

What's the F in specialized people? Let's talk FSP - the models, variations, and what it takes to be successful

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ABSTRACT

FSP means something different to every client and service provider. Why are there so many variations?

What are the pros and cons? Why is everybody talking about it? Let's explore different models and approaches, what makes collaborations successful, and how the roles and expectations can differ from traditional CRO models.

We will explore the variety of FSP models, how the roles and responsibilities vary by collaboration, the challenges and expectations, and what it takes to realize success. We strive to shed light on the benefits and detriments to the client company, the FSP provider company, and the workers within these models.

Our take home message is that while FSP seems to have so many meanings and so many different configurations, some things remain unchanged despite size and model. Establishing clear communication, expectations, and escalation pathways is key to making the collaboration successful.

INTRODUCTION

What does Functional Service Provider (FSP) mean to you? FSP collaborations have been around for many years, originating to drive efficiency and cost savings in clinical research. There are many different definitions of FSP out there that can cause a lot of confusion. A quick search yields many definitions, a few as examples:

- An FSP is a vendor arrangement that provides a variable number of headcount, usually across one or a limited number of functional areas that support the development operations for some number of clinical trials or other development efforts.¹
- A Functional Service Provider (FSP) is a personnel sourcing model in which a clinical research organization (CRO) provides staff to biotechnology and pharmaceutical companies in order to perform specific tasks—in a dedicated manner—on a contract basis and under the procedures of the sponsor.²
- A Functional Service Provider (FSP) offers a variety of clinical trial services on an “a-la-carte” type basis – as opposed to a full suite of services. This allows large pharmaceutical companies to outsource only what they need to fit their budget (and other factors).³

None of these definitions dig very deep to answer questions, such as, which systems or SOPs will be used, who will have responsibility for quality, and/or who will manage resources. It requires collaboration at all levels to develop and deliver a successful FSP relationship.

As with any relationship, trust and communication are the key factors to success. To truly understand success, there also must be failures. Lost opportunities, unqualified candidates, and missed deliverables may be viewed as failures, but in fact, should also be considered successes in that they are an opportunity for lessons learned that drive quality within the FSP.

The goal is to help provide some better understanding of FSP models and roles, how they differ from traditional CRO engagements, and how those differences translate into skillsets and aspirations. This will drive your career choices as you navigate the jobs available in the marketplace.

¹ Guest Column, Clinical Leader, July 3, 2018

² Sofpromed.com/functional-service-provider-fsp-for-clinical-trials

³ Criterium.com/news-blog/the-fsp-functional-service-provider-in-pharmaceutical-research

OVERVIEW OF FSP

What does “FSP” stand for? Is it functional or fractional services? Is it services or staff? Is it functional service provider or partner? The acronym “FSP” has become standard language in the clinical research arena, and nobody really agrees on what the letters stand for. However, most can agree that an FSP is an arrangement intended to drive efficiency and timeliness in clinical development, leveraging dedicated resources across multiple studies or programs.

WHAT ARE THE BENEFITS TO THE CLIENT OF USING AN FSP MODEL?

Why do clients use FSP? Clients use the FSP model for several reasons. FSPs can provide the ability to scale up or down quickly to meet their business needs. They can focus on certain skills and expertise that the client may need but not have. Clients often rely on FSP vendors for innovation, as these vendors have visibility into other client’s processes and directives. Clients may choose to augment their current staff with a few resources, have entire FSP teams within one department, or choose to have multiple services provided under this model. Clients may choose to maintain control of deliverables or turn the quality and timeliness over to the vendor. All these parameters are flexible in an FSP model.

Lower costs

Sponsors are often under pressure to increase productivity while maintaining or lowering costs. This can be difficult when deliverables require expertise and are often time sensitive. A functional service provider in clinical research can help in several ways:

- FSPs can allow team members to become experts in certain functions, driving efficiency through less learning curves and allowing more focus on individual tasks.
- FSPs reduce the operational friction and oversight costs that often result from a unit-based model, making re-work and changes expensive.
- FSP resources can be embedded into the sponsor team and utilize sponsor systems, processes, and SOPs to standardize deliverables across all sponsor’s projects and programs.

Quality

The ultimate goal of any clinical study is clean data and quality output. Quality is of the utmost importance in clinical research and should be a top priority for all contributors supporting a clinical trial. From a Biometrics perspective, the Data Management team must work to ensure data has been reviewed thoroughly and cleaned according to the study guidelines. This is extremely important as the biostatistics and programming teams are tasked with the responsibility of driving the analysis of the clinical trial data, as well as creating the data submission packages for regulatory agencies. Every deliverable needs to be accurate and on time to ensure clinical development decisions are made at each critical junction. A collaborative FSP works as an extension of the sponsor team, often with their systems, and can demonstrate quality, progress, and project control in real-time.

Not only does this ensure the work is of the highest caliber, but it also allows continued focus on core business processes. FSPs let clients make the most of day-to-day efforts and provide the flexibility to quickly respond to changes in scope and timelines during clinical trial execution. The sponsor workforce is free to focus on other value-adding activities during the clinical trials, while the expert talent of the FSP team drives deliverables across the projects and programs.

Flexibility and Scalability

Shifting resources can increase efficiency and speed up timelines but can be complicated. An FSP allows the sponsor to find a team that fits their needs and can shift the cost and management of redeployment to the vendor. An FSP will utilize expert staff in the best ways possible to scale projects appropriately and move personnel into new projects as they become available. This will result in efficient scalability without lengthy and costly hiring or onboarding processes.

WHY DOES THIS MATTER IN A JOB SEARCH?

FSPs may not seem so different as it is all about getting deliverables completed on time with the highest quality possible, however there are subtle differences that can be big differences when it comes to job satisfaction. Many of us start out in a traditional CRO setting working with multiple clients, multiple types of studies, and on many different standards and systems. As careers develop, some may want to become subject-matter experts, work directly with pharma or biotech, or be an independent contributor as opposed to running a team or department. Some of these opportunities are better found in the FSP positions. Let's explore some of the differences that set FSP jobs apart from traditional CRO jobs.

CHARACTERISTICS OF A SUCCESSFUL FSP TEAM

Team characteristics are often different in FSP arrangements as the teams tend to stay more static, and that unique dynamic brings its own challenges and opportunities.

- It is crucial that the FSP team are embedded in the company culture, both at the client and vendor level, and see themselves as part of an integrated team. The team should be trained effectively, have clear expectations set, and have appropriate support. A true partnership with all client and vendor team members will contribute to making team members feel valued and lead to a trusting relationship.
- Retention is key for successful delivery in a market where there are many opportunities and incentives to move. The need to create that sense of belonging is crucial. This can be achieved by having a transparent career ladder, investment in training, a strong and developing compensation package, and strength in leadership. This can be achieved by growing at all levels; our experience is that growing further strength from the bottom up drives long-term continuity, brings career movement within the model, and offers alternative mixes of staff.
- Ensuring quality is a key focus and this is where vendor and client leadership have key roles to play. This is enabled by communication that provides transparency to the team members, an understanding of expectations, and support as needed. Training and ongoing support is primarily provided by the client team.
- Empowered employees are critical to a successful FSP. The philosophy revolves around the culture of both the vendor and the client. The FSP team should feel empowered to ask questions and make suggestions. Good leadership and mentoring, where you can lean on other experienced FSP resources on the team for advice and oversight, allows people to feel supported and ensure they know they are not alone in figuring things out. The key to developing future mentors and leaders is to give them new experiences and challenges. With those new experiences, providing feedback, actively listening, and effectively communicating are key to building success, trust, and accountability.

CHARACTERISTICS THAT MAKE FSP ROLES DIFFERENT

Typically, FSPs use client systems, SOPs, and processes. While this may not seem like a differentiator, it allows the team to become efficient at using a single standard platform and set of processes across multiple projects or programs. This not only saves time in learning something new every time you change projects, but also helps with quality control. A lot of times in the traditional CRO setting, people are faced with juggling several studies from several different clients, all of which have their own requirements. Extra care needs to be taken to make sure that each project is following the client's requirements. This becomes a challenge with competing deadlines.

FSP roles connect you with the client. You and your work are client facing. While this can be daunting for some, being dedicated to a single client drives deeper relationships and more opportunity for client interaction. Down the road, it could lead to further opportunities within the sponsor company.

In general, FSPs have a set utilization. Most FSPs establish a set average number of billable hours per month, allowing you to have more control over your schedule. In the traditional CRO setting, there are many more competing deadlines and little downtime. Not to say that you are not just as busy in an FSP setting, it is just that your focus is on fewer tasks at a deeper level.

The key is understanding the “why.” The mindset of milestones in a traditional CRO model is much more “get it out the door” because the CRO is focused on completing the particular project milestones, whereas the sponsor, who is managing the FSP, is focused on the analysis and potential submission. Some other considerations and nuances include:

- You may become an expert in one or a couple of focus areas across different projects (e.g., standards, biomarkers, PK).
- It is likely you will get bucketed into one disease, one therapeutic area, one function at least for a period of time which drives specialization in your career.
- There may be limited opportunity to develop processes as the sponsor often drives processes and systems.
- There are potential opportunities to supplement the client team as a subject matter expert (SME).
- You may find that you will have a deeper investment in the client and/or the product(s).

SELF-ASSESSMENT

Now that you have an idea of how FSP roles are different from traditional CRO roles, you need to take a deeper dive into figuring out what you want out of your job. Ask yourself:

- What motivates you?
 - In the FSP environment, you can get exceptionally good at 1 set of processes and become an expert.
 - In a CRO setting, you will likely wear many hats and use many different processes. You will have exposure to all kinds of therapeutic areas, analyses, and tasks.
- Do you want to be an independent contributor and/or become an SME?
- Do you want a management track?
 - There can be limited people management roles in the FSP, depending on the structure of the FSP.
- Are you self-motivated and are you to be able to work independently, with little direction?
 - In an FSP, your work is typically client facing and you may find it more difficult to ask questions. Remember that your FSP team is still there to support you.
- Do you worry that you will become tired or bored of working on just one sponsor/one set of standards/one product?
- Do you feel like you may be pigeon-holed (e.g., I am a little concerned that I may become siloed and that working in FSP will slow my progress to the manager role)?

QUESTIONS TO ASK YOUR RECRUITER

FSP roles vary enough that it warrants asking some deeper questions. When presented with an opportunity, some questions to ask as you contemplate the role:

- Who will be the manager, will the manager be with the client or the vendor?
- Who will drive the communication when there's issues?
- Who is going to assign the work?
- Who will QC the work?
- What hours requirements are there for this role?
- How are the holiday schedules and paid time off handled?

- How many people are on this team?
- How many products or programs does this FSP opportunity support?
- What does a potential career path look like?
- Are there opportunities for merit increases? Promotions? Benefits?
- Is this a full-time employee opportunity or a contract role?
- Will I work with other members of the FSP team?
- How long is this assignment expected to last?
- Will there be other opportunities after this assignment is over?
- How long has this client relationship been established?

SUMMARY

FSPs are widely used and accepted in clinical research today, yet are not well defined. This can lead to confusion and misconceptions in the workforce. They also vary from FSP to FSP, from client to client, and from program to program. Bottom line, not all FSPs are created equal. As you consider roles on an FSP team, carefully assess the opportunity by asking lots of questions of both your recruiter and yourself. Understand the challenges and opportunities, and align yourself with the right client and the right FSP vendor. The right FSP can lead to an extremely rewarding career.

REFERENCES

1. Guest Column, Clinical Leader, July 3, 2018
2. Sofpromed.com/functional-service-provider-fsp-for-clinical-trials
3. Criterium.com/news-blog/the-fsp-functional-service-provider-in-pharmaceutical-research

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