PPD Functional Service Partnership (FSP) Clinical Data Management solutions

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Empower study teams to make faster and smarter decisions to meet your timelines

As the industry moves toward more complex designs, including adaptive trials and the use of direct data capture from patient-reported sources such as wearables and biosensors, the volume of clinical trial data is increasing exponentially. This makes clinical data management (CDM) critical to efficiently consolidating disparate data sources into one centralized place and ensuring proper validation and review — all done with speed and transparency while maintaining data integrity and quality.

Through comprehensive CDM solutions available in a functional service partnership model, **PPD™ FSP (FSP) Clinical Data Management solutions** helps biopharmaceutical, biotech, and medical device organizations safeguard the integrity of their clinical trial data. With expertise built over 30 years, our end-to-end CDM solutions provide the technology, processes and know-how needed to quickly deliver quality data, empowering study teams to make faster and smarter decisions to meet your timelines.

Key areas of focus

- Embracing new technologies and better processes
- Reducing manual burdens
- Driving real-time data management and collection
- Consolidating disparate data sources

End-to-end clinical data management solutions safeguard data integrity

Our customized end-to-end CDM solutions offer the technology, processes, and expertise needed to deliver quality data across a broad range of therapeutic areas, electronic data capture (EDC) technologies, third-party vendors, Phase I-IV clinical trial services, and advanced data cleaning strategies.

As an extension of your internal workforce, our team embraces new technologies and processes to introduce efficiencies and reduce manual burden. More than just technologists, our data managers are data stewards, always seeking opportunities to drive real-time data collection and management and consolidate disparate data sources.

By combining clinical trial data — whether from a single study or a collection of studies, at the compound or portfolio level, or from external vendors — we significantly increase data transparency and the quality of decision-making to help you meet your timelines.

Comprehensive solutions encompassing the full data lifecycle

- Strategy and setup
- Execution
- Technology

…across a broad range of…

- Therapeutic areas
- Electronic Data Capture (EDC) technologies
- Third party vendors
- Phase I-IV clinical trial services
- Advanced data cleaning strategies

Local control with global delivery

We offer global CDM delivery with country-level control to provide dedicated, unified support from our experts in more than 30 countries on five continents. For every enagement, on-site and virtual teams work seamlessly together within your data management function, with client-facing roles filled in the same time zones as your functional and clinical teams. With this proven approach, we collectively create successful teams, encourage knowledge sharing, and produce positive, productive interactions throughout the duration of our partnership.

Global footprint and 24-hour coverage

- Client-specific support for country, regional and global deliverables
- 1,000+ CDM employees in 30+ countries
- Global teams integrated into client functions
- Client-facing roles in same time zones as client teams
- Employees across time zones for 24-hour coverage
- Virtual teams working seamlessly and productively

Track record of success spanning 30+ years

- More than 30 years of delivering results
- More than 1,700 studies and 350 submissions delivered in Clinical Data Interchange Standards Consortium (CDISC) format
- 0% of databases unfrozen due to quality concerns in the past year
- 100% of databases in production prior to first patient in when within our control

Working closely with you to custom-fit the best possible model

We partner with you to find the best bespoke outsourcing model for your needs, including a flexible mix of systems, processes, oversight, and facilities — either yours or ours. Our solutions provide flexibility to embed staff within your workforce or take the business fully in-house using innovations. And our project teams include a custom mix of roles led by a director who oversees processes, timelines, contracts, and quality standards.

We also work closely with you to develop customized data collection technology and processing solutions, focused on improving the speed of data acquisition and review while strictly adhering to operating and quality procedures. All staff assigned to a partnership receive full training (client SOP, internal, and study-specific) prior to beginning work. And our professional development and learning culture help increase CDM employee engagement and retention.

Flexible models

CHOOSE
Processes, oversight and facilities…
YOURS OR OURS

ADD
Staff to your workforce
OR
Bring the function in-house

CUSTOMIZE
Project teams with:
- Group leads
- Clinical DM project leads
- Clinical data team leads
- And more

Flexible systems

CHOOSE
SOPs, systems and technologies…
YOURS OR OURS

SUPPORT
The most frequently used EDC systems in the industry

SUPPORT
Decentralized (DCT) technologies including:
- eCOAs
- ePROs
- Wearables

We have supported
1,700+ studies
across the most-used EDC systems

- Rave EDC (Medidata)
- Oracle Inform
- TrialMaster (OmniComm)
- Vault EDC (Veeva)
- AutoEndcoder
- Medidata eCOA

Thermo Fisher SCIENTIFIC

Talk with your account representative or visit **ppd.com/fsp-clinical-data-management** to learn more about how PPD FSP Clinical Data Management solutions can help you safeguard data integrity to meet your timelines.

Learn more at **ppd.com**

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