Functional Service Provision and Full Service Outsourcing Models Have Key Roles to Play in Outsourced Drug Development as Clinical Trials Evolve

The relative merits of the functional service provision (FSP) and full service (FS) outsourcing models have been debated repeatedly over at least the last ten years. There is a place for both in the outsourced market although, over time, there have been shifts between them in terms of market share. Recent developments have seen hybrid models come into the market as service providers seek to both align their products with customer wishes and also gain competitive advantage.

The pros and cons of each model are well known. Proponents of the FS approach point to the convenience of the 'one-stop-shop', simplified contractual arrangement, the integrated team, and the potential for cost savings both in efficiency gains and through increased bargaining power, particularly if a sponsor awards several programmes of studies to a single provider. Supporters of FSP will point to access to specialist providers, similar cost savings from efficiencies, flexibility in terms of team size, and the plug-and-play nature of functional contracts. The downsides of each tend to be the flipsides of the list of the advantages above: for 'one-stop-shop' read generalist vs specialist support; for specialist providers, read the need for staff to complete repetitive tasking. The arguments for and against each model are well worn.

To a certain extent, the models shape the fabric of companies offering them. Specialist companies attract talented technicians because of their reputation within their field and their investment focus. Recruitment teams can identify strong candidates more readily because they become expert in the specialism. They have extensive networks, often stemming from the company's management team. That same management team typically features technical experts with deep expertise. It is not hard to see why such businesses become function-centric and why sponsors consider FSP not only when looking for volume provision, but also when they are grappling with a difficult problem.

FS companies offer a different proposition for candidates. These companies are typically larger than their FSP counterparts – the largest CROs are all FS. For some, working in a big company is very attractive. Once established within a large company, a candidate can seek out more varied opportunities – perhaps having a career change within the same employer. Staff in FS companies can see more of the clinical trials process going on around them – they may feel more part of the overall team. The larger CROs deliver more of the 'mega' trials and these can drive excitement within the working environment. For specific roles, such as project management, the remit is wider than typically seen in the specialist setting. Sponsors may be drawn to large FS CROs when outsourcing large programmes of work or individually big studies.

Making the Choice – FSP, FS, (or Hybrid)?

Sponsor companies have seen successes with both approaches and neither shows any sign of disappearing. However, if you are new to outsourcing, or are coming across your first big program of work, what are the considerations that shape your decision between the two, and is hybrid the compromise that will deliver the optimum outsourcing strategy?

Moreover, it is when examining the detail that the focus on the pros and cons of a methodology is strongest. Where the work product involves a high volume of functional expertise, FSP can deliver efficiencies which translate to significant cost savings. Where a study might be difficult to recruit for, a FS provider with their established strong site network can help reduce the risk of missing a deadline. And it is perhaps the complexities of clinical studies that have led to some FS providers offering a hybrid approach. Sponsors want to have access to both options.

Any outsourcing strategy must work for both sponsor and service provider. Where outsourcing involves FS or FSP services, it is normal for the sponsor to work through a procurement group. Before any outsourcing decision, it is essential that the study team correctly inform the procurement group as to their needs. The first key consideration is the nature of the package to be outsourced and how much of the work will be delivered or overseen by the sponsor. At the extreme ends of the scale, this might be a virtual company outsourcing a single, but complex, study as opposed to a major biopharma company outsourcing a large volume of programming work. In these situations, it might seem obvious that an FS approach is correct in the former case and FSP in the latter. However, if the biopharma budgets on a study or therapy area (TA) basis, it can become more challenging to operate a successful FSP model. If the study sponsored by the virtual company has complex needs and involves their only product, maybe specialist advice will reduce the risk of failure? The desired operational model, the budgeting structure, and the contractual arrangement must all be aligned. Only then can the other elements come into play.

The first consideration calls for an introspective review and in the real world, the package or packages of work will not always be as clear cut as those examples above. It may be difficult to model how the budgets may break down, it may not be obvious what impact shifting timelines will have on resource availability, and the question as to the level of expertise required may be open. At this stage, there may be several outsourcing strategies that appear feasible. Where the sponsor is seeking to outsource a programme of studies, it may not be evident as to which methodology is the better fit.

At this stage, the buyer's operational team must give input and advice as to the nuances of the work and how these will influence the choice of service. The buying team needs to understand how the programme may develop based on the success or failure of component trials. If a submission is involved, the benefits of one integrated team working to the deadline versus functional teams with the flexibility to grow at busy times can be debated. Is global reach more important than therapeutic expertise; is therapeutic expertise more important than domain knowledge? For smaller companies, the decision might be based more on how much oversight they can provide or how much vendor management they can cope with. It is only after considering the work in detail that the buying team can make an informed decision.

The Changing Climate

In recent years, there has been a shift away from FSP as a cost-saving device. There have been new entrants into the market and

the emphasis has been on staff augmentation. The mood is changing somewhat: Sponsors are expecting domain expertise from their FSP providers and quality and innovation feature as much as cost in requests for information. The trends toward patient-centricity and data-driven portfolios have focused minds on quality and more in-depth understanding of study design and analytics. The introduction of machine learning and artificial intelligence into study conduct has changed the game again. Domain expertise is becoming more and more critical.

The requirement for highly specialist domain knowledge would suggest the expertise provided under the FSP model is now more important. Sponsors still require the flexibility that FSP brings and will continue to need access to a high number of resources but that will not be enough in the longer term. They will require access to the expertise that comes with specialist providers.

This interesting shift leads to the final consideration. Sponsors need to be building relationships with those companies that can help them deal with new techniques and new technologies. They need to assess where the very best domain knowledge resides and build links with those providers. The FS approach will still provide a large proportion of services for some sponsors, but the complexity of the drug development environment has driven up the demand for specialist providers. Such companies have turned to FSP to scale operations and retained groups dedicated to project-based deliverables to retain the credibility needed to win business.

Sponsors can derive value from both the FS and FSP models. Some FS providers have recognised this and offer a hybrid approach – deploying FSP for components of the drug development process. However, FSP as part of a hybrid model does not deliver the benefits outlined above. Where FSP sits in the FS environment, management, recruitment, and investment are not targeted solely towards the area of specialism. An FSP business unit might have a director, but they will sit on a board bringing together the various players involved in FS delivery. The FS company will attract a different group of candidates. Where FS companies are attempting to establish specialist units, they must consider these factors. Sponsors, in turn, must account for them when selecting a hybrid model.

On the flipside, FSP providers may offer to run a FS approach by acting as the single point of contact and even offering to hold the central contract. A sponsor adopting this approach must assess the associated risks. FS companies have the expertise to manage complex contracts, understand the complexities of site payments, have experience of the logistics involved with running a successful study and how to contract appropriately with those third-party providers. An FS provider working with integrated processes can simplify life for the sponsor when agreeing on the contract.

There are a great many studies that utilise FSP in part and then use one CRO for the remainder of the work. Companies have grown used to this way of working. As study design has evolved and the amount and types of data have increased, the demand for specialist FSP has increased. While a drive for cost savings drove the growth of early FSP arrangements, now a desire for access to specialist expertise plays a significant part too.

Considerations for All Models of Clinical Trials Management

These are some of the areas a sponsor must consider when deciding between an FS approach or bringing in FSP for some services. There will be others, especially when the sponsor examines the detail of any package of work. A sponsor can establish key considerations from the project risk assessment.

The market shares of FS and FSP tell us there is a place for both methodologies. We may not have seen the end of the current cycle which is seeing a trend back towards the FSP approach. It will be interesting to see if the introduction of new techniques coupled with the increasing complexity of drug development will help to power the FSP market to new heights. FSP itself must evolve if that is to happen. If access to expertise is the driving force, then it seems likely specialist companies will underpin such growth. FS companies may respond; we have already seen specialist divisions established within the larger CROs. It is likely we will see further acquisitions of specialist firms as the mid-size and mega CROs seek to meet the demand for expertise.

While these changes occur, it will be more difficult for those charged with procuring services to have a clear view of the best option. Certainly, sponsors will need to look past the marketing of these products and gain a real understanding of the expertise on offer. The implication of this is that smaller companies will need to have access to independent expertise to guide the procurement process and preferably oversight during the study conduct. We have seen the introduction of regulations emphasising the importance of vendor oversight. As in-study tasks become more technical (think artificiaI intelligence, machine learning, new statistical techniques), such monitoring becomes more challenging but also more critical.

Perhaps, in the past, there has been an option to 'throw a study over the fence', bring in a FS provider at the beginning, and then wait for the final report sometime later. Things have moved on and the need for specialist advice has seen demand for FSP grow. The work involved in submissions has increased too. For large companies, access to FSP on the volume side has proven very successful and saved money. It is easier for the FS companies to establish FSP for volume services and most have responded with some element of staff augmentation services. Various providers from outside the life sciences sector (for example consultancy firms and recruitment companies) have entered the market to deliver under the staffing model.

For the sponsor, the volume of work might be the most important consideration when weighing FS against FSP. Where FSP is procured to deal with a large quantity of work, the risk assessment is different versus the case where FSP is procured for access to expertise. It is this area where we will see companies seeking to differentiate and specialist providers grow to meet the demand.

Conclusion

FSP and FS both have roles to play in outsourced drug development and neither appears to be under threat in the medium term. The nature of clinical trials is evolving, and as regulatory and perhaps political factors shape drug development there may be a swing towards one or the other. Procurement groups will typically work over three-year cycles, occasionally five. These run times will protect them against shifting models which, unless there is a profound change in approach, would take several years to play out.

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