

Partnering with PPD Clinical Data Management in a Functional Service Partnership (FSP) Model



Our highly experienced **clinical data management team** offers **customized services** to meet your technology, process and portfolio needs.

PPD® FSP provides the local control you need with global delivery, **making our team an extension of your internal workforce**. This approach, combined with our culture of continuous improvement, ensures efficiencies and quality that drive down fixed costs and shorten timelines, based on:



Synergies of experience. Collaboration expands joint experience and expertise enhancing operational delivery.



Flexible resources. Scalable resources with expertise and training in your processes.



Enhanced performance. Metrics form the foundation of process improvement to increase productivity and reduce timelines.



Quality and innovation. Continuous improvement programs result in high-quality deliverables along with time and cost savings.



Financial benefits. Efficiencies and optimization of resources drive down costs.



Global presence. Local control and global delivery provide client-specific support for country, regional and global deliverables.



Customization. Tailored services to align with your technology, process and portfolio.

Quality and Innovation

Innovation to improve the quality of both the process and data is key to our data management business and is reflected in our commitment to continuous growth. Technology and operating process investment underpin operational solutions, leading to efficiencies and quality, driving long-term partnership success.

Local Control with Global Delivery

Our integrated resourcing approach provides you control at the local, country-level with global delivery, supported by core and flexible resources. PPD FSP staff are a unified, dedicated group who become integrated within your data management function. This structure is proven to create successful teams, generating a “one team” approach, encouraging knowledge sharing and positive, productive interactions across the partnership.

Clinical Data Management Services

Clinical data integrity is paramount to the success of any project. PPD FSP offers the technology, processes and expertise to deliver high-quality data and meet the operational needs of your projects with our clinical data management solutions. With a team of experts committed to partnering we deliver efficient and cost-effective services of the highest quality.

PPD FSP will work closely with you to develop customized data collection technology and processing solutions to meet your unique operational delivery needs. Using either PPD standard operating procedures (SOP) and technologies or leveraging your SOPs and systems, we improve the speed of data acquisition and review. This enables strict adherence to operating and quality procedures to drive data integrity.

Located in multiple offices around the globe, our clinical data management staff has the flexibility and expertise to meet your local and global needs. Productive communication across all development phases and projects ensures partnership goals and operational delivery are aligned, while mitigating risks and delivering projects on time. PPD FSP covers the following data management services:

- Electronic case report form (eCRF) design
- Database design and study setup
- Integration with your 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
- CDISC study data tabulation model mapping and consolidation
- Resource management flexibility
- Strategy consultation

CASE STUDY



PPD FSP has delivered clinical data management and EDC services on more than **160 trials** for a top 10 biopharmaceutical client. With a global core team that has grown to more than **200 full-time equivalents (FTE)** throughout the partnership to address high data volumes. By establishing a strong, global team, **PPD FSP has delivered consistently on timelines and quality** across the entire portfolio. The team is organized to support the varied requirements of **multiple therapeutic teams**, while delivering consistency across the entire portfolio. Our operational transparency and application of relevant process and data standards are critical to this success. Through effective governance, team empowerment and the sharing of **best practices, our relationship with our client** has resulted in a cost-efficient, high-performing team clearly aligned with our client's corporate goals and objectives.

Our Talent, Your Team

Get dedicated resources using your systems, processes and standards. Our FSP staff has the same high standards, training, career development opportunities and support as PPD staff assigned to full service. Our clinical data management group offers global solutions with flexible models spanning all time zones allowing for 24-hour coverage. We deliver clinical data management services in several widely accepted electronic data capture (EDC) environments with interfaces to virtual technology, core laboratory, imaging and other ancillary systems. Our goal is to provide our customers with speed and accuracy of data acquisition to improve data quality, transparency and review, and to minimize timeline risks.

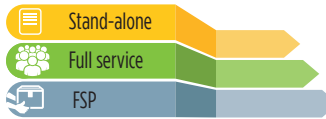
The clinical data management team at PPD maximizes the quality and integrity of patient data delivery to support protocol requirements. Ensuring that validation processes are in place for all patient data sources, we identify critical risks, design data-capture systems to drive real-time data collection and implement processes to minimize errors. Here, we do work that helps save lives.



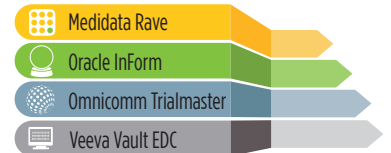
1000+ CLINICAL DATA MANAGEMENT STAFF
REGIONAL HUBS IN **10** COUNTRIES ACROSS **4** CONTINENTS

OUTSOURCING SOLUTIONS FROM LARGE TO SMALL

Multiple Outsourcing Solutions



Flexible CDMS Offerings



We Set and Achieve Demanding CDM Cycle times and Performance



Final Specifications to Electronic Data Capture (EDC) Go-live



EDC prior to First Patient Enrolled (FPI)



FPI to Study Data Tabulation Model (SDTM) in production (eCRF)



FPI to Data Management Plan (DMP) Approved

100% of Databases in Production Prior to FPI in PPD control

Critical Audit Findings - 0

FPI to Back-end Checks in Production



Last Patient Out (LPO) to Database Lock



We Increase Efficiencies

- One “study team” approach
- Pre-planning, beginning with the end in mind
- Detailed project plan encompassing all stakeholders
- Metrics published to measure team performance
- Data flow forecasting and measuring to match need with resource deployment
- Feedback mechanisms within study team to ensure site enters data and resolves queries in real time
- Use of data collection and reporting standards (new standards developed at the planning stage)
- Apply lessons learned from prior experiences
- Consistency of team members across a program of studies
- Cross-functional review of key documents by key decision-makers
- Facilitated reviews to make review time more efficient and effective for team members
- Holistic communication aided by technology (essential for keeping track of progress and working together efficiently)

