

Flex Your Outsourcing Model to Maximize Drug Development

How to choose—and optimize—combinations of service models to fit your needs



Strategically selecting the right outsourcing models can bend the cost and time curve of drug development by maximizing quality, operational success and financial efficiencies. But how do you identify the right service model—or even mix of models?

A recent report on outsourcing from Tufts CSDD summarized data from numerous surveys and data sources since 2017 and concluded that outsourcing practices tend to be fragmented and tactical, inviting inefficiencies.¹ The report found that clients often use a variety of outsourcing models, including transacting for individual tasks, functional/program service relationships and full-service relationships, but that only a third of companies believe these processes are well established and only a fifth rate them as “highly effective.”

This article explores the rationale behind selecting one model versus another, the advantages and disadvantages of each and how clients can use data to evaluate the success of their model to drive more strategic outsourcing decision-making.

To begin, we present below, an overview of the core models and the general pros and cons of each. Of note, to date, there is little industry consensus on these terms and descriptions, so, therefore, they vary widely among our customer base.

DECISION-MAKING: WHICH MODEL IS BEST FOR ME TODAY?

For many years, clients tended to embrace one model versus the other. That is, they kept everything “in-house” or they “relied completely on everything FSO.” Now we are seeing more flexibility in the outsourcing decision-making process and a greater blending of the various models.

Therefore, what goes into the decision-making process when selecting which model to use? The first consideration is often historical precedent. We tend to trust what we know. Many organizations are simply designed to rely more on one model versus another.

The second major consideration usually comes down to the level of internal resources and expertise. This can vary wildly from one drug, device, indication or even study versus another. For example, a client with significant internal knowledge and history about a therapeutic area or indication may turn to staff augmentation as an alternative to hiring internally. This drives fixed costs and carries the risk of layoffs down the road if, usually when, setbacks occur.

A client who wants to supplement internal capacity by function versus by people (staff aug) may prefer FSP outsourcing arrangements, particularly for functions that are not seen as a differentiating, or core, competency. For example, clients rarely outsource

Model	Common features	Typical pros and cons
Staff Augmentation (staff aug)	<ul style="list-style-type: none"> • Vendor staff supplements client staff on internally managed (“insourced”) projects • Typically uses client systems/SOPs • Contracts are usually hourly or full-time equivalent (FTE)-based 	<p>PROS</p> <ul style="list-style-type: none"> • Using client systems/SOPs better supports integration of multiple vendors • Multiple projects can be supported by a single contract • Client retains overall project control with the vendor usually providing 100% dedicated FTEs <p>CONS</p> <ul style="list-style-type: none"> • Increased co-employment risk • Vendors may not be incentivized to invest/innovate • Information technology costs and management/training burden usually falls on clients
Functional Service Provider (FSP)	<ul style="list-style-type: none"> • Clients outsource entire function(s) (e.g., data management, drug safety, clinical monitoring, etc.) • More often uses the vendor’s systems/SOPs • Contracts more often unit-based • Usually not 100% dedicated FTEs 	<p>PROS</p> <ul style="list-style-type: none"> • Process consistency and efficiency gains from project to project • Volume discounting • Vendor more incentivized to innovate <p>CONS</p> <ul style="list-style-type: none"> • If there are multiple FSPs, there may be process handoff issues between vendors • Vendor coordination places increased management burden on clients
Full-Service Outsourcing (FSO)	<ul style="list-style-type: none"> • Clients outsource the majority of, if not all, study-related tasks • Overall study management often a vendor task • Typically uses vendor systems/SOPs • Contracts usually unit- or milestone-based • Usually not 100% dedicated FTEs 	<p>PROS</p> <ul style="list-style-type: none"> • Most if not all coordination shifts to the vendor • Reduces management burden on client • More seamless integration of multiple services and systems within the vendor <p>CONS</p> <ul style="list-style-type: none"> • Unique contracts per project reduces administration/financial efficiencies • Less efficient in driving process/efficiency gains across multiple studies in a portfolio

Table 1. Core features of outsourcing models

the scientists driving preclinical research, but they may be happy to outsource site contracting, payment administration or statistical programming. FSP is gaining traction as an outsourcing model as clients realize that by outsourcing individual functional services, they gain flexibility, volume discounts and efficiencies while retaining more control over what they consider their core competencies.

Finally, a client who believes they have knowledge, experience and people-gaps on a study, especially if they are entering an indication that is new to them, are more likely to rely on FSO models.

Today, clients are realizing they don’t have to choose one model over another, but that they can adopt hybrid approaches that mix and match features of staff aug, FSP and FSO within portfolios of studies to get the best of each model. The Tuft’s report validates this finding by reporting that 42%, 56% and 77% of

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clients reported “routinely using” staff aug, FSP, and FSO models, respectively.¹ That “total” of 175% demonstrates that the models overlap for many organizations.

A hybrid model offers the flexibility to create optimized, highly

Function	KPIs	Trend
Site startup	Turnaround times (TATs) for site contracts, essential document collection and IRB/ethics approvals	Comparative data reveal that FSP models tend to generate faster turnaround times – sometimes 25% faster or more
Site monitoring	Visits within window, trip report/follow-up letters in window	We don't usually see significant differences between models. The metrics tend to be stable regardless of which model is selected.
Data management	Database build TATs, data backlog and query aging	Comparative data tend to drive clients from staff aug models toward FSP.
Pharmacovigilance/ regulatory/ marketed Products	Submission compliance to health authorities, case processing quality, and acceptance of dossiers by regulatory agency with no validation errors (marketing authorizations and variations) and major/critical audit findings	Comparative data tend to drive clients from staff aug models toward FSP.

Table 2. Example metrics to track across outsourcing models

tailored solutions that may have the greatest impact on key operational metrics and deliverables. Even within a single client, different models may be preferred by region or country, functions, by phase of development or post-approval, by therapeutic areas, or even by asset.

USE METRICS TO INFORM OUTSOURCING DECISIONS AND DRIVE PROCESS IMPROVEMENTS

Clients who use multiple and/or hybrid outsourcing models can compare key performance and quality indicators (KPIs, KQIs) across models. We find that these comparative data are the backbone of strategic selection of outsourcing models and process improvement. The data may support “doing it our way,” in either vendor or client systems and SOPs, or it may reveal areas where current processes are inefficient, increase audit findings or lead to expensive rework—or often, all three at the same time.

Recently, we worked with a client who employed a hybrid outsourcing model on a portfolio of studies. Within this portfolio, we ran their FSO studies using one set of SOPs and templates for site contracting, and we worked on their insourced/FSP trials using a different set of SOPs with broader legal language fallback parameters and budget negotiation limits. With roughly 50 protocols in each model and comparative data generated starting in January 2016, the global average of contracting TATs (Turn Around Times) was reduced by 40 days when using the systems and SOPs within the FSP model. This example is not meant to illustrate the superiority of the FSP model, but rather to demonstrate that data stemming from two different models can cross inform each other to highlight areas of strength, as well as areas in need of process improvement.

CONCLUSION

The key is to be open to the insights that the data reveal and to be willing to challenge your thinking to strike the right balance. In truth, there is no optimal outsourcing model. Each delivers a set of pros and cons. The core need is to be agile and strategic enough to flex to meet the unique needs of different organizations and studies. As well, a hybrid approach, which offers the flexibility required to deliver time-efficient, high-quality services, while having trans-

EXAMPLES OF MIXING MULTIPLE OUTSOURCING STRATEGIES

Client A: Studies are insourced in the countries where they have affiliates with a significant dependence on staff aug clinical research associates (CRAs), primarily using client systems and SOPs. Studies that are run mostly or entirely in countries without client affiliates are FSO.

Client B: Metabolic studies are insourced using staff aug CRAs. Oncology studies use FSPs for data management and pharmacovigilance, using vendor systems/SOPs, while all other Phase II-III studies are FSO.

Client C: Using a “hybrid FSO/FSP model,” a biotech client with FSO studies has certain key roles (project managers, CRAs, statisticians, medics, etc.) wrapped into a 100% dedicated (ring-fenced) FSP contract that spans multiple protocols in their portfolio.

parency into the metrics to drive process improvement, may prove to be a good tool to keep in your tool kit. **CP**



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Reference

1. *Outsourcing outpaces internal spending but remains tactical and reactive.* Tufts Center for the Study of Drug Development. *Impact Report.* March/April 2019.