

Common Technical Document Table Generator for Pharmaceutical Companies

Overview

A regulatory application to automate and streamline part of the Common Technical Document (CTD) creation process was developed by Nagarro to help a global pharmaceutical company better manage and produce CTDs, while complying with FDA 21 CFR Part 11. As a result the company was able to efficiently generate and manage non-clinical study tables, while complying with European, Japanese, and U.S. regulations.

Problem Description

Prior to working with Nagarro, the drug safety group at a global pharmaceutical company was able to generate study level tables for non-clinical studies, but its process of using a combination of semi-automated and manual processes lacked efficiency and was not FDA 21 CFR Part 11 compliant. The company needed a validated system that could expedite the generation of drug safety evaluation study tables and tabular project summaries while meeting International Conference on Harmonization (ICH) and FDA requirements. This required devising a tamper proof process that could produce standardized documents.

Solution

In a phased approach, Nagarro created a solution to help the drug safety group meet its needs. First, Nagarro developed a web based application to generate study level tables on summary and individual data from toxicity studies. ETL tools were used to build the data warehouse from backend LIMS systems. The solution enabled data extraction, statistical analysis using SAS, data summarization, and report generation. Further, the system was compliant with all 21 CFR Part 11 requirements including data backup archival and retention, audit trail for changes, data security, and data retrieval. The next phase of development allowed for cross-study tabulated summaries to be created by users. In addition, development allowed the system to have the flexibility of ad-hoc report generation and enabled users to further analyze the data at various levels of detail and granularity. Finally, to keep the client ahead of the curve, Nagarro added XML exports into the system, which can be used for future eCTD submissions.

Specific features of the system include:

- Data extraction from multiple geographically diverse and separate LIMS systems
- Specialized adapters to allow communication with LIMS system using varying languages
- Periodic synchronization with LIMS systems

- Statistical analysis for study level data performed using SAS
- Output made available as SAS datasets, XML format, or PDF format
- Centralized data warehouse
- Generation of 'canned' reports, as well as user configurable reports

Benefits

- Enabled client to be FDA 21 CFR Part 11 compliant
- Followed harmonized approach as outlined by the ICH Steering Committee
- Reduced time required for FDA submission process, as well as potentially quicker product releases as a result of refined process and accuracy of system
- Allowed scientists to generate data tables and monitor internal progress of studies on demand
- Ability to integrate into new LIMS systems, generate new types of reports, and conduct new types of analyses
- Flexibility of style sheets allow formatting to change if needed
- Use of XML data in subsequent eCTD generation