

# Life Science Leader

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## Contract Sourcing

### What To Look For In A Functional Service Provider

By Dan Schell

I recently sat down with Eleanore Doyle, group VP for Kforce Clinical Research ([www.kforce.com/clinicalresearch](http://www.kforce.com/clinicalresearch)), to discuss the increasing dependence on functional service providers (FSPs). These firms perform specific functions during clinical studies, such as study monitoring and data management, assuming complete control of these functions. Meanwhile, the sponsor maintains overall management and control of the study.

*Today's pharma companies are challenged with revolutionizing the drug development process. As a result, are FSPs becoming even more popular?* Yes. Sponsor companies are realizing the need to get back to the basics of drug development. With that refocus comes an interest in partnering with FSPs to manage specific functions of the drug trial.

#### **What factors should a sponsor company consider when selecting an FSP?**

The decision to work with an FSP should be approached strategically and in alignment with corporate goals and objectives. A cultural fit is also important, as sponsors and FSPs align their activities along their shared passions for getting medicines to people in need. Sponsors should also look for a track record of functional expertise with real, measurable results. Reviewing the FSP's client list will help them determine the depth of experience, number of studies, and longevity of relationships with which the FSP has worked.

Based on their experience, FSPs should be able to make some recommendations on resourcing capacity and meeting key performance milestones. Working together, sponsors and FSPs can manage performance with real-time data.

#### **What about scalability? That seems to be a buzzword among sponsors.**

Accurate resource planning is an industrywide challenge. With robust pipelines across a broad range of therapeutic areas,

a large pharmaceutical company's human capital resource needs change almost daily. However, most sponsor companies don't have large recruitment engines or a simple process for ending employment contracts when they need to scale back. To mitigate this, they either outsource the nonstrategic competencies of monitoring and data management, or resort to a "full pantry" approach with stockpiled resources. While the full pantry may seem to be scalable, that static level of resources is inefficient and wasteful when monitoring needs are at a lower level. FSPs are cost-effective when they have the ability to recruit, train, deliver, and manage just-in-time monitors based on lead indicators and capacity forecasting models.

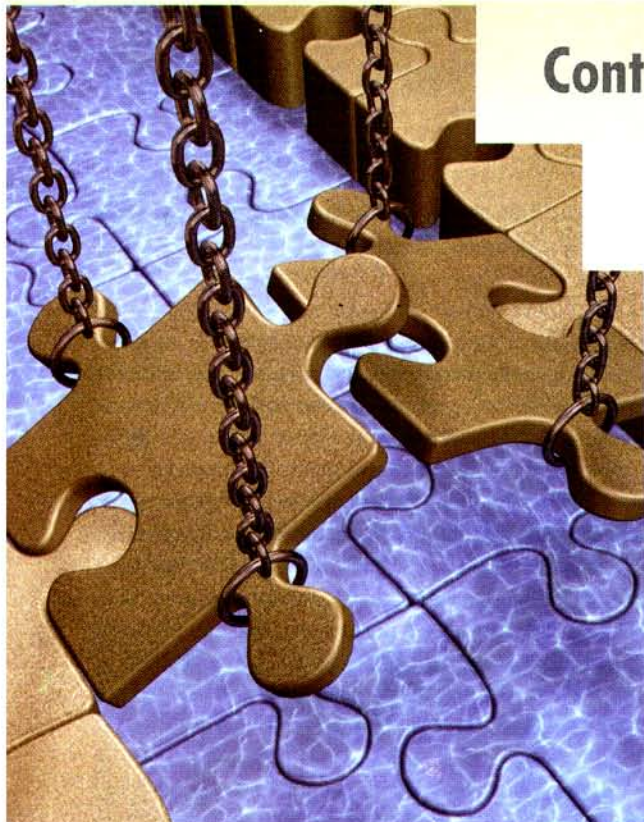
As a project progresses, FSPs have the ability to project workloads across monitors and validate FTE demand on a real-time basis, unlike CROs, whose rigid structures and cumbersome change-order procedures don't lend themselves to real-time changes. A few FSPs have recently begun identifying time requirements for different monitoring tasks like

screening data, routine monitoring, and reviewing log pages. Seeing standardized results develop, they have begun building a complete protocol view of demand to forecast capacity needs in advance. Their nimble approach enables FSPs to quickly move resources across therapeutic areas, across sites, and/or from one study to another, depending on the operating model and strategy of the sponsor company.

#### **How do sponsor companies benefit from an FSP relationship?**

FSPs bring the distinct advantage of having worked with multiple pharmaceutical companies. They have evolved to become repositories of industry best practices. While FSPs can certainly provide rapid-response resourcing needs, truly evolved programs are offering more strategic consultation and are actually building models that forecast accurate capacity demands and manage project milestones.

Additionally, FSPs can plug into a sponsor's own clinical trial management system (CTMS) and other management systems, unlike CROs, which use independ-



ent systems and transfer data upon the conclusion of the trial. By limiting the data integration points where errors might occur, FSPs provide sponsors with real-time data which they can collaboratively review more often during the trial.

### ***What about the cost benefits involved?***

FSPs offer flexible and customizable programs that utilize a combination of cost-saving strategies that can include things like full-site management, therapeutically aligned study start-up leads, standardization, regionally based site monitoring, or resourcing across multiple therapeutic areas. But



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Eleanore Doyle, group VP for Kforce Clinical Research

the more significant benefit can often come in the form of revenue gains associated with getting a drug to market sooner. Then the real measure becomes the reduced cycle time.

### ***Give me an example of a customizable solution you've used.***

One option is a model in which the outsourcing provider is 100% dedicated to the sponsor company, knowledgeable in that company's protocols, and devoted to establishing relationships on behalf of that sponsor with investigative sites. Essentially, clinical sites do not “feel” any difference between a sponsor company monitor and an outsourced monitor. By receiving the same training as core employees, outsourced

monitors are well-versed in the company's standard operating procedures and policies. These models can be small with just a few resources or really large with hundreds of resources. This is just one example, but certainly not the only flexible customized solution an FSP can offer. The models are changing as quickly as the needs are evolving.

### ***What are some of the challenges sponsor companies should be aware of when partnering with an FSP?***

Some realignment and business process reengineering is necessary. Study teams may worry that having an outsourced partner managing monitors will create more work, when in fact, the opposite proves true. One point of contact to manage all resources streamlines the process. With FSPs, study teams design the protocol and then leave the resourcing and process management to the FSP, which provides continuous updates and real-time data. These types of concerns are easily addressed with frequent communication of performance metrics. ●