FMD K&L

Raising the Standard of Excellence

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Data Management

Biostatistics

Statistical Programming

eSubmission / CDISC

Medical Writing

Drug Safety

Data Management

- Data Management Plan (DMP) and all Related Data Management (DM) Document Development
- Database Development (including eCRF and Edit Check Specification Creation and User Acceptance Testing)
- Data Entry
- Data Review and Query Management
- External Data Transfer and Reconciliation
- SAE Reconciliation
- Dictionary Coding (MedDRA and WHO Drug)
- Database Lock
- Study Archival

Biostatistics

- Clinical Development Planning
- Power / Sample Size Estimation
- Protocol Development
- Statistical Analysis Planning
- Randomization Scheduling
- Interim Analysis / DMC
- Annual or Periodic Reporting
- Statistical Modeling / Exploratory Analysis
- Statistical Reporting and Publications
- Clinical Study Reporting
- ISS / ISE

Drug Safety

- Case Entry and Quality Control
- Narrative Writing
- Medical Review
- SAE Reconciliation
- World-wide Case Submission

Statistical Programming

- Development of Study Data Tabulation Model (SDTM) Datasets
- Development of Analysis Datasets (ADaM)
- Creation of Tables, Listings, and Figures (TLF), In-text Tables, and Appendices
- Support of Clinical Study Report (CSR), Integrated Summary of Safety and Efficacy (ISS / ISE), Interim Analysis, Agency Filings, Safety Surveillance, and Publications
- Support of Database Edit Checks, Query Creation, Patient Profiles, and Ad-hoc Reports as well as Data Review Tools such as SpotFire
- Support of Data Monitoring Committee (DMC) meetings as unblinding programmers
- Support for Statistical Method Development, Simulations, Sample Size Calculations, Exploratory Analysis, and Research Projects

Medical Writing

- Clinical Study Protocols
- Investigator's Brochures
- Statistical Reports and Clinical Study Reports
- Subject Narratives
- IND Annual Safety Reports
- Integrated Summaries of Safety / Efficacy
- ICH E3 Compliant Templates for CSRs or Utilization of the Client's Template
- Scientific Publications and Meeting Support
- Manuscripts, Abstracts, or Slides for Posters or Presentations

eSubmission / CDISC

Process Improvement and CDISC SDTM / ADaM Implementation Consulting

- Help to develop your company's standards based on CDISC current models
- Optimization of data flow from data capture CDASH to SDTM to ADaM and then to TLFs
- Optimization of clinical tool sets to achieve the standards and return on investment
- Knowledge transfer of the data standardization process

Legacy / Ongoing Study Data Conversions to SDTM Standards

- SDTM annotated CRF (aCRF.pdf)
- SDTM mapping specifications
- Conversion of legacy raw datasets to SDTM datasets
- SDTM define.xml
- SDTM compliance checks using OpenCDISC / Pinnacle 21Validator
- SDTM Reviewer's Guide (SDRG)

ADaM Standards

- ADaM specifications
- Creation of ADaM datasets
- ADaM define.xml
- ADaM compliance checks using OpenCDISC / Pinnacle 21Validator
- ADaM Reviewer's Guide (ADRG)

We constantly strive to raise the standard of excellence through efficiency, innovation, and expert attention to detail; therefore, providing comfort in your mind that your job will be delivered on time, within budget, and at the highest quality standards you have come to expect.

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