We are awaiting clarifications from the sponsor.
Regards,
Flora

Success story:

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.

Key responsibilities of an effective SME



3. Build relations

Case 1: Task allocation: who will do what?

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

Below are the hours allocated to TLF programming:

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

*KR,
Flora*

Key responsibilities of an effective SME



3. Build relations **Case 1:** Task allocation: who will do what? Contd.

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.

Working with people's strengths is the key to strong and fruitful relations

Key responsibilities of an effective SME



3. Build relations

Case 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*

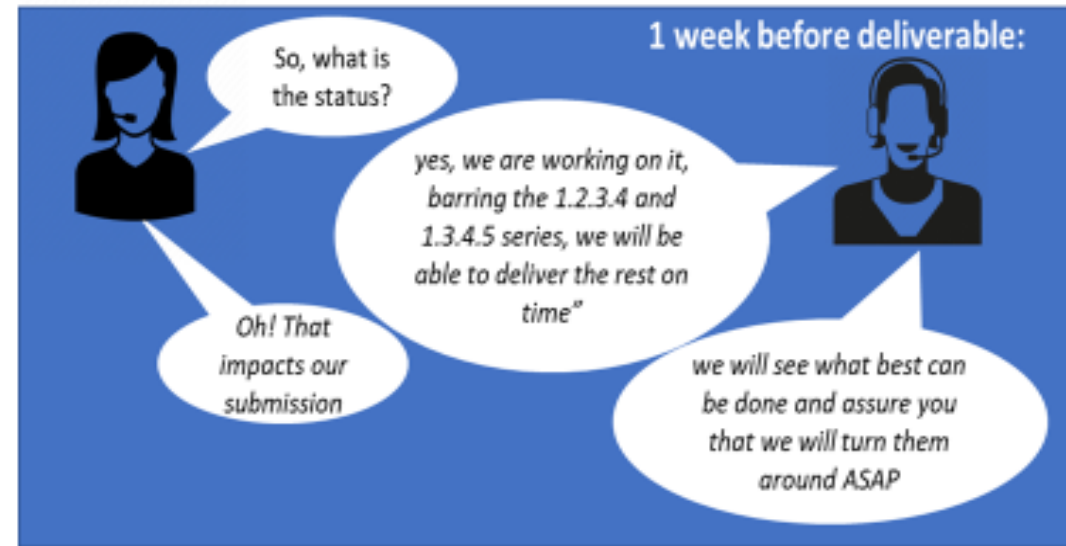
What we communicate is important. It is also how we communicate, which matters in building fruitful work relations.

Key responsibilities of an effective SME



3. Build relations

Case 3: The great wall of SME



Success is always about teamwork. At the times of failure, a SME's responsibility is to take the feedback and work on improvement for future. This is called leading from front.

Key responsibilities of an effective SME



4. Accept Change

Case: Setting the right way to change

Case characters:

Lynette: Long time SME in a study is moving from current study to another study

Gabrielle: SME who will be taking over Lynette's study

Juanita: SME of the study, Lynette is set to take over

Lynette to Gabrielle – Transition Plan – Lynette's plan

- All documents maintained in order and shared with Gabrielle
- Personal notes pertaining to deviations or new methodologies transitioned
- KT sessions are recorded and shared for easy future reference

Success story:

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. Her KT processes is formalized into the company's project transition process.

Taking over from Juanita – Lynette's plan

- Make notes during the KT sessions
- Take necessary acknowledgement & signatures
- Record the KT sessions

What is RASCI Matrix?



Beginner SME Programmer ~ RASCI



Our representation:

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										

Acknowledgement



- Efficacy – Our organization
- Our colleagues who helped us
- Google images – we have used google images in this presentation
- Our family & friends

This paper is a representation of our experiences in the last year and half, of being in the SME role in the projects, we have worked on.

Conclusion



- Careers are not made; they are built.
- 4 to 5 years into a field, we learn our strengths, weakness, likes and dislikes.
- SME role facilitates to be an integral part of technical aspect of study and delivery management.
- Programming job is mind challenging and scratches the algorithmic aspects of our mind.
- The best part of becoming a SME is, we can still program while we manage to some extent.

Questions?



Thank you!

