

Clinical Application Development for a Leading Global Pharmaceutical Company



North America

Business Issue

The Statistical Programming and Analysis unit within a top 5 pharmaceutical company needed to streamline its programming processes to reduce the time it took to generate tables, listings, and figures. The company's leaders recognized that the statistical programming effort that supports Clinical Research would be a viable area to improve efficiency through automation. To gain efficiencies, the company wanted to create a standard clinical macro system for statistical programmers. However, they did not have the application development expertise or the time available to build a system themselves.

Solution

Our client engaged the Clinical Solutions team to:

- Review the current statistical programming processes
- Design a client-specific statistical programming package in collaboration with IT, programmers, managers, biostatisticians, and clinicians
- Develop the statistical programming suite in a feature roll-out phased approach
- Test and validate the package capabilities with audit-ready documentation
- Create system and user documentation
- Train statistical programmers to incorporate the new features into their processes
- Provide technical support through a user request and bug tracking system

A team of Clinical Application Developers was assembled to create the statistical programming package that revitalized and revolutionized the client's clinical programming processes. This package has been rolled out to all therapeutic areas and is currently in use by over 100 clinical programmers. The application continues to be extended and enhanced to take advantage of new features.

Results

With this collaboratively designed statistical programming package, our client was able to:

- Standardize algorithms for reporting and statistical analysis
- Reduce errors
- Standardize processes across teams
- Reduce time to FDA submissions

