Data Management & Biostatistics

TRI provides data management and statistical analysis services for all phases of clinical research as well as for toxicology and research program management. More than a decade of continuous improvement and investment in automation allows us to offer the quality, speed, and cost that your project requires, regardless of its size or complexity.

Key Services

- **Clinical Data Management**
  Our Clinical Data Management Department has completed a wide range of drug and device trials. In all our projects we rely on:
  - An extensive library of data collection tools
  - Electronic Data Capture with special emphasis on user training
  - Integration with Safety Systems, EHR/EMR Systems, laboratories, and central readers
  - Automated randomization
  - Automated enrollment and data quality reports
  - Integration with mobile devices for collection of PRO data
  - Expert MedDRA, CTCAE, ICD-9/10, SNOMED, and WHO Drug coding
  - Extensive implementation of automated data discrepancy checks
  - Systems and personnel to support centralized monitoring
  - 21 CFR Part 11 compliance and ISO-certified information security system
- **Biostatistics and Statistical Programming**
  Our PhD-level Statisticians are adept at determining the most suitable experimental designs and analytic approaches that will focus on the outcomes and endpoints essential to the sponsor's objectives. We offer the following services:
  - Study design and power calculation
  - Statistical Analysis Plans
  - Statistical reports and interpretation of results
  - Unblinded statistician services for DSMBs
  - Figures, tables, and listings for Interim Analysis Reports, Final Clinical Study Reports, manuscripts, presentations, and posters
  - Integration of data from disparate sources
  - CDISC SDTM and ADAM datasets for FDA submission and archiving

- **Program Management Database Support**
  Making effective decisions while managing research programs requires accurate and complete information. We host and maintain databases for programs ranging from a few studies to 700+ interventional and observational trials.
  - Abstraction of study design descriptors
  - ClinicalTrials.gov registration and results submission, either manually or through XML file transfer
  - Maintenance of research sites, contacts, and organizations directories
  - Funding sources and status tracking
  - Study milestones completion reports

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