

GlaxoSmithKline Streamlines the Design, Analysis and Reporting of Clinical Trial Data with Clinical Graphics Solution from Insightful



The clinical graphics solution developed by Insightful is being utilized by GlaxoSmithKline (GSK) to streamline the design, analysis and reporting of clinical trial data. By using the clinical graphics solution, GSK's Biomedical Data Sciences statistical community is facilitating better scientific analysis and interpretation, and enabling more effective communication across functional areas.

Situation:

Since it takes an average of 12-15 years and over £500 million to develop a new drug, there are compelling reasons to find new and innovative ways to improve drug development efficiency and quality.

One of the areas GSK saw for improvement was the role of the statisticians working in drug development. Statisticians rank near the top as one of the busier functional groups in drug development because their skills for turning raw data into interpreted results are needed for many drug development tasks. A survey within GSK Biomedical Data Sciences regarding its graphics tool revealed a number of challenges including: too few graphs were being produced; graphs took too long to create; existing graphs were sometimes of poor quality; and some platforms within GSK were not able to produce high-quality graphs. The company realized that providing statisticians with an easy-to-use, quality graphics tool would have a noticeable impact on drug development; facilitating better science and more effective communication through exploratory analysis, submissions, presentations and publications.

Solution:

The GSK Graphics Team and their IT colleagues joined with Insightful Corporation to implement a cross-platform graphics solution based on S-PLUS®, Insightful's software platform for statistical data analysis and predictive analytics. The clinical graphics solution developed by Insightful, the S-PLUS Graphics Toolkit, works cross-platform, enabling creation of graphics for data exploration and review on Windows; and for clinical reporting and regulatory submission in GSK's regulated UNIX environment.

INSIGHTFUL CASE STUDY

Solution Overview

Profile:

GlaxoSmithKline (GSK) is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. GSK produces medicines that treat six major disease areas: asthma, virus control, infections, mental health, diabetes and digestive conditions. In addition, GSK is a leader in the important area of vaccines and is developing new treatments for cancer. The company is headquartered in the United Kingdom and has operations in the United States.

Business Need:

GSK recognized that in order to improve drug development efficiency and quality, it needed to provide statisticians with a software environment that made it easier to produce good-quality graphs to aid in data exploration, team discussion, decision-making, clinical reporting and scientific presentation and publication.

Insightful Products Used:

- Clinical Graphics Solution
- S-PLUS Enterprise Server
- S-PLUS Enterprise Developer

Customer Quote: Dr. Roger Liddle, Discovery Biometrics Vice President, GSK

"We are committed to Insightful's clinical graphics solution to assist the statistician in understanding our data and to improve the communication of results in submission, publications and presentations. We are seeing significant uptake of the clinical graphics solution, with the majority of users finding it an easy way to produce high quality graphs. The clinical graphs our staff is producing are being used by GSK statisticians, clinicians and publishing staff in several critical areas including data analysis, presentation, submission and publication"

At the core of the S-PLUS Graphics Toolkit is Insightful's S-PLUS software platform and Insightful's clinical graphics solution for automated and transportable graphics. GSK's implementation of the Insightful solution underwent an extensive testing phase, including two rounds of beta testing, an early adopter phase, final enhancements and validation.

In April 2007, GSK began to roll out the S-PLUS Graphics Toolkit to all members of the GSK's Biomedical Data Science statistical community. GSK reports there are currently more than 200 users and they expect to have 400 users trained by the end of 2008. Users are able to save and reuse their work via transportable metadata files. They are also able to produce quick and customized graphics in various formats including pdf and wmf files. Users have access to an internal support database that handles user problems and also have technical support and design advice across all therapeutic areas available to them.

"I am excited we can now generate high-quality, custom graphics with S-PLUS," said a senior GSK statistician in Oncology who is also an experienced S-PLUS user. "With its ease of use and functionality with our UNIX reporting environment, the S-PLUS Graphics Toolkit allows anyone to create quality, reproducible graphics, with little or no S-PLUS knowledge, in minutes."

Benefits:

By deploying the clinical graphics solution developed by Insightful, GSK is achieving its goal of improving graphics usage in clinical development decision making. High-quality graphics are now becoming the standard. The clinical graphics solution developed by Insightful enables:

- Rapid and accurate comparative analysis of treatment effects
- Exploratory analysis, cleaning, and understanding and interpreting results within GSK project teams
- Clear and effective presentation of study results in scientific presentations, publications and marketing applications
- Drug candidates to move through the development process faster while highlighting issues sooner
- Rapid and high-quality submissions to regulatory agencies

"We are committed to Insightful's clinical graphics solution to assist the statistician in understanding our data and to improve the communication of results in submissions, publications and presentations," said Dr. Roger Liddle, Discovery Biometrics Vice President and sponsor of GSK's clinical graphics initiative. "We are seeing significant uptake of the clinical graphics solution, with the majority of users finding it an easy way to produce high quality graphs. The clinical graphs our staff is producing are being used by GSK statisticians, clinicians and publishing staff in several critical areas including data analysis, presentation, submission and publication."

Through Insightful's clinical graphics solution, GSK is promoting use of statistical graphics principles and standards for clinical study reports and scientific presentation and publication. The integration of this solution with existing GSK data management and analysis environments, such as the GSK regulated submission environment, has clearly resulted in cost savings at GSK. This deployment of statistical graphics standards across drug development functional area environments eliminates graphics reworking and other manual processes, while providing built-in quality control.

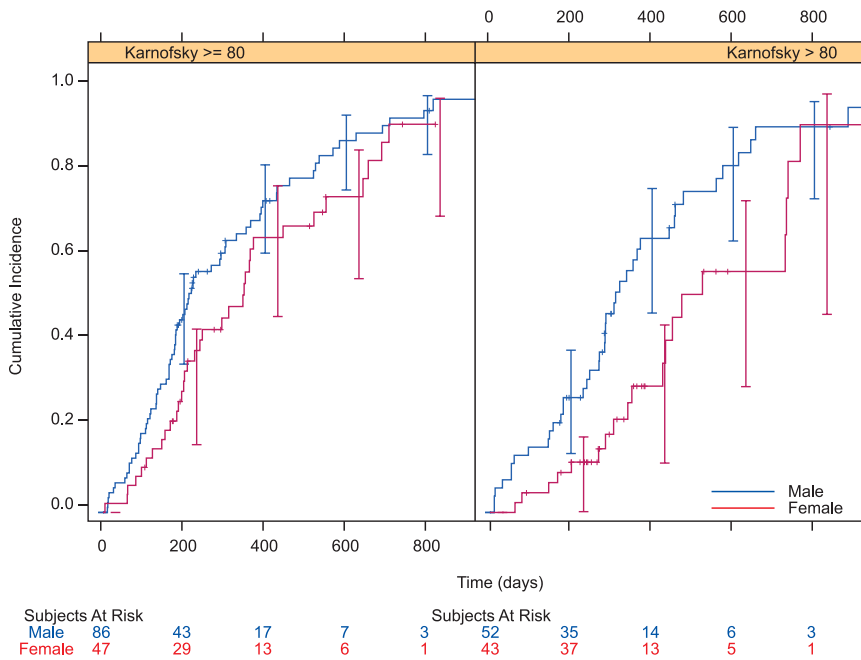


Figure 1. The Trellis Kaplan-Meier plot is one of the many plots included in the Insightful clinical graphics solution implemented at GSK.

All of these time and labor savings, coupled with the accuracy provided through the validated statistical graphics implementation, help move drug candidates through the development process faster while enabling better science and more effective communication. In this world, patients get new therapies faster while drug development is streamlined through the GSK organization and its interaction with global regulatory agencies.

For More Information

For more information about GSK products and services, visit Web site at www.gsk.com. For more information about Insightful products and services, visit our Web site at www.insightful.com.

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S-PLUS 8 and Insightful Life Science Solutions – Delivering the Power of Predictive Analytics Across the

Enterprise: S-PLUS and Insightful products have been delivering flexible, validated and streamlined data analysis results to the pharmaceutical industry for more than 18 years. Designed with an open architecture and flexible interfaces, S-PLUS 8 provides the scalability to handle gigabyte-size data sets and the flexibility needed to integrate advanced analytics into the business processes that decisions makers and researchers interact with every day. More information about S-PLUS 8 and our Life Sciences solutions can be found at www.insightful.com.