ALTASCIENCES

DATA MANAGEMENT AND BIOSTATISTICS

DATA MANAGEMENT

Altasciences' expert data management team delivers the timely design, build, and deployment of high-quality clinical databases. Through continuous data cleaning, proactive issue resolution, and transparent weekly metrics, we provide real-time visibility into study progress and data quality. Our comprehensive data management solutions include:

Strategic and Efficient Data Management Oversight

- End-to-end planning to ensure high-quality, compliant clinical data
- Accelerated, efficient operations, purpose built for early-phase trial needs
- Central management of site, laboratories, and external vendor data
- Standards-based eCRF design with CDISC alignment (CDASH, SDTM)

Rigorous Data Cleaning and Quality Control

- Continuous data review, query management, and real-time quality monitoring
- Governance and data reconciliation with external vendor data
- Medical coding with MedDRA/WHO Drug Dictionary

Database Lock and Submission Readiness

- Interim/final locks and support for regulatory ready datasets
- GCP, Part 11, and global regulatory adherence with robust documentation

Our **extensive library of eCRFs expedites the database building process**, allowing us to easily leverage forms from one study to the next. This results in cost effective data management, faster time to database "go-live", a functioning and intuitive clinical database, expedited database lock, and ultimately, accurate and clean data.

We work on a per-project or full-time equivalent (FTE) basis.

Efficient eCRF Setup and Fully Compliant Data

- Simple and flexible deployment of eCRFs
- Fully compliant with FDA 21 CFR part 11
- Adherence to SCDM and CDISC standards

We use industry leading software packages designed for entry into our electronic data capture (EDC) platform, or direct data capture. The data manager is your one point of contact for all data management activities and provides oversight of all activities from the database build to database lock.

The data management and biostatistics teams collaborate closely, from protocol development to final report delivery.

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BIOSTATISTICS AND STATISTICAL PROGRAMMING

Biostatistics and statistical programming are central to every clinical study—informing robust study design, guiding study conduct and driving high-quality data collection, analysis, and reporting.

Our experienced biostatisticians and statistical programmers are committed to meeting your timelines and supporting you throughout the development lifecycle. Rigorous quality controls at every stage ensure accuracy and integrity. Working seamlessly with our data management and medical writing teams, we ensure data is captured, analyzed and translated into clear, actionable evidence to empower confident decision-making at every step of your clinical program.

Our Biostatisticians are Dedicated to Delivering Excellence With:

- Study design and statistical consulting, including endpoint development guidance, power calculations, sample size estimations, and development of robust randomization schemes.
- Statistical Analysis Plan (SAP) development, including comprehensive mock tables, figures, and listings (TFLs) to provide full transparency into how study data will be analyzed and presented.
- Data review and statistical analyses to ensure accuracy, interpretability, and alignment with study objectives and regulatory expectations.
- SAS® programming and independent validation of TFLs to support high-quality clinical study reports and ensure analytical integrity.
- Comprehensive SDTM and ADaM dataset packages generated using SAS®, including all required supporting documentation to ensure traceability and compliance.
- CDISC-compliant datasets delivered in a fully FDA submission-ready package, validated using Pinnacle 21 Community to confirm conformance, completeness, and regulatory readiness.
- Mapping and conversion of legacy data to current CDISC standards, ensuring consistency and usability across programs and submissions.
- Biostatistics and statistical programming support for clinical study reports (CSRs) and publications, delivering high-quality analyses and outputs to support clear and accurate scientific communication.

Biostatisticians are available on a per-project or **full-time equivalent (FTE)** basis, according to your needs.

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