CASE STUDY

Conversion of Legacy Pain Management Studies to SDTM/ ADaM Datasets

THE CHALLENGE

Legacy data issues delay standardized dataset generation.

A biopharmaceutical company needed to convert 14 legacy pain management studies to SDTM/ADaM datasets and subsequently generate pooled datasets for Integrated Summaries of Safety and Effectiveness (ISS/ISE).

The scope of work included converting data from legacy studies to CDISC-compliant datasets, which involved the following:

- Generating an annotated case report form (CRF), Define.xml, Reviewer's Guides, and pooled ADaM datasets
- Mapping of SDTM/ADaM data
- Programming and validating datasets, including P21 Enterprise for compliance

The challenges included the following:

- Different study designs, some with multiple participant enrollment across studies
- Frequent client change requests for analysis objectives, as well as subgroup and sensitivity analyses
- Data issues:
  - Non-conformance to CDASH standards
  - Data quality issues and missing data
  - Undocumented questionnaire data and scoring algorithms
  - Multiple vendors with different EDCs and coding versions

THE SOLUTION

A collaborative approach was required.

The company partnered with Veranex Data Management & Analytics, and our Statistical Programming and Biostatistics team devised a plan to systematically address the data issues before conversion.

We used the following approaches to cleaning and standardizing the data:

- Communicated with the teams involved in the original data collection to minimize misinterpretation of the data
- Went back to the source data from the CRF or the clinical study report (CSR) mapped to SDTM — to improve the data quality
- Resolved any data discrepancies with input from the sponsor
- Documented and tracked the resolution of data issues — to ensure correct implementation
- Manually reviewed and confirmed the derivation of scores for questionnaires
- Up-versioned MedDRA and WHODrug coding across studies

Then, we harmonized the study design and data needs by performing the following steps:

- Prepared the metadata based on design aspects across studies
- Performed a gap analysis of the datasets by identifying commonalities and differences across studies
- Prepared a data harmonization plan and data pooling plan based on basic rules and data handling conventions
- Implemented a change request approach that was flexible enough to accommodate reasonable requests
- Communicated openly with the stakeholders regarding the time and cost consequences

THE OUTCOME

The datasets met the requirements for regulatory submission.

The data were successfully converted and pooled into the datasets for ISS/ISE by our team of experienced statisticians, programmers, and data managers. Using a comprehensive, documented process enabled the team to reach the following key outcomes:

Programmed, validated datasets

A robust, pooled database that met the client's safety and regulatory requests and reporting needs

In addition, good communication with the sponsor and within the team led to the successful resolution of the challenges that were encountered and provided the flexibility to incorporate requests and changes in the study objectives and analyses.

Contact our team to discuss how we can support conversion of your legacy datasets.