

PPD® FSP: Biometrics Functional Services

PPD® FSP is bending the cost and time curve of drug development through our global infrastructure and experience, delivering scalable and flexible resourcing models across a full range of biometrics services. Leveraging more than 30 years of experience as a global CRO, PPD delivers a robust, best-in-class functional service partnership (FSP) biometrics offering, that includes:



Clinical data management



Biostatistics and programming



Medical writing

PPD FSP's biometrics offering brings you the local control you need with global delivery. We tailor our services to meet your technology, process and portfolio needs, making us an extension of your internal workforce. This approach, combined with our culture of continuous improvement, delivers efficiencies and quality that drive down fixed costs and shorten timelines.

CLINICAL DATA MANAGEMENT

You can employ the services that best meet the needs of your projects with PPD's clinical data management strategic FSP solutions. Across a broad range of therapeutic areas and data collection technologies, PPD leverages extensive data management experience from functional partnerships, Phase I-IV clinical trials and medical affairs.

Our globally located clinical data management staff has the flexibility and expertise to meet local needs and applies quality standards and processes to successfully complete even the largest and most complex clinical programs. Your dedicated team communicates frequently throughout a project to provide the most efficient and cost-effective services of the highest quality. From PPD FSP's clinical data management team, you can expect:



Global standards that ensure consistency of clinical data management



Flexibility to meet your needs throughout project life cycles



Quality management of data integrity



Seamless software implementation with your systems and processes



Specific technologies and best practices customized to your project

BIostatistics AND PROGRAMMING

PPD FSP's global clinical biostatistics and programming staff offers more than statistical analyses. We bring a deep understanding of the science of disease and compounds, as well as providing valuable upfront study design and comprehensive planning assistance that:



Our extensive clinical biostatistics services are comprehensive and tailored to meet your needs, and PPD FSP's global biostatistics staff has a broad range of therapeutic experience. Our statisticians hold advanced degrees and add value to your projects with data-driven information, analysis, interpretation and study design. The strategies developed by our statisticians are implemented by our experienced programmers who drive efficient technical solutions. PPD FSP provides:

- Thoroughly researched clinical development plans, study designs, analysis and endpoint strategies, with supporting methodologies and statistical analysis plans
- Scientifically sound interpretation and reporting of results with quality production of full-output deliverables
- Submission-ready data delivery in Clinical Data Interchange Standards Consortium (CDISC) format, new drug application (NDA) deliverables and strategy development

SUMMARY

PPD has strong experience in a number of strategic FSP contracting models and believes the cornerstone to maximizing return is based on appropriate alignment of our shared incentives. PPD FSP models are flexible and can evolve at any time depending on your needs and drivers. Whether it is through full-time equivalent (FTE) outsourcing, functional outsourcing or outputs-based contracting, PPD FSP is your partner of choice for biometrics FSP services.

MEDICAL WRITING

PPD FSP offers global medical writing services from our medical writers, quality reviewers and editors who prepare and review documents in support of clinical trials, regulatory activities and post-approval drug information. The team has offices in North America, United Kingdom, Spain, India, Philippines and China.

The global medical writing team's expertise includes Pharm.D., M.D., Ph.D. and master's degree-level writers with experience in diverse therapeutic areas and more than 10 years of average writing expertise. Board-certified editors with advanced degrees support the team, and our highly trained staff is accustomed to applying creative, technology-driven solutions to meet acute business needs even under the most aggressive and changing timelines. PPD FSP's medical writing team delivers:

