



Leveraging Our Knowledge for Your Success...Biostatistics • Data Management • Development Consulting

PharPoint is a drug development service company offering efficient and quality biostatistics and data management services to the pharmaceutical and biotechnology industries. It is our mission to be an extension of your project team and to provide the right solutions for your drug development model.

At PharPoint, we believe that every client's needs are unique and deserving of personalized attention. Our approach is to work closely with you to identify immediate, near-term and long-term requirements, then to create specific project teams and solutions designed to meet your goals. We take great pride in providing solutions that enhance and extend your internal capabilities.

Our business model is designed with minimum overhead and maximum efficiency within a framework of validated computer systems, regulatory compliance, and industry best practices. This low cost, adaptable approach, combined with our team of highly experienced professionals, enables us to deliver projects on time, within budget, and always of impeccable quality.

The pathway to a successful regulatory submission is laid from the very foundation of drug development. Strategic development consulting, followed by customized and robust data management and statistical services, leads to more effective study designs and data analyses that highlight successful submissions.

Experience

At PharPoint, we have experience in all phases of clinical development from strategic consulting and Phase I first-in-man studies to Phase IV post-marketing studies and patient registries. Our management team has over 130 years of combined pharmaceutical development experience and have worked together an average of 12 years. Our team has taken active roles in the preparation of eight NDAs and the development of industry guidelines. We have broad therapeutic expertise encompassing:

- Cardiology
- Endocrinology/Metabolics
- Infectious Disease
- Oncology
- Pain Management
- Dermatology
- Gynecology
- Neurology
- Ophthalmology
- Respiratory





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Biostatistics

We are knowledgeable in a variety of statistical programming software including SAS®, StatXact®, and WinNonLin®. We strive to ensure integrity of your data, organize the results in a clear and compelling presentation, and provide the information needed in a timely manner.

In fact, time from database lock to delivery of verified tables, listings, and figures is generally seven to 10 business days. Top line results can be delivered sooner.

PharPoint provides the following biostatistics and statistical programming services:

- Strategic clinical development consulting
- Protocol development
- Sample size planning and power calculation
- Randomization planning
- Detailed statistical analysis plans including mock tables, listings, and figures
- Statistical support for interim, futility, and DMC analyses
 - DMC support includes assistance with committee composition, preparation of the DMC charter, generation of the analyses, attendance at the meetings, and preparation of the meeting minutes
 - Experience with conditional power, sequential analysis methods, and other specialized statistical techniques
- Collaboration on integrated summaries of safety and efficacy and regulatory submissions including e-submission Item 11 preparation
- Quality output generated and verified using independent programming of all derived data, tables, and listings
- Experience with quantitative epidemiology including patient registries
- Data mining/exploratory analyses
- Regulatory and Advisory meeting support

Data Management

PharPoint offers an array of data services for both traditional paper and EDC based trials. Through tried and true data processes and the industry's leading technology for data capture, we clean your data and deliver your validated database on schedule.

PharPoint provides the following data management and database programming services:

- Data management plan creation
 - Data Flow
 - Pre-entry Review Guidelines
 - Data Entry Specifications
 - Clinical Coding Specifications
 - Data Quality Control Plan
- Study tools development (CRF, diaries, surveys, questionnaires)
- Data management project management
- Clinical database development and validation
 - Annotated CRF
 - Database Testing
 - Data Import Specifications
 - Data Export Specifications
- Data cleaning and validation
- Clinical coding of terms
- Systems validation
- Data management consulting services
- Data warehousing
- EDC vendor selection and data management study management/oversight
- CRF Tracking in Clintrial 4.5®
- Pre-entry review based on pre-approved Pre-entry Review Specifications
 - Obvious corrections document
- Single or double data entry
 - Single entry with 100% QC
- Query generation and resolution
- Clinical Coding (WHO, MedDRA)
- Quality Control Database Audit
 - Acceptable error rate of < 0.1%
 - Quality Control Audit Summary Report

Contact us to learn how our experienced team, streamlined processes, and intuitive software solutions can accelerate your product's time to market with quality data and comprehensive analyses, all while lowering your overall clinical development costs.