White paper

FSP solutions

PPD FSP Pharmacovigilance solutions

Transitioning pharmacovigilance services to a single FSP partner

As drug and medical device developers contend with an array of complex financial pressures and struggle to find talent in competitive employment markets, they are increasingly turning to Functional Service Partnership (FSP) models to outsource individual functional services. Recent research shows the FSP market has been growing quickly, and this expansion is expected to continue. For example, in one survey of 150 leaders in biotech and biopharma, **87% of participants reported using FSP or hybrid FSP/FSO (full-service outsourcing) solutions**.[1]

Among the functional services widely selected for FSP outsourcing is pharmacovigilance (PV), which is key to every drug or medical-device developer's ability to ensure excellence in patient safety. Although maintaining a diverse set of partners or redundant in-house staffing occasionally offer advantages like risk mitigation and enhanced business continuity, a critical capability such as PV more often benefits from consolidation. Consolidated FSP PV capabilities can:

- Reduce current and future financial pressures.
- Mitigate problems related to breakdowns in communications and/or lack of efficiency.
- Deliver global and local PV solutions.
- Streamline operations to provide a more trustworthy, comprehensive view of the entire product portfolio and its varied regulatory needs.

This white paper demonstrates the value of consolidating PV services to a single FSP partner and highlights some of the ways an FSP partner can overcome the challenges associated with consolidation.

Strategically selecting the right outsourcing models can bend the cost and time curve of drug development by maximizing quality, operational success and financial efficiencies. For today's pharma, biotech and medical device companies, pharmacovigilance is high on the list of functional services to be outsourced.[2] Some of the key PV capabilities that are commonly contracted to an FSP partner include:

- Case processing and safety report submissions both in clinical trials and post-marketing settings.
- Literature surveillance.
- Aggregate safety report preparation.
- Signal detection and management.
- Monitoring, analyzing and interpreting regulation changes.
- Guiding the development of new and updated regulations and guidance.

As the use of FSP and hybrid FSP/FSO solutions have become more common over recent years, developers are now finding value in consolidating their FSP engagements (including PV capabilities), to use a single provider. By choosing a single FSP partner, these companies gain resource flexibility and financial efficiencies while retaining more control and complementing their internal expertise.

Using an FSP partner for PV

There are two primary reasons that developers turn to an FSP partner for PV functions. The first is to retain more control over their own projects. By working with an FSP partner, the developer can focus on core business processes, strategic decisions and risk mitigation. The second is to take advantage of a best-in-class vendor for these critical capabilities, enabling the developer to benefit from access to top PV talent and expertise in global locations without needing to directly manage those resources. Using one FSP partner for PV maximizes these benefits.

What to look for in an FSP PV partner

To find a best-in-class vendor, drug and medical device companies should look for an FSP partner that has an established track record of completing projects on time and on budget, a depth of therapeutic expertise and the ability to scale resources, when required. Additionally, when transitioning PV services to a single FSP vendor, the client companies also look for:

- Historical and current key performance indicators (KPI) from safety report submission compliance, quality, aggregate safety writing, etc.
- Experience with transitioning services to a single FSP partner.
- Ability to create an effective transition plan with realistic timelines.
- Hyper-care monitoring and process optimizations for post-merger performance.

Keys to success

Ideally, the primary FSP PV partner will have a wealth of experience in transferring services from other service providers and will exhibit a deep understanding of the complexities involved and how these will be successfully managed. It is important that the primary FSP partner identifies risk, proposes effective change management to overcome any challenges (including those unforeseen) and ensures a successful shift to steady-state operations. The FSP partner also needs PV expertise in providing turnkey project implementation, undertaking all necessary tasks and processes involved in establishing the future FSP operational model. Early planning and effective communication throughout the process are critically important to a smooth transition.

Ultimately, the FSP PV partner must be able to provide:

- **Effective oversight:** Oversight of the complex transition process starts with effective and experienced project management, ideally delivered by a single oversight director capable of leading a cohesive, customer-focused strategy; streamlining communications; and understanding all the processes necessary to deliver a zero-disruption, friction-free transition. While no two transitions are alike, the FSP partner should be able to present a standardized implementation plan to optimize the transition while retaining the ability to deviate from that plan to meet the developer's unique needs.
- **Comprehensive planning:** Together, the FSP partner and client will draw up a comprehensive transition plan that includes coordinating and documenting activities across all client stakeholders and the current vendor. The transition plan will present a clear, step-by-step approach and will detail timelines and expectations for all stakeholders, with each element assigned to a responsible party.
- **A collaborative approach:** Any transition is by nature a collaborative undertaking, requiring stakeholders who can identify and mitigate risks throughout the implementation and transition process.
- **Performance management:** The FSP partner and client will work together to design and implement performance metrics and tracking, documented within a Governance Charter, to ensure key information, metrics and issues are brought to the appropriate level of management in a timely manner.
- **Continuous support:** Throughout the process, the FSP partner will continually undertake a comprehensive gap analysis to determine what processes are working well and where there are opportunities for improvement. The FSP partner will also have access to a set of tools and practices proven to help guide the developer through the transition and integrate the new solution into the developer's culture to create the optimal team environment.
- **Customized training:** A top-tier FSP partner will also be able to offer customized coaching in a "train-the-trainer" model to ensure all staff (FSP and client) have the knowledge, engagement and support necessary to meet productivity KPIs.

Single-FSP vendor deployments mitigate PV challenges

For drug and device developers, PV presents several challenges on its own, most of which are exacerbated when multiple FSP PV vendors are involved. One such challenge — the one that often drives these companies to engage an FSP partner in the first place — is the dynamic nature of PV in general. Documenting a new product's safety and efficacy, and then maintaining that product's ongoing availability, requires the developer to comply with safety and quality standards across every region where the product is marketed, for as long as it is marketed. This requires an expert PV team capable of processing large volumes of cases and routine submissions to support any changes to market expansion or safety and quality reporting — for every drug or device in the company's portfolio. Accordingly, across a product's lifecycle there are times when it requires significant PV resources, and times when it essentially requires minimal allocation. During busy times, some PV workloads require senior-level expertise, while others are well suited to support staff.

The challenge of dealing with fluctuating workloads while maintaining quality and consistency across geographies requires an FSP PV partner that can flex as trials and products evolve, managing partner agreements and cross-reporting obligations while meeting regulatory timelines. However, the advantage of outsourcing these capabilities to an FSP PV partner is sometimes diminished when the workloads are dispersed among multiple vendors. This can create a whole new set of challenges, including:

- **Resource allocation and scalability:** Having the right subject matter experts on hand and being able to easily ramp up or down is fundamental. With multiple vendors, however, the developer may not always be sure that the optimal resources are dedicated to any given PV-related task. With a single vendor, only one party is accountable for success and there is never any question whether the right resources are in place at any given time.
- **Budgetary considerations and fiscal management:** A developer's ability to engage an effective, cost-conscious outsourcing partner and create realistic cost projections is dramatically simplified when there is a single vendor. Back-end planning, negotiating, and developing contracts are all time-consuming, expensive undertakings and the developer's legal and outsourcing departments benefit when those activities are curtailed through consolidation.
- **Consistency:** The developer rightly expects the best possible performance from its outsourcing partners, FSP or otherwise. Whenever multiple vendors are engaged, however, maintaining high levels of output across the board becomes more challenging and requires a larger commitment of resources to track and document vendor performance.

The advantages of transitioning to a single vendor

- Eliminating the need to engage multiple FSP PV vendors can make processes more efficient, particularly in cases where the exchange of information among providers may be lacking. A unified project team with a single point of contact can foster a more responsive environment where tasks and details are handled with greater precision.
- Single-vendor environments can avoid roadblocks that might hamper an FSP PV partner's understanding of the client's business and their ever-changing needs. Engagements are built on solid foundations of shared knowledge with fewer gaps in communication.
- By following a consistent set of processes, FSP PV vendors can maintain data uniformity across everything from data collection to processing, analysis and records retention.
- A single FSP PV team can yield cost savings through resource sharing, reduced need for oversight, and opportunities for financial discounts (volume, multi-year, multi-service, etc.).

PV solutions from leading FSP experts

Developers seek out an FSP partner with an established record of completing projects on time and on budget, depth of therapeutic expertise and the ability to provide additional resources when required. Consolidating PV services with a single FSP partner maximizes the benefits of outsourcing, reduces costs and enables greater accountability.

The PPD™ clinical research business of Thermo Fisher Scientific has extensive experience with transitioning services to a single FSP partner, built on the successful implementation of more than 100 post-marketing and clinical trial projects over the past five years. PPD™ Functional Service Partnership (FSP) Pharmacovigilance solutions deliver the full range of capabilities discussed above, including:

- Development of an effective transition plan with realistic timelines.
- Resource scalability and expertise.
- Process optimizations that come from merging multiple vendors into a single FSP partner.
- Tracking of and adherence to established KPIs.

PPD FSP Pharmacovigilance solutions leverage new technologies, analytics, process improvements and automation to gain efficiencies, improve quality and increase consistency, accuracy and reliability — all while reducing the cost of PV services. Our PV experts are continuously advancing systems and technologies in areas such as adverse event management, regulatory intelligence, regulatory agency and ethics committee submissions, investigator site safety-report distribution and clinical monitoring, workload coordination, and site inquiry submissions to physician teams.

Our suite of advanced tools and services drives efficiency and automation across all outsourced PV activities. By integrating robust processes with state-of-the-art software solutions, real-time analytics and automation, we streamline workflows and reduce manual intervention. Furthermore, our PV service offering includes comprehensive training and ongoing support to ensure adoption and optimal utilization of these technologies. This approach reduces errors and accelerates processes to enhance productivity, reduce costs and deliver a robust foundation for sustained growth and operational excellence.

PPD FSP Pharmacovigilance solutions experts have also developed a comprehensive safety tracking management system designed to deliver robust process automation functionality. This system significantly streamlines processes, enabling our PV teams to drive efficiency and reduce overall costs through centralized resource management, quality control tracking, oversight and compliance. Our powerful automation capabilities are used to capture incoming individual case safety reports (ICSRs) and follow-up information and to automatically route relevant data to the processing team. This enables our PV teams to generate and track follow-up queries to ensure due diligence through multiple engagement attempts.

By leveraging this system, handoffs and workflow organization become easy and efficient, keeping deliverables on schedule and ensuring quality is continuously monitored. The system also enables us to compare processing metrics across all clients to establish meaningful benchmarks. This information is critical in driving our continual process improvement strategy and allows us to constantly refine and improve. By comparing benchmarks across clients, we can identify when a client-specific process falls outside the norm so that we can identify and target specific areas for potential efficiency gains.

One area that differentiates our PV teams from other vendors is our wide range of experience. We have more than 30 years of PV and FSP expertise with a solid record of delivering reliable, high-quality services, as demonstrated through our industry-topping levels of PV staff retention and extraordinary compliance rates.

- While the industry average turnover rate is 20% or greater, turnover for PPD FSP solutions engagements is ~12%.
- We submit safety reports to an average of more than 4 million recipients per year, with 99.6% ICSR submission compliance.
- We provide convenient and flexible solutions via our global experts across more than 35 countries.
- We support all clinical trial and post-marketing service needs, with robust therapeutic area experience.

A commitment to resourcing and scalability

Our 1,400 PV professionals deliver high-quality pharmacovigilance services across a diverse range of key therapeutic areas, from major markets like oncology and chronic conditions to innovations in cell and gene therapy. Our PPD FSP Pharmacovigilance solutions are built on a model that employs a lead global director located in one centralized area to oversee the management of case processing staff that can be situated in up to three other areas. For example, this flexible staffing model might include hiring a share of staff in the Philippines and/or India to work both day and night shifts, which enables work to be completed in U.S. and U.K. time zones, or whichever time zone is appropriate to the client's headquarters. Such a team would be further supplemented with our specialized literature surveillance, aggregate report, centralized safety reporting, and signal detection teams — again with staff strategically located around the globe to cost-effectively capture the necessary skillsets for these specialized tasks. This model delivers:

- Financial efficiencies with centralized leadership that is responsible for creating consistent, clear and succinct communication.
- A full PV staff, all trained with the same globally codified documents.
- Adherence to consistent quality standards and oversight.
- Staff pre-screened for fluency in reading, writing, speaking and understanding of the English language.

Overall, our PPD FSP Pharmacovigilance solutions represent a highly scalable, flexible and efficient operating model that enables:

- Efficient communication via a single point of contact (project delivery manager [PDM]) who is directly engaged with the client's regional management.
- Project timeline compliance assurance through a share of staff working across global time zones, including adequate coverage of holidays.
- Streamlined operations and enhanced efficiencies delivered by specialized teams that continually strengthen and refine processes and capitalize on the repetitive nature of tasks.
- Program scalability through a dedicated, trained flex team that makes up an additional 20–30% of the daily case processing staff needed to meet timelines. The flex team allows regular staff to have time out of the office and provides additional trained staff for spikes in volume or to be available for ad hoc requests.
- Proven quality output and compliance through highly qualified, dedicated quality and training specialists to train and assist with compliance monitoring and procedural development/revisions.
- Information technology (IT) system/performance support through a designated contact to work closely with client's IT staff.

Built on a foundation of targeted hiring and comprehensive training

To identify resources with both speed and quality, we have built a global talent delivery strategy that combines our internal resourcing and external recruiters. This strategy ensures a seamless implementation and transfer of work by committing to:

- **Hiring ahead of the curve:** We are dedicated to proactive, strategic hiring ahead of our clients' resourcing needs. This approach ensures access to a pool of trained employees who are ready to mobilize with short notice, ensuring rapid deployment for back-fills, volume spikes, scope changes or ad hoc requests.
- **Focused resourcing:** We prioritize the onboarding of experienced PV professionals for specific project needs, ensuring our clients have access to an integrated talent pool of experienced professionals for every need.
- **Innovative talent delivery:** Our talent acquisition team utilizes both artificial intelligence (AI) and machine learning (ML) solutions to enhance internal and external talent management, coupled with proprietary resourcing technology for forecasting consistency.

PPD FSP Pharmacovigilance solutions quickly launch and ramp up services as needed due to our global infrastructure, training systems and highly trained resources. PV staff must meet the required qualifications and credentials needed to fulfill each FSP role, while having the required experience, knowledge, skills and abilities to perform their essential job functions. To maintain these prerequisites, our layered training strategy strengthens the knowledge of our PV staff and enhances retention. Initial onboarding includes foundational training via our PV Academy to ensure a deep understanding of governing policies, standard operating procedures (SOPs) and global regulations.

For project-specific training, these teams undertake a collaborative approach, particularly when a client prefers adherence to their own SOPs. This ensures resource preparedness while respecting the client's training standards. The PV staff also undergo rigorous mentoring, mock cases in a training environment, and ongoing peer and manager quality reviews.

Our customized training is known throughout the industry to produce highly qualified staff, having earned us six awards for enterprise learning, strategy and development programs in the past two years. We apply specialized and client-customized training and operational know-how to ensure the assigned team has the education, engagement and support necessary to deliver whatever our clients need. Overall, this well-established global onboarding and training program ensures the highest level of quality, retention, consistency and productivity across the client's project.

As an example, our training framework focuses resource behavior on key elements that drive project success, such as:

- **Providing the highest level of quality, retention and productivity:** We assign each new hire to a line manager and provide a mentor to guide them through the process, review role expectations, ensure compliance tracking, and discuss overarching expectations around working in client's culture and systems.
- **Consistent training delivery to ensure skill gaps are addressed:** We implement a "train the trainer" model, where one experienced team member manages the training for all other team members as the partnership evolves, thereby reducing the client's need to continually assess and train these personnel.

How PPD FSP solutions experts ensure an effective transition of PV services

PPD FSP Pharmacovigilance solutions teams possess extensive expertise in employing diverse approaches to transitioning PV activities customized to the client's products, volume, complexity and business needs. As a first step to establishing a comprehensive transfer plan, we conduct transition meetings and collaboratively develop a proposal in close alignment with any outgoing contract research organizations (CROs). Through these interactions, we identify the scope of the FSP service needs so we can customize our approach. This includes asking focused questions surrounding current resourcing models, challenges or areas needing improvement in the existing strategy, current and future PV support requirements, preferred location of staff, implementation and go-live dates, cost considerations and duration of contractual period. In this way, we identify the client's current and future needs, areas of opportunity and improvement, and operational and budgetary considerations.

In our experience, a product-based approach is typically the best way to ensure that tasks are transitioned in an organized and methodical fashion that never loses sight of quality and compliance. A final transition schedule is developed in collaboration with the client, taking into consideration all the appropriate complexities. Our FSP experts maintain the flexibility to pivot as the real-world needs of the project shift or change.

Strategy

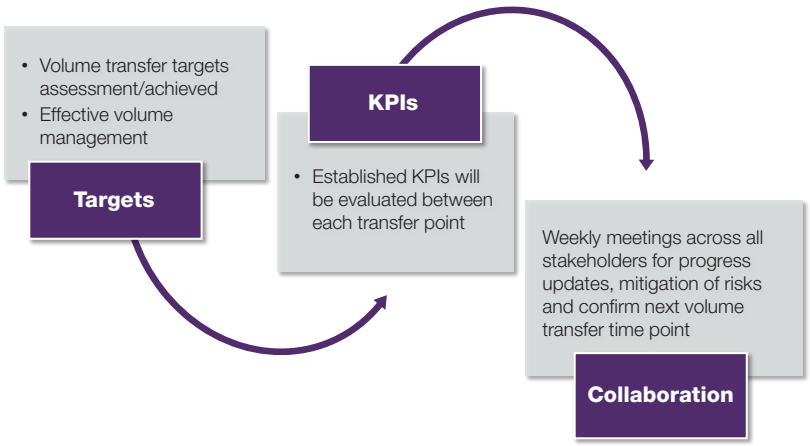
- Transition by product
- Develop transition schedule
  - Complexity
  - Volume
  - Upcoming data locks
  - Resourcing

Benefit to client

- Focused learning by product promotes
  - Quality
  - Productivity
  - Consistency
- Ensures team has a "layered" approach to training

Keys to success

- Change management
- Clear lines of communication
- Defined roles and responsibilities



Case study 1:

Global safety reporting transition to FSP sole provider

Below is an example case where global safety reporting was transitioned to a sole-provider FSP PV model to meet timelines and reduce costs. This drug developer sought to transfer all safety reporting services for their clinical trial portfolio and post-marketing submissions for certain countries to a single, innovative FSP partner able to exhibit strong safety reporting compliance.

CHALLENGE

The developer required a large volume of safety submissions while maintaining a high compliance rate. Its large, complex portfolio included:

- 20 investigational products and upwards of 50 different studies.
- Cross-reporting across different clinical CROs.
- Dated, paper-based submission processes that were inefficient and slow.

SOLUTION

PPD FSP Pharmacovigilance solutions provided a team of seven safety reporting specialists and 10 safety reporting administrators to develop:

- An effective transition plan with realistic product timelines.
- A universal safety management and expedited reporting plan.
- Process optimizations for transitioning to an electronic distribution method.
- Streamlined electronic trial master file (eTMF) filing.

RESULTS

In a short time, we seamlessly transitioned the developer to PPD FSP Pharmacovigilance solutions for investigational products and complex studies with no gaps in safety reporting compliance, including:

- Meeting all milestone transition timelines within two months.
- Delivering more than 400 safety submissions and a compliance rate above 99%.
- Generating a cost savings of more than $17 million from reduced courier fees and labor expenses.

Case study 2:

PPD FSP Pharmacovigilance solutions delivers on-time transition with compelling KPIs

In another case, a drug developer based in the U.S. with an operations center in China was seeking to outsource clinical and post-marketing case processing and safety reporting services supported by about 150 full-time equivalent (FTE) employees.

CHALLENGE

The client was dissatisfied with performance under their current solution and wanted to re-focus, but they needed a strong partner able to:

- Consolidate processes and governance.
- Deliver a global solution.
- Transition smoothly and quickly with no impact to data locks.

SOLUTION

PPD FSP Pharmacovigilance solutions delivered a bespoke offering that provided greater flexibility, organization, quality and problem-solving and included:

- Cost-effective global staff positioning.
- Efficient communication, consolidated processes and focused governance.
- Collaborative transition planning and risk mitigation.
- Focused workstreams with key decision-makers.

RESULTS

Throughout the transition and through steady state, all process, quality and compliance KPIs were met or exceeded. Additionally, we:

- Delivered 100% on-time compliance during and post-transition.
- Transitioned with no impact to data locks.
- Supported more than 2,600 cases/month.
- Onboarded more than 100 staff in Bulgaria, Philippines, U.S. and China.

The ease of working with a single FSP partner

As drug and medical device developers face an onslaught of pressures related to financing and staffing their operations, they often seek relief by engaging FSP partners to outsource critical functions such as PV. In many cases, additional benefits are to be had by consolidating multi-vendor engagements to a single FSP partner, thereby increasing resource flexibility and increasing financial efficiencies — all while retaining control over development projects and complementing internal expertise.

By moving all PV services under one select FSP partner, that partner can more easily adapt to the developer's pipeline and corporate goals. A single FSP partner develops and retains knowledge and expertise specific to each client, achieving long-term cost sustainability while providing high-quality staffing and ensuring on-time deliverables. Transitioning to a single-source PV vendor reduces the complexity of working with multiple vendors, ensures process standardization, and allows for a centralized approach to compliance oversight.

PPD FSP Pharmacovigilance solutions enable biotech, biopharmaceutical and medical device companies to meet their timelines by delivering the best of the best: hard-to-find, top-tier staff who bring a customer-first problem-solving mindset to a range of clinical development services, including PV.

Where a drug or device developer can't always predict — or find and retain — the staff and services it needs, our experts deliver a breadth and depth of therapeutic and functional expertise unmatched in the industry, uniquely positioning PPD FSP Pharmacovigilance solutions to deliver the right experience and knowledge to fill immediate resource gaps. To ensure projects launch on time and stay on budget, we have dedicated roles focused on rapidly ramping up engagements, keeping clients informed with high-touch communications, and applying on-demand staff and services as needed.

We know what it takes to reliably solve the full range of PV challenges. Whether filling small gaps in services or outsourcing multiple functions across a portfolio, PPD FSP Pharmacovigilance solutions are tailored to each developer's individual requirements to provide much-needed resource flexibility, reliability and continuity. Our PPD FSP Pharmacovigilance solutions specialists support more than 250 clients and maintain PV compliance for medicinal products and medical devices across almost 100 countries. Our commitment to PV ensures that companies everywhere can count on us to deliver value-added capabilities, high levels of efficiency and cost savings to ensure on-time, on-budget delivery, every time.

Ready to consolidate your critical PV processes to a single FSP partner for increased efficiency and savings?

Partner with **PPD FSP Pharmacovigilance solutions** today.

References

1. The PPD clinical research business of Thermo Fisher Scientific, FSP Engagements Continue to Gain Popularity, Drive Success blog, https://www.ppd.com/blog/fsp-engagements-gain-popularity-drive-success/
2. The PPD clinical research business of Thermo Fisher Scientific, Ensuring Effective Pharmacovigilance Regulatory Intelligence with FSP Partnerships white paper, https://www.ppd.com/our-solutions/clinical/functional-service-providers/pharmacovigilance/regulatory-intelligence-white-paper/

Learn more at **ppd.com/fsp-pharmacovigilance**