

## Solutions for Clinical Research Standards Management

Now more than ever before, the pharmaceutical and biotechnology industries are experiencing increased pressure to improve the efficiency of conducting clinical research in order to decrease costs and bring safe and effective treatments to market faster. The medical research community can no longer tolerate the high level of manual effort and rework that is inherent in their processes and methodologies.

Eliassen Group's Biometrics and Data Solutions team can help. Our resident expert team includes clinical and molecular standards SMEs, statisticians and programmers who have deep knowledge and experience in data standards to optimize the analysis and reporting for data integration and electronic submissions. We assist sponsors with the implementation of standards to facilitate the entire research process, streamline data integration and promote higher quality data.

### Service Offerings

- Organizational Solution
  - Help set up internal standards group
  - Integration of standards within the organization
  - Assist in SOP development
- Implementation of Clinical Data Interchange Standards Consortium (CDISC) Standards
  - Customize CDISC to fit study safety and efficacy needs
  - Implementation and customization of standards for genomics
  - Integration of genomics with clinical data
  - PGx, SDTM, SHARE
- Metadata Repository Services
  - Selection and proof of concept for metadata systems
  - Metadata management of the standards process
    - Development of governance policies
    - Management of taxonomy and terminology
    - Integration of metadata from disparate sources to produce desired lineage
    - Loading and maintenance of CDISC and internal standards

### Depth in Resources and Expertise

Our standards team members have extensive expertise in extending CDISC standards to accommodate client data requirements. We can help to create strategies to manage data integration challenges brought on by mergers and acquisitions plus disparate data sources from external partners. The team employs best of breed technologies and processes such as metadata repositories, agile software and verification tools to perform data validation and efficiently manage CDISC standards along with the prerequisite business rules.

