



GETTING DRUGS TO MARKET FASTER

Vertex Pharmaceuticals saves millions using SAS® for clinical trial simulations

Industry

Life Sciences

Business Issue

Get new drugs to market faster.

Solution

SAS® provides analytic strength to make sense of 2 terabytes of data.

Benefits

Millions of dollars in savings and getting drugs to market faster.

For pharmaceutical and biotechnology companies, the development of a new medicine can take more than a decade – a decade of great expense for the developer and of prolonged anxiety for patients in need of new treatments. Meanwhile, the escalating cost of research and development, accompanied by the increasing complexity and expense of human clinical trials, threaten pharmaceutical innovation.

That's why, several years ago, the US Food and Drug Administration (FDA) recommended that the industry expand and accelerate development through simulated clinical trials – a method that was already being advocated at Vertex Pharmaceuticals Inc.

Using SAS®9 technology, Vertex Pharmaceuticals has designed simulations of clinical trials and analyzed millions of data points created by thousands of virtual patients in each simulated trial. As a result, Vertex Pharmaceuticals is saving potentially millions of development dollars and possibly increasing the speed at which it is able to advance drug candidates through the development process.

Based in Cambridge, Massachusetts, Vertex Pharmaceuticals is a global biotechnology company focused on the discovery, development and commercialization of breakthrough drugs for a range of serious diseases. Vertex Pharmaceuticals collaborates with major pharmaceutical companies, such as GlaxoSmithKline, Merck & Co. and

Novartis Pharma AG, in the discovery and development of drugs for the treatment of HIV infection, various forms of cancer and other diseases. Vertex Pharmaceuticals is also independently developing several first-in-class drugs to treat hepatitis C virus infection and a range of inflammatory diseases, such as rheumatoid arthritis and psoriasis.

Where no drug company has gone before

Simulated clinical trials are virtual replicas of actual clinical trials. Mid-stage human clinical trials commonly enroll 500 or more patients. Simulated trials take data models developed from actual clinical trials and develop clinical trial design scenarios and putative trial results that take into account variability caused by treatment effects, survival times, adverse events such as the occurrence of headaches or nausea, and other events that occur during trials. Researchers might perform 10,000 simulations of a single scenario, which means an entire trial can generate millions of observations.

Across the industry, nearly one-third of all clinical trials produce results that are not definitive. Thus, additional trials may be designed to augment poor initial trial results. Additional trials can add months to the development timeline for a drug candidate, explains Steven Schmidt, Vertex Pharmaceuticals' Vice President of Information Services.

"A lack of power in a company's computer environment can seriously

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Paul Dupuis

Senior Director of IT
Vertex Pharmaceuticals

inhibit productive research and development initiatives for serious simulation,” Schmidt says. “Properly powered clinical trial simulations could save tens of millions and greatly reduce overall development costs while also helping the development team avoid the lost time associated with repeating a clinical trial – potentially a year of sales revenue.”

With the parallel computing capability provided through SAS, Vertex Pharmaceuticals believes that it may be able to reduce the length of future trials by using reliable analyses from previously successful trials. “Over the course of a drug development program, market time can be critical,” Schmidt says. “If

you can reduce the length of clinical trials by three months, you may be able to garner an additional \$100 million in sales on a product with \$400 million in annual sales,” he notes.

The parallelized solution adds a dialog box to Vertex’s trial simulation interface that allows massive distribution of replicated simulations. SAS/CONNECT® gives desktop SAS users access to up to 120 parallel processors for analyzing the simulated data. According to Paul Dupuis, Vertex’s Senior Director of Information Technology, a single desktop computer runs a simulated clinical trial that is analogous to the popular Sims video games. While the game’s players simulate real-life

activities with virtual characters, researchers at Vertex simulate real-life trials with virtual patients. These simulations can produce as many as 1 million patients for 2 terabytes of data in a single simulation.

“Instead of simulating one patient going through his clinical trial, taking his medication, having his side effects and getting better from his disease, we now have 100 processors simulating in parallel the data in each step of the process,” Dupuis explains. “With SAS, we already have the ability to do 10,000 replicates in an hour, whereas before we could only do 1,000 replicates in a day. And we’re just getting started.”



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POWER
TO KNOW.

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