

Mind Over Matter: Building an Army of Passionate Soldiers Dedicated to Saving Patients' Lives

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ABSTRACT

The clinical research industry is one of the fastest paced industries, where sponsors are continuously introducing newer and better products to improve patients' lives. SAS® Programmers are expected to deliver speedy analysis results, with high standards of quality and accuracy. In this extremely demanding and competitive culture, managers are responsible for developing and maintaining a positive mindset and attitude within their teams, towards a common goal of benefitting patients.

The demand and expectations of our profession can be comparable to that of the soldiery, due to the importance given to saving human lives. Passion, selflessness, integrity, professionalism, seamless quality, efficiency, timeliness, expert insight, and teamwork are just a few common traits.

This paper talks about various strategies and approaches to building and grooming a high performance SAS® programming team, which can function efficiently under extreme circumstances, concurrently maintaining an optimistic upbeat attitude. Some real world industry scenarios will be shared.

Hiring Strategies – Hiring individuals with skillset and personalities that complements the existing group

Team Building – Building a sense of community within the team, responsible for each other's growth and success

Relationship Management - Developing internal and cross-functional relationships by building Trust, Faith and Reliability

Coaching – Clear expectations for quality, efficiency and conduct

Feedback – Timely and specific feedback, focused towards improvement

Mentoring – To help enhance skillsets

Motivation – Sharing bigger picture and long-term goals. What's in it for each individual?

Stress Management – Keeping team upbeat and positive. Understanding challenges and removing obstacles

Leading by Example – Walk the Talk

INTRODUCTION

The Clinical Research Industry is one of the most demanding industries, for all of the right reasons. The pace at which it is growing is astonishing, and it will be unfair to expect anything less than that, due to the importance given to the improvement to patients' lives. It is essential for anyone associated with this industry to have the appropriate attitude and mindset to help foster peace and harmony in the work environment, and to the success of the projects that benefit patients' lives.

It is the responsibility of the organization, management, and line managers to ensure that an open, positive, optimistic, and strong mindset is nurtured and cultivated, in order for the clinical SAS® programmers to give their best to this industry, and their roles. We can learn from the defense service personnel about how their values and attitudes help them serve their desire to improve and protect human lives. It is extremely important for us to see ourselves through similar lenses, if not equivalent. Having the right state of mind is half the battle won. Knowing that what we are doing, and how we are doing, has an impact and a purpose, and directly affects our patients, will help us better manage our work challenges with a more compassionate and positive spirit.

Once that culture is assimilated, it is important to ensure the efforts are ongoing, maintained, and carried over to the wider group to reap exponential benefits.

To provide better relevance, learning, and implementation, a case study from a real world example will be presented.



Figure 1: Soldierly values and mindset need to be cultivated in order to be sensitive and compassionate towards our role, and the importance it plays in improving human lives

ROLE OF A MANAGER

A manager's role is not limited to project management or admin related tasks. In a typical day, a good manager or a people's leader is expected to efficiently juggle wearing many different hats. A manager plays a vital role in building and nurturing a robust team of talented individuals, which will eventually benefit and lead to many successful projects, for the organization, the industry and ultimately patients.



Figure 2: Various Roles of a Manager

Let's talk in more detail about the employee-centric roles of a manager in the following section.

HIRING STRATEGIES

As a first step it is critical to hire the right candidates. This involves evaluating candidates' experience, technical competencies, qualifications, soft skills, and personalities to ensure that they will complement the existing group.

Recruitment challenges are common across all industries, and demands exploring new and innovative recruitment methods and ideas, such as the social media networks LinkedIn and Twitter. Attending various industry conferences not only helps with networking, training, and skill development of existing employees, it can also help highlight the work and culture of the company. Doing presentations and holding company booths gives potential recruits an opportunity to interact with current employees and learn about the work and culture. Most individuals look for a great work environment, which also gives them opportunities, challenges, and growth prospects.

While engaging in recruitment efforts, it is highly important to understand and consider cultural, generational (Gen X, Gen Y, Millennials, etc.), and personality differences. This is even more important when designing an attractive, custom, and deserving compensation package, since different generations, cultures and personalities may have unique priorities and motivations. For example, some individuals value receiving opportunities at work, for others stability or immigration security is critical. Therefore, an

employee's loyalty, contentment, and long-term commitment/retention may be highly influenced by the kind of compensation package offered.

Two other robust and established recruitment/hiring strategies are employee referral programs and contractor conversions. These methods help find reliable and trustworthy candidates who have more insight into what to expect through their acquaintance or previous experience as contractors.

TEAM BUILDING AND DEVELOPMENT

The efforts do not stop at hiring, in fact, they only really start there. Once the right candidates are onboard, it becomes critical to retain them. There is a well-known statement regarding employee turnover that states, "People leave managers, not companies". This places a huge responsibility on managers' shoulders to retain employees and keep them engaged, motivated, and challenged.

Here are a few pointers to be considered.

Team Building – Team building goes a long way and is an extremely important element. Building mutual respect and fostering a sense of community within the team and amongst individuals is vital. It helps ensure they feel responsible for each other's growth and success. This ingrains a sense of team spirit, positive attitude, and an optimistic and progressive work environment.

Employee Engagement and Retention – It is tremendously critical to keep employees engaged and challenged, to ensure their growth, development and long-term retention. All employees may not be at the same level or may not have the same needs, thus the approach needs to be personalized. This can be achieved by open and clear communication aimed at understanding their unique challenges and needs. In order to do that, the manager should be approachable and genuinely interested in listening to the reports and working closely with them to reach their desired professional goals.

Employee Performance Review – This is one of the highly efficient tools made available to us by our organizations, and it is vital to use this tool to help with employee's personal and professional development. Managers are encouraged to collaborate with HR partners when more clarity or direction is required. To reap highest benefits, the process should be followed correctly, and should never be considered an insignificant chore. All review cycles (goal setting, mid-year, year-end, etc.), should be done in a timely fashion, with appropriate engagement, and the discussion should be directional towards the desired growth and improvement.

Rewards and Recognition – The skills, growth, hard-work and dedication, of employees should be appropriately compensated in the form of rewards, recognition, appreciation, new opportunities, promotions, monetary compensation. However the same approach may not work for all individuals or employees. Meetings like 1-on-1 meetings and performance reviews should be utilized as an opportunity to understand how each individual feels appreciated at work. This helps employees feel valued and motivated. (Also read: *The 5 Languages of Appreciation in the Workplace*, by Gary Chapman and Paul White, 2012)

MOTIVATION, COACHING AND FEEDBACK

It is important to have an open dialogue with the employees, to understand their challenges and needs, and to make them aware/cognizant of the expectations that management has of them given their role. It is unfair to avoid candid feedback and constructive criticism with employees, since by doing that we are not setting the right expectation and not giving them an opportunity to work in the right direction.

Various meetings like 1-on-1s, performance reviews and other ad hoc meetings, are not just to have project status updates, rather they should also be invested for coaching, feedback and motivational conversation as well.

Coaching is an aspect of setting clear expectations for quality, efficiency and conduct. This will help employees to work in the right direction, towards their growth and development. It is crucial for employees to understand the importance of organizational and industry standards, compliance, SOPs, usage of general guidelines and documentation, general code of conduct, verbal/written business communication

skills, and behavioral skills, etc. Companies may have different guidelines and expectations on those aspects, managers should coach their employees to understand those factors.

Feedback giving, receiving and soliciting is highly important. Sharing feedback should be timely, specific, and focused towards improvement. Timely may not always mean instant, rather appropriately timed, when the employee is ready to take the feedback most constructively. Receiving feedback is as important, to learn the blindspots, as it is to look at the situation from a different perspective and work together to find an efficient solution. Soliciting feedback from employees or cross-function partners may help improve collaboration, work relationships and skills.

Motivation – Keeping employees motivated is one of the biggest goals for managers. In a highly challenging and intense industry and work environment, employees may often feel stressed, demotivated, burnt-out or unappreciated. It is a manager's responsibility to ensure the employees do not feel that way, rather feel valued, upbeat and motivated for new challenges. It is important to recognize their contribution and efforts. Utilizing various meetings to learn about what motivates them, the new challenges they are looking for, the training or skills they need in order to handle those challenges, and to learn and grow from them. Learning their sense of job satisfaction and engagement per their abilities, will help plan a more customized developmental plan for each employee. It is also important to ensure that employees have a good work-life balance that enables them to give their best at work.

Sharing the bigger picture and long-term goals, would help employees feel empowered, involved, connected and to take pride, personal accountability and ownership of their projects or assignments. It is extremely critical for managers to show employees a different perspective, to help them recognize the benefits of those experiences and challenges, for their long-term personal and professional gain.

PROJECT MANAGEMENT ASPECT

The nature of projects, deliverables and activities for a SAS® programmer's role in the biotech/pharma industry could be quite standard; however, many attributes should be considered, to lead the projects successfully and efficiently.

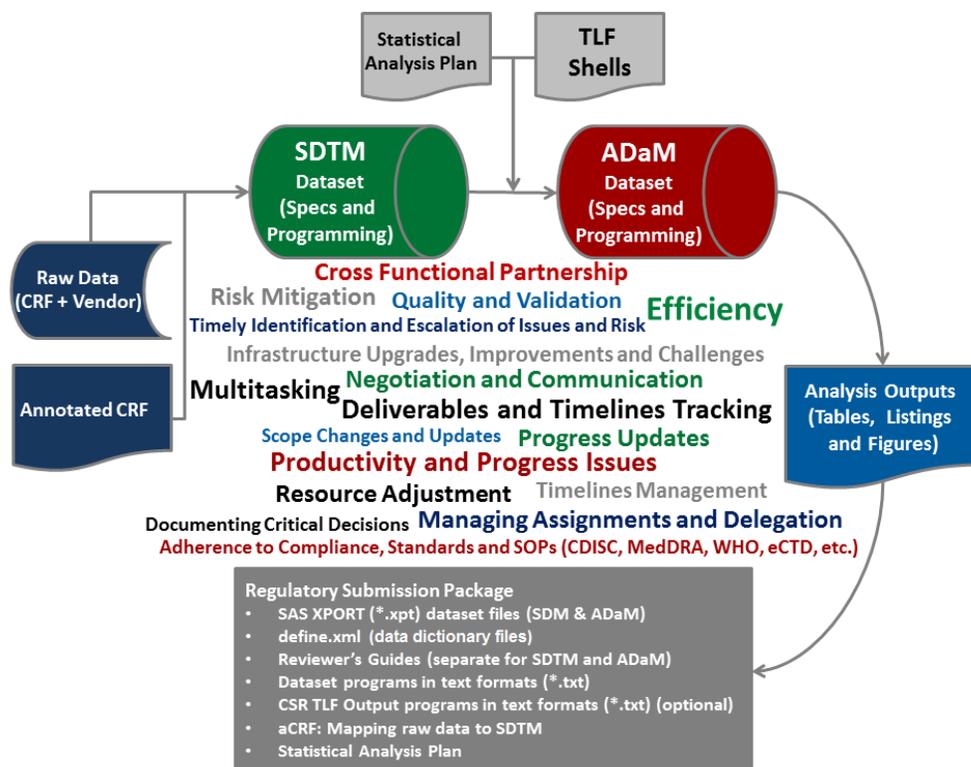


Figure 3: Typical end-to-end Study Project Process Flow, with core Project Management activities

Mentoring – Effective mentoring helps enhance skillsets and efficiency of the employees. Managers should maintain some level of hands-on activity in order to understand ground level challenges and provide mentorship to team members.

As a manager, it is important to give all employees equal opportunities to learn, grow and develop. Having the employees learn all skills equally also ensures that we are not putting all of our eggs in one basket. Our focus should be to make all employees jack of all trades and master of a few, may be better than master of one or none.

These decisions should be considered based on an employee's experience and criticality of the project or timelines, in order to not put the project at risk.

***Example:** Throughout their tenure, all programmers should get an insight into various standard activities in CP process flow. All programmers should be hands-on with annotating CRFs, study design, protocol, SAP, SDTM CDISC standards, ADaM programming, Pinnacle 21 OpenCDISC validator, know how to program the majority and variety of outputs, should know about various components in regulatory submission package (define.xml, writing Reviewer's Guide, Control Terminologies, etc.), however, the amount of their involvement should depend on their level and experience as well as the business need.*



Figure 3: Delegate assignments in a way that gives all employees exposure to a variety of projects. This enables employees to build multi-faceted skills.

Quality and Efficiency – Is the most important aspect in our industry, since we work on drug development that impacts patients' lives. We need to consider quality and efficiency at every step of the way, and look for tools and trainings that would help us improve on these aspects, to ensure projects meet requirements as expected.

***Example:** Parallel programming of datasets and outputs, datasets validation using Pinnacle 21 OpenCDISC validator to check CDISC compliance, Adherence to Compliance, internal and industry Standards and SOPs (CDISC, MedDRA, WHO, eCTD, etc.), Editors and tools that help improve efficiency.*

Understanding the **Infrastructure Development** requirements and needs may drive quality and efficiency aspects of the project.

On the other hand, inefficiently planned and implemented infrastructure upgrades or projects, may adversely affect the quality, efficiency, and overall results of a project.

Ongoing efforts like 'Best Practice Sharing' and 'Lessons Learned' may collectively boost the efficiency of the group. Employees should also be encouraged to think outside of the box and share creative ideas for Infrastructure improvement and efficiency gain.

***Example:** Developing creative macros to automate repetitive and iterative, or complex tasks.*

Training and Compliance – Adhering to training and compliance helps us learn and keep up with standards and expectations, to produce quality results. Noncompliance may negatively affect our projects

and may result in delay in getting the drug to our patients.

Examples:

Completing GCP trainings in a timely way, helps avoid any regulatory concerns during a drug submission.

Completing SOP and other internal trainings helps employees understand and follow processes correctly and consistently.

Resourcing – Resource planning is an ongoing activity, to ensure planned as well as unplanned analyses and tasks are handled most efficiently. To ensure smooth implementation of changes, with minimal disruption or unexpected delays, there may be a frequent need to reassess hiring and allocation of resources

Example: *A sudden change in submission scope with additional analysis for label expansion. Additional resources from lower priority studies may be moved to the higher priority project, to tackle the temporary resourcing challenge.*

There are many other possibilities and alternatives to facilitate resourcing needs, with the help of contingent work force for specific project needs. Some of the aspects that need more insight while deciding contingent work force are quality and efficiency expectations, training and compliance adherence, technical limitations, infrastructure needs, and geographic and time zone challenges. These aspects should be well examined with the help of IT, HR and Legal departments.



Figure 4: Resourcing options and designs

When it comes to resourcing, it is also important to be vigilant about non-performance that may affect the quality of the programming deliverables, motivation of other team members, and team credibility and relationships.

Timeline Management – Timeline management is required to ensure cross-functional agreement on tasks and timely completion of a project. It includes the development of timelines, decisions of project milestones, activity sequencing, estimation and scheduling. Various tools and trackers can be used to facilitate timeline management efficiently.

There is often a need to refer and re-visit the timelines frequently to ensure the project is on track. There could also be a need to reassess the timelines, to make sure they are realistic and if any changes are required based on an increased scope. In case of potential changes, all stakeholders should be queried or informed based on the impact of the changes to their respective role.

Relationship Management - Developing internal, cross-functional and stakeholder relationships by building trust, faith and reliability is the key.

Success of a project greatly depends on the right people receiving the right information at the right time. Relationship and communication management consists of identifying what information should be communicated with the cross-functional teams, and who it should be shared with, to use the information effectively.

It is important to identify, plan, analyze, respond, and control any factors that might adversely affect a project and put the project team or at risk of missing their timelines.

Transparency, collaboration and thoroughness, followed on a consistent basis, helps build trust between team members and increases **team credibility**.

Stress Management – It is essential for managers to foster a positive work environment by understanding challenges and removing obstacles. When problems beyond the team's ability arise, it is important to understand the teams' needs so that an appropriate solution can be implemented. It is also important for managers to be approachable, so the team members feel comfortable sharing their challenges, before the projects are negatively impacted. In addition to removing obstacles as a way to relieve some stress on the team, creating an environment where team members have time for physical activity or mindfulness exercises to reduce stress has been shown to lead to more productivity. (*Also read: Mindfulness at Work, by Oli Doyle, 2006*)

Leading by Example – When it comes to setting expectations it is crucial for leaders to serve as role models that others want to follow. By walking the talk and leading by example, both in action and words, managers can effectively translate intentions into reality. Acting on the concepts and messages they coach is leading by example.

CASE STUDY

An exciting sBLA submission was due in 6 months and the whole team was resourced and strategized to support the current timelines and scope.

After a discussion with FDA, it was decided to do ISS, ISE, with a few registration trials, and full CSR for two Investigator Sponsored Trial (ISTs), to support label expansion and breakthrough therapy designation.

Since the drug was shown to be highly effective, the team was motivated to get it to patients. .

The main study was being run by alliance partners, thus there were limited in-house sponsor resources assigned to this study.

CHALLENGES:

- Preplanned infrastructure upgrades due at the same time as the scope expansion
- Limited in-house resources
- In-house resources lacked hands-on regulatory submission and IST experience
- Time and scope was fixed, only variable factor being resources
- Unknown formats for IST data
- Main study run by alliance partners and did not follow CDISC compliance

BRIGHT SIDE: The team maintained positive attitude and saw the challenges as a great opportunity to learn and a professional and personal development opportunity. The team stayed focus on the impact getting the drug approved and on the market would have on patients.

PROJECT PLANNING:

- Understanding the scope of the project
- Identifying factors that are in clinical programming's control and can be initiated sooner
- Identifying external factors that clinical programming would need in order to meet the submission timelines
 - SAP, TLF shells, Analysis Scope finalization
 - List of studies to be integrated

- Timelines to receive IST data
- Timelines for output finalization for Medical Writing
- Regulatory Affairs submission timelines

RESOURCES:

Existing Resource: Two clinical programmers were resourced to support the alliance partner, to help with thorough review of datasets, specifications, analysis outputs and submission package components (define.xml, reviewer's guide, datasets specifications, etc.)

Projected Resources to support 4 additional submissions (ISS, ISE, 2 ISTs): 8 Programmers

As the heavy programming activities would only last 3-4 months, it was decided to hire only 4 additional contract resources, to avoid resource overspill. The remaining resourcing needs were met by shuffling existing resources, and deprioritizing some lower priority project deliverables.

IMPLEMENTATION

Team expectation setting: It was important to bring the programming team together to set clear expectations for quality, efficiency and teamwork. In addition, sharing the long-term benefits of being on the project helped the team members mentally and emotionally to handle such a large project in such a short timeline.

Quality and consistency standards: To meet the tight timelines it was essential to work collaboratively, learn from each other, and do all tasks and activities right the first time to avoid rework.

Timeline management:

- Granular weekly timelines were created and resources were distributed to ensure all 4 projects ran parallel to each other.
- Teams worked on similar activities together, reused tools and programs, and shared best practices.
- There were weekly project check-in and status update meetings.
- Most of the communication was encouraged via instant messenger, phone call, in person or through trackers, to ensure clarity, efficiency and to avoid ambiguity. Emails were limited to important decision documentation, to ensure everyone was well informed and on the same page. Extensive email communication was avoided for clarifications and decisions during development phase.

Various trackers and logs were maintained: Resource planning, timeline tracking, parking lot items for later discussion, reviewer's guide items, and a checklist for submission activities were all tracked and updated as needed.

The programming aspect of the project was broken into two parts:

- 1) **Output creation and generation:** To facilitate early output reviews and medical writing activities.
- 2) **Data preparation and sBLA submission activities:** Cleaning data for consistency, **Example-** Control Terminologies, creating sponsor defined Control Terminologies, cleaning data per Pinnacle 21 OpenCDISC validator findings, preparing define.xml files, writing Reviewer's Guides, ensuring eCTD compliance, identifying programs to be submitted to FDA and to convert them to .txt formats, etc.

Despite robust planning, there were a few challenges, however, the team was working towards a common goal, and was able to submit the project to FDA one month prior to the planned date and the

drug was approved within 4.5 months.

ACHIEVEMENT

Although extremely demanding, the project was a unique learning opportunity and experience for the whole team. From knowing just the basics about sBLA submissions, to becoming well-versed with the various elements of regulatory submission, standards, and in-house and industry tools. The team's learning of 4 months was equivalent to that of a few years.

The experience also helped the team become closer to each other, and to work collaboratively, managing the stress and challenges together. The team feel like one big platoon, working towards a common goal of improving patients' lives, and experiencing the sweet taste of success together.

CONCLUSION

Success stories often start with a positive attitude and mindset. Although there are many other technical skills and intellectual related aspects required, a positive attitude creates a strong foundation. With teamwork, collaboration, relationship building, communication, planning, training, and efficient infrastructure support, etc., it takes a village to make any story, a true success story. Projects eventually may or may not be successful, however, the benefits of learning, development, and a sense of satisfaction and purpose, that comes with it is deeper, and goes a long way. Thus, it is critical to understand that it is not what we do, but why and how we do it, that is more important. Just like our soldiers serve and fight for our safety and wellbeing, we need to keep working selflessly towards the wellbeing and betterment of our patients.

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