CASE STUDY

# FUNCTIONAL SERVICE PARTNERSHIP: GLOBAL SITE MONITORING AND MANAGEMENT OF INSOURCED TRIALS

## BACKGROUND

With the ever-increasing focus on quality, operational success and costs control, companies continue to look for innovative commercial models. With those as its goals, one of PPD's large pharmaceutical partners shifted from decentralized insourcing in local operating countries (LOC) to an FSP LOC model. This client consulted with PPD® FSP concerning its growing concern over disparate local resource utilization and a need for greater transparency and unified geographic management. PPD recommended a strategy to consolidate vendors and centralize internal clinical monitoring resources across 43 LOCs.

## OBJECTIVE

This large pharmaceutical company approached PPD for a solution to centralize its global site monitoring support, reduce its global footprint, consolidate vendors, maintain business continuity and quality, and reduce costs.

## CHALLENGES

The client was managing more than 100 insourced trials across 44 countries with nearly 20 new trials launching, all of which required 575 study managers, monitors and study assistants. Our client supplemented its internal staff of 125 with an additional 450 contingent workers. These workers came from more than 100 vendors and contracts. Financial and operational oversight was spread across each country affiliate, making it very difficult for our client to:

+ Forecast resourcing needs and oversee utilization
+ Budget effectively
+ Implement best practices and efficiencies
+ Manage administrative burden and
+ Control costs

## STRATEGY

The PPD FSP team worked with our client to:

+ Become the sole provider of global monitoring services for studies managed internally by the client
+ Transfer 125 internal clinical staff – as well as another 100 key contingent workers – to PPD over a six-month period. More than 75 percent accepted positions within PPD and retention through the first six months was more than 97 percent.
+ Recalibrate the workload to resources required based on study priorities and reduce its global clinical operations footprint from 44 to 20 countries

## RESULTS

In conducting a country-by-country analysis, PPD and its client determined that this partner's monitoring resources were substantially underutilized. PPD is performing the site monitoring and management tasks with approximately 400 staff, compared to the original 575 clinical operations staff. Deploying this model with PPD allows this client to manage its fixed costs by not over-hiring or needing to re-allocate internal clinical staff if research and development falls short of target.

For legacy studies, PPD uses the client's systems and hardware along with a mixed use of client/PPD facilities, as required. To ensure a smooth transition, each staff member

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transferred to PPD is 100 percent dedicated to our client's research portfolio and remains so until client need and work volume decreases. For new studies, PPD works with the client to assess the value of shifting to PPD systems and processes, as well as moving to an outputs-based model.

As the sole global provider of this client's internal site startup, monitoring, contracts and payments functions, PPD FSP has helped our client shift from decentralized insourcing to a truly global FSP model, resulting in significant improvements in transparency, administrative burden and resource efficiencies. Our client reports that the shift has generated at least $15 million per year in savings based on consolidation alone, with greater savings expected due to increased staff utilization.

**PPD FSP: People who deliver.**

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