CRO's FSP Model Proves to be the Right Choice

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The current pharmaceutical and clinical research environment is in a constant state of change. Business decisions resulting in mergers, acquisitions and resource depletion, coupled with increasing regulatory and pharmacovigilance (PV) safety requirements, have required business leaders to make pioneering decisions and consider innovative ways to conduct business. Pharmaceutical, biopharma and biotech companies must change their current thinking by creating contemporary resourcing models that emphasize the "doing-more-with-less" approach while finding novel ways to accelerate new drug development timelines and reduce costs overall to increase return on investment.

Every pharmaceutical, biopharma and biotech company needs to accommodate this new and ever-changing landscape. One of the emerging trends is to establish a functional service provider (FSP) relationship by partnering with an experienced and resilient contract research organization (CRO) that can serve as a partner rather than a vendor. An FSP model provides clients with added value such as increased flexibility, consistency and proven experience that reduce time and costs without compromising scientific/medical data integrity and quality. A strong FSP with the right CRO can help a company, not just survive, but thrive despite the current peaks and troughs of pharmaceutical lifecycle management requirements.

This article will explore in detail how in 2004, a mid-sized biopharma company ranked among the top 25 pharmaceutical organizations worldwide, embarked on such a journey by partnering with PPD to initially perform PV case processing activities using an FSP model. The biopharma company required timely, compliant, high-quality, cost-effective case processing with an experienced PV vendor with experienced PV resources.

Together, PPD and the biopharma company built a solid partnership of more than 10 years based on mutual respect, trust and collaboration. The framework developed for the program was essential to the success of this relationship, by providing adequate oversight and support of the company's growth. The governance structure implemented introduced a more sophisticated level of communication and escalation, which resulted in rapid problem-solving and created a strategic partnership platform that further provided the flexibility and adaptability required for continued success more than a decade later. The governance structure value included control, transparency and oversight, ensuring accountability, proactivity and forward planning.

As the biopharma company showed growth and success, it relied on PPD to manage its increase in case volumes, making this a win-win relationship for both parties. As the years passed, additional challenges arose, such as the legal and regulatory framework for case processing. These combined factors attributed to a 98% increase in case processing workload since 2004 and additional scope in providing literature surveillance as well as clinical trial safety report submissions. With the increases in case volume and scope of services, PPD has continued to maintain a high level of quality as highlighted by a 2017 case quality review score of around 98%, and safety reporting compliance as shown by a 2017 regulatory safety reporting compliance score of over 99%. Currently, PPD utilizes more than 200 dedicated staff across four locations to meet its partner's needs.

Relationship History

In 2004, the client determined that its infrastructure was not able to accommodate the rapid growth needs for its products. After evaluating several options, the company decided to outsource certain PV activities that would enable its internal resources to focus on in-house drug development activities. Initially, individual case safety report (ICSR) processing was outsourced on select marketed products. Over time, as figure 1 portrays, this was expanded to include additional marketed products and services. Then, in 2016, due to the sustained proven and positive outcomes, PPD ultimately entered into a five-year partnership contract to support case processing for all marketed products, along with adding clinical trial safety report submission services.

In 2004, PPD began case processing for its client with four staff based in the United States (U.S.) with a volume of about 300 U.S. cases per month for a single, marketed product. This activity cultivated the initial relationship between the client and PPD to the point that it became clear that the cultural fit between the two companies was aligned. Work ethic, philosophies, methodologies and strategic approach were symbiotic. Thus, trust and respect between the PPD and client PV groups developed rapidly.

In 2007, with proven efficient and effective processes, the relationship reached its first significant PV service expansion when medical review and a second marketed product were added to the scope. This further strengthened the relationship and continued to establish vendor/client trust, and ultimately resulted in additional process efficiencies, which subsequently reduced costs for the client.

In 2010, global expansion occurred by adding a case processing team based in PPD's Bulgaria office. This was necessary to accommodate the increasing volume and to provide a more cost-effective solution.

In 2012, the scope was expanded to include processing of ex-U.S. cases and additional marketed products. Furthermore, literature surveillance was included for two marketed products, which increased to four products in 2013.

That year, as the case volume rose by 50%, further global labor expansion of the case processing team occurred through the addition of PPD's PV Philippines office. The PPD PV Philippines office opened in August 2012 and was selected due to the high level of English language skills and strong medical background (nursing and pharmacy) available, while also providing a cost savings to the client. In addition, this office enables a "follow-the-sun-model," in which PPD is able to provide an extended day for case processing services.

In 2016, the client entered a five-year partnership agreement with PPD, along with an increase in scope to support all clinical trial safety report submissions. The Philippines PV project team expanded further, resulting as the primary case processing location on the program today.

The Partnership

The scope of the partnership currently includes the following activities for eight marketed products:

- ICSR processing (on average 19,500 cases per month) including triage, data entry, quality review, medical review, reconciliation and case follow-up
- Literature surveillance – searches and reviews
- Clinical trial safety report submissions for marketed, pre-market or investigational products

The scale of the partnership required a different approach to FSP due to substantial case volume increases and the range of PV services. The client required a solution that delivered:

1. Best cost location
2. Scalability
3. On-demand availability for additional work
4. On-time deliverables
5. High calibre of quality and compliance metrics
6. Experienced PV staff
7. Managing fluctuations in resource needs

PPD met the client's business needs by applying the strategies in Table 1.

Based on the implementation of the preceding strategies, the average ICSR quality (as determined by peer quality control of select fields defined by PPD based on case seriousness) has consistently scored around 98% (figure 2), while the regulatory authority safety reporting compliance in 2017 has averaged in excess of 99% (figure 3). Note, the information represented in the figures below are PPD metrics.

Operational Structure

The operational team (figure 4) supports the global delivery and includes a project director as the single point of contact, along with established regional associate directors/management contacts. The project director provides focused operational support to both the client and PPD management/staff for all of the provided services. The management team is aligned to the staff based on a defined ratio, which has proven to be successful to ensure availability and engagement with staff. Day-to-day operations are managed and coordinated by dedicated PV managers who report directly to dedicated project associate directors. This resourcing model has enabled PPD to provide the biopharma company with the ability to manage capacity needs and fluctuations in case volumes while maintaining compliance, a high level of quality, timely delivery and, ultimately, an efficient economic model.

Figure 1. How the relationship has grown

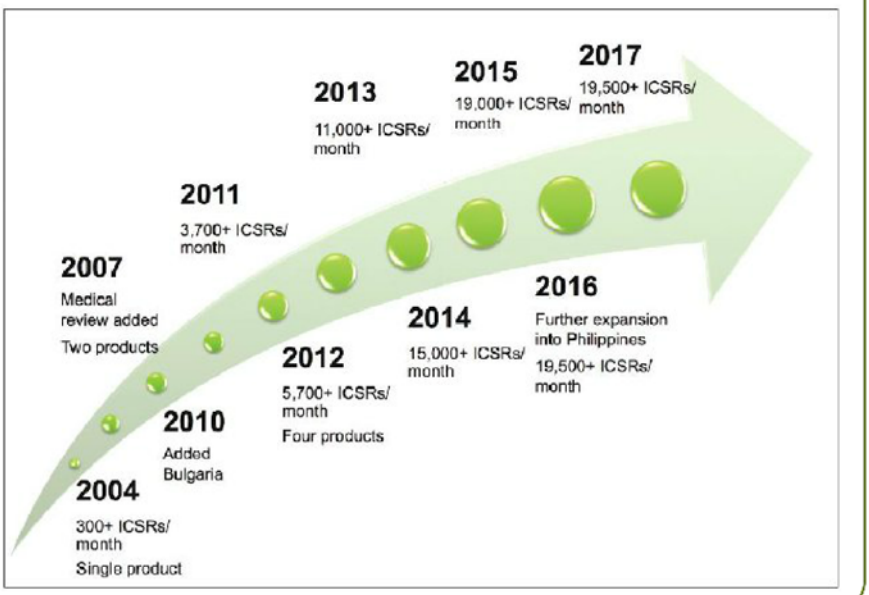


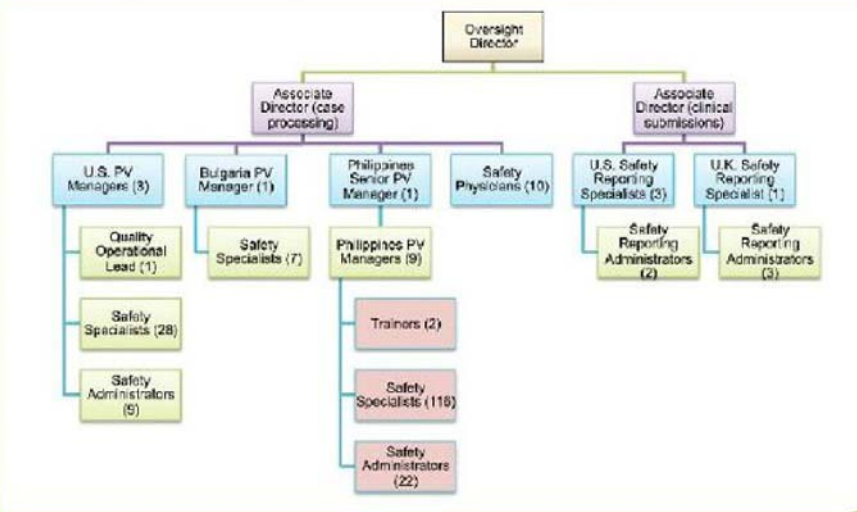
Table 1. Successful strategies that have delivered success

Reduction in ICSR cost	• Transitioned the placement of work to primarily reside in PPD's Philippines location
Scalability	• Leveraged PPD PV's global footprint to provide adequate coverage for case processing (mainly U.S. and Philippines) and clinical safety report submissions (U.S. and U.K.)
On-demand availability for additional work and on-time deliverables	• Utilization of a dedicated flex team (Bulgaria) to absorb ad hoc requests and volume spikes • Percentage of Philippines staff adhere to a U.S. work schedule and holiday calendar
High quality and compliance metrics	• Dedicated trainers provide consistent and efficient training to staff to promote high quality and compliance • Dedicated quality operational lead to assist with quality management activities
Technology and innovation	• Non-serious AE batch medical review performed by safety specialist with appropriate education/background • Development of electronic safety reporting process to investigator sites • Ongoing machine learning pilot – automation of initial entry and triage process

Figure 2. Acceptable quality standard scores per PPD's procedures

Figure 3. ICSR regulatory authority safety reporting compliance for submissions performed by PPD

Figure 4. Operational team structure



The roles of the team (e.g., safety specialists, safety reporting specialists, safety physicians, safety administrators and additional support staff) are summarized in Figure 5.

Effective Governance

In addition to this staffing model, PPD, in collaboration with the biopharma company, introduced an effective governance structure (Figure 6) to ensure key information, metrics and issues were consistently addressed at the appropriate level of management. The governance structure included key personnel from PPD and the client who were empowered to make decisions and serve as the primary contacts within the defined escalation pathways. The governance structure illustrates at a high level the program oversight and daily operational structure for the program. Experience has shown that this governance structure provides the oversight that guarantees customer satisfaction and project longevity, as the project oversight is constantly reviewing, and implementing process enhancements that improve efficiencies and ensure the processes and team always are optimal for the volume and content of the work.

Cost-Efficient Resourcing and Process Optimizations

PPD's proactive recommendation to conduct marketed-product ICSR processing activities in cost-efficient countries provided a cost control solution in response to program expansion. By utilizing PPD's Bulgarian PV resources, with further expansion into the Philippines in 2012 and then again in 2016, this approach resulted in annual cost savings to the client of approximately 40% compared to the original resourcing model, while continuing to meet key performance metrics measuring quality and compliance.

PPD's PV management team worked to identify process optimizations to enable the team to achieve optimal case handle times. These optimizations were implemented for narrative generation, medical review of non-serious cases and follow-up request activities, which provided approximately 22% in annual cost savings.

Furthermore, for clinical trial safety report submissions, a process improvement was implemented to automate the distribution of safety reports to clinical trial investigators via a portal. This resulted in annual cost savings to the biopharma company of approximately 80%.