



HELPING DELIVER LIFE-CHANGING THERAPIES



PPD® FUNCTIONAL SERVICE PARTNERSHIP (FSP) SOLUTIONS
BIostatistics AND PROGRAMMING

APPLYING DEEP UNDERSTANDING OF SCIENCE TO STATISTICAL ANALYSIS



Under the challenges of collecting and analyzing increasing volumes of data from a growing number of disparate sources, it's imperative to find a partner with the specialized biostatistics expertise necessary to keep current with evolving industry practices, maintain accuracy, and meet global regulatory standards.

Through comprehensive strategy, design, and analysis expertise — available in a functional service partnership (FSP) model — **PPD FSP Biostatistics and Programming Solutions** helps biopharmaceutical, biotech, and medical device organizations drive insights and accelerate outcomes. With a proven track record built from decades of experience, we provide the right talent and expertise to help our clients meet their timelines — while providing much-needed resource flexibility, reliability, and continuity.

25+ years of experience in every phase of clinical development

Our biostatistics and programming team has supported **350+** biopharmaceutical, biotech, and government clients in nearly **1,200** studies spanning multiple therapeutic areas

We have conducted nearly **150** adaptive trials in a wide range of therapeutic areas

PPD contributed to **21** FDA approvals and **9** European approvals in 2022

COMPREHENSIVE BIostatISTICS SERVICES DRIVE INSIGHTS AND ACCELERATE OUTCOMES

PPD's global clinical biostatistics team combines expert study design, planning, and programming, robust data analytics, and comprehensive reporting to drive insights and accelerates outcomes. Our team supports every stage of the development lifecycle to accelerate timelines, reduce risk, and improve the quality of decision-making.

Solutions encompassing all facets of biostatistics and programming



Planning and Design

- Study design and endpoint strategies
- Adaptive designs, randomization methods, and schedules
- Statistical analysis planning and strategies
- Feasibility analysis



Evidence and Analysis

- Statistical analysis plans
- Modeling and simulations
- Powerful and innovative statistical methodologies



Reporting and Submission

- Comprehensive and concise reporting of key results and statistical assessments
- Integrated analyses and data visualizations
- Regulatory submission support and representation
- Support for manuscripts, abstracts, and data safety monitoring boards

BIostatISTICS AND SCIENCE EXPERTISE PROVIDE CONFIDENCE, CLARITY, AND FOCUS

Our biostatistics team offers more than statistical analyses. They combine biostatistics expertise with a deep understanding of the science of disease and compounds to provide unmatched confidence, clarity, and focus. By applying experience in all phases of clinical trials — in all parts of the globe and across a broad range of therapeutic areas — our biostatisticians and programmers blend scientific and technical knowledge that delivers more effective clinical designs, more detailed data analytics, and more accurate data interpretations.

Statistical areas of experience

- Adaptive trials
- Innovative design approaches (e.g., platform, basket, and umbrella designs)
- Bayesian analyses (e.g., continual reassessment method, or CRM)
- Statistical forecasting
- Simulations
- Estimands
- Missing data
- Interim analysis
- **And more**

We proactively facilitate collaboration and idea-sharing across the industry to help advance innovative methods that:



Accelerate timelines and decision-making



Reduce costs and risk of errors



Focus development on the most promising agents

ROBUST TECHNOLOGIES, PROCESSES, AND GLOBAL INFRASTRUCTURE DRIVE QUALITY AND COMPLIANCE

With an insider's understanding of the challenges of collecting and analyzing data, we use our solutions, processes, tools, and technologies — both industry standard and proprietary — to support our teams every step of the way, driving quality, efficiency, and compliance with every statistical deliverable. As the industry evolves, we embrace new procedures and technical solutions, such as wearables/data collection devices, virtual sites, or metadata solutions, to quickly adapt and apply novel solutions to the projects we support.

PPD also has the global infrastructure needed for client-specific support for country, regional and global deliverables. Programming based on written specifications, senior statistical review of deliverables, and independent quality validation verify accuracy and audit-readiness and drive consistent worldwide standards of quality delivery. We also take an active role in standards development as industry leaders participating in global regulatory standards groups, including the Clinical Data Interchange Standards Consortium (CDISC) advisory board and Clinical Data Acquisition Standards Harmonization (CDASH) team.



Technology systems employed

- **Biostatistics Technology Infrastructure (BTI)**
computational platform
- **Data Transfer Exchange (DTX)**
metadata-driven macros
- **Define on Demand (DOD)**
industry standard for eCRTs
(electronic case report tabulations)
- **Program Builder Tool (RACE-PBT)**
for creating executable SAS Programs
- **Preclarus®**
proprietary patient data dashboard
- **FACTS™**
software for early-stage adaptive trials
- **East®**
software for later-stage adaptive trials
- **R**
programming language for statistical
computing and graphics

CUSTOMIZED SOLUTIONS TO MEET YOUR SPECIFIC NEEDS

Since every project is unique, we customize our solutions and make your PPD FSP biostatistics team an extension of your internal workforce. Each team is empowered with the flexibility to provide solutions that meet your unique needs and include a customized mix of roles to efficiently plan and execute study analyses and ensure scientific integrity.

With key locations in North America, Europe, and Asia Pacific, we also allocate and onboard staff across time zones for 24-hour coverage to keep your study on schedule. And our professional development and learning culture also help make PPD a great company to work for, increasing employee engagement and retention.

Typical biostatistics team members



- Lead Biostatistician
- Senior Statistical Reviewer
- Lead Programmer
- Additional Supporting Staff

Over 70% of team members have advanced degrees

Nearly **900** biostatistics and programming staff in 16 countries across 3 continents



Training for all team members

Dedicated staff managers ensure that all those assigned to a partnership receive:

- Project-specific and/or therapeutic training
- Internal PPD corporate training
- “Just-in-time” training for particular tasks



Ongoing statistical training

Statisticians and statistical programmers also stay up-to-date on:

- Industry information such as 21 CFR Part 11
- Good Clinical Practice (GCP) and ICH standards
- SAS® software programming skills
- Statistical methodology including adaptive design

Talk with your account representative or visit ppd.com/fsp-biostatistics to learn more about how PPD FSP Biostatistics and Programming Solutions helps drive insights and accelerate outcomes so you can meet your timelines.



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