

Customized FSP Models to Improve Processes and Promote Clinical Outcomes



Introduction

In the complex and risk-laden landscape of clinical trials, Functional Service Provider (FSP) models have emerged as a compelling strategy for life sciences companies. This white paper delves into the role and significance of FSP models in clinical research and development, with a particular emphasis on their customization to meet the unique demands of individual projects.

FSP models offer a potent solution to the challenges posed by fluctuating demand, providing efficiency and expertise while mitigating associated risks. Specific services within the scope of a clinical trial project or program, such as data management, biostatistics, or medical writing, are particularly well-suited to FSP outsourcing.

This white paper aims to provide a comprehensive exploration of customized FSP models, highlighting their potential to enhance operational efficiency, improve processes, and drive positive clinical outcomes. The focus is on how these models, when tailored to the specific needs of a project, can act as a flexible and scalable approach to resource management.

The document also underscores the importance of the scale of a portfolio of work in determining the suitability of an FSP partnership. It is noted that FSP models typically yield greater cost and efficiency gains with scale, making them less ideal for single outsourced projects. However, many life sciences companies leverage FSPs to access specific expertise in a therapeutic area, indication, or functional specialty, such as clinical trial management or medical writing.

The objectives of this white paper are to provide insights into when to use FSP models to gain access to expertise in functional areas, reduce fixed operational costs, quickly scale up by accessing FSP talent and resources, reduce employment- and cost-related risks, save time and resources related to clinical trial management, and retain control over your study.

By the end of this white paper, readers should have a well-rounded understanding of customized FSP models and be equipped with the knowledge to effectively leverage their potential in their own clinical research endeavors.



Background

Functional Service Provider (FSP) models represent a strategic approach to outsourcing in the discipline of clinical research and development. These models involve the delegation of well-defined services within the scope of a clinical trial project or program to an external provider. Such services often include, but are not limited to, data management, biostatistics, and medical writing. For example, a pharmaceutical company may choose to outsource their data management services to an FSP. This external provider would handle tasks such as collecting, organizing, and analyzing the clinical trial data, ensuring accuracy and compliance with regulatory standards. Additionally, the FSP may also offer biostatistics services, conducting statistical analyses of the data to determine the effectiveness and safety of the drug being tested.

The genesis of FSP models can be traced back to the growing complexity and risk associated with clinical trials. As the demands of these trials began to fluctuate and escalate, life sciences companies sought ways to mitigate risk while enhancing efficiency and expertise. This led to the emergence of FSP models as a viable alternative to full-service strategic models, offering a means to reduce the dangers associated with fluctuating demand.

Over time, FSP models have evolved and matured, adapting to the changing landscape of clinical research. They have grown in popularity and are now considered both a component of strategic partnership arrangements and a standalone option for outsourcing. The demand for greater control and oversight, a high degree of resourcing flexibility and efficiency, and a less expensive solution have all driven the evolution of FSP models.

In the current context, FSP models are being leveraged to access specific expertise in a therapeutic area, indication, or functional specialty. They are typically utilized when the scale of a portfolio of work is substantial, as cost and efficiency gains are greater with scale. The trend is towards customization of FSP models to meet the unique needs of individual projects, offering a flexible and scalable approach to resource management.

The ongoing developments in FSP models reflect the dynamic nature of the clinical research industry. As we move forward, it is anticipated that these models will continue to evolve and adapt, playing an increasingly vital role in the successful execution of clinical trials and research.



The Rising Trend of Functional Service Provider Utilization

Evolving Trends in FSP Utilization

As we explore the evolving landscape of clinical research, it becomes evident that the industry is experiencing a significant shift in its approach to outsourcing. Not too long ago, full-service outsourcing models dominated the arena. However, recent years have seen an appreciable pivot towards Functional Service Provider (FSP) models. In 2018, FSPs were utilized by a mere 28% of sponsors, but fast forward to 2023, and this figure has doubled, reaching a noteworthy 53%. As the clinical research landscape becomes progressively complex and demanding, it is reasonable to anticipate a continued preference for FSP models in the years to come.

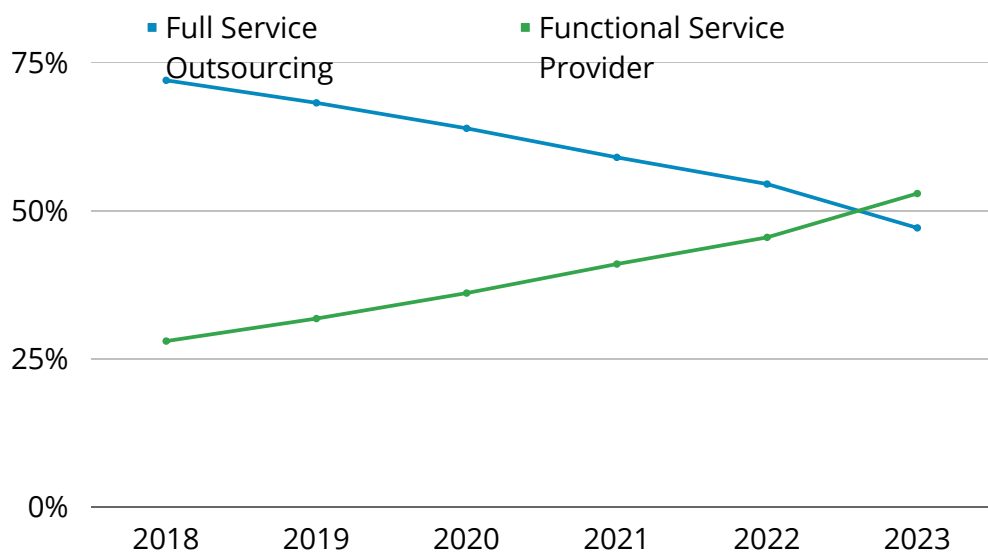
The Reasons Behind the Shift

Unpacking the reasons behind this shift, it's clear that multiple factors are driving sponsors to transition from traditional full-service outsourcing to FSP models. The "Top Reasons for Selecting Changing an Outsourcing Model" graph illuminates these key drivers. Cost savings is a prominent motivator. FSP models often allow sponsors to leverage specific expertise without the overhead costs of a full-service model. Additionally, FSP models provide the flexibility to scale services to meet the fluctuating demands of clinical trials. These compelling advantages have played a pivotal role in enticing sponsors to adopt FSP models.

FSP Across Various Functions

As we delve deeper into the utilization of FSP models, a fascinating pattern emerges across different functional areas within clinical research. The "Breakdown of Outsourcing by Function" chart reveals how services such as Clinical Operations, Data Management, and Biostatistics are increasingly being outsourced under the FSP model. The reason behind this trend can be attributed to the specialized expertise FSPs bring to these areas, resulting in more efficient and accurate outcomes.

Shift Trends of Sponsors from Full-Service Outsourcing to FSP Outsourcing



The line chart highlights the industry's shift from Full-Service Outsourcing (FSO) to Functional Service Provider (FSP) models from 2018 to 2023. Beginning with a 28% adoption in 2018, FSP usage has grown consistently to 41% in 2021 and is projected to reach 45.5% in 2022 and 52.89% in 2023. This rise, with a CAGR of approximately 13.56%, underlines the industry's preference for the flexible solutions offered by FSP models.

The Future of FSP Models

Looking ahead, we anticipate that the functional and economic advantages of FSP models will make them the go-to choice for sponsors. As the industry continues to evolve, so too will the FSP model. We can expect further innovations and improvements to meet the evolving needs of the clinical research industry. The dynamism of FSP models is a testament to their adaptability and their future role in the successful execution of clinical trials and research.

This shift towards FSP models is a clear indicator of a wider transformation in the clinical research industry. As we continue to navigate this evolving landscape, these insights underscore the importance of flexibility, expertise, and strategic resource management in delivering successful clinical outcomes.

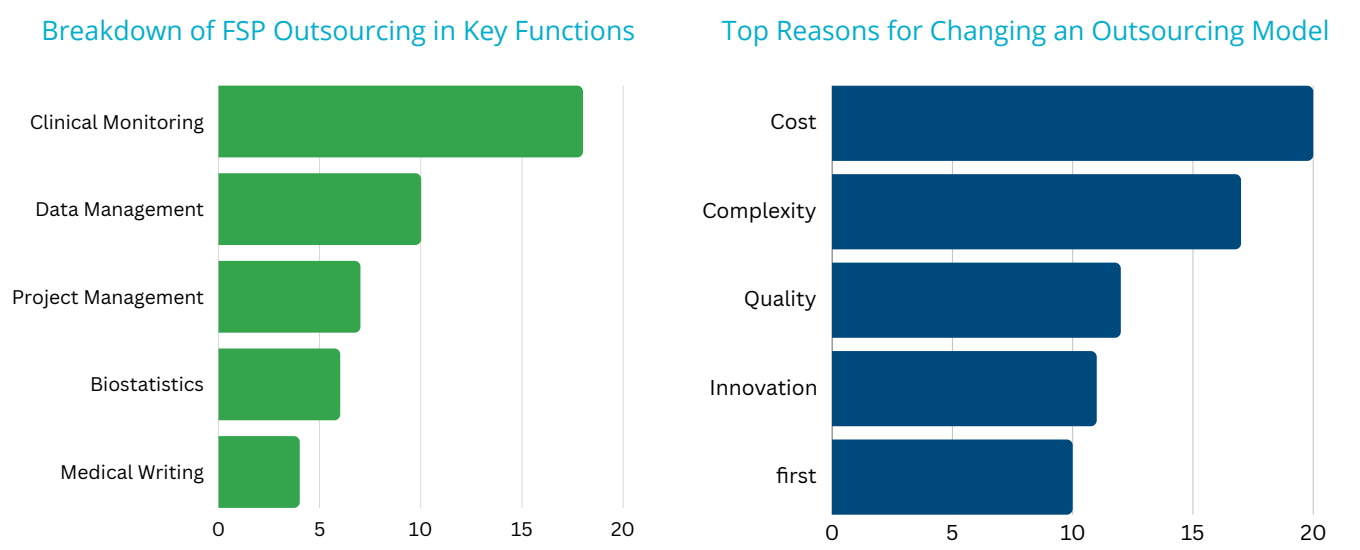
The increasing adoption of FSP models is a testament to their effectiveness and efficiency. As we move forward, these models will undoubtedly continue to play a significant role in the successful execution of clinical trials and research, driving progress in the clinical research industry.

The genesis of FSP models can be traced back to the growing complexity and risk associated with clinical trials. As the demands of these trials began to fluctuate and escalate, life sciences companies sought ways to mitigate risk while enhancing efficiency and expertise. This led to the emergence of FSP models as a viable alternative to full-service strategic models, offering a means to reduce the dangers associated with fluctuating demand.

Over time, FSP models have evolved and matured, adapting to the changing landscape of clinical research. They have grown in popularity and are now considered both a component of strategic partnership arrangements and a standalone option for outsourcing. The demand for greater control and oversight, a high degree of resourcing flexibility and efficiency, and a less expensive solution have all driven the evolution of FSP models.

In the current context, FSP models are being leveraged to access specific expertise in a therapeutic area, indication, or functional specialty. They are typically utilized when the scale of a portfolio of work is substantial, as cost and efficiency gains are greater with scale. The trend is towards customization of FSP models to meet the unique needs of individual projects, offering a flexible and scalable approach to resource management.

The ongoing developments in FSP models reflect the dynamic nature of the clinical research industry. As we move forward, it is anticipated that these models will continue to evolve and adapt, playing an increasingly vital role in the successful execution of clinical trials and research.



The Need for Customization in FSP Models

Clinical trials are inherently complex and multifaceted, presenting a diverse array of challenges that can vary significantly from one project to another. These challenges can range from fluctuating demand and resource limitations to regulatory compliance and data management issues. Each trial sponsor encounters a unique set of hurdles, any of which could potentially derail the successful development of new medical products.

In this context, customization in FSP models emerges as a critical factor in effectively addressing these challenges. Customization allows for the creation of an FSP model that is tailor-made to the specific needs and objectives of a project. This includes the ability to scale resources rapidly, adapt to changing project needs, and leverage specific expertise in a therapeutic area, indication, or functional specialty.

To illustrate the need for customization, consider the case of a global pharmaceutical company that was struggling with the management of a large-scale, multi-regional clinical trial. The company was facing significant challenges in terms of resource allocation, data management, and regulatory compliance across different regions. By partnering with an FSP provider that offered a customized solution, the company was able to effectively address these challenges. The FSP provider developed a model that provided the necessary resources and expertise in each region, implemented a robust data management system, and ensured compliance with regional regulatory requirements. As a result, the company was able to successfully conduct the trial and bring the new medical product to market.

This example underscores the importance of customization in FSP models. By tailoring the model to the specific needs and challenges of a project, life sciences companies can enhance efficiency, mitigate risks, and ultimately drive positive clinical outcomes. As the landscape of clinical research continues to evolve, the need for customization in FSP models is likely to become increasingly critical.



Benefits of Working in an FSP model

1. Flexibility and Scalability: The FSP model offers the flexibility to scale resources up or down based on the needs of the project. This flexibility is particularly beneficial in the dynamic environment of clinical trials, where project needs can change rapidly. This increased resource flexibility allows organizations to manage their resources more efficiently and effectively.

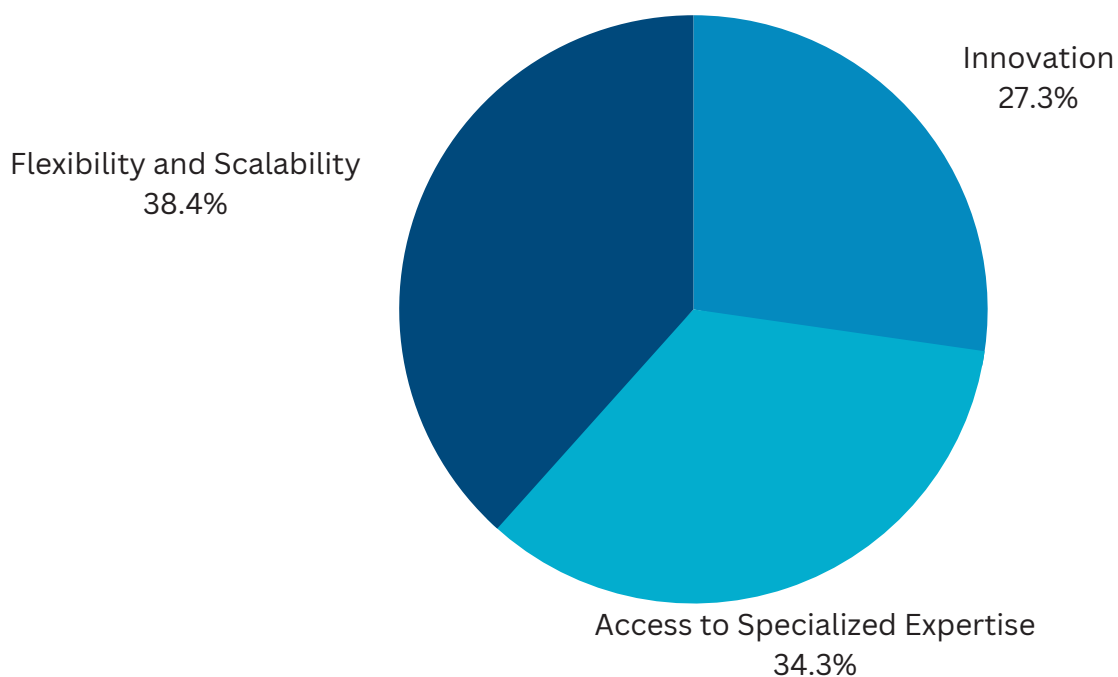
2. Access to Specialized Expertise: FSP models provide access to a pool of specialized talent and expertise that may not be available in-house. This includes professionals with expertise in areas such as biostatistics, data management, and clinical trial management. By leveraging the expertise of an FSP, organizations can ensure that each function is being handled by experts in the field.

3. Innovation: FSPs often have access to advanced technologies that may not be available within the sponsor organization. These technologies can enhance the efficiency and effectiveness of clinical trials, improving data quality and facilitating faster decision-making. By working with an FSP, organizations can stay at the forefront of technological innovation in clinical trials.

4. Operational Efficiency: By outsourcing specific functions to an FSP, organizations can focus their resources and efforts on their core competencies. This can lead to more efficient clinical development activities, as resources are not spread thin across multiple areas. Instead, each function can receive the focused attention it requires.

5. Vendor Management Optimization: Working with an FSP can also lead to vendor consolidation, minimizing the number of vendor relationships that an organization needs to maintain. By working with a single FSP that can provide a range of services, organizations can simplify their vendor management processes, saving time and resources. This streamlined approach can also improve communication and coordination among different functions.

Top Three Benefits of Working in an FSP Model



Customized FSP Models: A Comprehensive Exploration

Customization in Functional Service Provider (FSP) models is a multifaceted process that involves tailoring various aspects of the model to meet the specific needs and objectives of a clinical trial project or program. Here, we provide a detailed examination of different types of customized FSP models:

FSP Talent Augmentation:

This approach involves supplementing the sponsor's existing team with skilled professionals from the FSP.

- **Strengths:** Offers a quick and flexible solution to resource limitations, enabling the rapid scaling of resources as needed, and allows for seamless integration with the existing team.
- **Benefits:** Provides immediate access to expertise, enables flexible scaling of resources to meet project demands, and serves as a cost-effective solution for short-term needs.

Dedicated FSP Staffing Services:

In this model, the FSP provides a dedicated team to handle specific functions or services within the clinical trial project.

- **Strengths:** Provides a consistent team dedicated to the project, reduces management workload, and allows for greater control and oversight.
- **Benefits:** Ensures consistent access to expertise, minimizes management workload, and amplifies project supervision.

FSP Partnership Solutions:

This approach involves a comprehensive outsourcing of clinical development functions to the FSP.

- **Strengths:** Offers a flexible approach to managing functional requirements,

allows for cost and efficiency gains with scale, and fosters a collaborative relationship with the FSP.

- **Benefits:** Provides a flexible approach to managing a majority or all functional requirements in a steadfast partnership, boosts productivity and efficiency.

Innovative FSP Services:

This model involves the use of cutting-edge technology and innovative methodologies to enhance the efficiency and effectiveness of clinical development.

- **Strengths:** Provides access to the latest technology and methodologies, can accelerate execution and decision-making, and promotes productivity and efficiency.
- **Benefits:** Provides access to skilled staff in biostatistics, programming, and data management, complemented by cutting-edge technology and infrastructure.

Tailored FSP Services:

This approach involves a mix of the above models, providing a custom-made solution that meets the unique needs of the sponsor.

- **Strengths:** Provides a flexible and efficient solution that fully supports project goals, allows for on-demand resources in key functions, and maximizes cost efficiencies.
- **Benefits:** Provides a custom-made solution, providing a carefully selected mix of FSP services to meet your unique needs, fully harnessing our expertise across a diverse range of clinical studies.

Each of these models offers unique strengths and benefits, and the choice of model will depend on the specific needs and objectives of the sponsor. By understanding these different types of customized FSP models, and the unique strengths and benefits they offer, sponsors can make informed decisions that best align with their project demands. This understanding enables sponsors to leverage the strengths of the chosen model and maximize the benefits, thereby enhancing the efficiency and success of their clinical trials.

Impact of Customized FSP Models on Clinical Outcomes

The FSP models, which can be tailored to the specific needs of each trial, provide a powerful response to this increasing complexity. They may lead to better clinical outcomes by increasing productivity and streamlining processes. This section looks into the major impacts of these models.

Process Improvement:

FSP models have emerged as a viable solution to improve operational efficiency in the challenging environment of clinical trials, tailored. These models allow for better resource management and greater collaboration between trial sites by adapting to the specific needs of each study. This level of customization, akin to the arms and legs of the sponsor organization, allows for a high degree of resourcing flexibility and efficiency, thereby reducing the risks associated with fluctuating demand.

Promotion of Positive Clinical Outcomes:

Customized FSP models, by virtue of their design, can dramatically improve the quality of clinical trials. They achieve this by reducing selection bias, ensuring a representative set of patients, and enhancing data quality and integrity. As a result, sponsors retain control over their study while gaining access to expertise in functional areas, leading to more reliable trial results and successful clinical outcomes.

Cost-Effectiveness:

When it comes to the cost of conducting clinical trials, a tailored FSP model can make a huge difference. These models allow for

more accurate budgeting and forecasting of trial costs, helping sponsors and stakeholders make informed decisions. By providing a flexible and scalable approach to resource management, these models can lead to substantial cost savings. Effective resource management, lowering of fixed operational costs, and rapid scalability in response to changing project demands all contribute to this goal.

Regulatory Compliance:

Clinical trial regulations can be difficult to understand and implement. These regulations are often complex and can vary across different countries and regions. Moreover, staying updated with the evolving regulatory landscape adds another layer of complexity for researchers and organizations involved in clinical trials. Customized FSP models can significantly ease this burden by providing access to regulatory experts and robust compliance systems. This can lead to improved compliance with local and international regulations, reduced risk of non-compliance, and ultimately, smoother and faster regulatory approvals for clinical trials.

Time Efficiency:

Clinical trials rely heavily on timely procedures. Delays in any part of the trial process can have significant consequences, such as compromising the validity of the results or hindering the development of potential life-saving treatments. Therefore, efficient coordination and adherence to strict timelines are crucial for successful clinical trials. Customized FSP models can significantly improve time efficiency in clinical trials. By providing access to expert resources and implementing streamlined processes, these models can reduce cycle times, accelerate decision-making, and ultimately, bring products to market more quickly. This can provide a significant competitive advantage in the fast-paced world of clinical research.

Key Considerations for Evaluating FSP Outsourcing Models

The decision to adopt an FSP outsourcing model is not one to be taken lightly. Several key considerations must be taken into account to ensure the chosen model aligns with the organization's unique needs and objectives.

FSP Model Structure and Experience:

Organizations must assess their familiarity with the FSP model structure, before setting out on an FSP journey. Does your team have prior experience working within this framework? If not, it may be beneficial to seek consultative support to develop a model that is tailored to your specific needs.

Outsourcing Objectives:

The reasons for considering an FSP model can vary greatly. Whether you're looking to outsource a new function, consolidate vendors, expand geographically, accommodate demand for additional resources, or seek a more cost-effective solution, it's crucial to clearly define these objectives. Additionally, identifying any expertise gaps within your organization can help determine which functions would benefit most from outsourcing.

Volume and Cadence of Work:

The anticipated workload is another critical factor. An accurate estimate of the volume and cadence of work can help determine the scale of resources needed and inform the choice of FSP model.

Systems and Processes:

Organizations often have preferred systems and processes in place. When considering an FSP model, it's important to assess whether you're open to using the provider's systems and processes or if you prefer to

stick to your own. This can significantly impact the integration process and the overall success of the outsourcing endeavor.

Oversight Expectations:

Finally, the level of oversight you wish to retain and expect from providers is a crucial consideration. Clear communication about expectations can help ensure a successful partnership and prevent potential misunderstandings down the line.

By carefully considering these factors, organizations can make informed decisions about adopting an FSP outsourcing model, ensuring it aligns with their strategic goals and operational needs. This thoughtful approach can pave the way for a successful partnership, driving efficiency and positive clinical outcomes.



Maxis Clinical Sciences' Approach to Customized FSP Models

Successfully handling the challenging landscape of clinical trials calls for a collaborator who not only has a deep knowledge of the industry but also the flexibility to adapt their services to meet specific requirements. This is because clinical trials are complex and constantly evolving, requiring a collaborator who can navigate regulatory changes and incorporate new technologies or methodologies. Additionally, having a collaborator with a strong network of industry connections can provide access to specialized expertise and resources that may be needed throughout the trial process. Maxis Clinical Sciences, with its robust Functional Service Provider (FSP) solutions, stands at the forefront of this domain, offering a blend of expertise, technology, and unparalleled efficiency.

Maxis Clinical Sciences holds the view that each clinical trial sponsor faces a unique set of challenges, requiring a nuanced understanding of the impediments obstructing optimal efficiency. Our approach to FSP is rooted in this understanding. We construct an FSP model tailor-made for the sponsor's needs, synergistically blending essential elements into a cohesive, optimized strategy. This approach allows us to meet our clients at their point of need and customize solutions specifically tailored to their unique requirements.

Our FSP solutions are not a one-size-fits-all offering. Instead, they are meticulously designed to correlate with your distinct clinical research objectives. We offer comprehensive clinical development support with access to our skilled workforce and world-class services in:

- Data Management
- Statistical Programming
- Biostatistics
- Centralized Monitoring
- Medical Writing

Whether you need expert guidance within your team or are seeking to outsource more complex responsibilities, we are here to design the perfect model for your needs.

Our track record speaks volumes about our commitment to excellence in FSP. With over 20 years of FSP partnerships, a dedicated team of over 300 global talents, and successful support for over 3,000 clinical trials, we have proven our ability to deliver. Our purpose-fit FSP teams across the US, Europe, and India have demonstrated a 30% cost reduction for our clients, further underscoring our commitment to efficiency and value.

At Maxis Clinical Sciences, we extend beyond the role of just a service provider; we want to be a key partner in achieving your goals. Our adaptable, committed workforce is prepared to engage with your project, ensuring trial management remains on course and achieves its objectives. The pioneering advancements in technology and analytics within our FSP models enable key tasks and activities to be completed centrally, effectively allocating resources to streamline your journey.

Think of Maxis Clinical Sciences as your trustworthy guide, always ready to help you spot and overcome the obstacles that could jeopardize the success of your project. Maxis Clinical Sciences will help you maximize the effectiveness of your organizational functions and resource allocations.

“With so much happening in the industry, it's the opportune moment for sponsors to rethink their traditional roles and consider more adaptable, efficient, and specialized options like FSP. By adopting a long-term approach to FSP outsourcing, we help sponsors effectively deal with the complexities of clinical research, set a shared course for success, and maximize the value of our partnership.”

CEO - Maxis Clinical Sciences

There is a pressing need for innovative and thoughtful solutions in the ever-changing landscape of clinical research. We at Maxis Clinical Sciences are mindful of this evolution and have tailored our FSP services to fit the industry's shifting needs.

There was a time when a one-size-fits-all approach was the norm in clinical research. However, those days are behind us. Today, the ability to adapt and customize services as per individual project requirements is the key to success.

With this understanding, we've refined our service offering, focusing on Functional Service Provider (FSP) models that provide flexible resources and specialized expertise. As our partnerships with sponsors grow stronger, our dedicated FSP teams contribute more than just their functional expertise.

By adopting a long-term approach to FSP outsourcing, we help sponsors navigate the complexities of clinical research, set a shared course for success, and maximize the value of our partnership.



510 Thornall Street, Suite 180 Edison, NJ 08837
T+1 (732) 889-2444
www.maxisclinical.com
info@maxisclinical.com