



Service Listing

Biometrics

Statistical Services

Our statistical support spans from study design to final analysis for a single trial and also to Integrated summary of safety and efficacy (ISS, ISE). We evaluate designs based on comparison of the operating characteristics, our understanding of the therapeutic area, the indication under investigation and the primary objective of the study.

We also assess the potential complexity of study conduct that may adversely affect data quality before recommending a particular design. We focus on helping our clients achieve their trial objectives in the most optimal and cost effective manner.

Our statistical services are:

Study Design

- Model-based drug design (MBDD), including adaptive and Bayesian designs
- Sample size calculation for traditional designs
- Inputs into Protocol
- Randomization
- Statistical Analysis Plan

Study Conduct

- Interim Analysis, design, plan and execution
- Data Monitoring Committee
- Monitoring study quality during conduct

End of Study

- Oversight and review of PK/PD, safety and efficacy analyses
- Statistical report, contribution to and review of CSR
- Exploratory analysis, Meta analysis

Programming Services

Our statistics team is ably complemented by our strong programming team. Many of our programmers have experience in delivering a variety of programming services in a global delivery model, right from programming process standardization to programming TLGs and mapping data between standards.

We offer programming services in the following areas:

Specifications & Standards

- Programming specifications, Rulebook
- Development of SDTM datasets
- Design and Development of Analysis datasets (ADaM)
- Mapping legacy data to SDTM

Tables, Listings, Graphs (TLGs) for safety and efficacy

- Development and validation of TLGs
- Independent programming for validation of derived data and TLGs

Data Validation

- Design and development of edit check programs
- Design and development of listings and reports to monitor data quality and study quality

Post-hoc and Submission support

- Programming for exploratory analysis
- eSubmission support (blank eCRF, define.xml, xpt files)
- Publish TLGs for regulatory submission

Data Management Services

We have the capability to provide all services in data management as listed below. This is particularly useful for clients who prefer to have a single partner to provide all Biometrics services.

Study Design

- Data Management Plan
- CRF design, database design
- Validation specifications and procedures, including cross-panel checks

Study Conduct

- Data entry, vendor data load, CRF imaging and archival
- Discrepancy management
- Medical coding


End of Study

- Safety data reconciliation
- Database audit and database lock
- Extraction of SAS datasets from database

Sciformix is a knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.



For more information on how Sciformix Biometrics services can benefit your enterprise contact us at

Sciformix Corporation

1500 West Park Drive, Suite 250, Westborough, MA 01581

Phone : 1(877) 576 - 5005

Fax : 1(508) 302 - 6520

Mail : ask@sciformix.com

URL : www.sciformix.com