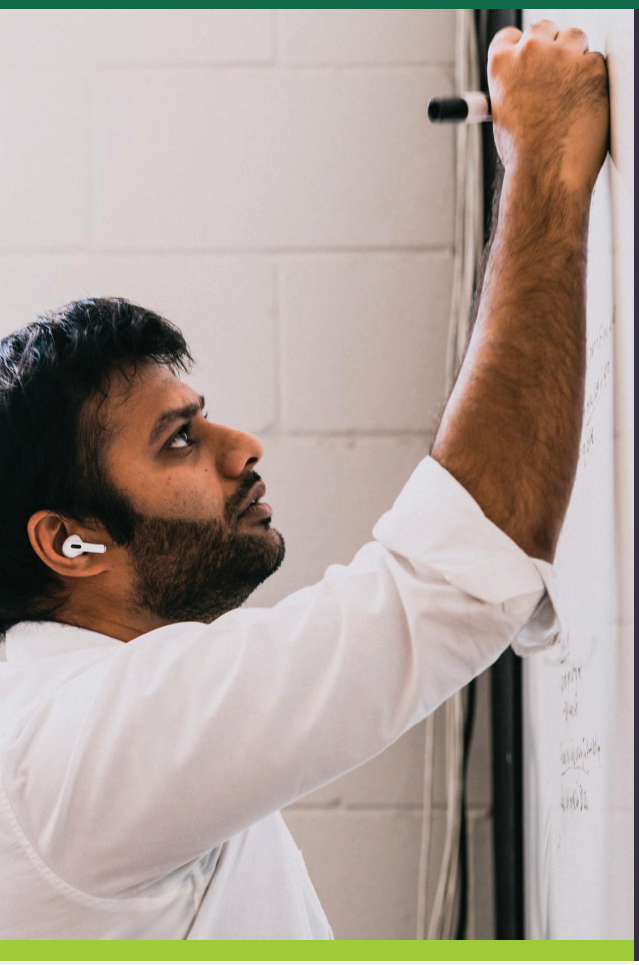

CASE STUDY

Comprehensive and Systematic Conversion of 100s of Legacy Studies to Pooled Datasets

THE CHALLENGE

Converting legacy datasets can be challenging and time-consuming.

127 studies spanning **25** years

A biopharmaceutical company needed to convert 127 ongoing and legacy studies to 3 pooled datasets for the adverse event (AE), demographic (DM), and exposure (EX) domains for regulatory reporting. The challenges included the following:

- The studies spanned 25 years and involved different investigational products.
- There were multiple data sources of data, including SDTM; SDTM+; analysis datasets; tables, listings, and figures (TLFs); and clinical study reports (CSRs).
- Variables different in name, type, and label needed to be mapped.
- Study designs included different phases; cross-over, core, and extension studies; intra-individual studies; and global studies with different numbers of treatments, populations, and indications.
- Some of the study data needed to be translated to English.

THE SOLUTION

A systematic approach was adopted.

The company partnered with Veranex Data Management & Analytics, and our Statistical Programming and Biostatistics team devised a plan to systematically address the volume of data requiring conversion to pooled datasets:

- Perform a gap analysis to ensure the availability of the necessary study documents and datasets (e.g., protocol, annotated case report form [aCRF], CSR).
- Use translating services when necessary.
- Compile an inventory of studies, categorizing the following study details: design, number of treatments, indication, population, and data pooling conditions based on analysis requirements.
- Collect information about the investigational product, Development International Birth Date (DIBD), and reporting period or cut-off dates.
- Itemize a list of variables required for analysis in each domain (AE, DM, and EX).
- Prepare a data harmonization/data pooling plan based on basic rules, data handling conventions, and assumptions.

THE OUTCOME

The datasets met the requirements for regulatory submission.

The data were successfully converted and pooled into the datasets by our team of experienced statisticians, programmers, and data managers. Using a comprehensive, well-planned data mapping scheme and data process flow enabled the team to reach the following key outcomes:

- Metadata documentation for the datasets and formats
- Up-versioned MedDRA and WHODrug coding for consistency
- Programmed, validated datasets
- A robust, pooled database that met the client's safety and regulatory requests and reporting needs

In addition, good communication throughout the study led to early and successful resolution of challenges.

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