

Beat the Clock: How an FSP Model Can Optimize a Follow-the-Sun Approach in Clinical Development Functions

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As the race to bring promising new treatments to market intensifies and the complexity, size, and sophistication of clinical trials grows exponentially,¹ pressure is mounting to deliver on ever-more challenging timelines. One powerful solution gaining popularity is the adoption of a follow-the-sun (FTS) model delivered in a flexible functional service provider (FSP) outsourcing model.

FTS solutions strategically leverage global teams and time zone differences to maximize productivity and minimize bottlenecks. The advantages are compelling; however, their implementation requires flexibility, deep functional capabilities, and operational excellence. This is where the FSP model shines, offering an approach to outsource clinical development functions and post-marketing surveillance built on an adaptable global resource allocation framework.

Because FSP models offer a host of advantages, including flexibility, a depth and breadth of functional capabilities, global reach, and the ability to deliver on aggressive timelines, organizations are increasingly turning to FSP partners to outsource specific functions

of clinical trials (e.g., clinical operations, pharmacovigilance, data management, biometrics, centralized monitoring, etc.). The result has been substantial growth. A 2023 survey of biopharma and biotech leaders revealed an increase in FSP outsourcing over the past two years with 41% of respondents reporting greater use of FSP models compared to the full-service outsourcing (FSO) model's 29% growth.² The survey also found that a mix of hybrid FSP/FSO models has become more common with FSP or hybrid FSP/FSO arrangements being used by 87% of drug developers. FSP partnerships are projected to continue growing at a compound annual growth rate of more than 8.5% from 2024 to 2029.³

Follow-the-Sun Solution: Potential Benefits for Drug Developers

An FTS approach leverages around-the-clock productivity by using global teams strategically located across different time zones. In this model, as the sun rises and sets in different geographies, tasks are

handed off between teams, ensuring a continuous flow of work, resulting in increased productivity.

FTS strategies can be applied in a variety of ways to improve productivity. They may be used to hand off tasks between synchronized teams performing the same function. As an example, when a pharmacovigilance (PV) team located in Asia completes their workday, they can pass the baton to their European counterparts, followed by a North American team, thereby achieving 24-hour productivity in a single day to expedite critical tasks, ensure compliance and keep projects on or ahead of schedule to drive project success.

The FTS model also can be strategically applied between different functional teams to hand off data to minimize bottlenecks. For example, data collected from one region can be analyzed in real time by cross-functional clinical data management teams operating in another time zone, facilitating rapid decision-making and enhancing overall operational efficiency. Or, as another example, if a client based on the East Coast of the United States reviews a document and submits comments at the end of the business day, a medical writer based in Asia-Pacific can triage and incorporate those comments to progress the document before the client is online the following morning.

FTS models have long been successfully used in other sectors, especially among technology organizations, to deliver uninterrupted access to customer-facing functions. In the context of clinical development functions, FTS models can be used to provide prompt responsiveness to patient or sponsor questions, technical issues, and urgent needs.

Additionally, by distributing workloads across teams providing the same functions in different time zones, FTS models reduce the burdens on individual teams, promoting a healthier work-life balance, and ultimately enhancing employee engagement and retention. The distributed nature of the model also provides built-in risk management, as disruptions in a single location can be mitigated by other sites continuing their operations to ensure uninterrupted progress and maintain business continuity.

Furthermore, the model optimizes resource allocation. In a talent market where demand far outstrips supply, strategically locating various functions in different regions also can offer new access to skilled clinical development professionals in different labor markets. By strategically allocating teams—either between split-shift functional teams handing off tasks at the end of the day or cross-functional teams handing off data—drug developers can tap into both higher-cost and lower-cost labor markets to find the right talent and ensure quality output.

Why Use an FSP Model for an FTS Approach?

FSP partnerships are designed to offer a breadth and depth of functional capabilities and teams around the globe, making it

the optimal outsourcing model to extract the full potential of FTS solutions. In addition, staff sourced from an FSP partner's internal talent pool already are vetted and trained, they can be mobilized quickly to fill staffing and service gaps. FSP partners with a large internal talent pool spanning many different functional areas and the globe—including emerging markets—are especially well positioned to rapidly deploy swaths of qualified employees to support FTS engagements when and where they are needed. This adaptability and global reach ensure clinical development functions can operate seamlessly across time zones, even during peak workloads, keeping timelines and budgets on track while ensuring high-quality outputs. It also means drug developers can easily scale their operations up or down to meet fluctuating demands without the need for extensive internal infrastructure investment.

Furthermore, FSP partners with a wide global footprint bring valuable expertise in navigating different regulatory landscapes. This is crucial to ensure compliance with regulations and the safety and reliability of clinical development and post-marketing surveillance processes while optimizing productivity.

FSP relationships also bring a partnership mindset, fostering the kind of collaborative global environment that encourages knowledge exchange and cross-pollination of ideas across different teams and locations—a requirement for any FTS environment to thrive. A collaborative culture enhances communication and better enables around-the-clock collaboration between global stakeholders. This seamless flow of information and expertise further strengthens decision-making, accelerates problem-solving, and ultimately enhances the efficiency and effectiveness of clinical development and post-marketing surveillance.

Essential FTS Best Practices to Ensure a Smooth Workflow

Operationalizing an efficient and collaborative FTS environment requires excellent communication, clear processes, and a robust technology infrastructure. An FSP partner should have global systems in place based on best practices. For example, teams need to be tightly synchronized despite physical separation and time zone differences. Communication channels such as technology-enabled platforms, regular virtual meetings, and established standard operating procedures (SOPs) are needed to connect all the dots. All team members also must have standardized training. As an example, a pharmacovigilance (PV) team with split shifts in different geographies for case processing support would follow the same SOPs and receive ongoing upskilling through standardized training to be able to harmonize shared tasks and ensure that there is reliable consistency as tasks are handed over, while always delivering quality and compliance.

Cultural differences and language barriers also are critical considerations to navigate. Clients and service providers must promote a sense of unity and shared purpose among teams that might be scattered across the globe. Cultural sensitivity training and

language/translation support lessens misunderstandings and helps promote effective teamwork.

Data security and compliance is another key consideration. Proven measures and protocols must be in place to ensure that all regional and country data protection regulations are consistently upheld across geographic locations.

To help maintain consistent quality standards across all locations, cross-team quality checks and review processes are needed to ensure that work handed off from one team to another meets the required standards. To this end, an around-the-clock monitoring system also can track progress, identify bottlenecks, and address any issues that arise. This proactive approach prevents delays and keeps activity on track. It's also important to develop contingency plans for potential delays or issues that may arise during the handoff process. Backup resources or alternative solutions mitigates risks and prevents disruptions.

Finally, a dedicated team of senior leaders for each region or team provides oversight and orchestrates the handoff process to ensure smooth transitions and address challenges promptly throughout the FTS workflow.

Selecting an FSP Partner for FTS Solutions: Key Considerations

In addition to having global resources, knowledge and systems in place to facilitate best practices, several other key considerations come into play when evaluating an FSP partner to implement an FTS model. It's important to select an FSP partner with a track record of delivering projects on time with quality and compliance. The FSP partner's reputation may be evaluated through their longevity of their experience providing FSP services, the longevity of their client relationships, client references, and case studies.

Collaboration is also critical in a globally distributed environment. Assess the FSP partner's ability to foster communication between teams, regions, and with clients. Look for established communication protocols, technological infrastructure, a strong culture of collaboration, and, importantly, dedicated roles that are in place to consistently drive implementation and ongoing communication. For example, would the provider put a seasoned lead in place to act as a single point of contact to coordinate the interactions between different teams and departments globally and ensure the seamless execution of project objectives? Responsibilities for this dedicated lead role may include oversight of key performance indicators (KPIs), finances, development and roll-out of governance, and system integration coordination.

Another factor to consider is the breadth and depth of expertise offered by the FSP partner, especially in any specific geographic regions under consideration. Can the provider cover all the needs of the engagement? Selecting a single FSP partner with expansive

therapeutic and functional expertise instead of engaging multiple partners with different capabilities can streamline the outsourcing process and facilitate more effective collaboration.

Tailored solutions also are critical when selecting an FSP partner. Each project and client have unique needs and requirements. The ideal provider should have established operations in global locations to fully leverage a more flexible infrastructure and greater support coupled with the ability to customize engagement models, systems, and processes to address the specific challenges and goals of a clinical development program. And they should have the capability to quickly ramp up or down to accommodate fluctuating workloads.

Last, it is important to evaluate the FSP partner's recruitment and training strategies. The quality of an FSP partner is only as good as the quality of its team. Because skilled and experienced professionals are in high demand—far surpassing supply—an FSP partner with established global recruitment capabilities and an ongoing training program is a necessity. Ensuring the provider has a pool of skilled resources ready to be deployed for specific project needs is also critical. For example, does the FSP partner have consistent processes to vet personnel for written and spoken language competencies and function-specific capabilities, regardless of location? Do they have consistent training and onboarding processes in each location, ensuring every team is comprised of highly qualified individuals who can perform consistently across the board?

It is also important to engage in open discussions to address any concerns or specific requirements, ensuring the development of a strong partnership built on trust, transparency, and shared objectives.

Conclusion

As the biopharmaceutical industry faces growing competition, coupled with increasing clinical development complexity, the adoption of an FTS approach supported by the expertise of an FSP partner has emerged as a powerful solution. By strategically leveraging global teams across different time zones, drug developers can unlock around-the-clock productivity, enhance operational efficiency, and foster a collaborative work environment. The successful implementation of FTS models requires careful planning, clear communication, adherence to best practices, and robust technology infrastructure. With a seasoned FSP partner by their side, organizations can tap into global talent pools, optimize resource allocation, and achieve remarkable advancements in clinical development programs, making FTS solutions a game-changing strategy to help meet ever-more challenging timelines, getting new medications to patients faster.

References

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