

WHITE PAPER



Leveraging the Follow-the-Sun Model to Optimize Your FSP Solution

Benefits and Best Practices for Clinical Development and Post-Marketing Surveillance

In today's interconnected world, in which businesses are striving to provide continuous services, support and operations to customers worldwide, the follow-the-sun (FTS) business model is becoming more prevalent. This strategic approach enables organizations to operate around the clock by leveraging global resources in different time zones. The core principle of FTS revolves around seamlessly transitioning work and tasks across different geographic locations as the sun rises and sets, ensuring uninterrupted business processes.

To date, FTS has traditionally been used to deliver critical functions such as customer service, IT and manufacturing support, without interruption. However, there is increasing interest within the biopharmaceutical industry as clients explore FTS models to more effectively meet timelines in a rapidly changing drug development environment. For drug developers, partnership with an FSP provider that employs the FTS model - and thereby has proven expertise in maximizing their global expertise and capabilities - ensures their projects stay on schedule and on budget.

This white paper will provide more on the key elements sponsors must consider when exploring and implementing an FTS model through an FSP partnership:

- The potential advantages of FTS models
- Why an FTS model is a good fit for clinical development and post-marketing surveillance
- Best practices
- What to look for in an FSP partner utilizing an FTS model

First, Consider the Potential Advantages

One of the most significant advantages of an FTS model is that it **provides continual support and responsiveness** regardless of time or location. Clear communication and regular meetings ensure that each handoff is performed comprehensively, enabling the next person to carry on the activity. With the ideal FSP partner, functional teams stationed across the globe will continuously perform tasks and respond to a customer's questions, technical issues and urgent needs as soon as they arise.

Additionally, the model enables clients to **optimize resource allocation**. By strategically locating various functions of the business in different regions, drug developers can tap into both higher-cost and lower-cost labor markets. This can be especially valuable for many tasks that don't require a physical presence and lend themselves to remote management, such as data entry, basic customer inquiries and aspects of clinical monitoring. By engaging skilled professionals in lower-cost locations, companies achieve cost savings while maintaining high-quality output.

The FTS model may also **enhance operational efficiency**. Having teams work across different time zones minimizes the risk of bottlenecks or delays caused by limited work hours. Tasks that are handed off at the end of one team's shift can be picked up immediately by another team in a different location, ensuring a continuous flow of work, with the potential to have



An FTS model distributes work across various regions, each operating during its respective daylight hours. As one region's workday ends, another region's workday begins, allowing for seamless handoffs of tasks and responsibilities.

clients find deliverables in their inboxes when they arrive in the morning. This can result in faster project completion times and a shorter response time to critical incidents, as well as better business continuity.

Additionally, FTS reduces the burden on any one country or region, which can maintain employee engagement by supporting work-life balance.

Taking steps toward round-the-clock clinical development and post-marketing surveillance holds promise for advancing scientific discovery and improving patient outcomes—with the correct global resources in place.

Why Follow-the-Sun for Clinical Development and Post-Marketing Surveillance?

Many existing characteristics of the clinical development and post-marketing surveillance process make it a particularly rich area to consider using an FTS business model.

- **Global collaboration and outsourcing:** Drug developers partner with research organizations, contract research organizations (CROs) and academic institutions around the world. Different functions carve out tasks that can be conducted by teams in different time zones, ensuring continuous progress.
- **Accelerated drug development:** Round-the-clock operations, including both research and manufacturing, significantly expedite the traditionally long and complex drug development process.
- **Real-time data analysis:** Clinical research demands ongoing data analysis and interpretation, especially during clinical trials. Data collected from different regions can be analyzed in real time by clinical data management teams operating in other time zones, enabling faster decision-making and adjustments to trial protocols.
- **Follow-up patient monitoring:** Clinical trials often involve patients in various global locations. Clinical operations teams that use FTS to establish follow-up and monitoring processes ensure patients receive timely attention, regardless of geographical location.
- **Global regulatory compliance:** Development involves adhering to regulatory requirements in different countries and regions. Having regulatory affairs teams in various time zones aids in addressing compliance issues promptly and ensures alignment with local regulations.
- **Risk management and business continuity:** The distributed nature of an FTS model provides built-in risk management by reducing the impact of disruptions in a single location. If one research or manufacturing site faces challenges such as natural disasters or political instability, other sites can continue the process and maintain business continuity.



How PPD® Offers FTS Support to Meet Timelines

PPD FSP Solutions has comprehensive global capabilities, dedicated leadership, proactive and accountable team members, access to top-tier talent, and the breadth and depth of therapeutic and cross-functional expertise that a successful FTS model demands.

Our highly trained teams provide round-the-clock support from multiple regions throughout the world. For every PPD FSP Solutions engagement, we have detailed discussions upfront to understand the client's program-specific needs and then map out where an FTS model makes sense strategically. Here are a few examples.

- PPD FSP Pharmacovigilance (PV) Solutions has established hubs in Bulgaria, India, Mexico and Philippines along with hubs in the U.S. and U.K. The Philippines team employs a split shift, providing 24/7 support to accommodate specific client needs including the provision of U.S. holiday coverage. Furthermore, PPD FSP PV Solutions hubs support local complexities and languages, including China and Japan. In addition to utilizing an FTS model for case processing support, our global locations provide other PV activities including literature surveillance, safety reporting, safety writing and signal detection.
- PPD FSP Clinical Data Management Solutions employs a split shift approach in India and the Philippines, ensuring a presence for clients' requirements while maintaining uniform quality standards within the team.
- The PPD FSP Regulatory Publishing Solutions team also follows an FTS model for their services, streamlining processes for top 10 pharma companies, providing 24/7 support across the U.S., Canada, U.K., France, Bulgaria, Poland, India, China and Australia as well as employing shift work (e.g., Thursday through Monday), to manage high submission volumes.
- PPD FSP Biostatistics and Programming Solutions has hubs in the North America, Europe, Middle East and Africa (EMEA) and Asia-Pacific (APAC) regions that provide support to handle client comments for Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), Tables, Listings and Figures (TLFs) and electronic Case Report Tabulation (eCRT) packages for key deliverables for any region that needs to be addressed based on a rapid response to meet client or health authority deadlines.
- The PPD FSP Medical Writing Solutions team spans North America, EMEA and APAC. This global reach supports agile solutions for changing client needs (e.g., submission timelines) and short notice requests (e.g., requests from regulatory agencies).

Drawing upon these capabilities and more, PPD FSP Solutions provides extensive expertise and the customer-first, problem-solving mindset needed to deliver an FTS model, partnering with clients to meet timelines more effectively in a rapidly changing drug development environment.

Careful Planning and Coordination Based on Best Practices

Operationalizing a highly efficient and collaborative FTS environment can be complicated. Effective communication, clear process and a robust technology infrastructure are keys to success. The right FSP provider will have global knowledge and systems in place, based on best practices, to ensure a seamless transition into an effective FTS model.



Knowledge transfer and communication

Effective communication and collaboration tools are essential to bridge geographical and time zone gaps. Teams need to be synchronized despite physical separation.

Tools: Communication channels include technology-enabled platforms, regular virtual meetings, robust processes and established standard operating procedures.

Hiring, onboarding and training: All team members must have standardized training to ensure that everyone knows how to fulfill their role and that there is reliable consistency as tasks are handed over.



Quality and risk management

Implement a **monitoring system** that operates around the clock to track progress, identify bottlenecks and address any issues that arise. This proactive approach prevents delays and keeps things on track.

Develop **contingency plans** for potential delays or issues that may arise during the handoff process. Having backup resources or alternative solutions mitigates risks and prevents disruptions.

Maintain **consistent quality standards** across all teams involved. Implement cross-team quality checks and review processes to ensure that work handed off from one team to another meets the required standards.



Cultural navigation

Cultural differences and language barriers 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 promote effective teamwork.



Leadership and oversight

To manage the level of fine coordination that an FTS model requires, **designate a team of senior leaders** for each team or region that is accountable for the FTS governance structure and for oversight of the handoff process, addressing challenges and ensuring smooth operations.



Data security and compliance

Data security and compliance must be maintained rigorously, especially when dealing with sensitive client information or proprietary data being accessed across regions. Proven **measures and protocols** must be in place to ensure that all regional and country data protection regulations are upheld, regardless of where the teams are located.

PPD FSP Solutions has two dedicated leadership roles that are responsible for efficient program execution and partner satisfaction and smoothly transitioning through each phase of the FSP partnership:

- **Implementation Lead (IL):** Prior to project award, the IL starts to clarify project needs and develop a timely implementation plan, managing internal workstreams to identify and allocate the right resources at the right time in the right geographies to launch projects on schedule.
- **Operations Delivery Lead (ODL):** The ODL is the single point of contact for a partnership, always putting client interests at the forefront and promoting consistent collaboration. The ODL delivers laser-focused oversight and strategic planning to deliver proactive, high-touch communications that enable greater stability and on-time, on-budget delivery.

What to Look for in an FSP Partner for FTS

An FSP outsourcing approach is an ideal fit for FTS models, offering many benefits including:

- Global resource flexibility
- Access to specific skills and expertise not available in-house
- Ability to scale up and down with the peaks and valleys of operational requirements
- Tailored launch, oversight and governance provided by dedicated leadership roles



Cost-Efficient + High-Quality

PPD FSP Solutions locations in Bulgaria, China (Shenyang), India, Mexico and the Philippines offer cost-efficient services while maintaining the same high-quality standards as traditional geographies. This approach has led to substantial cost savings for clients, particularly in the areas of PV, clinical data management, biostatistics and medical writing.

Effectiveness rests upon:

- Dedication to seamless handoffs and communications
- Ongoing upskilling through standardized training
- Focus on continuous improvement, including using artificial intelligence (AI) and automation
- Extensive reviews and knowledge-sharing after project completion

Implementing and maintaining an FTS model is complex, so it's critical to select the right FSP service provider. There are four essential areas to consider.

1. **On-time delivery of projects:** A provider's track record of on-time performance is critical, and for good reason. Keeping a development project on time has significant implications for overall success but depends on a provider's service offerings, logistical and operational resources, and capacity to adapt to changing needs. Look for strong functional and therapeutic expertise, a high-touch communication style and roles that are dedicated to your project. In an FSP partnership employing FTS, these competencies are particularly important to launch and evolve the partnership, meet timelines and maintain quality and compliance.
2. **Breadth and depth of expertise:** Drug developers pursuing outsourcing through an FSP model face the challenge of finding partners suitable for each of the functions they're looking to outsource. Instead of assessing the quality and credibility of numerous potential partners and building piecemeal relationships, working with a partner offering expansive therapeutic and functional expertise can simplify the outsourcing process.
3. **Tailored solutions:** No two clients or projects are the same, so it is critical to select an FSP partner able to customize solutions directly to your needs and requirements. By choosing a partner with the flexibility to combine various engagement models, systems and processes, drug developers can be confident in deploying a solution that solves their challenges with the greatest efficiency.

4. **Recruitment and training:** Since the quality of an FSP partner depends on the quality of its team, recruitment and training processes and resources are crucial factors to consider when evaluating potential partners for an FSP engagement. Recruiting and retaining skilled talent is also a critical consideration because the number of registered clinical trials has tripled in the past decade and demand for global talent remains competitive. The ideal partner will have an established global recruitment engine and training function to ensure you have skilled resources, ready to deploy.

PPD FSP Solutions has comprehensive global capabilities, dedicated roles to drive on-time delivery and provide ongoing support, and bespoke recruiting strategies for every FSP engagement. With access to more than 30,000 research professionals in more than 160 countries, that enable superior operational efficiency around the clock, we rapidly identify and deploy resources to ensure that your project stays on schedule and on budget.

Rely on an FSP Partner to Realize FTS Models

The biopharmaceutical industry is exploring FTS models to enhance customer satisfaction, optimize resource allocation and improve operational efficiency. The model's potential to facilitate continuous, round-the-clock operations and maximize global expertise and capabilities is a game-changer for sponsors in the competitive drug development environment. While challenges such as communication and cultural differences exist, working with a seasoned FSP partner will enable drug developers to successfully implement and reap the rewards of this innovative business model.



About PPD FSP Solutions

PPD FSP Solutions has supported nearly 300 clients, including nine out of the 10 top pharma organizations, over the past five years. Backed by more than 25 years of FSP support for clinical and marketed products, we know what it takes to deliver customized solutions tailored to the unique needs of each client, providing much-needed resource flexibility, reliability and continuity to help clients meet their timelines. Our global FSP solutions provide the breadth and depth of therapeutic and functional expertise needed to facilitate successful product development for our partners, big and small, and help accelerate the next generation of life changing therapies.



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