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COLLICULUS

Case Study

FDA Submission-Ready SEND Datasets for a Non-Clinical Toxicology Study

Client's Business Influence

The SEND dataset project had a strategic impact on the client's regulatory and R&D operations:

✅ Regulatory Compliance: Enabled timely IND submission with no data-related queries from the FDA

⏱️ Time Savings: Reduced internal review time by 40% due to clean, validated datasets

💼 Operational Efficiency: Established a reusable SEND framework for future studies

🌐 Global Readiness: Positioned the company for submissions to other regulatory bodies (e.g., EMA, PMDA) that are adopting SEND standards

Project Scope:

A mid-sized pharmaceutical company developing a novel oncology compound and they needed to submit non-clinical toxicology study data to the U.S. FDA as part of their IND (Investigational New Drug) application. The FDA mandates that such data be submitted in SEND (Standard for Exchange of Nonclinical Data) format, a CDISC standard.

The project scope included:
❖ Converting legacy study data into SEND 3.1-compliant datasets
❖ Validating datasets using FDA-recommended tools
❖ Delivering a submission-ready SEND package with define.xml and Study Data Reviewer's Guide (SDRG)

Methodology/ Approach:

Data Assessment & Mapping
❖ Reviewed raw data from the toxicology study (Excel, SAS, and PDF formats)
❖ Mapped source data to SEND domains (e.g., DM, EX, LB, CL, MA, MI, TX)
❖ Identified gaps and inconsistencies in legacy data

SEND Dataset Creation
❖ Used Pinnacle 21 and SENDIG 3.1 guidelines for dataset structure
❖ Created SEND datasets using SAS programming
❖ Populated controlled terminology from CDISC and NCI Thesaurus

Validation & Quality Control
❖ Performed automated validation using Pinnacle 21 Validator
❖ Conducted manual QC checks for domain relationships and consistency
❖ Addressed all FDA validation rules (Reject, Error, Warning)

Documentation
❖ Generated define.xml using Define-XML 2.0 standards
❖ Created Study Data Reviewer's Guide (SDRG) to explain data structure and decisions
❖ Compiled a complete SEND package for eCTD submission

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