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Future Workforce: How to invest in your team through Innovative transformation.

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ABSTRACT

Every leader struggle to keep their team motivated in the heat of this blooming industry and getting the work done within the team's comfort zone.

The roles of a Statistical Programmer are drastically changing to accommodate new programming languages, automations, novel therapies, data visualization, and methodologies for study conduct. The biggest challenge here for the team is bridging the gap between the present and future.

This paper focusses on

- The Future prospects for Stat Programmers leveraging open-source technologies.
- Keeping the team abreast of all skills needed to support successful clinical trials through excellent Mentorship.
- Interacting with the team at every level to give the feel that they are significant part of the organization's growth.
- Using resources more efficiently to empower their career growth & in turn adding value to the organization.
- Summarizing insights from industry leaders through discussions
- Summarizing expectations & thoughts from the team through surveys.

INTRODUCTION

It's not surprising to learn that employee motivation is flagging these days. Leaders are noticing the sense of gloom and angst within their teams and wondering what they can do to curb the anxiety about the future and their job due to automation. Change is already happening, and accelerating and leaders need to Act Now. Leaders can't protect jobs which are made redundant by technology, but they do have a responsibility to their people. Nurture agility, adaptability, and re-skilling within the team. The skills required in many industries are changing. Leaders recognize that upskilling employees and career pathing can help close skills gaps. Skill development can also help organizations meet their most urgent business needs. As more leaders prioritize upskilling in the workplace, they aim to embed a growth mindset into their organization's culture.

This paper focusses on common challenges faced by leaders in the Clinical Workforce with Statistical Programmers in the limelight, how to overcome the same, the future of Stat programmers and how to upskill the team. The discussions and opinions stated in this paper is, of course, inspired and informed by our own workplace.

COMMON LEADERSHIP CHALLENGES

Leaders originate from all corners of the globe, across different industries, organizations, and work environments. But you will be surprised to find so much consistency in the challenges faced by these leaders globally, regardless of their location, industry, or organizational culture. But facing these challenges with the right skill set, understanding and perception will route a strong course.

In the clinical environment, statistical programmers play a key role in turning the data from clinical trials into knowledge, supporting the development of new medicines. Stat programmers have shifted roles, hands-on activities which includes collecting data, execute statistical analysis, and analyze data sets. Stats research and analysis, data integration, utilities development for automation, managing and coordinating the requests for statistical analysis of clinical data, project management etc. are couple of other caps worn by a stat programmer. But recently with demands such as CDISC compliance, big data, automation, data transparency initiatives, new open-source technologies, and cost pressures the role is evolving to become ever more multi-dimensional. As leaders, at some phase, we will all face these questions from our team and the list is endless.

- Is our job generally still safe with the onset of these new open-source technologies?
- Will there still be SAS® in e.g., 5 years?
- Will we, statistical programmers, only be project managers in the future?
- Do we have opportunities to upskill ourselves alongside the future growth?
- Can even project managers without statistical programming background do our job?

Before we tackle these questions and challenges, let's look at what the future for statistical programmer entails.

FUTURE OF STATISTICAL PROGRAMMING

Statistical Analysis System (SAS®) & R programming remains the latest trending programming languages for Statistical analysis. Basic roles of a statistical programmer include understanding clinical trial concepts, CDISC development, SDTM, and ADaM datasets, eCRT package submission, generating TFLs and more. Though Stat programming deliverables will remain the same around the corner, the underlying work to deliver this analysis will only undergo a transition. Introduction of new trial design, real world data, biomarker and genetic data sources, precision medicine, new open-source technologies, automation will all lead to reducing the approval time and stat programmers will play a vital role in this paradigm.

Be it in a CRO or biopharma environment, the team needs to have a mindset geared to process innovation and improvement, get things done faster and more efficiently, while maintaining the highest standards of quality.
Current customer needs require combining static reports with visual interfaces. For the same, some organizations use R or Python to streamline interactively data review process, and certain others use JMP@, Spotfire@ etc. to leverage the customized interface. The new demands in development and statistical analysis will make statistical programmers more proficient in logic thinking and more flexible in the use of different analysis tools. They now can follow their specific interests and specialize in a range of areas as mentioned below.

REGULATORY STANDARDS & SUBMISSIONS EXPERT

Over the last decade the clinical research industry has attempted to work toward a common data standard with the goal of accelerating the drug development process. Be it your FDA, EMA, PMDA or NMPA related submissions, Study data standards describe a standard way to exchange clinical and nonclinical study data. Statistical programmers are required to be familiar with the concept and application of CDISC and different regulatory needs and be up to date with its various versions or releases.
We can pursue a career in this field where we can work with departments/TA, clinical, regulatory, and other functional leads to help establish strategy for the programming discipline. We can excel in clinical review, analysis, recommendation, decision and documentation of prior authorization requests, review medication request guidelines for clinical appropriateness and operational efficiency etc.
Stat Programmers will have to upskill themselves to have a thorough understanding of the drug development process, clinical data, data operations, regulatory submissions or requirements, safety updates and relevant data standards to become the CDISC/clinical Subject Matter Expert.

STATISTICIAN

At Genpro majority of the stat programming team comes with a Masters in Statistics. Performing an analysis on the trial data and creating an inference from the data usually go hand in hand. As interaction between Statisticians and programmers happen daily, the transition to statistician role will also be smoother. Initial Stats activities that we can start with during the transition involves creating TFL shells, generating and validating the specifications for your CDISC standards, validating the clinical reports, performing data checks, identifying initial inferences from the data, parallel programming validations etc.
As stats programmers, all you must ensure is to have a solid statistical background which can add value to these activities.

DATA MANAGEMENT

Two closely linked aspects are Data Management and statistical programming. To get the cleaner data for analysis, stat programmers work very closely with the data review team. Differences are more obvious in the day-to-day technical activities: the data manager focuses on ensuring data quality according to the data conventions he/she follows whereas the programmer focuses on statistical analyses and coding. We would be responsible for clinical study databases and associated data quality and integrity. We will create and review the Case Report Forms (CRFs), focus on data cleaning, resolving data issues, performing edit checks and data reconciliation. We will also prepare reports and organize presentations or meetings about clinical trial progress.
As stats programmers, we need to improvise on data handling within the clinical study process as well as our ability to work in a delivery focused environment. Soft skills like observational, analytical skills and communication also becomes handy.

PROJECT MANAGEMENT

There are many statistical programmers who aspire to move into the managerial roles. Project management includes parameters like Scoping, Costing, Project planning, Resourcing for the study etc. Through PM role, we can get exposure to handling various clinical trials across therapeutic areas. We would need to properly follow well-established and well-defined formal techniques. The technical competence of stat programming will be an added advantage for this transition.

Your roles will include more client interactions, multi-tasking, variety of work across TA's and phase of studies. But for strong & capable programmers, this often translates to more feathers in the cap with a faster career growth. Programmers will have to upskill themselves to also understand the roles of a PM and improve on all necessary soft skills associated like communication, delegation, teamwork, time management etc.

DATA VISUALIZATION

A data visualization expert in clinical domain helps to convert the results of the trial analysis into easy-to-read reports with graphs and charts. They take data and turn it into insights. It promotes interpretation of data and supports interdisciplinary communication and decision making about the clinical trial. Safety signals and enabling fast drill-down from a program to a study population to cohorts to individual subjects can be achieved at a faster pace. Visualizations can add value to DSUR's, Interim Analysis or early phase studies where early decisions are needed to analyze the study. Platforms or dashboards for the same can be either created inhouse using Python or R or we have various platforms like Spotfire, Tableau, Power BI that can be utilized. The advantage is that once a study has been designed, the same configuration can be utilized across other similar studies across same therapeutic areas.
As stat programmers, you will need to build on your visualization skills and knowledge of designing. Else we will have to upskill ourselves with learning the various Visualization platforms.

BEYOND SAS INTO OPEN-SOURCE TECHNOLOGIES

Industry is now moving towards utilizing more Open-Source technologies like R, Python, Tableau, Spotfire, Visual Studio etc. From the viewpoint of a statistical programmer, R & Python are the most common where the transition or switch is being evident. The transition from SAS to these technologies are not easy and it will come with huge challenges and will have to be reflected across the whole team, the infrastructure etc. But under the leadership of strong mentors and support team the transition will have a significant effect to the resource and organization.
As a programmer the team should be proactive and motivated to adapt the new technology. Upskilling in R along with SAS will also take you up a notch as it is the most popular language across Statisticians and Data analysts and rated the best data analytical tool.

BRIDGING THE GAP

The first thing that a future tool for statistical programming should do is bridge the gap between learning and doing. The transition from Statistical Analysis System (SAS®) to R programming or any of the options mentioned above takes time and effort, needs support from the leaders and a new approach. Implementing a new technology leads to changes across all the below different aspects. The list is endless, and we need to get going into the stage with a proper solid goal and vision.

- Career
- Organization
- Technology
- Reporting
- Standards
- Validation
- Software's
- Infrastructure
- Quality

The role of a leader in bridging this gap is very crucial and the team will expect us to provide inspiration and motivation to their progress. This can feel tough in a challenging work environment or if you're not feeling motivated yourself. As a leader, you can help your team overcome the hurdle from a technical perspective and from a general competencies view. We need to adapt leadership styles that nurture the transition.

GENERAL COMPETENCIES

<u>The Big Picture</u>

As leaders, we need to share the vision for the team and make sure each of them can connect to how their piece of work makes a difference. All team members should be on board on how the vision can be accomplished and a clear understanding on the Big Picture or the ultimate goal. Focusing and targeting on the bigger picture means understanding how your actions affect the overall success of the project or the organization and in line leading to your personal growth.

<u>Inspire to Lead change.</u>

Change is often scary and comes with its own share of uncertainty. As a leader, this is a difficult challenge and helping our team find purpose is critical in employee engagement. Employees do look up to leadership for guidance ad

reassurance. Addressing the individual needs of each member of your team is the key. Even with a clear vision, getting your team on board is challenging. The team needs to feel inspired by the work and leaders should know how best to inspire them. Organization can go that extra mile only when employees invest in the organization's goal alongside their personal goals.

Nurturing development and innovation. A key part of your role as a leader is talent and employee development. It's important to search out the potential in your team members and encourage their growth. You'll need to understand their hopes for the future and find ways to help challenge and stretch them. We need to create a learning culture and manage the people not the stereotypes.

Communication

Leaders needs to understand what motivates different employees as individuals and how best to communicate with them. We need to listen to our team about how they want to progress in their career and support them to take those steps.

Motivation

Team can be easily demotivated and thus it's up to the leaders to keep the tech team focused and happy, something that can help prevent burnout and turnover. This can be achieved by considering the below steps.

- Make Sure You Understand Them
- Help Them Learn and Innovate
- Empower Them to Have a Growth Mindset
- Ensure Transparency, Clear Communication
- Provide Meaningful Work
- Staying Honest
- Help Them Feel Challenged in the learning process.
- Recognize Their Achievements & Celebrating the Wins
- Give Them More Freedom

TECHNICAL COMPETENCIES

Training Programs

A leader should strive towards helping their employees advance their skills and knowledge within their position, and for this Training is a solid requirement. It boosts employee confidence and makes it more likely to accept new unfamiliar technologies. Tech related training programs must be initiated and led by the leaders where all functional aspects of the program are covered which will be followed by hands on exposure. Giving employees opportunities to learn at work is the best method to get them on board with the new technology. As time passes and they have a good understanding on how to use it, it becomes less overwhelming.

Training programs can be conducted in various ways-

- Guided learning can be one approach where instructors train the resources with bite sized sessions which is followed by trainees trying these out.
- Self-Learning is another technique that can be implemented. Leaders need to ensure providing enough online resources or reading/learning materials, videos etc. which can support the learning process.
- Classroom style
- E-Learning

This can all be also supported by conducting workshops, organizing friendly competition like assessments or quiz, measuring performance results, implementing reward system etc.

A tried and tested method at Genpro was where we combined multiple training approaches to help our team transition from SAS into R.

We utilized the **SMART** Goals approach which highlights Specific, Measurable, Attainable, Relevant and Time-bound goals.

We targeted **Specific** goals on what needs to be accomplished which was clearly defined and understandable by the team.

Quantifying or **Measuring** the goals with selected criteria enables to track the progress.

Achievable goals must be set by the leaders which are not impossible to attain.

Relevant goals that align with the vision of the training program and business objectives should be incorporated.

Timeline oriented programs with defined start and end dates creates the sense of urgency and keeps the goal on track.

We started by defining a detailed Training plan on what all different areas where to be covered in R that can help a Statistical programmer. We split the sections into different training modules and further sub categories. We had a mix within the team where certain resources had the basics in R others were novice. For such resources we suggested to

go for E-learning from an online course which covered the basics. We then followed this with a guided learning approach where experienced tech members took the training and hands on assignments were provided.
To motivate the team, we conducted this as certified training and ensured proper review of the hands on tasks.

Recruiting Tech Savvy Members

For the transition to new technologies to work out, we need to have resources who are experienced in the technology to be available to guide and mentor the team. Tech savvy members need to be paired up with colleagues that are less confident so that they can be helped to speed up.

Getting Certified

Leaders must encourage their team to pursue certification in the technology they are transitioning to. This also gives our clients a confidence in the quality of our team members.

Attending Tech Events

Promoting the team to attend conferences, panel discussions and webinars helps them stay close to the market and keep in touch with the community. It also helps to stay on top of the changes in the pipeline.

Encourage Collaboration

Leaders must encourage collaboration be it internal or external. Internal collaboration can happen when resources work closely with the different functions within the same organization that helps them grow on their technical skills and explore new options. External collaborations can be in the lines of being part of and contributing to technical working groups like PHUSE or Pharmaverse. This also definitely leads to building partnerships with the experts in the field.

THE ART OF MENTORSHIP

WHAT IS MENTORSHIP?

Employees do not always come to work with the necessary skill set. Some may excel in one area but lack important skills in others. This can accelerate low satisfaction and retention rates among employees and missed opportunities for your company.
Mentorship includes experienced mentors helping or guiding new hires or less experienced resources in their professional journey to reach their full potential thus welcoming a corporate culture.

A mentoring program is supported by proper leadership. Mapping potential mentors and mentees is a must as the most effective mentoring happens at a personal level. Proper pairing and leadership with open communication not only helps the mentees but helps mentors grow in their coaching, management, and communication skills.

BENEFITS OF MENTORSHIP

Mentorship programs benefits employers and employees in multiple measurable and visible ways:

- MENTORS
  - Robust people and leadership skills
  - Effective communication & listening skills.
  - Provides a channel for the mentor to contribute to the organization’s growth.
  - A sense of self-worth.
  - Alternate perspectives & Builds diversity.
  - Mentors become better leaders.
  - Adds a sense of purpose.
  - Growth to become subject matter experts.

- MENTEES
  - Foster Career Development & professional growth.
  - Effective communication skills
  - Broader networks
  - Better utilization of skills
  - Mentees become better team players.
  - Gains confidence to work on the task in hand.
  - Starts to accept constructive criticism.

- ORGANIZATION
  - Workforce aligned with the vision of the organization.
  - Solid leadership growth.

- Increase in employee retention.
- Boost workplace satisfaction.
- Smoothens Induction & Onboarding
- Knowledge retention
- Promotes Talent acquisition.
- Training Cost reduction
- Increased teamwork

CHALLENGES IN MENTORSHIP

There is no doubt in the success of a mentorship program, but it does come with its own share of challenges:

- Need for highly skilled/talented mentors.
- Setting right goals for the mentees and understand the expectation of the program.
- Setting the right balance of mentors and mentees.
- Effective matching between and mentor and mentee.
- Providing open feedback.
- Tracking program outcomes or managers facing difficulty to have visibility over the success of the relationship, or even know if it's happening at all.
- Demographic issues/remote working
- Over dependence on the Mentors/Mentees.
- Mentoring programs often fade away after a few months.

FORMS OF MENTORSHIP

You would have now got an idea on mentorship and its pros and cons. There are various models in which mentorship can be conducted which can be implemented across various situations based on the objectives.

1) One-on-One Mentoring
   This is the traditional approach where 1 mentee is assigned to 1 mentor and the focus can be more on the individual development and career growth.

2) Group-Based Mentoring
   Another common approach where a group of mentees are assigned to a single mentor. This approach helps to create an impact on many mentees in shorter span.

3) Situational Mentoring
   Most common approach implemented whereas per the need basis, mentors are assigned on a time bound manner for a short-term skill improvement. This can happen within your specific team or across various functions.

4) Peer Mentoring
   In this type, equally skilled resources will be paired with each other. Both resources act as the mentor and mentee. This will develop through mutual support and guidance by sharing experiences and learning together.

5) Reverse Mentoring
   This includes a reverse psychology where the roles of mentors and mentees are switched. More experienced or seasoned resources can learn on improvement factors through direct feedback and instructions provided by junior team members.

6) Virtual/Remote Mentoring
   In this era of hybrid working models, remote mentoring plays a highly crucial role. Having a solid platform for communication and mentorship is the solid requirement for this category and we can ensure that the program is not put on hold.

TIPS FOR MENTORSHIP

From Genpro' s personal experience, consolidating couple of recommendations to ensure a successful mentorship program.

- Pairing of mentees and mentors in a manner where their skills, strengths and weakness balance each other.
- Evaluating and Rewarding Mentors/Mentees increases the dedication and enthusiasm.
- Mentees should be given the charge of the process like setting up meetings and review, etc. This will help in the program not fading away.
- Provide Mentorship training.
- Setting and explaining clear goals to mentors
- Mentors need to have a component of Emotional intelligence and Empathy.

- Promoting the feedback loop
- Encourage open communication.
- Leaders to interact with team at all levels and ensuring them that they are significant part of the organization's growth.

SUMMARY OF SURVEYS CONDUCTED WITHIN THE TEAM

Employee Engagement Surveys are a crucial way to gather and collect open feedback and also to formalize the best practice within your organization. It gives us a feeler of what is working with our team and what is important and needs improvement.

With a core focus on the above paper and to justify our points, we conducted surveys within our team on the below–

a) The upcoming Open-Source technologies within the clinical industry and how to enrich growth alongside the same.
b) Rating on the Mentorship approach.
c) How leaders can empower the team

We pitched certain questions to our team and collated all the responses. Below is a summary on all the feedback received.

1) Latest Open-Source technologies applicable within the clinical domain.
   We received a huge data bank from the team on various new open-source technologies. Some of these include R, R Shiny, Python, Tableau, Power BI, Julia, Dash, SQL, SPSS, Anaconda, Montecarlito, tranSMART etc.

2) Which of the above Open-Source Technologies are useful for the future of Statistical Programmer?
   - R and Python - In future most of the stat/programming activities can be automized with the help of AI and ML where R & python play a major role. Also, R is now being extensively used for submissions where CDISC programming, analysis are all performed in R with better capabilities over SAS.
   - R Shiny, Tableau, Power BI can help in Data Visualization, for a better understanding, interpretation of data and decision making.
   - Python for Machine learning - There are various ML approaches available for managing large and heterogeneous sources of data, identifying intricate and occult patterns, and predicting complex outcomes which are needed in the clinical domain.
   - Anaconda - An open-source python distribution which is used for processing a large amount of data, predictive analysis, and computation.
   - tranSMART - An open-source data warehouse designed to store large amounts of clinical data from clinical trials, as well as data from basic research, so that it can be interrogated together for translational research.

3) How can the team be upskilled in these new technologies?
   - Mentorship
   - Proper structured training with assignments
   - Continuous exposure to new technologies through work
   - Proper review from skilled team members
   - Live Project exposure in these new skills
   - Regular Workshops
   - Certifications
   - Peer to peer knowledge sessions.
   - Collaboration with other organizations & Industry experts

4) On a scale of 1-5, how would you rate the Mentorship activities we are performing in house?
   On an average the Mentorship process conducted within Genpro was rated a score of 4 by the team which portrays the importance and positive effect it had on the team.

5) Feedback on how to improve mentorship.
   - Mentors to be assigned based on domain expertise.
   - Dedicated mentor for training and for review separately
   - Trying and testing various other types of mentorships
   - Mentor to have flexibility of using available team members for review.

6) How can leaders empower your growth?
   - Provide more training to enhance exposure to leadership.
   - Allowing communication across all the levels of the team.
   - Round table discussions once every quarter.
   - Opportunities for research especially for statisticians.
   - Inspiring the team and instilling confidence.

- Give opportunities to explore and grow in other technologies.
- Open Feedback
- Setting clear goals and expectation based on your career and personal dreams.
- Setting an example
- Appreciation & encouragement.

CONCLUSION

This paper spans across various aspects on developing, building, and motivating your team and specifically on how a leader can contribute and inspire to the team's growth. Various methodologies have been outlined and details on tried and tested methodologies within Genpro have been elaborated. Training programs and Mentorship are 2 core aspects that contributes to the Innovative transformation needed for the current workforce transition to open-source technologies. How this can be accomplished, and the benefits have been accounted. The success factor of these tested methods is also clearly visible through the team's technological advancements and summarizations from the survey. If you are a leader and plan to invest in your team's growth, try out couple of the above fool proof methods combined with your individual style of leadership and it can create wonders in your organization.

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