

A Look at the Functional Service Provider

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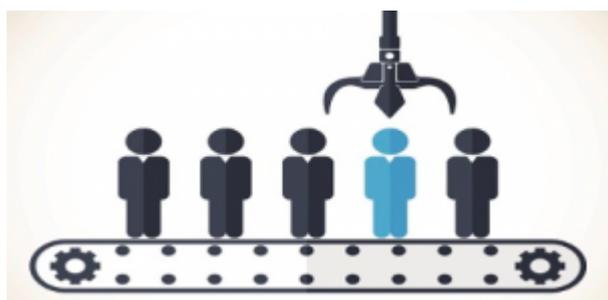
By Jodi Fletcher

What are functional service providers—FSPs—and how can they help you have a successful clinical trial?

With so much data to analyze and process, documents to keep track of and regulations to follow in a clinical trial, outsourcing some of the work offers a cost effective and efficient approach. Contract Research Organizations (CROs) have long been used by trial sponsors to achieve completion and compliance in clinical trials. According to the [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice](#), the definition of a Contract Research Organization (CRO) is: “A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor’s trial related duties and functions.”

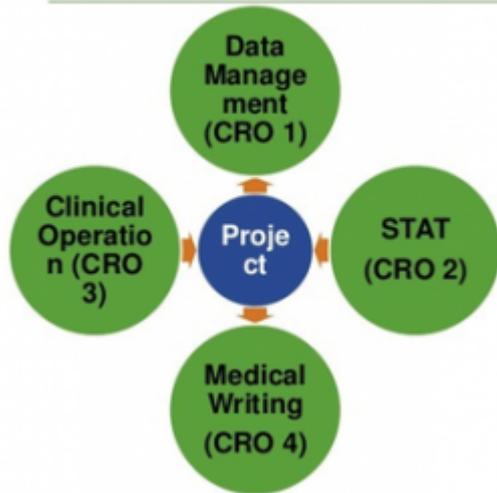
[Large, global companies](#) have customarily outsourced responsibilities to full service CROs that perform multiple duties related to the trial, while smaller companies have often used “specialty CROs” designed to offer specialized services, such as source document monitoring, data management, or device training, where needed. However, in recent years, there has been a shift in how companies have been utilizing these organizations. The increasing demand for complex clinical trials and the high overhead of building

comprehensive, in-house, specialized clinical operations departments is driving the need for more outsourcing of services such as data management and analysis. Specialty CROs have filled this role in the past, but recently a re-branding of these organizations has more accurately labeled them as FSPs. This model is becoming a more popular choice in both large and small sponsor companies.



The name of FSP for organizations providing high-level expertise in one or two areas of clinical operations has been gaining popularity because it more accurately delineates a full-service CRO from an organization which specializes. An FSP provides [more flexibility and efficiency](#) than traditional full-service providers. These organizations offer individual, focused services where the sponsor has the option to “pick and choose” which provider fits the area of the trial best. FSPs offer the option of expertise in the area of service or methodology. [Companies may offer FSP services](#) for clinical operations, data management, statistics, or medical writing. A sponsor may choose to use one or more FSPs for the trial, but it may also have several companies under contract per function to provide the most agile and complete coverage for individual studies.

Functional Service Provider



FSPs, which can be generically referred to as functional outsourcing options, have become popular through the growing desire for a [relationship driven approach](#) rather than a project focused one. Long term, flexible partnerships can be developed with targeted specialists, where several smaller vendors can be better than a single large one. Partnership development is crucial for the trial's success. Partnerships in large CROs may take too long to develop because of the infrastructure necessary for a large vendor to operate and this may hinder startup or closure of certain trials.

Benefits of using an FSP:

- Focused expertise
- Competitive benefit
- Risk mitigation
- More efficient
- Lower cost
- Invested development in focused areas
- Higher degree of control

Trust in the experience of the vendor is critical for a relationship to develop. This and cost are areas of concern in the process of service provider selection in clinical trials. (For more information go [here](#) and [here](#)) There are many ways that an FSP addresses these concerns. Often in an [FSP](#)

[arrangement](#), the technology and systems needed are provided by the sponsor, reducing the cost to invest in additional systems. This enables the sponsor to use existing personnel to focus on the management of the vendors and to oversee clinical operations. [In an FSP relationship](#), the vendor manages its staff, although the sponsor provides study-specific training and access to policies and procedures. This arrangement creates teams that are essentially an extension of the sponsors' team. The result is increased transparency in the relationships that is easier to oversee and assess. An FSP relationship provides ["senior-level governance, structure, and attention"](#) throughout the process with this model aiming for efficient delivery while maintaining high quality and consistent service.

[What to look for in an FSP:](#)

- Cultural and company values and strategies
 - Customer service approach, level of communication, conflict resolution, oversight
- Experience and best practices
 - Does the company have plans in place based on what has worked previously?
- Consistency
 - Turnover rates, human resource management
- Flexibility to adapt
 - Strategic and proactive planning
- Scalability to demand
 - Ability to tailor team relative to study size and complexity



The ability of the FSP to “fit” with the sponsor’s needs is imperative to the selection and the relationship that will be developed. Flexibility, integrity, trust, and experience are key factors in the success of the relationship.

Sometimes, a “one-size-fits-all” approach can be the right choice for a research service organization. However, in this era of specialization, an FSP may offer the most expertise and flexibility for the best results in your clinical trial.