

Biostatistical Services for the Biopharmaceutical Industry

PharmaStat LLC Drug Development Consulting and Services

*Integrating good science,
information technologies,
and experienced implementa-
tion for successful drug
development*

Statistical Capabilities

- Clinical Development Plans
- Study Design & Protocol Development
- Statistical Analysis Plans
- Statistical Programming and Reporting
- Independent Data Monitoring
- Study Reports
- FDA liaison
- Consulting

PharmaStat can perform the full range of statistical services for pharmaceutical drug development. Use us as your outsourcing vendor for statistical analysis and study reporting. Alternatively, we can work as part of your in-house team, either onsite or offsite. We can even help you build and direct an in-house Biostatistics group if you need one. We have developed best practices and SOPs over many years of experience as statisticians and statistical programmers. We offer the following statistical services.

Collaborative clinical protocol development

We'll work with your clinical group to develop successful protocols for your upcoming clinical trials. Our protocol development services include:

- Study design
- Definition of objectives and endpoints
- Sample size and statistical power determination
- Statistical analysis strategy and methodology

Clinical Study Report Preparation

A prerequisite for a clinical study report is a prospectively defined statistical analysis plan. PharmaStat can develop the statistical analysis plan for you and then produce the following standard deliverables:

- Write-up of the statistical findings
- Tables, figures and listings
- Creation of statistical analysis files according to CDISC standards
- Creation of study data tabulation model (SDTM) data files for regulatory submission

PharmaStat uses a set of validated analysis programming tools for analysis and reporting of statistical tables.

Technical Consulting Services

We can perform the following activities in collaboration with your team:

- Drug development strategies
- Review of analysis plans and reports
- Independent statistical analysis
- Interaction with regulatory authorities
- Coordinate activities with CRO statisticians
- Integrated summary of safety and efficacy
- Standard operating procedures for biostatistics and statistical programming
- Analysis programming and software infrastructure

Data Monitoring Committees (DMCs)

An FDA draft guidance recommends independent statistical analysis for DMCs. PharmaStat offers:

- Creation of the operating charter
- Preparation of interim reports and group sequential monitoring boundaries
- Maintenance of DMC meeting records
- Organization of meetings

Statistical Programming

Statistical programming activities are required to develop final study reports and associated data for regulatory submissions. The data architecture for statistical tables is different from regulatory submissions. FDA recommends submission of data that follows the standards from the Clinical Data Interchange Standards Interchange Consortium (CDISC). The data architecture for statistical reports follow separate standards. Both types of data files require custom programming.

Programming Services:

- Creation and documentation of data files for regulatory submission: CDISC Study Data Tabulation Model (SDTM) and statistical analysis files
- Data import/export from CROs
- Data validation through data integrity reports
- Validated statistical programs for regulatory submissions
- Integrated safety data bases
- Software quality assurance
- Support for electronic regulatory submissions

About PharmaStat

PharmaStat provides business consulting and technical services to the biopharmaceutical industry for clinical drug development. PharmaStat seeks to integrate good science, information technologies, and experienced implementation for successful drug development.

Areas of expertise are: biostatistics, statistical programming, information systems, management services, electronic regulatory submissions, management consulting, and business process development.

Operational Capabilities

- Data Architecture and Standards Management
- Operations Plan
- Integrated Data Warehouse
- Document Management
- Project Management
- Quality Assurance & Validation
- CRO Oversight

PharmaStat LLC
Newark, CA 94560

Telephone: 510-656-2080
Fax: 510-656-2081

e-mail:
info@pharmastat.com

Internet:
www.pharmastat.com