Biometrics and Data Solutions

The mission of Eliassen Group's Biometrics and Data Solutions division is to positively impact lives by helping pharmaceutical, biotechnology and medical device companies to bring safe and effective treatments to market faster and more economically. Our specialty contract research organization (CRO) facilitates and supports the analyses required throughout the lifecycle of product development which includes clinical data standardization, ensuring data integrity, and regulatory submission support.

Our experience spans a broad range of therapeutic areas including Oncology and Rare Diseases. Our services enable our clients to ensure adherence to and compliance with data standards and integrity, and to expedite data analysis and output reporting for clinical trials (phases I-IV).

Our Team

The Eliassen Biometrics and Data Solutions group is dedicated to the long-term support of analyses required for many decision points throughout the lifecycle of drug development. Our tenured subject matter experts bring extraordinary technical expertise and exceptional product knowledge spanning support of over 30 major submissions in multiple therapeutic areas and indications over the last 10 years.

Statistical Programming and Analyses

Biostatistics

CDISC Consulting and Data Standards

Health Economics and Outcomes Research

Our Core Competencies

- Statistical programming (SAS, R stat, other) and reporting
- Biostatistics
- CDISC and data standards expertise
- Data monitoring committee (DMC/ IDMC) support
- PK/PD modelling and programming
- Health economics and outcomes research programming and reporting
- Regulatory submission support (ISS/ISE, pooled analyses, regulatory authority responses)
- Data mapping
- Independent validation of programming
- Rescue Work

Our Engagement Models

Our flexible solutions enable you to contract with us on an individual resource need or scale up to a dedicated functional service provider model.

Functional Outsourcing: Dedicated staff is an extension of your functional lines.

Staff Augmentation: Traditional staffing support for specified duration with work performed on-site, remotely, or in-house in one of our facilities.

Subject Matter Consulting: Customized objectives and deliverables to address your specific needs including process review, analysis, and recommendations for implementation.

Our Services

Statistical Programming and Analyses

Reporting (Tables, Listings and Graphs)

- SAE Reconciliation
- Clinical Study Reports
- Blinded Data Reviews
- Drug Safety Monitoring Board Data Reporting
- Manuscripts, Publications, Posters Support
- PK/PD Reporting
- Legacy Data Conversion
- Ad hoc Reporting (exploratory analysis, scientific commercial support, label changes)

Electronic Submission

- FDA Rapid Response Reports
- Regulatory Queries (world-wide)
- Third party Data Reporting Validation
- SAS Transport Files and Define.XML
- Annotated CRFs
- Study Reviewer Guide (Data attributes)
- SDTM and Define Validation

Biostatistics

- Trial Design and Protocol Development
- Power Analysis and Sample Size Calculation
- Randomization Schemes Generation and Management
- Statistical Analysis Plan (SAP) and Shells Development
- Integrated Regulatory Submissions of Statistical Sections
- Independent Data Monitoring Committees (IDMC) Statistical Support
- Ad-hoc Analysis and Publicaion (abstract, poster, manuscript) Support
- Integration of data from EDC, IVR, Adverse Event
- Due Diligence

CDISC Consulting and Data Standards

Organizational Solution

- Guide Set up of Internal Standards Group
- Standards Integration within Organization
- SOP development assistance

Implementation of CDISC Standards

- Customize CDISC to fit study safety and efficacy needs
- Implement and customize standards for Genomics
- Integrate genomics with clinical
- SDTM, SHARE and PGx

Metadata Repository Services

- Selection and POC of Metadata systems

Metadata Management

- Development of Governance policies
- Management of taxonomy and terminology
- Loading and maintenance of CDISC and internal standards
- Integration of metadata from disparate sources linking to produce desired lineage

Health Economics and Outcomes Research

- Retrospective Database Studies
- Adherence/Persistence Studies
- Epidemiology
- Comparative Effectiveness Research
- Prospective Study Design
- Patient Reported Outcomes
- Cost/Utilization Analysis
- Outcomes Research Programming
- Program Evaluation
- Publication Support

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