ALTASCIENCES

DATA MANAGEMENT AND BIOSTATISTICS

DATA MANAGEMENT

Altasciences' expert data management team delivers timely design, build, and deployment of quality clinical databases. Our data management solutions include:

Protocol review and planning

- DMP, DVP, eCRF data entry guidelines*

*DMP=Data management plan, DVP=Data validation plan, eCRF=Electronic case report form

Database build and validation

- Protocol-specific functional database, reviewed and compared prior to "go-live"
- Average four to eight weeks from final protocol to "go-live"

External vendor data reconciliation

Draft data transfer specification

- For reconciliation of test transfer and first live data transfer

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, accelerated database lock, and ultimately, **accurate and clean data.**

Altasciences' data managers average over 15 years of experience.

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 standard 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 participates in the database build and the data cleaning.

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

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BIOSTATISTICS

Biostatistics is at the heart of every clinical study, driving study design, study conduct, data collection, data analysis, and reporting.

Our experienced biostatisticians are dedicated to meeting your timelines and supporting you throughout the entire development cycle, with quality controls applied at all stages of your project to ensure high quality results. Working in unison with our data managers and medical writers, the biostatistics team ensures that the correct data is captured.

OUR BIOSTATISTICIANS ARE DEDICATED TO DELIVERING EXCELLENCE IN:

- Study design and statistical consulting, including endpoint development guidance, power calculations and sample size estimations, and randomization schemes
- Statistical analysis plan creation, including mock tables, figures, and listings (TFLs)—so you know how your data will be presented
- Data review and statistical analyses
- SAS® programming and validation of TFLs for clinical study reports
- Full suite of SDTM and ADaM dataset formats generated using SAS and including supporting files
- CDISC-compliant datasets delivered in an FDA submission-ready package
- Mapping of legacy data
- Engagement for clinical study reports and publications

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

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