sciformix

Trusted **Services**. Built on **Science**.

Statistics, Programming and Data Management

Data to Decisions

The key to the success of any clinical trial is the availability of high quality data in a timely and cost effective manner to facilitate faster and better-informed decisions. Thus it becomes all the more important that organizations ensure their analyses are based on appropriate statistical methods, are accurate and are acceptable to the regulators. This in turn helps reduce potential delays in the drug approval process.

At Sciformix we understand what it takes for organizations to succeed. We offer end-to-end data management, statistics and programming services from study design to clinical study report based on a unique blend of domain depth and attention to detail.

At Sciformix, we have years of experience in supporting all aspects of clinical studies across all phases and a wide range of therapeutic classes in a globally distributed model.

Partnership to transform your data into knowledge

Partnerships

- Global top-5 pharmaceutical company
- Global top-20 pharmaceutical company
- Small and midsize biotechs
- Generics companies

Experience

- All major Therapeutic Areas such as Oncology, CNS, Infectious Diseases, Metabolic Disorders, Immunology, etc.
- Over 300 studies
- Trial Phases supported: I to IV
- Robust processes, standardization and global infrastructure
- Support of various submission types
- Regulatory defense support including from FDA and EMA submissions

People

Our biostatisticians, programmers and data managers have built a reputation of excellence by being responsive, flexible and collaborative, producing quality deliverables and maintaining the highest level of scientific integrity.

Sciformix has one of the most highly educated biostatistics departments. With University origins and continuing academic ties, our biostatisticians also continually hone their skills and explore cutting-edge methodologies. Most programmers have Master's degree in Statistics and we have statisticians with PhD degrees from internationally reputed universities.

Innovations

By standardizing and implementing our Quality Management System and LEAN processes, we are able to automate error-prone, time consuming and repeatable tasks. This reduces the average TAT (Turn Around Time) for our outputs. By reusing programs across multiple clinical trials we are able to reduce programming and validation efforts for individual trials. In addition to SAS, our programmers also have expertise and experience in R.

Expertise in End-to-End Biometrics Services

	Study Planning	Study Conduct	Study Reporting
Statistics	• Sample size calculation • Statistical input into Protocol and CRF review • Generate randomization lists • SAP, mock tables & TOC • Programming specifications / guidelines • Model-based design, including adaptive and Bayesian designs	• Interim analysis and DSMB Support • DMC Membership • Statistical inputs into programming • Statistical review of blinded tables • Central statistical surveillance • Real World Evidence generation and analysis; Outcomes Research • Complex analyses, Pharmacometrics, simulations	• Final output review • QC of break-blind • Statistical report writing • Input into and review of CSR • Regulatory requests • Exploratory and Meta Analysis; publication support • ISS, ISE • Signal detection • Regulatory defense
Programming	• Review statistical analysis plan & mock tables • Write programming plan, rulebook, specification, using CDISC (SDTM/ADaM) standards	• Develop codes to perform required safety and efficacy analysis • Validate programs (parallel coding), blinded data review • Develop macros when possible, especially for safety analysis, using SDLC	• Generate final TLGs after DB lock & break-blind • Assist with exploratory and meta analysis • Mapping of data across standards • Create dataset package for submission including define files and reviewer guides
Data Management	• Data Management Plan • Design of patient diaries • Design CRFs and databases • Write and validate specifications • UAT of CRFs and database	• Data Capture • CRF imaging and archival • Discrepancy management • Medical coding – MedDRA and WHO drug • Third party data load and reconciliation	• Reconcile safety and project database • Database QC & QA • Lock database • Break blind and release of data

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Sciformix Corporation is a global scientific process organization (SPO) that partners with life sciences companies to develop, launch and sustain medical products that aim to improve the quality of healthcare worldwide. We collaborate with our clients through the entire product development lifecycle to provide a full range of services from study design to post marketing surveillance and commercialization support.

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