

WHITEPAPER

PPD[®]



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Partnering with PPD's Biometrics Teams in a Functional Service Partnership (FSP) Model

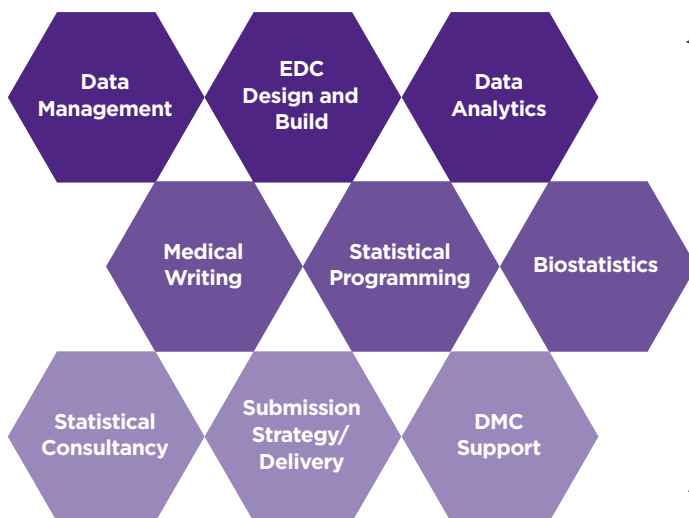
PPD® FSP is a global leader with more than 20 years of experience delivering FSP solutions to its partners. Our experienced staff has worked with nine of the top 10 biopharmaceutical companies, providing customized outsourcing solutions with high-quality, measurable outcomes and proven cost savings across a broad range of service areas.

With an experienced, best-in-class biometrics FSP offering, PPD FSP provides you the local control you need with global delivery. We customize our services to meet your technology, process and portfolio needs, making the PPD FSP team an extension of your internal biometrics workforce. This approach, combined with our culture of continuous improvement, ensures efficiencies and quality that drive down fixed costs and shorten timelines.

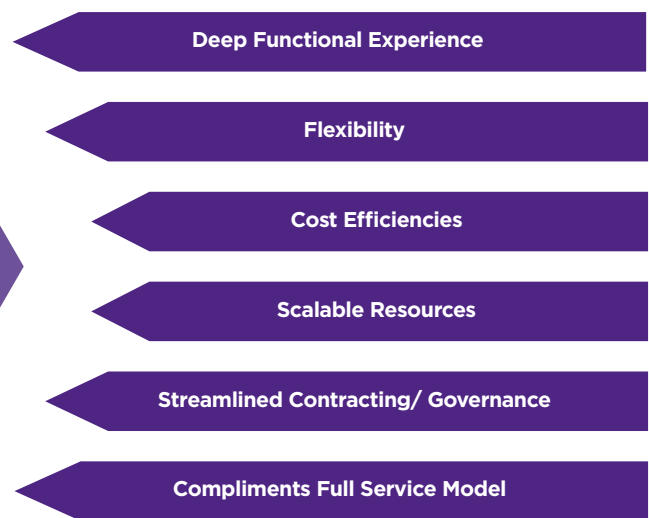
PPD offers FSP partnership models that ensure operational, budgetary and timely success based on:

- **Synergies of Experience.** Partnership collaboration expands the experience and expertise for both organizations, helping to enhance operational delivery and management.
- **Flexible Resources.** Scalable, trained resources with expertise in your processes and systems.
- **Enhanced Performance.** Key performance and relationship indicators measure success and form the foundation of process improvement opportunities to further increase productivity and reduce timelines.
- **Quality and Innovation.** Leading problem-solving methodologies and quality practices ensure robust, yet flexible, continuous improvement programs that generate time and cost savings.
- **Financial Benefits.** Efficiencies, optimization of resources and project management overhead, along with competitive pricing, drive costs down.
- **Global Presence.** Local control and global delivery provide client-specific support for country, regional and global deliverables, across single and multiple functions.
- **Customization.** Tailored services to meet your technology, process and portfolio needs, making PPD FSP an extension of your internal workforce.

Key Services



Benefits



In the marketplace, FSP services are too easily seen as simply staffing or fulltime equivalent (FTE) offerings. At PPD, we see things differently and divide the FSP market into three categories:

- Staffing/FTE-based
- Unit-based
- Outputs-based

Scalable Partnership Models

A successful and productive partnership is the result of ensuring a common foundation is established to drive the success of the partnership for current and future projects. Utilizing FSP commercial models that generate process improvements and utilize innovative operating models result in greater efficiencies in processes and resourcing that produce time and cost savings.

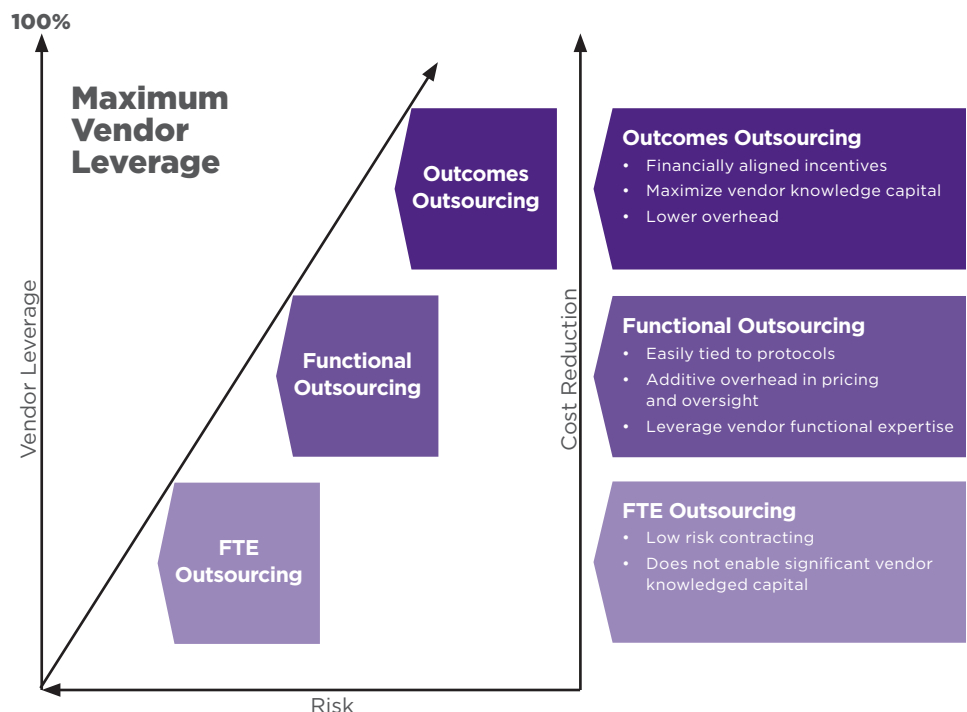
A staffing/FTE-based approach to FSP models does not always encourage continuous improvement in performance, processes or deliverables because the CRO is reimbursed for the number of staff members provided to the client. While staffing solutions offer strong transparency in costing they offer less incentive for process improvements. PPD's strategy is to offer clients outputs-based FSP models, which encourage innovation and drive ongoing efficiencies.

PPD's outputs-based FSP approach offers several key advantages when compared to a traditional staffing/FSP-based model:

- Direct alignments between payments and desired end goals
- Incentivizes PPD financially for performance
- Minimal administrative overhead
- Reduced vendor performance risk
- Cost savings shared over time with simple and transparent pricing

This model would allow PPD to bend the time and cost curve by aligning incentives without reducing margins.

The increasing benefits of these flexible FSP models are represented in the following figure and can evolve depending on your needs and decision drivers at any point in time. As your needs change, we can move gradually from the low-risk FTE outsourcing model, through the functional outsourcing model and then to the outputs outsourcing model across any period of time.



PPD's FSP Biometric Experience

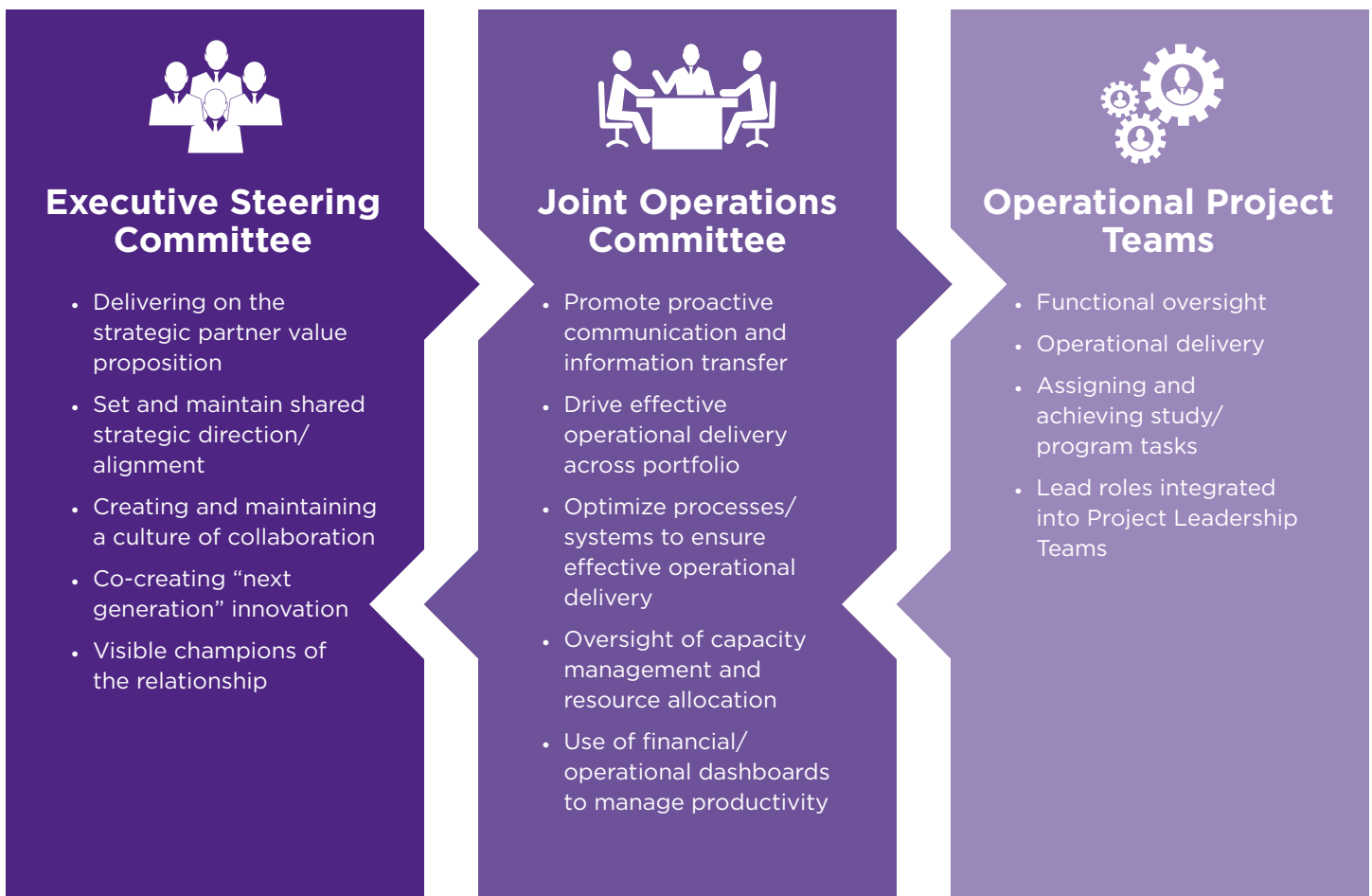
PPD offers a full and comprehensive range of biometrics FSP services, including data management, electronic data capture (EDC) build and management, data analytics, medical writing, statistical programming, biostatistics, statistical consultancy, submission strategy and delivery, and data monitoring committee (DMC) support, thus enabling you to have a single CRO providing all your biometric FSP services.

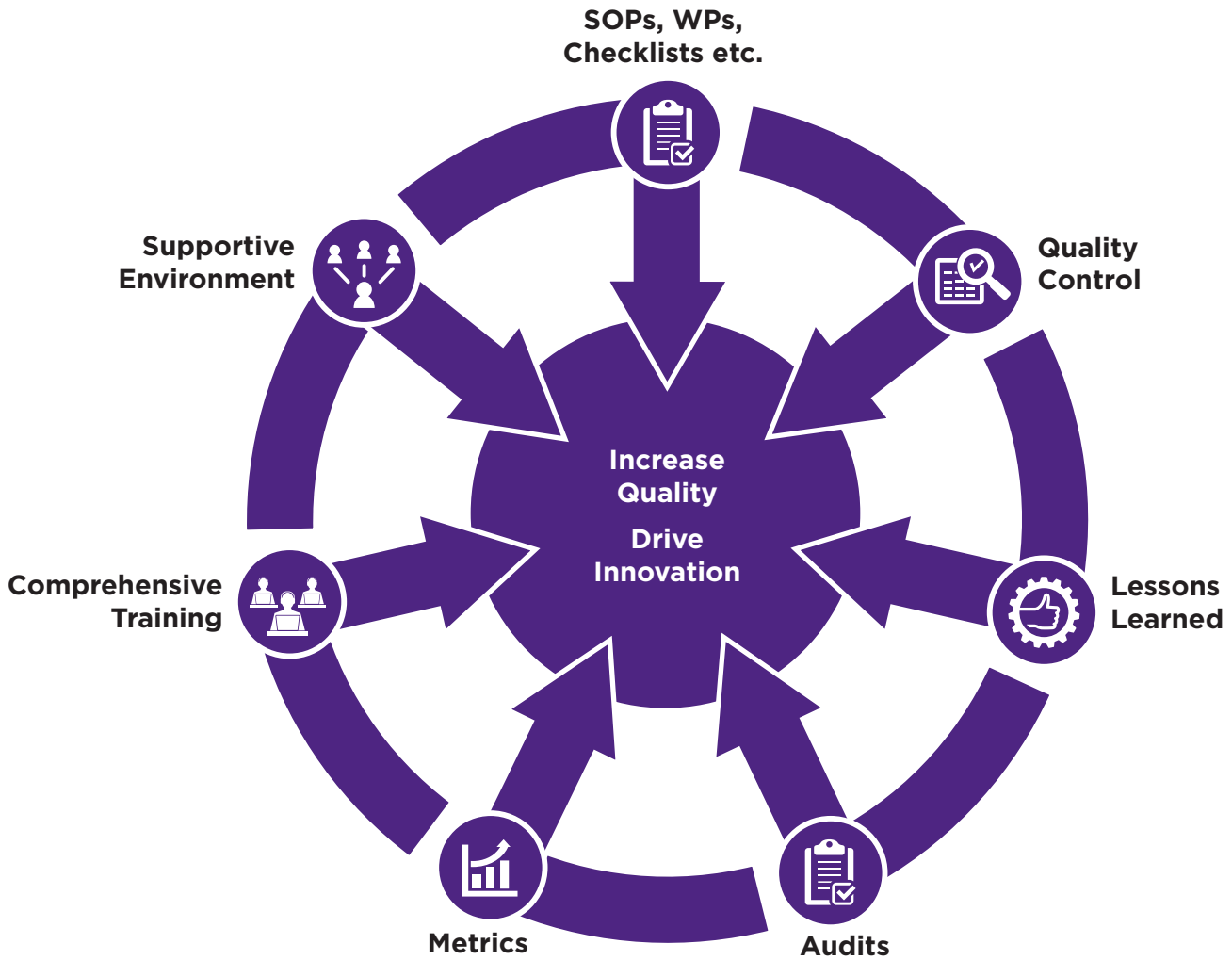
We provide a flexible approach to resourcing through a matrix-organized management environment, allowing us to break the traditional siloed staffing models and offer you dedicated resources with broad corporate knowledge capital. This resourcing approach enables PPD employees to work within the FSP area of our business while leveraging the innovation and expertise of our Phase II-IV business.

Partnership Governance

The success of an FSP partnership is largely dependent upon the level of collaboration and commitment between the partners at every level of the partnership from executive management to the operational team, as well as all stakeholders. PPD prides itself in providing you strong, cohesive, collaborative partnerships and recognizes the intrinsic values these partnerships help to create and sustain success. To establish a successful governance model to support a partnership, PPD recommends establishing close relationships at several levels of our organizations as shown in the following figure.

The goal of the governance model is to be as streamlined and flat as possible to maximize communications between the teams and accountability to the partnership, while minimizing the duplication of roles between your internal teams and PPD. The governance structure provides clear lines of communication and engagement to facilitate the optimal conduct of the partnership and the studies delivered under it.





Quality and Innovation

PPD FSP is committed to quality and innovation in every aspect of our business. Throughout our partnership, key quality indicators (KQI) will be implemented based on mutually agreed upon metrics and key performance indicators (KPI). In addition, we will integrate quality control measures throughout the processes of each operational department to ensure high-quality data is generated across all functions at key milestones/or critical time points of a study.

Innovation is at the core of our business, which is reflected in our ongoing commitment to the process improvements that are necessary to ensure our long-term relationship is a success. Through our technology, innovation and performance teams, PPD provides a leading-edge focus by combining technology solutions with process improvement, analytics and training. This integrated approach to addressing your challenges will ensure that a comprehensive, integrated and operational solution is achieved, resulting in efficiencies to the partnership.

Local Control with Global Delivery

Our integrated resourcing approach provides you control at the local and country level with global delivery, supported by core and flexible resources, is the foundation of all our FSP engagements. Staff allocated to you are treated as one unified group of dedicated resources and become integrated with your functional team. This structure is proven to create successful teams, generating a “one team” approach, encouraging knowledge sharing and positive, productive lessons-learned sessions.

All staff assigned to a partnership receive internal PPD corporate training and will be provided with training on your specific standard operating procedures (SOP) and processes technologies. In addition, study-specific training is conducted prior to beginning work under the partnership and all staff will have the appropriate access to your systems and the PPD systems required to deliver their work.

PPD’s client-facing roles are in the same time zone to optimize communications and interactions with your functional and clinical teams. These client-facing resources are responsible for all operational delivery and project manage all deliverables and any project risks, as well as being charged with driving innovation and operational standardization to increase efficiencies. Our resources are therapeutically aligned and assigned to a project based on their experience, their location, the project indication and your requirements. When possible, PPD FSP utilizes our current employees and, when required, newly hired resources from within the clinical trials industry or staff transferred from your company. This customized approach ensures we quickly and efficiently attract the best talent available for your projects while minimizing the transition time.

Standard Management Operation



Client Facing (Local) – Actively participate within the client team and engage with primary leads



Core Team (Global) – Activities that can be globally standardised requiring minimal regulatory currency are maintained off-shore



Core Team (Local) – Activities that need regional specific knowledge, regulatory currency or complicated communication are kept local

Our clinical data management services include:

- Electronic case report form (eCRF) design
 - Database design and study setup
 - Integration with clients' existing systems and processes
 - Medical coding to industry standards and client-specific dictionaries
 - Data validation and query resolution
 - Management and reconciliation of third-party data
 - Project management of all data and technical services
 - Clinical Data Interchange Standards Consortium (CDISC) study data tabulation model (SDTM) mapping and consolidation
 - Resource management flexibility
 - Strategy consultation
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Service Area Capabilities

Clinical Data Management Services

Clinical data integrity is paramount to the success of any project. You can employ the technology, processes and expertise to deliver high-quality data and meet the operational needs of your projects with our clinical data management strategic FSP solutions. PPD offers functional outsourcing capabilities across a broad range of therapeutic areas, EDC technologies, third-party vendors, Phase I-IV clinical trial services and medical affairs.

PPD works closely with you to develop customized data collection technology and processing requirements to meet your unique operational delivery needs. PPD offers the ability to work within our SOPs and technologies, or leveraging your procedures and systems. By leveraging primarily PPD SOPs and data capture technology software, including “real-time” interfaces with third-party core laboratory, imaging, electronic patient reported outcomes (ePRO) technologies, we can improve the speed of data acquisition and review. Regardless of the underlying operating model, PPD enforces strict adherence to the partnership’s operating and quality procedures throughout every stage of a project to drive data integrity

Located in multiple offices around the world, our clinical data management staff has the flexibility and expertise to meet your local and global needs. Our commitment to the partnership and each individual project includes efficient and cost-effective services of the highest quality, and a comprehensive and integrated package of services with a team of experts dedicated to your success. Our teams communicate closely with you throughout all phases of development and across each project to ensure alignment, proper escalation paths and delivery to timelines.



Case Study: Data Management FSP

PPD FSP has delivered data management and EDC services on more than 160 trials for a biopharmaceutical client over the last five years. Our global core team has ramped up to more than 200 FTEs at various times to address high data volumes. By establishing a strong, global team, PPD has delivered consistently on timelines and quality across its entire portfolio. The team is organized to support the varied requirements of multiple therapeutic teams while delivering consistency across the complete portfolio through operational transparency and application of relevant process and data standards. Through effective governance, sharing best practices and team empowerment, our relationship with our client has resulted in a cost-efficient, high-functioning united team clearly aligned to our client’s corporate goals and objectives.

Our deep understanding of the science of disease and compounds, along with valuable upfront study design input and comprehensive planning assistance serve to:

- Accelerate decision-making.
- Drive proactive risk management.
- Ensure consistency and quality of global deliverables.
- Optimize efficiencies with robust processes and global infrastructure.

Biostatistics Services

Statistical veracity from effective study design through data analysis and beyond is paramount in this highly competitive drug development environment. Having the right data at the right time can make a significant difference in your research and development investments. PPD's global clinical biostatistics and programming team offers more than statistical analyses.

Our commitment to quality is demonstrated through effective processes, detailed documentation for global auditability, and independent quality and senior statistical review activities that deliver a comprehensive quality control and validation process. Colleagues from any of our global sites follow those same SOPs and exploit the same software and data on the same biostatistics technology infrastructure (BTI). This centralized computing platform with a full audit trail, enhances our ability to deliver secure/firewalled, quality reporting and data analysis using both client and standard templates ensuring efficient high-quality real time analyses to meet your timelines.

PPD's extensive clinical biostatistics services are comprehensive and can be tailored to meet the needs of any partnership. That includes:

- Clinical development planning, study design, analysis and endpoint strategies, as well as supporting methodologies.
- Protocol development support, statistical analysis plans and the development of comprehensive methods reports describing planned and exploratory analyses.
- Analysis strategies that are ICH-compliant.
- Randomization schedule creation and integration within interactive response technology (IxRS).
- Production of audit-ready tables, listings and figures.
- Scientifically sound interpretation and reporting of results with efficient, quality production of deliverables.
- Real-time analysis presentations throughout the study with automated and secure web postings.
- Data and safety monitoring board (DSMB) output, interim analysis and investigational new drug (IND) safety updates.
- Integrated submissions of statistical sections.
- New drug application (NDA) submission-ready data delivery in CDISC format and strategy development.
- Collaboration with medical writers and clinical scientists to ensure appropriate interpretation of quantitative results.
- Manuscripts and abstract support.

As a leader in advanced statistical methods, our statistical scientists:

- Promote, design and implement the most advanced, effective and efficient statistical methods.
- Provide short-term consulting and collaboration on the designs and statistical analyses of individual trials.
- Partner in the long-term planning and execution of entire product development programs.
- Offer technical proficiencies in a variety of therapeutic areas, including oncology, neuroscience, rare diseases, vaccines and many more.

We also provide external training and development in new statistical methodologies, such as:

- Simulations
- Bayesian analyses
- Statistical forecasting

Expert Knowledge of Advanced Statistical Methods

PPD's statistical science team helps clients apply the right statistical methods and trial designs at the right time to make a significant difference in their R&D investments. We are committed to helping maximize returns on your products through the promotion and implementation of innovative, efficient and informative statistical approaches.

Advanced Technology Solutions Provision

Our team of statistical scientists helps streamline and enhance drug development by applying innovative statistical solutions to optimize study design, accelerate timelines and ultimately improve the quality of regulatory submissions. Adaptive design



Case Study: Biostatistics FSP

PPD designed an FSP partnership to support a client's biostatistics and programming services across all phases in the U.S., Europe and Asia. This longstanding partnership has grown and evolved over time, starting with a biostatistics FSP partnership and expanding to include full-service outsourcing support. The client's satisfaction is evidenced by a recent five-year contract extension. Our dedicated teams balance the delivery needs of both outsourcing models, while using data and analysis standards and the lessons learned across each outsourcing approach to drive efficiencies across the whole partnership. Along with the client's team, many of PPD's senior biostatistical team members are based in the U.S., ensuring a collaborative relationship, while the PPD programming team and a number of senior statisticians are located in Asia, which helps drive down costs significantly. The team located in Asia supports global trials and specific in-country requests, and represents a critical element of PPD's global approach to FSP.

Medical Writing Services

PPD has an experienced team of medical writers that excels at translating complex scientific data into clear, robust scientific arguments in well-written documents designed to exceed expectations in terms of both content and formatting.

PPD has a comprehensive global suite of medical writers who are located in North America, United Kingdom, Spain, India, China and the Philippines, which enables PPD to support its partners regardless of time zones. The highly educated, highly trained and experienced writing team prepares and reviews support of clinical trials, regulatory activities and post-approval drug information for a diverse range of therapeutic areas. In addition, this team deploys technology-driven solutions to increase document development, collaboration and review to meet increasingly aggressive and changing timelines and manage volume fluctuations.

The PPD team has excellent interpersonal and collaborative skills ensuring that document development occurs with regular consultation with appropriate stakeholders to maximize expert input, ensuring study and program needs are incorporated.

Our wide range of medical communication materials includes:

- Phase I-IV protocols
- Phase I-IV integrated clinical statistical reports (ICSR)
- Global clinical trial applications
- Drug, device and biologic marketing applications
- Formulary dossiers
- Standard responses
- Investigator brochures
- Scientific slide sets
- Manuscripts and posters
- Risk evaluation and mitigation strategy (REMS)
- Medication guides and patient information leaflets (PIL)
- Premarketing and post-approval annual reports
- Periodic safety reporting
- Patient safety narratives
- U.S. Food and Drug Administration (FDA) briefing documents
- Risk management plans
- Pediatric investigational plans
- Medical editing
- Lay summaries



Case Study: Medical Writing FSP

A long-time biopharmaceutical partner required a dedicated writing team, aligned by compound, with a flexible pool of resources to manage workflow peaks and troughs as well as unanticipated deliverables. Through a unique combination of FTEs, unitized and T&M pricing models, PPD FSP is able to dedicate and maximize resource flexibility while minimizing cost to provide medical writing services across multiple therapeutic areas, and the full product life cycle. Key to the success of this partnership is governance, including activities such as portfolio planning/resourcing, while partnership lessons learned have fostered a strong PPD-client relationship. This partnership is now in its third year.

Combining Functions

Over the past few years PPD FSP has seen a move from single function outsourcing to a logical combination of functions e.g. biostatistics and medical writing or data management and biostatistics to increase the inherent operational, financial and quality advantages to drive further efficiencies, increase innovation and further reduce cost.



Case Study: Biometrics FSP

PPD has entered into a partnership to provide data management, biostatistics, programming and medical writing services support for a top 10 pharma client across multiple protocols and therapeutic areas, spanning Phases I-IV. Projects encompass a wide range of therapeutic areas, including oncology, cardiovascular, respiratory, vaccines and infectious diseases. This end-to-end biometrics service partnership is increasing efficiencies through deeper integration than a traditional single-function outsourcing relationship and allows the partnership to develop cross-functional innovation. The success of the project to date is due to the robust implementation phase in which clear roles and responsibilities were agreed on with both the client and the PPD teams. Incorporating change management principles into the implementation plans ensured a smoother transition and minimized resistance to change and helped establish a “one team” approach early in the project partnership.

Summary

PPD FSP is a global leader with more than 20 years’ experience in delivering strategic biometrics FSP solutions. PPD FSP supports all FSP models from time and materials to long-term output models, enabling us to provide the flexibility you need to meet your specific requirements. We look forward to partnering with you.

