



Clinical
PROFESSIONALS

White Paper

Revealing the flexible
nature of FSPs.



Revealing the flexible nature of FSPs

- how they can supplement your existing outsourcing strategy

Outsourcing in the industry has evolved in the last decade from the traditional full outsourcing or 'transactional' models via Clinical Research Organisations (CROs). Companies in the biopharma industry are now faced with multiple outsourcing models from the traditional, through to insourcing (including the use of Master Service Providers [MSP]), functional service provision (FSP) and strategic or alliance partnerships, all to reduce costs and drive efficiencies as they are faced with bringing new drugs to the market quicker.

This white paper looks specifically at FSP models and how these can sit comfortably and flexibly in a mix of outsourcing strategies, how they do not have to be large in number and all-encompassing to be effective, and defines this model alongside the increasing numbers of strategic / alliance partnerships currently being formed.

The value of the market regarding outsourcing is currently \$33 billion (Frost & Sullivan white paper), which demonstrates how much investment is put into outsourcing strategy by biopharmas.

There are several options available for outsourcing, as discussed in a white paper published by Quintiles (1). Most recently there has been a shift towards strategic or alliance partnerships in the past 5 years between large pharma and CROs (Pfizer with Icon and Parexel, Covance with Sanofi and Lilly, GSK with Icon and PPD). These partnerships leverage the capabilities of the selected CRO in order to decrease the cycle time from identifying a new chemical entity through to submission and approval by required regulatory authorities. They have branched into new areas and taken outsourcing to another level. Some CROs have bought assets from clients, for example Covance buying Eli Lilly's early drug development campus in 2008, and the purchase of two laboratory sites (France and UK) from Sanofi in 2010. Other CROs work directly with the client to determine the strategic direction of the client company with their upcoming pipeline. The recent Strategic Partnerships 2013 report published by Parexel explores this part of the market.

However, this is not to be confused with Functional Service Provision, and strategic or alliance partnerships are not necessarily the right outsourcing strategy for all companies.

Whilst FSP is collaborative in nature and sets out to achieve a lot of the same goals as the strategic / alliance partnerships, it does not involve the use of provider systems in place of client systems, and no assets change hands.

The true definition of an FSP is to fully outsource a whole function such as clinical monitoring, data management, or regulatory to a provider across all studies and therapeutic areas as a sole provider. Depending on the scope of work and the regions involved, companies may decide to use a secondary provider to support the primary provider. The FSP would utilise the client systems, SOPs and processes, with the client retaining overall responsibility for the deliverables. This is a collaborative partnership.

The attraction of the FSP model lies in the flexibility it offers to become a bespoke solution to each client, provided the right partner to collaborate for the FSP is chosen. It is a scalable model, allowing clients to adequately resource their departments in line with increased or decreased resource requirements in real time, without the additional burden of HR processes associated with permanent headcount. FSPs can be anywhere from two staff in one country, through to upwards of 50 staff or more across multiple countries. Companies may choose to use one provider globally, for example the agreement between Astellas and INC Research to provide 600+ staff for 3 years across clinical monitoring, data management, TMF management, start-up and feasibility, or they may choose to use a variety of different providers across countries to ensure that they have the 'best in class' for each function and country like the 'hub and spoke' model utilised by Amgen. The focus of FSPs is that it can be tailored to client requirements.

No FSP is too small to be put into practise or make an impact.

FSP gives another choice for resourcing outside of the traditional outsourcing or insourcing models historically used to upscale the required workforce. Collaborating and integrating your selected partner utilising an FSP model can offer greater:

- Control / oversight – client is still responsible for overall deliverables and has tighter control on this as they are directing staff on a daily basis
- Quality of staff – clients utilising an FSP model have the ability to choose the staff they have working on their studies via the FSP, in contrast to fully outsourced studies where no choice is given to which staff are used to resource the studies
- Consistency – dedicated pool of resource fully integrated to understand and use client SOPs and systems, plus appreciation of the company culture, vision and values
- Flexibility and efficiency of resource - Can increase / decrease resource as required for the study without HR burdens of permanent staff
- Vendor support and commitment – integration of the vendor into the client to improve understanding & sharing of market intelligence
- Value added service – collaboration can be used to also review items such as overall recruitment process, resourcing etc
- Increased staff retention – stability of staff being permanently employed by vendor, but full integration into the client
- Efficiency with regards to recruitment, line management of staff and training – enabling your managers to spend time more effectively managing the studies

The reason for introducing an FSP model is often driven by the desire to create efficiencies within the resourcing and conduct of studies, without compromising on quality. However, these efficiencies create immediate cost savings such as the reduced amount of time spent by clients in resourcing their teams and subsequent management of them, in addition to the appropriate strength and quality of the workforce versus the workload required. The more significant but indirect cost saving relating to the efficiencies generated via an FSP is the reduced cycle time enabling clients to get drugs to market sooner and in a more cost efficient manner. Also vendors are more likely to reduce rates for contracted staff if there is a guaranteed volume of staff over a length of time.

FSPs go further than staff insourcing due to its collaborative nature. Support can be provided within each part of the process from the provider, from line management of the employees to review of the client recruitment or on-boarding procedures to enhance the experience.

If there is a lot of training to on board new staff such as client systems, a train the trainer approach could be taken where a staff member from the provider is trained to perform this function, therefore further decreasing the resource burden on the client. FSPs focus on the recruitment and implementation of staff in the first instance - get the right candidate and train them correctly, giving them support along the way coupled with opportunities within the FSP, which in turn should see a high staff retention rate and an engaged workforce working towards the goals of not only the FSP, but the client company also.

Essentially, FSPs can be what the client makes it, and they can continue to evolve and mould to whatever new strategic direction a company needs to take without severely impacting contracts that were established at the beginning of the relationship. Some FSP relationships may commence with the client maintaining a tight control over all aspects, but with time and experience between the two parties, more and more responsibility can be given to the provider, releasing more resource within the client to dedicate to study management.

Flexibility does not just have to be in regards to the ability to flex resource up and down with no internal HR impact, but also the ability to work side by side with a variety of outsourcing options within one company.

One leading biopharma company successfully utilises a variety of different outsourcing methods within their local affiliate office. There is a core team of permanent staff members sitting on the senior management team, with a small group of headcount project managers, CRAs and CTAs. The wider team is supported by insourcing of staff from a variety of providers via an MSP. The majority of studies are conducted using in-house staff (permanent and contract staff), but there are also some larger studies (not complex, but high patient numbers for low risk studies) which utilise a transactional outsourcing route with a CRO.

However, the CTA function is resourced utilising an FSP, the decision driven by a desire for higher quality candidates, in turn increasing staff retention, plus added line management support over an above the traditional insourcing route via the chosen MSP.

Another biopharma company employs the FSP model across the CRA function globally, with a different primary provider in each region (US, Western Europe, Eastern Europe). Each provider is able to act as a 'back-up' if suitable staff cannot be found to fill resource needs. The FSP commenced in Europe in 2009 with 10 CRAs across 4 countries. The study management teams are a mix of permanent staff and insourced staff from their assigned MSP provider. Embedded line management from the FSP providers have been added to the model to support the permanent client line managers, and a trainer brought into the FSP model to on board new starters and release this burden from the client line managers. The FSP has evolved to encompass new positions which give sight of more career opportunities for FSP staff, which in turn has decreased staff turnover within the FSP. A separate FSP has been established within Europe for study start up, with the chosen provider supplementing the work of the in-house study start-up team.

These two examples demonstrate how an FSP can sit comfortably with a variety of different outsourcing strategies. It also shows that FSPs do not have to start with high numbers of staff across more than one country, but they can start locally within one part of a function and grow organically as the wider company and local affiliates see how the strategy can work and bring efficiencies to the business, whilst forming a successful and collaborative partnership with the chosen provider.

FSPs can also be started on one particular study, in one particular country, or one particular therapy area. For example, a client with a complex oncology study which has a lot invested in it may wish to retain the management and conduct of this in house, but needs to supplement the team with contract staff. Instead of insourcing staff, an FSP partnership could be entered into to ensure the right staff are brought on board and have extra management support from the provider. Once the model has proved successful, it may next be employed across the suite of studies for that particular compound, and then utilised across the whole business if it is deemed that is the right resourcing strategy to be followed.

In summary, FSPs still have an important part to play in the outsourcing market place despite the rise in the strategic / alliance partnerships between the top biopharma / CRO companies. We may start to see a shift in the type of companies both utilising and providing FSP services. Small to mid-size biopharma companies looking to partner with a provider who will give them the attention that they may not necessarily have been afforded from bigger CROs on a transactional basis may look to utilise FSP models. We could also see a rise in pharma recruitment companies offering FSPs as a service, giving an alternative but just as successful experience as CROs have traditionally given.

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Rachel Oakley is Associate Director, FSP for Clinical Professionals. Rachel has 11 years experience in the industry from CTA through to CRA line management. For the last 5 years Rachel has effectively set up, managed and grown FSP relationships, and has joined Clinical Professionals to increase our FSP offering to complement our diversification of services.

To discuss FSP models further or your future outsourcing needs, please contact Clinical Professionals. Recent independent market research shows Clinical Professionals is Europe's leading independent pharma recruiter, with 95% of hiring managers rating Clinical Professionals as consistently superior in quality, speed of response, staff retention and communication, and 9 out of 10 customers rating Clinical Professionals as their most trusted partner.

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