



GENAISSANCE PREDICTS INDIVIDUAL RESPONSES TO DRUGS

SAS® powers sophisticated informatics system

Industry

Life Sciences

Business Issue

Detect correlations between genomic variations and patient responses to drugs.

Solution

Genaissance incorporates advanced analytical capabilities into the sophisticated DecoGen™ Informatics System with SAS®.

Benefits

SAS® provides advanced calculations in a fraction of the time required.

With a client list that includes Johnson & Johnson, Biogen and Pfizer, Genaissance Pharmaceuticals is a world leader in the field of pharmacogenomics. This exciting new discipline unites biology, pharmacology and population genomics to study inherited differences in human genes and to create personalized medicines for individuals based on their unique genetic makeup.

Measuring human genetic variations and individual responses to drugs is an extraordinarily delicate task that requires the use of complex information management systems, custom algorithms and data analysis tools. With the help of SAS software, scientists and engineers at Genaissance have developed a sophisticated informatics system that analyzes data from clinical trials and detects correlations between genomic variations and patients' responses to drugs.

SAS® offers analytical powers

"We've developed our own software, called the DecoGen™ Informatics System, to manage genetic and clinical data and to perform statistical association analyses," explains Richard Judson, Senior Vice President of Medical Affairs and Informatics at Genaissance. "Our specialty is dealing with genetic data."

It's a complicated specialty, considering that approximately 15 million sites of genomic variation are found in the human genome. And because most drugs interact with a variety of genes, variations in multiple genes must be analyzed to

predict response to a specific drug. But DecoGen, the company's proprietary informatics system, makes it easy for researchers to manage and visualize their clinical data.

And SAS makes the advanced analytics possible. "SAS is an integral part of the DecoGen product," explains Judson. "The earlier versions of DecoGen did not have SAS, but once we started doing more sophisticated statistical analyses, it made sense to incorporate a package with all the bells and whistles. So we brought in SAS."

Zongwei Shen, Senior Software Engineer, uses the Java development environment in SAS AppDev Studio™ software to incorporate the power of SAS into the Genaissance system, making it easy for scientists to perform complicated SAS analyses through a user-friendly interface.

"SAS essentially acts as a back-end software module to our program, so the user doesn't have to be a SAS expert," Judson says. "When we want to ask a very detailed statistical question, we just pass it off to SAS, and the system comes back with an answer that we can parse out and visualize in various ways."

Currently, more than 20 scientists at Genaissance use DecoGen to analyze clinical data. In addition, Genaissance plans to market this exciting new technology to pharmaceutical and biotechnology companies that seek

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Medical Affairs and Informatics
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to improve the development, marketing and prescribing of drugs.

DecoGen™ reveals insight into high-cholesterol treatments

To illustrate the kind of work Genaissance is doing, Judson cites a recent clinical trial that examined a variety of statin medicines, which are used to treat patients with high cholesterol. Statins work by inhibiting an enzyme that controls the rate of cholesterol production in the body. Essentially, they slow down the production of cholesterol and increase the liver's ability to remove the LDL cholesterol already in the blood. Previous studies have shown that statins can lower LDL cholesterol levels by 20 to 60 percent in patients with high cholesterol.

The new study, conducted by Genaissance, seeks to determine which of three statin drugs already on the market work best for patients with various genetic differences. Using SAS for complex analyses, scientists can easily examine each patient's genetic makeup alongside his or her responses to the various medications.

The clinical outcomes will be used in a variety of ways. In the future, for instance, when a patient's blood is sent for a cholesterol screening test, the results might indicate not only whether that patient has high cholesterol, but also which of the available statins would be the best treatment for that individual. Additionally, for those patients who don't have high cholesterol, the tests might determine whether they are at risk for high cholesterol later in life.

“We know that all of the patients in our study have high cholesterol,” explains Judson. “So we can compare their gene versions with those of healthy individuals. If it turns out that a specific gene version is an indicator of risk for high cholesterol, then we could develop a diagnostic test to identify who is likely to develop high cholesterol in the future.”

SAS® instills confidence, saves time

When Genaissance submits data to a client or to the US Food and Drug Administration, the recipient can have confidence in the data, because SAS enables FDA compliance and provides an ideal solution for analyzing

pharmaceutical data. “With SAS, we know the results are regulatory grade, and we know the data will be accepted and integrated easily by our pharmaceutical partners,” says Judson.

In addition, SAS provides advanced calculations in a fraction of the time required before. “There are a lot of fancier calculations we can do with SAS that we could not do otherwise – not without doing a lot of programming. We're able to do all of our association analysis and pull together clinical and genetic data in a professional, regulatory-compliant way. For Genaissance, information is the ultimate product. And with SAS as a component of DecoGen, we're doing that as well as anybody can.”



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