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Craft Your Career as a Statistical Programmer: Opportunities and Challenges at CROs vs. Pharmas

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ABSTRACT

As Statistical Programmers (SPs), we are presented with a wide range of opportunities in the pharmaceutical industry. Throughout our careers, our paths may at times diverge or converge. With numerous options available, how can we identify the direction that best aligns with our goals and strengths? Drawing on the experiences of others can provide valuable insights to help us effectively plan and shape our career trajectories.

This paper is based on the author's experiences and observations as a mid-career professional, providing a comparative analysis of statistical programming in two distinct settings: Contract Research Organizations (CROs) and pharmaceutical companies (Pharmas), specifically from the perspective of in-house employees. The discussion will focus on the similarities and differences between these two environments in terms of work content, work approach, work styles, personal development, and work-life balance.

INTRODUCTION

Making informed career choices is essential for building a successful career. As individuals progress from one position to another, ideally, each role serves as a stepping stone, allowing them to continuously develop their skills and broaden their career vision. When evaluating a new position, key factors to consider include the roles and responsibilities, team culture and expectations, and opportunities for development and advancement.

I spent 10 years working in a CRO as an in-house SP, progressing from contributing programmer to lead programmer and manager, before transitioning to a programming role within a Pharma. I was fortunate to have an incredibly supportive manager at the CRO who guided me in building my knowledge base and skill set in the industry. Although I was motivated to take the next step and broaden my experience, making a switch from CROs to Pharmas was still a difficult decision. After joining the pharmaceutical company, I realized that adaptation and adjustment were necessary even though I was not new to the field. Therefore, I wish to share my experiences and observations to help early-career professionals make informed decisions and plans for their careers. Given the growing partnerships between sponsors and CROs, this discussion can also foster better understanding between both parties, promoting smoother collaboration when project teams work together.

This is not a scientific paper and is not intended to collect or survey data from the broader industry. It is primarily based on my firsthand experiences in daily work and conversations with colleagues, reflecting my personal views, and therefore may be limited and subjective. In addition, this comparison focuses on the daily in-house work at CROs versus Pharmas, excluding the full-service provider mode at sponsor sites.

SIMILARITIES AND TRANSFERABLE SKILLS

While each organization has its own processes, tools, and infrastructure, SPs in both settings share core responsibilities, including data manipulation and executing statistical analyses. Both roles require proficiency in statistical software, such as SAS, R, etc., and a strong understanding of clinical trial protocols. SPs in both environments must collaborate with various stakeholders, including clinical data managers, statisticians, project manager, clinicians, and regulatory liaisons, while adhering to company standard operating procedures and regulatory requirements. Both settings have a strong regulatory focus, ensuring that compliance is considered and verified during the work plan and implementation phases to minimize surprises and last-minute rushes later. Career tracks in both settings include technical and managerial paths, requiring strong skills in communication, multitasking, prioritization, time and project management, negotiation, and decision-making.

DIFFERENCES

Despite the significant similarities in work content, nuances exist in daily operations, even within a single clinical study, due to the differing purposes and focuses of the organizations. At CROs, the primary aim is to provide quality customer service to clients, assisting them in achieving their objectives, whether that involves resolving scientific questions or preparing drug application submissions—essentially adopting a client-focused approach. In contrast, Pharmas seek to harness the power of science and innovation to enhance the lives of humans and animals, focusing on products and their impacts. These differing focuses contribute to variances in daily work content, approaches, and communication styles among SPs, ultimately shaping the distinct strengths of their workforces.

WORK CONTENT

At CROs, it is common that a SP works across various therapeutic areas depending on the client's specialty and may be involved in all stages of programming work, from SDTM to ADaM to TLFs (tables, listings, and figures) and define. A SP also engages in diverse types of studies and reporting, ranging from Phase I to Phase IV, and from clinical study reports, integrated studies to data monitoring committee meeting support. Beyond daily programming tasks, a SP may perform work beyond programming that requires programming knowledge to ensure project success. This includes but not limits to reviewing CRFs (case report forms) and data transfer agreements to ensure that data collection and transfer meets programming expectations, tracking programming deliverable units, and assessing out of scope work. Strong interpersonal skills are essential for building trust and maintaining relationships with clients, especially when clients may lack knowledge or proper processes.

In Pharmas, a SP typically delves deeper into specialized areas, often organized by therapeutic indications and compound development stages. In some companies, SDTM and A&R (analysis and reporting) are handled by separate groups. Additionally, specialized teams may exist, such as standardization teams or submission data standards teams, allowing a SP to develop highly specialized knowledge. In-house roles at Pharmas often lead to deeper involvement in specific projects, resulting in a more comprehensive understanding of the drug development process. Project teams tend to be smaller, with each member dedicated to the study from start to finish, and a SP interact with a broader range of stakeholders, including clinicians and regulatory personnel. Conversely, in CROs, a SP’s involvement is typically limited to programming development and execution stages, with less engagement in database design, submission finalization, and post-submission regulatory communication.

WORK APPROACH

In CROs, the services provided are well-defined through contracts. The project manager prepares a scope of work that outlines deliverables and expectations, which is then shared with the programming team. A SP must understand the agreed-upon scope and keep budget considerations in mind, striving to execute the work plan within the allocated budget. If new scopes arise during the project, the SP must approach the sponsor to address any gaps. Official programming work commences only after a contract is executed.

Given that clinical trial data are rolling in and cleaned dynamically and study documents are living documents before finalization, effective project management at CROs involves upfront communication of expectations and processes with sponsors. This includes but not limits to rounds of review for study documents, availability of prerequisite documents for analysis work, snapshot data for dry runs, and mutual commitments that are required to ensure smooth project progress. Time spent on each task is closely monitored to assess project health.

CROs’ work is results-driven, focusing on deliverables and revenue generation. This emphasis on meeting strict deadlines and managing multiple tasks with competing priorities can create a high-pressure environment, necessitating quick decision-making to ensure timely execution and delivery. Project teams may be larger to accommodate challenges such as possible overlapping timelines, unexpected new data pattern, vacations and sickness, and urgent ad hoc requests.

In addition to timeline commitment, quality control (QC) is a crucial component, as it helps build a strong reputation, fosters relationships with clients, and supports long-term business partnerships. Validation is

typically conducted through double programming performed by the CROs. The lead SP and statistician—if statistical services are included in the contract—will perform a final review before the official release to the client. Depending on the client's capacity and processes, their review may involve checking key numbers or conducting full-scope independent programming, resulting in triple-programmed outputs. Occasionally, a sponsor may specifically request single programming from a CRO or seek an early view of unvalidated results. In either case, the lead programmer's review is a critical step to ensure work quality and identify any issues or errors before the client's review. The lead programmer must balance delegation and trust in the team with the need to control work details; a risk-based approach is effective at this stage.

In contrast, programming work in Pharmas is initiated and planned based on study status. While timesheets are analyzed from a project management perspective, there is generally less financial pressure compared to CROs. The focus is on long-term studies and outcomes, providing a richer experience in understanding research implications. The work is impact-driven, aiming to accelerate development, submission, and patient access. Validation can be conducted at different levels, depending on the processes and tools used. The company has leveraged macros to enhance efficiency, accuracy, and consistency.

CROs typically engage in short-term work that is highly focused on specific sponsor requests. The diversity of projects and varying client conventions can make the work engaging, as it involves providing creative solutions and integrating new requirements into existing CRO processes. Job satisfaction often stems from helping clients and resolving issues, which enhances a programmer's versatility as they adapt to different therapeutic areas and study designs. Conversely, a SP in Pharmas works on projects with a long-term perspective, adhering to established company processes. While there are opportunities to contribute to process innovation and improvement, these typically occur through team efforts and a stringent approval process.

CROs implement standardized processes to ensure quality control, providing proper training and conducting internal audits to proactively address potential issues. They establish individualized client conventions including both technical and study administrative perspectives and train teams to promote consistency among programmers and minimize disruptions during team turnover. However, standardization of programming tools at company level can be challenging, as different clients have varying needs, and management must weigh the costs of tool development against potential returns.

Pharmas may invest more in innovation, developing in-house tools and continuously enhancing prior work, offering opportunities to work with the latest statistical methods and technologies. With a streamlined end-to-end process, requirements for processes and tools are more restrictive, yet they also encourage experimentation and embrace learning in new scenarios such as external collaboration setting. Companies also promote active engagement with industry workgroups to establish company standards that meet evolving submission requirements.

WORK STYLE

Differences in work style between CROs and Pharmas are reflected in team dynamics, decision-making, work culture and communication dynamics.

CRO teams may be more transient, with programmers frequently moving between projects and clients, leading to a dynamic but potentially less cohesive team environment. The lead programmer plays a crucial role in aligning team members and minimizing interruptions, fostering team spirit to achieve common goals. Resource forecasting from each programmer aids managers in optimizing resource allocation.

In contrast, in-house teams at Pharmas tend to be more stable, fostering stronger relationships and collaboration over time. This stability enhances knowledge transfer and mentorship. Project programming teams are typically smaller, with each member assuming a leadership role that emphasizes strategic input and a strong sense of ownership over their work.

In Pharmas, there are both official submission tasks and intermediate exploratory work. Depending on urgency, resource availability, and the necessity of the work, different strategies and requirements apply. Project work tends to evolve, with issues identified and resolved as they arise. The work is conducted in a

relatively flexible internal timeline and action plan is developed based on a broader team's input. Hence, a SP in Pharmas must proactively follow up on pending issues to ensure resolution, engaging stakeholders to facilitate decision-making. Additionally, due to the fewer constraints on timelines, individuals may find it easier to concentrate on the matter at hand, allowing for more thorough consideration. In contrast, decisions at CROs are made with a sense of urgency, relying on the available information, and focused on achieving final results.

The work culture in Pharmas is research-oriented, focusing on long-term drug development and fostering deeper relationships with projects and therapeutic areas. The CROs are service-oriented, prioritizing the understanding of clients' needs, striving to meet and exceed their expectations, and fostering mutual trust for a win-win relationship.

Communication dynamics also differ; at CROs, a SP often have counterparts from sponsors who can quickly address questions and concerns, provide guidance, and clarify requirements. In Pharmas, a SP typically serve as the primary programming representatives, engaging with data managers, clinical scientists, and others, necessitating the ability to communicate effectively and drive decisions to advance work.

PERSONAL DEVELOPMENT AND WORK-LIFE BALANCE

Pharmas offer numerous opportunities for personal development, encompassing both technical and soft skills. These opportunities can be accessed through employee resource groups, training resources, lunch-and-learn sessions, side jobs within the organization, and rotations. The flexibility within Pharmas requires self-awareness and discipline to maintain focus on personal growth. Work-life balance tends to be better in Pharmas due to long-term planning and greater room for personal development, treating employees as whole individuals to maximize effectiveness at work.

In contrast, CROs provide a wide variety of exposure to technical work, allowing for rapid industry knowledge and hands-on experience. However, learning at CROs often occurs under pressure, with extended learning opportunities arising only during low-activity periods. The knowledge gained in these settings may be limited, as CROs often do not participate in the final submission uploads or post-submission regulatory communications. As individuals progress within a CRO, there is an increasing emphasis on the ability to scale work, foster teamwork, and secure and maintain client relationships. Work-life balance can be unpredictable, fluctuating between steady and hectic depending on project planning and unexpected challenges. With numerous remote work opportunities available at CROs, there tends to be greater flexibility regarding work hours and location. Generally, working in the pharmaceutical industry resembles a steady jog, while working at CROs is more akin to interval running, characterized by bursts of intense activity followed by periods of rest.

SUMMARY

To elucidate the distinct characteristics and work environments of statistical programming within Contract Research Organizations (CROs) and pharmaceutical companies (Pharmas), the following table summarizes the key differences outlined above across various aspects of their roles and responsibilities.

Aspect	**CROs (Contract Research Organizations)**	**Pharmas (Pharmaceutical Companies)**
Work Content	• Broad therapeutic areas • Involved in the whole process (SDTM, ADaM, TLFs, define) • Diverse study stages (Phase I-IV) • Client-driven and limited regulatory submission involvement	• Specialized by therapeutic indication, compound stage and programming responsibilities • Deeper project focus

Aspect	CROs (Contract Research Organizations)	Pharmas (Pharmaceutical Companies)
Work Approach	• Contract scope • Results-driven • High-pressure environment • Create tailored programming for each study	• Study-driven • Impact-focused • Less financial pressure • Use standard macros across studies
Work Style	• Dynamic, transient teams • Lead SP aligns team • Urgent decision-making • Service-oriented culture	• Stable teams • Strong collaboration and mentorship • Strategic input and ownership • Research-oriented culture
Personal Development	• Fast technical exposure • Learning under pressure	• Formal training • Long-term growth
Work-Life Balance	• Unpredictable, fluctuates with project demands	• Stable, predictable, balanced
Quality Control	• Standardized processes • Double programming • Individualized client conventions	• Streamlined end-to-end processes • Use of macros • Company-wide standards
Stakeholder Interaction	• Primary clients and sponsors within biometrics unit • Quick issue resolution support	• Broader stakeholders including clinicians, regulatory • Team-driven decisions

Table 1. Distinctive Aspects of Statistical Programming in CROs versus Pharmas

CONCLUSION

Both CROs and Pharmas present unique advantages and challenges for SPs. Choosing the right path often depends on personal career goals, work-life balance preferences, and the desired depth of engagement in the drug development process. Gathering insights from peers in the industry, attending conferences, and seeking mentorship can greatly aid in making informed decisions. Current trends in the industry, such as the integration of data science and machine learning in statistical programming, also play a pivotal role in shaping career trajectories.

Engaging with professionals who have experience in both settings can provide invaluable guidance on navigating these career choices and determining the best path for your unique skills and aspirations.

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“Please help construct an abstract that discusses on the differences on SP roles on CRO side and Pharma (sponsor) side. The main aspects to consider -- work/lifestyle, project management, responsibilities, business sense.”

“Please help compare the similarity and differences on SP roles on work style, Work life balance, project management, responsibilities, business sense, career path, valued skills, between CRO side and Pharma (sponsor side).”

Additionally, ChatGPT was utilized to refine the paper’s structure and revise the writing for clarity and word choice.

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