ELIASSEN GROUP®
Biometrics & Data Solutions

CDISC and MDR Expertise Results in Data Integration and Traceability

In the evaluation of clinical trial data, the use of a Metadata Repository (MDR) along with strong Clinical Data Interchange Standards Consortium (CDISC) skills can result in enhanced data collection, integration and quality processes. Developing efficiencies in these areas can lead to reduced review cycle times which result in faster time to market.

Management and alignment of clinical trial data can be a challenging endeavor, especially when information is collected from many sources which utilize widely differing processes, applications, data collection policies and standards.

When a major pharmaceutical client required assistance in migrating to a new version of the CDISC Study Data Tabulation Model (SDTM) and preparing their standards metadata for loading into their newly installed MDR, they turned to a noted Eliassen Group Biometrics and Data Solutions consultant for industry-leading standards development expertise. The metadata was not only enhanced with the newest domains and variables, but was also reformatted to support the upgrade or downgrade to a new release as required by regulatory agencies.

Problem Identification

The requirement was to establish a process to efficiently yield high-quality, standardized data for regulatory filings.

Nature and Scope of Challenge

The client required a mechanism to align data from all sources to fulfill integration objectives.

Problem Resolution

I. Developed metadata structures to support integration, data quality, traceability and optimization goals.
II. Utilized CDISC standard structures and terminology within a metadata repository to automate a significant amount of the mapping.

Value Proposition

I. Supported alignment of internally and externally collected data.
II. Provided ability to produce clinical data in multiple SDTM versions as requested by regulatory agencies.
III. Improved traceability of data from collection through submission.
IV. Validated SDTM adhering to published regulatory guidance.