PFIZER DEPLOYS INTRANET-BASED STATSERVER TECHNOLOGY TO IMPROVE FDA REPORTING

Business Challenge

Pfizer is devoted to discovering, developing, manufacturing, and marketing quality pharmaceutical products. A pharmaceutical leader, the company manufactures prescription drugs including Lipitor® for cardiovascular disease and Accupril® for hypertension and congestive heart failure.

Each year, the global pharmaceutical industry spends $40.1 billion on drug discovery, development and approval. Data analysis software can help researchers to analyze and translate their results into easy-to-read documents for Federal Drug Administration (FDA) approval. Professional reporting with informative, precise graphics translating results can help FDA decision makers to bring safe, effective drugs to market sooner.

Drug discovery and development requires accurate statistical analysis from initial experimental design to final delivery of a drug to a pharmacy. At Pfizer, researchers in its Pharmaceutical Delivery System (PDS) work closely with drug discovery, chemical development and manufacturing associates to bring the best pharmaceutical products to market. This team tests new products for stability, performance and degradation and provides results and recommended expiration dates in detailed reports submitted to the FDA.

At Pfizer, S-PLUS was deployed using StatServer software and a company-wide Intranet for data analysis and FDA reporting. "Historically, our company submitted hundreds of lengthy reports including 30 to 40 pages of graphs to the FDA. Each researcher was responsible for preparing their own reports and as a company we did not have access to standardized analytics. We were looking for a leading software solution that could deliver the powerful analytics and graphic capabilities we needed to our employee's desktops," says John Twist, Section Director, PDS Planning and Statistics. "We selected StatServer because it provided its cutting-edge analytics, browser compatibility and integration with complementary Microsoft Office reporting packages."

Business Solution

Twist was interested in streamlining his team's data analysis and reporting process. He created a Web-based application that allowed researchers to upload their data into customized analytic applications from a variety of common sources including, most notably, Excel spreadsheets. The data could then be analyzed using cutting-edge statistical techniques, like fitting analyses of covariance (ANCOVA) models with corresponding confidence bands for mean or individual values, offered in the S-PLUS software package. The results were then translated into conditioned multi-panel (Trellis) plots for submission to the FDA.

"In the past we needed to plot many variables in several different graphs. Usually, the software allowed us to have one plot per page. Graphics in standard FDA reports often were 30 to 40 pages. Using S-PLUS we were able to provide FDA decision-makers with valuable information on one page. Our new reports provide FDA reviewers with the information they need quickly to make informed decisions," says Twist. "S-PLUS has allowed each researcher to access standardized analytics and report tools from their desktops improving our reporting process," says Twist.

"We selected S-PLUS software because it provided us with graphic capabilities and powerful data analysis tools we needed to perform our work," says Twist. Now, researchers can prepare reports that are

consistent, easy-to-read and translate results effectively. Better reports can help bring safe, effective drugs to market faster improving the quality of human lives.

Benefits

- Powerful Data Analysis
- Efficient Visualization Capabilities
- Seamless Integration With Microsoft Office And Other Business Tools for FDA Reporting
- StatServer/S-PLUS

Source: Insightful Corp., 2007