

Trials and true

IT consulting firm trusts JMP® Clinical

Dr. Peter Bewerunge is a staunch proponent of a one-system approach.

Bewerunge is the Head of Life Sciences for accantec consulting AG, an IT consulting firm with offices throughout Germany. He advises his clients to get entire teams working in a single data system, one that provides a fully integrated solution for management and analysis.

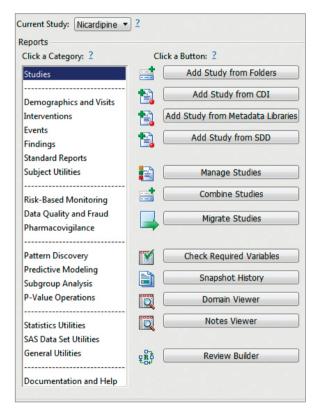
Increasingly, that one system for which he advocates is JMP statistical discovery software from SAS, including, most particularly, JMP Clinical.

JMP Clinical joins the industry-leading power of SAS® Analytics with the full suite of JMP graphical features. It provides "a powerful self-service analysis tool for the entire clinical trial team," Bewerunge asserts. "While everybody has access to the same trial data, JMP Clinical offers a user-role concept that provides each role with a specific set of analysis functions."

What's more, Bewerunge can assure his clients that the JMP portfolio is trusted - and used - by regulatory agencies worldwide and is designed to meet global clinical data standards. He can assure them they're in good hands.

One system for all

Every user role requires a specific view of clinical trials data, Bewerunge



JMP Clinical provides a Starter Menu that allows users rapid and focused point-and-click access to a variety of analytical processes.

acknowledges, but it makes no sense to assign every role its own user administration, programming language and specific processes.

Rather, he says, "It makes sense to integrate one system for the whole company. This saves time and money."

Workflows, templates and reporting tools that are customized according to role make it easy for data managers,

biostatisticians and medical writers to explore trends and outliers, and communicate their findings.

The flexibility of JMP Clinical makes it an easy sell as that one system of choice. It provides tools required by both trained statisticians and clinicians with no statistical background.

"Statisticians love to use script-based systems because it gives them the free-

"Our clients ... really like that they no longer require one tool for data manipulation, another for statistics and yet another for reporting. JMP does it all."

Dr. Peter Bewerunge accantec consulting AG

dom to compute everything they want without limitations," Bewerunge says. "For them, point-and-click software is a nightmare."

But others require ease of use.

"The good news is that JMP combines both," Bewerunge says. "On the one hand, we can use JMP Scripting Language, with all its potential for customized analysis, and on the other hand, we have an easy-to-use pointand-click user interface."

Bewerunge says that most of his clients began with Excel, which was useful for simple needs. But when users begin working with larger data sets, or when data is being redeployed time and again, "it's time to switch," he says, "to software that provides the tools you really need." After clients experience the powerful combination of interactive graphics and statistical analysis, there's no going back.

What's great about the switch to JMP, Bewerunge says, is that it's a very smooth transition: JMP is easy to learn; it's intuitive. Clinical reviewers can quickly become adept at exploring data in much more depth and viewing it interactively.

"Our clients go crazy over JMP because they've never seen software with such interactivity between data and graphics," he says. "They really like that they no longer require one tool for data manipulation, another for statistics and yet another for reporting. JMP does it all." JMP Clinical uses standard Clinical Data Interchange Standards Consortium (CDISC) data formats preferred by regulatory agencies around the world, standard reviewer guidances and standard visualizations. The outcome is the streamlined exploration, review and submission of clinical trial data.

And it's all done with ease. "JMP Clinical users who aren't programmers love that they get all relevant information with just a few clicks," Bewerunge says. "The interactivity allows them to do progressive clinical data exploration - to go deeper and deeper into their data."

A host of tools

The patient profile feature in JMP Clinical is the one his clients use most frequently, Bewerunge says. The software automates creation of patient profiles and patient narratives, reducing the time and complexity of producing output for review and submission, both to internal colleagues and to regulatory agencies. Users can very easily generate summary dashboards of events, findings and interventions.

"It gives them a really good overview of what happened with patients during a visit," Bewerunge says. They're able to then generate patient profiles for an individual or group simply by selecting subjects.

"And JMP Clinical makes it very easy for teams to share their results," he says. Findings can be exported as interactive JMP reports or PDF and RTF files. His clients also very much appreciate the Adverse Events Narrative feature, which identifies events associated with treatments, medications or other subject-level criteria. "It provides an overview of their data and then they can go deeper with specific questions," Bewerunge says.

Risk-based monitoring tools help clients guard against errors in their data. For example, the duplication of a birth date would suggest that a trial participant's data might have been entered twice. These tools work with fraud detection, data monitoring and statistical analysis capabilities to reduce trial failure.

Bewerunge's clients also like the integration of JMP Clinical with SAS Drug Development software, which allows them to consolidate their data into a single repository controlled with secure logins and role-based privileges.

"The integration of SAS Drug
Development into JMP Clinical makes
things very easy," Bewerunge says.
"It's just one click to upload the clinical
trial data into JMP Clinical and then a
couple of more into analysis."

Global tool of choice

JMP Clinical is built on a solid JMP foundation, and Bewerunge makes regular use of a range of standard features. For example, the JMP Distribution platform provides a comprehensive overview of large data sets.

"The JMP Distribution platform gives me a great initial view of my data," he says.

There are a number of JMP features he can deploy for deeper analysis histograms, distribution fitting and descriptive statistics among them.

"I often then like to use box plots to check for outliers," Bewerunge continues. "I click on the outliers to see where they're located in other graphs that belong to the same data set. This is how I get started."

The result is data that he and his clients can trust - and that regulatory agencies trust, as well.

"The fact that JMP is preferred by regulatory agencies gives our customers confidence," Bewerunge says. "SAS is a vendor that's very well known, and JMP also is very well trusted."

In fact, SAS is the US Food and Drug Administration standard for electronic submissions, and JMP is the most commonly used tool in the clinical review community. But what the folks in the lab most immediately appreciate are the results JMP Clinical delivers each day.

"Our customers tell us that JMP Clinical helps them to bring greater efficiency and accuracy to their studies. Now they have one integrated solution," Bewerunge attests. "They're impressed with how easy and fast JMP Clinical is. It's so easy to import clinical trial data, and then you're ready to do meaningful analysis."

CHALLENGE

Provide a system for analysis of clinical trials data that allows everyone access while offering tools customized for specific user roles.

SOLUTION

With JMP® Clinical, built on the power of SAS® Analytics, a German IT consultancy offers an internationally trusted software solution that "gives our customers confidence."

RESULTS

accantec's clients have an integrated data analysis solution that brings "greater efficiency and accuracy" to their clinical studies.



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