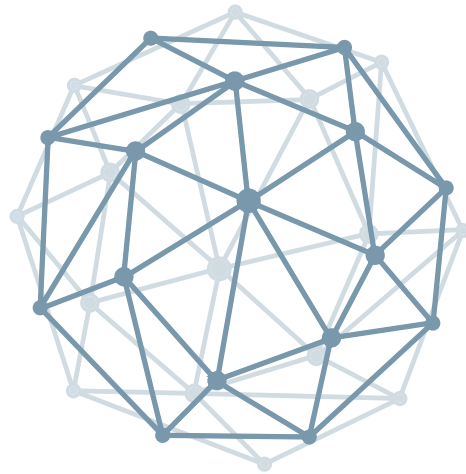




Formerly FMD K&L

WHITEPAPER

Tailored Functional Service Provider Models Fill Critical Gaps and Enhance Workflows



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1 What is a Functional Service Provider (FSP) Model?

Biopharmaceutical companies have a constant need for specific functional services, such as clinical data services, that often pose significant challenges due to dramatically fluctuating workloads, costs, and risks. An FSP model enables drug makers to efficiently respond to market needs and rapidly change course while maintaining a consistent pool of highly qualified professionals that can easily scale to meet a client's exact needs at any time, for as long as necessary.

An FSP model can be extraordinarily flexible, removing the burden of employment and many day-to-day management requirements while enhancing overall strategic control and direct integration within your business functions. Companies have the flexibility to choose the service they intend to outsource, and this choice can be based on financial components, lack of internal technical expertise, and other needs within the organization. Additionally, companies can quickly pivot within an FSP model as needs change, which often happens during pipeline development.

With an FSP model, companies need not have their existing technical teams concentrate on only one activity, which would take away their involvement from other core business activities. Rather, the FSP can address this work through their technical team, while the biopharmaceutical companies still retain control of the data and output.

In this whitepaper, we examine the characteristics of various FSP models and how they help bring new therapies to market faster and cost-effectively.

2 Functional Service Provider Characteristics

The primary purpose of an FSP model is to utilize outsourcing as a means to manage resources and capacity in what can be a highly fluid environment. The costs of maintaining staff can be significant, and an FSP allows for more effective and cost-efficient management of resources. In addition to effective resource management, an FSP can be tailored, allowing a sponsor to retain any amount of control they desire through the use of their own processes and systems, ensuring consistency across resources, and mitigating risks typically associated with disruption.



This highly collaborative partnership offers robust flexibility, where the FSP can deliver completely customized solutions to each client. It is a scalable model according to changing resource requirements. Clients may resource departments or individuals in real-time without needing lengthy hiring processes with the added risk of jeopardizing project timelines. Characteristics of a successful FSP model may include:

- Provides a single functional service to a sponsor, often across multiple programs, to maximize resource utilization and efficiencies
- Enables long-term relationships that develop greater efficiencies over time
- CRO works according to sponsor SOPs and systems if requested
- Flexibility to make the impossible possible
- Risk mitigation of employee turnover and business continuity are managed by FSP, including managing the additional hiring and training cost
- FSP can help companies to expand their footprint in new countries/regions by offering to carry out the services in low-cost centers without compromising quality
- Possibility for the companies to convert their fixed cost into variable cost, amounting to good operational savings

3 Choosing the Right FSP Model

While FSP approaches have common characteristics, they can be tailored to meet individual client requirements. Whether a short- or long-term contract, staff augmentation model, managed staffing model, full outsourcing model, or any combination of these strategies, ClinChoice tailors FSP models to suit your unique requirements and fill operational gaps in areas such as biometrics, pharmacovigilance, regulatory operations, project management, and site monitoring functional services. Our FSP models drive additional benefits over time by fostering long-term relationships through shared process building, expertise, and trust. Flexible, long-term FSP models offer the frameworks for innovation and continuous process improvement to reduce research costs and timelines for important therapies.

When considering whether to deploy a specific FSP model or a hybrid of multiple, there are several questions to consider when identifying the best model:

- What are the business needs and the scope?
- What is the anticipated volume and length of needed resource?
- What level of control of deliverables do you wish to maintain?
- What level of expertise is already available in-house?



- What is the capacity of in-house resources to manage contracted resources?
- What is the overall corporate vision for the resourcing of the particular function?

Staff Augmentation Model

With the staff augmentation model, ClinChoice provides immediate resources to clients globally. Our experts become an extension of your team, working to your processes and environment.

- Immediate staffing support provided by individuals with the necessary skills or experiences.
- Staffing support can be located either remote or on site at client location, dependent on client and complexity of required support.
- Dedicated FTEs working as part of the client's team.
- Utilization of sponsor processes and systems.
- Sponsor retains control of all deliverables and work assignments.
- Provides the opportunity to leverage specific CRO expertise in response to changing dynamics via consultancy design.
- Cost-effective for high-level scope change requirements.

For example, many biopharma companies choose to develop in-house biometrics capabilities but still require cost-effective support and experienced personnel to integrate immediately into their team. Through the use of a staff augmentation model, ClinChoice fully aligns with a client's procedures and may even provide staff for on-site work. Our experts fill in any gaps as a seamless extension of your own team.

Managed Staffing Model

The managed staffing model provides skilled staff and experienced management who offer functional oversight that enhances study development while working within the sponsor's system and processes. Managed staffing models are most often deployed into functional areas to better support larger volumes, such as clinical monitoring, data management, programming, etc.

- CRO provides experienced line managers provide functional, unit-based oversight.
- Client retains overall oversight, leadership, and control of all deliverables.
- Renewable resourcing capabilities.

For example, when a client needs biometrics professionals to handle their clinical trial programs, ClinChoice's managed staffing model provides them with the experts they need for a contracted length of time. Headcounts are calculated based on the work scope and approved by clients. Beyond that, the day-to-day functions of these specialists can either be in the client's hands or managed by ClinChoice, depending on the need. Salary payments, benefits, employment status, and performance management are all conveniently and cost-effectively handled by ClinChoice, freeing up additional client resources.



System requirements, SOP requirements, and training requirements can all be tailored to the client's needs with the same result of timely, quality deliverables.

Full Outsourcing Model

In clinical development, the Outsourcing Model gives biopharmaceutical companies the flexibility to contract out full or partial aspects of a specific function or functions to ClinChoice. The Full Outsourcing Model is a single-source solution for managing functional needs through a dedicated partnership.

- Versatile resource allocation.
- Expertise in project delivery.
- Optimal, cost-effective workflows.
- Can utilize CRO systems, technology, and processes for clients who require them.
- Sponsor systems and/or processes may be used.
- Allows for realization of geographic efficiency of scale for smaller clients.
- CRO ensures team members are fully trained and proficient.
- CRO assumes more risk.

A Full Outsourcing Model can range from one or two employees to teams of 50 or 100+. These partnerships can be contracted on an FTE level, a deliverable (unitized) level, or a combination of both. In these partnerships, the CRO takes responsibility for delivering individual projects on time and budget.

Hybrid FSP Model

ClinChoice's Hybrid Model allows for any combination of models to meet the client's needs. It offers the flexibility and agility to deliver on project goals when you need additional support as part of an ongoing service.

- Leverage, flexibility, and agility to deliver on project goals.
- Provide resources across a program as required.
- Access to ClinChoice SOPs and global SMEs.

Wherever there is a resource shortage for a particular expertise or skill set, and you need immediate implementation for any budget, ClinChoice provides the right talent to cater precisely to the business needs. It is an easily scalable solution that offers significant cost savings in hiring, processing salary, benefits, and other employee needs.



4 Key Outcomes of ClinChoice FSP Models

- Continuously develop new efficiencies in all biometrics functions and sharing
- Efficient ramp-up with exceptional talent mapping capabilities
- Increased control and oversight over deliverables
- Increased control over recruiting costs
- Increased quality assurance
- Reduced sponsor oversight over contractors and other resources
- Reduced risk of underutilization
- Reduced administrative burdens
- Cost-effective contract rates
- Measurable quality and speed improvements
- Access to CRO insights and recommendations

An FSP is what you make it. It can provide one specific function for a specific amount of time or continue to evolve to meet your strategic direction. FSPs let you keep as much control over resources as you need or want. ClinChoice delivers quality staff who offer exceptional technical skills, work ethic, and a drive to succeed. With the right FSP, you get a consistent, fully integrated resource that understands your SOPs and systems and is committed to appreciating your company culture, vision, and values.

ClinChoice's Proven Formula for Success



**RECORD OF
QUALITY**



**FLEXIBLE
APPROACH**



**DEDICATED
PEOPLE**



**FAST
TIMELINES**



**BROAD TA
EXPERTISE**



**Discuss FSP models
with us today.**

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About ClinChoice Inc

ClinChoice, formerly FMD K&L, is a global clinical stage Contract Research Organization (CRO), with over 2000 clinical research professionals in seven different countries across North America, Asia, and Europe. ClinChoice has been a leading provider of contract research services offering high-quality solutions to pharmaceutical, biotechnology, medical device and consumer products customers for the past 25 years, working across a wide array of service functions and therapeutic areas. Under its new brand, ClinChoice continues to offer high-quality, full-service clinical development and commercial solutions to pharmaceutical, biotechnology, medical device, and consumer product companies globally. For our partners, it means a reliable partner and quality results.