

## Guide

# Functional Service Providers in Clinical Development:

## A Strategic Guide for Sponsors & Biotech Industry

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The flexibility of the partnership distinguishes a high-performing FSP engagement from a transactional staffing arrangement.

Clinical development demands more from sponsors than ever before. Pipelines are complex, science is specialized, and regulatory expectations are advancing. This increases pressure to compress timelines without losing quality. For many sponsors, deciding how to structure clinical operations is now as crucial as science itself.

For decades, sponsors engaged a full-service CRO and delegated end-to-end trial management. That model still works in many situations, but it is no longer the only good option. The Functional Service Provider (FSP) model shows that outsourcing does not need to be all or nothing. Sponsors can keep strategic and operational control while also accessing deep, scalable expertise exactly when they need it.

This guide will help you decide whether an FSP or a hybrid FSP model better fits your needs. We provide a framework to explain what FSP engagements are and how they differ from traditional models. We describe when FSPs work best and show how to structure a partnership that delivers lasting value.

### What Is an FSP & How Does It Differ from a Full-Service CRO?

An FSP is an external partner engaged to deliver one or more specific clinical development functions rather than managing an entire trial from end to end. In the traditional client-managed FSP model, the sponsor does not hand off a program; it augments its own capabilities at the functional level. In a client-managed FSP, the operational context frequently remains the sponsor's, including systems, standard operating procedures (SOPs), governance structures, and quality standards. The FSP's role is to provide talent, technical depth, and bandwidth to execute within that context. When well-structured, the result is a partnership that can grow and contract in response to program needs without the friction and cost of permanent headcount changes.

This is meaningfully different from a full-service CRO-managed engagement, in which the CRO assumes comprehensive trial management under its own systems, processes, and governance. The sponsor receives deliverables, including data packages, monitoring reports, and regulatory submissions, but may have limited visibility into day-to-day execution. Knowledge built within the CRO engagement tends to stay with the CRO. For sponsors who have invested in building internal infrastructure, or who want to maintain genuine operational ownership of their programs, this transfer of control can be a structural limitation.

The most productive FSP relationships show genuine alignment of purpose. FSP personnel should be chosen for cultural fit, partnership mindset, and technical competence. They should use a consultative style that adapts as program needs change. Both parties should share a commitment to outcomes that outlast any contract.

## The FSP Value Proposition

The case for FSP partnerships rests on three interrelated pillars: flexibility, cost efficiency, and risk mitigation.

Flexibility and scalability are the most immediate and tangible advantages. Clinical development is inherently nonlinear. A Phase II study may require a clinical monitoring team of a dozen clinical research associates (CRAs) at peak enrollment and significantly fewer as sites mature. A data management function operating at modest volume during early study build may face acute demand as the database lock approaches. Because FSP engagements are scoped at the functional level, resource adjustments can be made with precision rarely permitted by full-service contracts. Sponsors can select the right-sized monitoring teams, bring in additional statistical programming support ahead of a data cut, or

add site management capacity in response to a protocol amendment, all under the same contract. For organizations managing multiple programs at different development stages, the ability to share FSP resources across a portfolio, all with consistent talent, consistent processes, and compounding institutional knowledge, creates enterprise-level value that grows over time.

A strategically significant cost advantage is access to deep functional expertise, available precisely when needed. Maintaining a full-time senior biostatistician or a dedicated medical writing team is a meaningful investment that is difficult to justify for organizations running one or two studies at any given time. On the other hand, engaging an FSP partner to provide that expertise on a flexible basis, including senior-level access that would otherwise require permanent investment, delivers functional quality without the overhead. Engagement structures can also be tailored to organizational needs. For example, full-time equivalent-based models, unit-based contracts, and milestone-driven payment frameworks all allow sponsors and their finance teams to design cost structures that align with program risk profiles and planning cycles. Risk mitigation takes several forms under the FSP model ([Table 1](#)).

Table 1: Primary risk mitigation considerations

| Risk                 | Addressing & Mitigating                                                                                                                                                                                             |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operational/Capacity | The risk that a capacity gap at a critical moment will delay a milestone or compromise data quality is directly addressed by the model’s scalability and rapid access to qualified functional specialists           |
| Regulatory           | Addressed through the quality infrastructure that leading FSP providers maintain, which involves defined oversight mechanisms, audit-readiness protocols, and demonstrated adherence to ICH E6(R3) GCP requirements |
| Capability Gaps      | Particularly in specialized therapeutic areas or technical functions, this is addressed through the depth of experience that a well-resourced FSP network can provide                                               |

For biotechs building regulatory capabilities for the first time, or for sponsors entering a new indication area, access to subject matter experts with deep, relevant experience can be a meaningful differentiator in program quality and potentially impact trial success.

## When FSPs Work Best

The FSP model adds the most value when its core strengths (i.e., rapid adaptation, resource scalability, and specialized expertise) directly fit the sponsor's needs.

- **Pipeline expansion** is the clearest trigger. When sponsors add programs to a portfolio, be it through internal advancement, licensing, or acquisition, the FSP model allows functional resources to be deployed in alignment with actual program advancement rather than ahead of uncertain milestones. This may be relevant to smaller biotechs entering a new Phase II-III program. Support can be resourced through an FSP engagement that supplements the internal team, providing additional monitoring, data management, clinical operations, or safety support for the expanded portfolio. They can do this without committing to permanent headcount expansion, which allows them to scale up operations when the team might otherwise be small.
- **Geographic expansion and global programs** are particularly well-served by FSP partners with established global infrastructure. Building internal teams with the regional expertise, language capabilities, and site relationship networks needed to manage multi-regional clinical trials is a long-term undertaking. Regionally experienced FSP staff who understand local regulatory environments and have established site networks can meaningfully accelerate site activation and patient enrollment in markets.
- **Temporary, surge, and backfill needs** suit the FSP model. Whether triggered by an unexpected departure, protocol amendment requiring more monitoring, or a database lock needing data management support, FSP provides rapid access to qualified personnel who can quickly join existing teams and maintain momentum without the delays of formal hiring. In considering how to address these dynamic resource demands, it is important to recognize the wider variety of FSP options available.

## FSP Engagement Models

The FSP landscape is not monolithic; therefore, understanding the primary engagement models and the circumstances in which each works best is essential to structuring a partnership that fits both the program and the organization.



### Client-Managed Model

In a client-managed model, the sponsor maintains direct oversight and operational control while leveraging the FSP's ability to source, support, and retain qualified functional talent. FSP staff work within the sponsor's systems, follow the sponsor's SOPs, and report through the sponsor's management structure. This model is most appropriate for sponsors with robust internal clinical operations leadership and the management bandwidth to provide meaningful day-to-day oversight of embedded staff. Its primary advantages are maximum operational visibility, strong team cohesion between internal and external personnel, and maximum preservation of institutional knowledge within the sponsor organization.

### In Practice: Client-Managed Delivery on a Tight Timeline

A development-stage sponsor kept control of its own sites and brought in Worldwide Flex to resource data management and safety for an anti-nausea study. The team reused an electronic data capture (EDC) build from an earlier study with the same sponsor, mapped the differences between the two protocols, and moved from IRB approval to database lock in 119 days across more than 500 enrolled subjects. The sponsor held operational oversight while Flex supplied the functional depth to meet a four-month target.



## CRO-Managed Model

In a CRO-managed model, the FSP assumes management responsibility for the contracted function, providing functional staff, oversight infrastructure, quality management processes, and operational governance. The sponsor defines strategic objectives, while the FSP manages day-to-day execution. This model is designed to reduce the oversight burden on sponsor teams and is particularly well-suited for sponsors who are still building internal clinical operations management depth, or who are managing multiple programs simultaneously and cannot sustain direct oversight of each functional team across each program. A dedicated FSP account or program manager provides a clear accountability point and a structured mechanism for performance review and issue escalation.



## Hybrid Model

Hybrid models are among the most effective arrangements in practice. A sponsor might maintain direct management of clinical monitoring staff while engaging the FSP's management infrastructure for data management functions where internal oversight capacity is limited. Some benefit from the hybrid approach, where it is a natural expansion into full-service offerings, depending on the therapeutic and sponsor. The most effective FSP partners design their engagement models to support this kind of dynamic adaptation rather than locking sponsors into fixed structural frameworks.

Hybrid structures also accommodate natural evolution over time: a relationship that begins with a CRO-managed structure, while the sponsor builds internal management capability, can gradually transition toward a more client-managed arrangement as internal depth develops.

## The Hallmarks of a Strong FSP Partnership

Not all FSP relationships deliver equal value, and the differentiators that consistently distinguish high-performing partnerships from underperforming ones span four critical dimensions.



### Cultural Alignment

Cultural alignment and people investment are often underweighted during provider selection, even though they are among the strongest predictors of partnership quality. Providers that build beyond technical competence, adding communication skills and a collaborative, partnership-minded approach, place staff who integrate quickly with internal counterparts and take ownership of the work. The strongest providers treat culture as a deliberate design choice. They select people for cultural fit as carefully as for expertise, and they give embedded staff a safe environment to raise issues openly. Sponsors should weigh cultural indicators alongside capability and pay attention to how representatives engage during business development conversations: whether proposed team members can speak to the specific program context, and whether the provider shows active curiosity about the client's internal environment.



### Technology & Procedural Integration

Technology and process integration have direct operational consequences that are easy to underestimate. The client-managed FSP model works best when the FSP team works within the sponsor's systems. The key to this model is to work with an FSP provider that has teams with system-agnostic skills in EDC platforms, clinical trial management systems, safety databases, and document management tools, rather than defaulting to proprietary provider platforms. Working within client systems ensures that sponsors retain real-time access to their own program data, preserves the value of existing system investments, and eliminates the disruption of migrating data at engagement end. On the other hand, within a CRO-managed partnership, the sponsor's team need not worry about the CRO adopting their technology, as the selected CRO will have their operations optimized to step in and support in full. This can also lead to additional flexibility in scope and delivery, as your FSP team would have had exposure to other requests and needs in the past and may already have a setup in place.

In a client-managed partnership, process compatibility is critical. In these cases, FSP staff should be trained on sponsor SOPs and default to sponsor process standards, identifying gaps constructively as recommendations rather than unilaterally defaulting to provider processes. Real-time data transparency, which includes proactive issue escalation, regular operational reporting, and clear visibility into program signals as they develop, should be an explicit design element of the engagement.

### ✓ Quality Control & Compliance

Quality and compliance infrastructure is a foundational requirement, not a differentiating feature. FSP providers operate within the same ICH E6 GCP framework that governs sponsor activities, and the sponsor's ultimate regulatory accountability does not transfer to the FSP. This means the quality management infrastructure an FSP maintains, such as SOPs, training programs, audit-readiness protocols, and corrective and preventive action (CAPA) processes, is directly relevant to the sponsor's compliance posture.

Outsourcing doesn't reduce the sponsor's regulatory responsibility, so you must actively verify that your provider's quality systems are real, measurable, and consistently applied.

### ✓ Team Continuity

Team stability and knowledge continuity are particularly critical in long-term FSP engagements. Staff turnover within an embedded FSP team erodes institutional knowledge, disrupts sponsor relationships, and introduces quality inconsistencies, especially in functions like safety case processing, where consistent interpretive judgment across cases is a material compliance consideration. Sponsors should ask specifically about retention rates and understand the processes in place to manage staff transitions without disrupting program continuity.



Low turnover is a meaningful proxy for a provider's people investment and organizational health.

## Implementing & Measuring an FSP Partnership

Starting with a clear internal assessment is the essential prerequisite, including an assessment of where any issues or gaps may be and any solutions that can be designed to successfully address them. The purpose is to understand where capability gaps are structural rather than transient, where volume and complexity will exceed what internal teams can sustainably manage over the program horizon, and what realistic management bandwidth exists to oversee an embedded external team. A candid assessment of these dimensions, alongside budget parameters and program timeline, provides the foundation for a well-calibrated engagement that is neither under-resourced nor over-scoped.

The most important questions are not about a provider's service catalog, but whether the specific individuals proposed for a given engagement have the functional depth and therapeutic-area experience the program requires.

## In Practice: Stabilizing a Function Mid-Study

A biotech moved data management and biostatistics to Worldwide Flex after running into data quality and clean-up issues with an incumbent provider. On taking over, the team found the EDC database had no programmed edit checks and little prior cleaning. Flex assumed programming and administrative ownership of the platform, built and deployed the edit checks and manual review checks, and ran systematic data cleaning. Data quality improved and the program reached an interim database lock within the first year, with final lock activities on track.

Selecting the right partner deserves more rigor than it sometimes receives. Equally important selection criteria involve systems and process flexibility, with a demonstrated track record of deploying teams within client environments. There should be governance that includes flexibility to adapt models and offer the potential for a natural evolution of FSP over time, representing a true partnership to solve the client's issues.

Red flags worth noting include:

- Vague staffing proposals that omit specific individuals' names
- Reluctance to commit to working within client systems
- Limited transparency into quality metrics
- A business development approach that emphasizes breadth of capabilities over depth of expertise in the areas most relevant to the program at hand

Onboarding and integration are also highly important. Hurried or inadequately structured FSP resource onboarding creates integration problems that can compromise program quality and team cohesion for months. For vendor management, the resourcing manager and client partnership must be strong to successfully onboard these assets. Effective onboarding means defining communication protocols, ensuring system access and SOP training are complete before FSP staff are expected to operate at full effectiveness, and establishing success metrics — specific, measurable indicators of what strong performance looks like — at the outset. The initial investment in thorough integration pays off over the engagement in the form of faster performance ramp, stronger team cohesion, and fewer mid-engagement disruptions.

Measuring performance and evolving the relationship are the final elements of a well-managed FSP

engagement. A meaningful performance framework tracks quality metrics (e.g., data error rates, protocol deviation rates, and timely report submission rates), adherence to agreed-upon timelines, cost efficiency relative to the contracted scope, and staff and client satisfaction as leading indicators of engagement health. Beyond operational metrics, the most strategically valuable FSP partnerships demonstrate long-term benefits that extend from these measures. The strategic flexibility gained, the risk reduction due to consistent quality and team continuity, and the capability development that occurs when sponsor teams work alongside deeply experienced external specialists across multiple programs are all direct results of strong performance on key metrics. Organizations that approach FSP relationships as knowledge partnerships consistently find that their internal clinical development capabilities grow stronger as a direct result.

## Building for an Adaptive Future

The best-positioned organizations to meet the demands of clinical development will be those whose operating models are genuinely adaptive, capable of accessing the right expertise at the right time, scaling in response to program realities, and building external partnerships that compound in value across programs, phases, and the inevitable uncertainties.

The FSP model, when implemented thoughtfully, is a powerful instrument available for building adaptive capacity. It is not a compromise between internal execution and full outsourcing, but rather a sophisticated approach that combines the strategic accountability of an internally led program with the specialized depth, scalability, and partnership orientation that only a truly invested external partner can provide. For sponsors and biotechs building for the long term, understanding how to structure and manage FSP partnerships effectively is a strategic capability.

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