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HEART CENTER

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Clinical trial data is invaluable – and irreplaceable – to the drug companies and other entities that sponsor the trials. Data security and data protection are primary objectives for Hendricks and the six-member C5 Information Systems staff.

Heart disease continues to be the leading cause of death in the United States accounting for more than 700,000 deaths last year, according to the Center for Disease Control. But researchers at the Cleveland Clinic Cardiovascular Coordinating Center (C5) are teaming with pharmaceutical giants such as Eli Lilly, Merck, Centocor and others to accelerate the development of new drugs designed to minimize or prevent the devastating effects of heart disease. Qualstar Corporation has supplied an integral piece of C5's information technology infrastructure providing the data access and data security mandatory for this caliber of collaborative research.



BACKGROUND

The Cleveland Clinic's Cardiovascular Coordinating Center (C5) is an Academic Research Organization within the Department of Cardiovascular Medicine at the Cleveland Clinic Foundation. C5 contracts with pharmaceutical companies and other organizations – such as the National Institute of Health – to provide comprehensive planning, coordination and management of FDA-regulated cardiovascular clinical trials.

The Cleveland Clinic Heart Center has a sterling worldwide reputation for excellence. C5 offers a compelling case to pharmaceutical companies to outsource their cardiac drug clinical trials.

Patient data and statistical analysis form the cornerstone of a drug company's case when it submits a new drug application (NDA) for approval to the FDA's Center for Drug Evaluation and Research (CDER). CDER is responsible for ensuring that drugs are safe and effective, but does not actually test drugs; instead, it is the responsibility of the company seeking to market a new drug to test according to FDA guidelines and submit evidence that it is both safe and effective. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists review the sponsor's NDA submission containing

the clinical trial data and grant or deny approval based upon the trial data.

C5 is staffed with more than 150 researchers, analysts and other professionals that have refined the art of patient data collection and analysis. Their experience and expertise ensures that the trial patient data records are designed, collected, analyzed and reported in the most efficient manner, thus helping their pharmaceutical company clients complete the trials in a shorter time, speeding up the process of submitting new drugs to the FDA for approval. When approval can take many years, any improvement in the clinical trial process that can get new drugs to market sooner can be worth millions of dollars in revenue to the client, and save the lives of thousands of patients.

The benefit to pharmaceutical companies of having C5 manage their clinical trials for the FDA NDA process is obvious. The Cleveland Clinic Heart Center is home to the largest and most prestigious cardiovascular specialty group in the world. Its doctors are credited with inventing cardiac angiography and developing the coronary artery bypass procedure. *U.S. News & World Report* has ranked the Cleveland Clinic Heart Center as the best in the nation for seven consecutive years. More than 88,000 patient visits were recorded at the Cleveland Clinic Heart Center last year, providing an abundant research base of potential drug trial participants.



“This is the largest institution in terms of number of heart patients both on the cardiology side and also on the surgery side. That's extremely attractive to pharmaceutical companies as we have the patient population that they're looking for,” said John Hendricks, Manager of Information Systems for C5.

THE CHALLENGE

Clinical trial data is invaluable – and irreplaceable – to the drug companies and other entities that sponsor the trials. Data security and data protection are primary objectives for Hendricks and the six-member C5 Information Systems staff. The C5 IS team is challenged not



The more Wayne Bienia, Systems Administrator for C5 Information Systems (standing), learned about Qualstar's tape libraries, the more he liked: "It just seemed that we were getting a lot more flexibility than with other tape library vendors, especially for the cost."

only to ensure continuous data availability, but to keep the data secure and backed up at all times. Research and analysis staff – as well as site managers in remote locations who are overseeing clinical trial patients outside the Cleveland Clinic Heart Center – require continuous access to the clinical data to keep the program moving. In addition they also have to comply with FDA data security, privacy and recovery regulations.

C5 SYSTEM CONFIGURATION

Until recently, the C5 computing infrastructure had been centered around a Network Appliance Network Attached Storage (NAS) filer as the main data repository. The NAS system was used to store Windows NT application files as well as the Oracle databases used for the various clinical trials in progress. Backup was performed with a single-drive DLT autoloader equipped with just seven cartridges. The NAS-only solution was proving to be a hindrance, rather than an enabler, for the C5 researchers, data entry team and others. The NetApp filer is not optimized for database applications and delivered very poor response performance for the required Oracle applications. Of even greater concern was the backup situation. The data on the filer was backed up to the single DLT loader over the Ethernet LAN. This operation was taking from 14 to 16 hours

per day. Even then, the reliability of the backup was suspect because of the inability of the system to properly backup live Oracle databases.

"Our main concern is restoration, and none of the data was completely protected since there was no way of dealing with open database files," said Wayne Bienia, Systems Administrator for C5 Information Systems. "We didn't know if we ever got accurate backups using the old system, so we knew we had to make fixing that a high priority."

In searching for a new backup solution, the C5 team not only had to consider all of the usual technology requirements: capacity, throughput, scalability and reliability. It was also tasked with being able to recover archived data years or decades later in the event the research is called into question, or to support any legal challenges that may arise. This could be a problem with any storage format, including tape, since technology continues to evolve and backward compatibility with older formats may suffer.

"That was one of the reasons we focused on AIT technology because Sony laid out an upgrade path to AIT-6 that says that these tape drives will be able to read the data back five years or more down the road," said Bienia. The decision to use Sony's AIT technology lead Bienia to Qualstar, one of Sony's largest AIT OEMs. Qualstar Corporation implements AIT drive technology in its TLS-Series of automated tape



In searching for a new backup solution, John Hendricks, Manager of Information Systems for C5, decided on Qualstar and Sony AIT technology, assured that their investment, and ultimately their data will be protected by a scalable, upgradable solution.

libraries. The more Bienia learned about Qualstar's tape libraries, the more he liked: "It just seemed that we were getting a lot more flexibility than with other tape library vendors, especially for the cost."

THE SOLUTION

The Cleveland Clinic settled on a Qualstar TLS-4660 library equipped with three AIT-2 drives and 63 tape slots for a native capacity of 3.15 terabytes. This configuration provides C5 with



room for future growth, by adding both additional slots and additional drives. The TLS-4660 library can be scaled up to a total of six drives and 126 tape slots. It also enables the C5 IS operation to upgrade to future generations of AIT drive technology simply by swapping out the tape drive carrier. The scalability and flexibility of the Qualstar library protects C5's hardware investment

without forcing them to continually change their backup environment, drive technology or library manufacturer to keep pace with requirements.

"The biggest challenge was getting our shipping department to bring the library to the building," said Bienia. "We unboxed it, installed the cartridges and everything worked perfectly." The implementation went so smoothly that Bienia completed the installation and setup of the library and the new backup software in just two hours, a project that was originally scheduled to take three days. After performing the initial library setup, Bienia called Qualstar and immediately got a technician on the phone who walked him through the proper SCSI termination settings. Within 30 minutes, the Qualstar library was connected to the Sun server, and everything worked as expected the first time. The Veritas NetBackup software was installed, configured and writing data to the TLS-4660 within another 30 minutes.

Along with the new backup solution, the C5 IS team also upgraded its server hardware architecture and now hosts the Oracle databases on a Sun E450 server with dedicated RAID storage. The NetApp filer is now used exclusively to store non-database files generated by the Windows NT clients.

The Qualstar library backs up both the Sun server and the NetApp filer. Veritas NetBackup

THE SOLUTION, CONTINUED

software running on the E450 controls the entire backup process. And to date, it appears that the C5 IS group made the right decision by installing a Qualstar library. Automated daily backup for the C5 installation now takes only about an hour to perform. One AIT drive in the Qualstar library is dedicated to backing up NetApp data, while the other two backup the Oracle database information stored on the Sun server. Each weekend a full 500 gigabyte backup is performed, and on the first of each month the Veritas software automatically creates a duplicate set of tapes within the library, which are then taken off-site to protect against catastrophic events.

The verdict from Bienia: "Flawless. We've been live in production since August; we've had zero trouble. The Sun server that is hosting the backup software has been up and running ever since we installed the new software and hasn't been re-booted."

The performance and reliability of the Qualstar library has been so good that Bienia can't comment on the quality of Qualstar's technical support capabilities as he's never had to use them. Qualstar's library technology even overcame the single small problem that C5 IS experienced – one bad AIT tape cartridge. "It went bad in the middle of a backup job, but still the backup job didn't fail," said Bienia. "The library ejected the bad tape, installed a new one and finished the backup job."

THE FUTURE

The ongoing challenge facing Hendricks, Bienia, and the rest of the C5 IS staff is to keep pace with burgeoning data requirements. C5 recently added 218 gigabytes of additional capacity to the NetApp filer



Bienia (left) and Hendricks (right) in the Clinic's Data Center. Qualstar's TLS-4660 Library equipped with AIT-2 drives and 63 tape slots can handle 3.15 terabytes of data. The performance verdict from Bienia: "Flawless. We've been live in production since August, we've had zero trouble."

and have already consumed 36 gigabytes. Their storage needs are expected to take another huge jump as C5 transitions to a completely digital environment. In the future, all laboratory radiology results will be stored digitally, requiring both additional primary storage as well as more archival storage.

The group is also embarking on a plan to transform all patient record reporting and data collection processes into web-enabled applications. "The web solution will enable electronic submission of case report forms, allowing the C5 team to speed up data gathering from remote research sites," said Hendricks. "This will all become possible once electronic signature standards are in place and the FDA gives its approval."

The web applications are being developed under Microsoft's .net architecture and Hendricks plans on adding additional Windows 2000 servers with RAID storage to host the new application. Those servers will likely be backed up by their own dedicated Qualstar library.

"In the future, as we develop more applications, we would obviously like to make everything web-based," said Hendricks. "The end result of what we do is saving lives. There's a tremendous number of challenges, but at the same time, opportunities too." As the Cleveland Clinic continues to address the challenges and opportunities the future will bring, they can be assured that their IT investment, and ultimately their data, will be protected by scalable, upgradable, *Simply Reliable* Qualstar libraries.

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