

FUNCTIONAL SERVICE PARTNERSHIP: LARGE-SCALE POST-APPROVAL CASE PROCESSING



BACKGROUND

Approval is just the first step – the increasingly complex regulatory requirements in the pharmaceutical industry demand that a robust, comprehensive pharmacovigilance (PV) program is built in to every trial. Early identification and management of potential risk help ensure well-informed patients and, ultimately, a safer product. But this process of collecting, monitoring, researching, assessing and evaluating information can be a challenge.

This client, a large biotechnology company, had been working with PPD on a small scale for some time. Though the company typically maintained full strategic oversight in outsourcing relationships, it approached PPD for a 360-degree view of multiple clinical studies and post-approval safety work (end-to-end processing from book-in/triage to submissions to RAs, ECs/IRBs and PIs).

OBJECTIVE

Help our client get out of the day-to-day work and provide strictly oversight. By partnering with PPD, our client wanted help in developing a program structure that allowed for maximum resourcing flexibility to better manage significant fluctuations in project volume and control fixed labor costs.

CHALLENGES

When PPD first began case processing for this client, just four U.S. staff members handled approximately 300 U.S. individual case safety reports (ICSR) per month for a single product. The client needed a partner capable of taking on much more project responsibility. That turned out to be nine high-volume products with more than 20,000 cases per month.

There was also a geographic component to the projects, needing the team to be located in multiple locations around the globe. Given that, our client needed a solution that provided:

- + Scalability
- + On-demand availability for additional work
- + On-time deliverables

- + The highest caliber of quality
- + Consistency

STRATEGY

Working closely with our client, PPD developed two different processing team models, one for the beginning phase of the program and one that could grow as the program expanded.

- + As the complexity level increased, PPD developed specialized processing roles and teams based on compound complexities, partner agreements and processing nuances
- + PPD chose to divide the team between North America and the Philippines, a high-quality, local operating country (LOC)
- + A dedicated global trainer, along with the global project management team, ensured consistent processes and high-quality work that met all deliverable timelines
- + New positions were key, such as a process optimization staffer who wrote processes and performed quality analysis, as well as a quality management person and a training specialist

- + To stay on track, PPD met monthly with the client to perform tactical assessments and review key performance indicators (KPI), confirm schedules, etc.
- + Quarterly executive governance also helped assure the program was achieving its goals

RESULTS

The highly collaborative relationship allowed PPD to create a development model with the scalability, flexibility and efficiencies our client wanted.

In the first few years of the relationship, the PPD® FSP team grew from four to greater than 80 staff globally, in all regions, supporting more than 70 clinical studies and 17 products. By 2012, more scope and significant volume increases enabled the addition of case processing teams in

PPD's Bulgaria and Philippines offices. Currently, there are more than 300 staff working with the client across three locations (U.S., Bulgaria and Philippines).

Effective project management ensured deliverables were achieved on time to a high quality standard. Certified trainers within each region ensured consistency, and maximized training schedules during the onboarding process and as the project continued.

Once specialized processing roles/teams were developed and the global trainer role was implemented, processing efficiencies increased. Over the course of this more than ten year relationship, the client was able to increase the case volume nearly 70 fold – from 300+ ICSRs per month to 21,400+ ICSRs per month.

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