

Cubist Pharmaceuticals streamlines clinical trial processes and improves CRO collaboration

Overview

■ The Challenge

The disparate set of systems Cubist Pharmaceuticals, Inc., was using to manage clinical trials could not scale to handle the company's growth, resulting in a lack of process automation and standardization and an inability for employees to share critical information

■ Why IBM?

IBM offers a flexible, comprehensive messaging and collaboration platform with a rapid development environment for creation of new applications

■ The Solution

To move the trial oversight in-house, Cubist deployed Protocol Manager™, a robust clinical trial management system from IBM Business Partner Winchester Business Systems that is built on the IBM® Lotus Notes® and Lotus® Domino® platform

■ Key Benefits

- Scalable platform will help Cubist support growth well into the future
- Automated workflow of key processes and standardization of forms and reports improves efficiency and allows workers to share information more easily
- Increased functionality helps Cubist reduce reliance on outsourcing, lowering overall costs
- Full offline functionality with easy synchronization



In hospitals and clinics all over the world, “super-bugs” are rapidly rendering traditional antibiotics obsolete, putting millions of patients at risk of developing hard-to-treat infections. To help doctors fight these life-threatening illnesses, Cubist Pharmaceuticals, a leading bio-pharmaceutical company headquartered in Lexington, Massachusetts, is dedicated to developing new anti-infective medications for the acute care environment. In fact, Cubist Pharmaceuticals is renowned for developing Cubicin®, the first antibiotic of its kind in a new class of anti-infectives called lipopeptides.

To help keep its life-saving pharmaceutical development efforts on track, Cubist relies on a dependable, integrated IT environment. “IT is an integral part of everything we do,” says Ed Campanaro, vice president of clinical operations and data management at Cubist. “From managing clinical trials to facilitating communication between our sales force and our headquarters, IT is essential to ensuring that our business processes run as smoothly and effectively as possible.”

Key Components

Software

- Winchester Business Systems Protocol Manager
 - IBM Lotus Notes
 - IBM Lotus Domino
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Cubist outgrows home-grown clinical trial management system

A few years ago, however, the Clinical Operations group was having a challenging time keeping pace with growth. In particular, as the number of new clinical trials grew, the task of managing them became increasingly difficult. “Clinical trials, especially phase 3 clinical trials, are very complex and very challenging to manage,” says Campanaro. “For example, a phase 3 clinical trial program typically involves between two and three thousand patients distributed over 100 hospitals and might run for up to two years.”

“Managing such a trial requires significant clinical and logistical oversight—from keeping records of all patients, investigators and sites to monitoring individual sites, managing grant payments and many other administrative tasks,” continues Campanaro. “It’s a huge job. And because the number of clinical trials running concurrently was increasing, the complexity of managing them got even worse.”

Although Cubist had a home-grown CTMS in place, it was inefficient and unable to keep pace with the rapid growth in clinical trials. “We had a system based on FileMaker Pro to help us manage the administration and coordination of clinical trials,” says Val Montanus, clinical supply and CTMS manager at Cubist. “And it worked fine when we were a small startup company with only one drug in clinical development. But once we got into large-scale, Phase 3 clinical trials and multiple products in trials, the system simply could not scale to meet the record-keeping and process management tasks required. In fact, we would have to juggle between clinical trials, taking one offline so we could work on another, just to keep the system operational.”

Also, because the FileMaker Pro database system had limited reporting capabilities, Cubist employees had to resort to other systems, such as Microsoft® Excel spreadsheets, to create reports and share information with other employees both at Cubist and at the various clinical sites. “We had no easy way of generating standardized reports,” says Campanaro. “So our employees used whatever they could—including spreadsheets and even pencil and paper—to analyze trial status data and share critical information with others. It was extremely slow and inefficient and limited our ability to report metrics, spot trends and take proactive steps to correct problems.”

Additionally, because the system currently in place had no way of automating workflow, managing critical administrative and monitoring processes was also inefficient. “Most of our business processes were handled manually, which was very cumbersome and time-consuming,” says Campanaro. “For example, when something needed to be taken care of, such as making a grant payment based on achievement of a milestone or other deliverable, there was no way of automatically alerting anyone that this action was necessary, resulting in delays and the need for human intervention at nearly every step of the way.”

Cubist selects Protocol Manager from IBM Business Partner Winchester Business Systems

Campanaro, Montanus and other representatives from the Cubist Clinical Operations and IT departments determined that it was time to look for a comprehensive clinical trial management system. After evaluating several vendors, they decided that Protocol Manager from IBM Business Partner Winchester Business Systems offered Cubist the right combination of functionality, customizability, scalability and cost. “Protocol Manager was very rich in clinical trial management functionality out-of-the-box,” says Campanaro. “But because it was based on IBM Lotus Notes and Domino, it also had the flexibility to allow us to create specific modules as well as the exact forms and reports that we needed for our particular business. Plus, the Lotus Notes and Domino platform has a powerful workflow engine that would allow us to automate critical processes. It was a very compelling combination.”

Campanaro and his staff were also confident that the system could scale to meet the demands of the rapidly growing company. “We were growing fast, so we had to make sure we had a platform that could handle the increasing amount of trial management data that complex clinical trials generate,” says Campanaro. “And knowing that the solution was based on the highly scalable and industry-tested IBM Lotus Notes and Domino platform gave us that assurance.”

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IBM Lotus Notes and Domino-based Protocol Manager allows Cubist to streamline clinical trial administration

Cubist Pharmaceuticals implemented Protocol Manager based on IBM Lotus Notes and Domino software to manage the administration of clinical trials. "All of the operational and administrative data needed for day to day management of clinical trials is now stored in and managed by a single system," says Montanus. "And that includes budget information, actual spending, trial status and milestones, site monitoring activities and reports, study supplies and more."

Because the system is based on the flexible Lotus Notes and Domino platform, Montanus and the staff were able to easily customize the system to adhere to the company's unique terminology, standard operating procedures and reporting requirements. "One nice thing about the system being based on Lotus Notes and Domino is that it is so easy to administer," says Montanus. "I'm in the Clinical Operations group, and, after just two Lotus Notes and Domino classes, I learned enough to be able to administer and modify the system with assistance as needed from IT. So we can get the functionality we need when we need it—it's a great time saver."

To facilitate process management, Cubist also integrated Protocol Manager with the company's e-mail system. "We modeled out business processes using the Lotus Notes and Domino workflow engine," says Montanus. "And then we integrated those processes into our e-mail system to provide alerts and notifications. Now, when an employee completes a task and submits it into the system, the next person in the process is automatically notified by the company's e-mail system."

In the future, the team plans to allow partners and clinical site personnel direct access to select areas of the system via the Web. "Currently, some of our partners access the system remotely using VPN," says Campanaro. "But with the help of Winchester, we plan to develop a Web portal so that external users at clinical sites can access our information securely over the Internet."

Standardization and process automation improve efficiency, collaboration

Montanus and Campanaro are impressed with the improved efficiency of managing clinical trials made possible by Protocol Manager. “With Protocol Manager, we have been able to standardize our business practices,” says Montanus. “Now, all of our employees and contact research organizations (CROs) see the same information in the same way, which dramatically improves their ability to communicate and collaborate with one another.”

Automated workflows have also allowed the company to improve efficiency dramatically. “Because of the built-in workflow engine, we’ve reduced the turn-around time for key processes while creating an audit trail where needed,” says Campanaro. “For example, if a task needs to be taken care of, such as paying a physician or auditing a site, the system will automatically notify the appropriate person without the need for manual intervention. It had really improved the efficiency of our operations.”

Reduced reliance on outsourcing helps Cubist lower overall costs

Additionally, the rich functionality available in Protocol Manager has allowed Cubist to lower costs by enabling the company to perform in-house tasks that were outsourced in the past. “We used to outsource a number of critical functions such as grant payments,” says Campanaro. “Now, because much of that functionality is already in the system, we can do it ourselves. It has saved us a lot of money already, and, as we adopt additional features of the product, we expect to reduce our outsourcing costs even further.”

Scalable platform will let Cubist support growth well into the future

Overall, the staff at Cubist is very pleased with the performance, reliability and scalability of the Lotus Notes and Domino-based system. “We have been putting data into the system for two years now and we haven’t experienced any slow-downs,” says Montanus. “Plus, it’s never gone down for any reason other than scheduled maintenance. And from a scalability standpoint, we are nowhere near capacity. In the coming years, we plan to optimize our return on investment in Protocol Manager by expanding usage and adding functionality that will be integrated into our clinical trial business practices.”

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For more information

For more information on IBM Lotus Notes and Domino software, please contact your IBM sales representative or IBM Business Partner, or visit ibm.com/software/lotus

For more information on Winchester Business Systems, visit www.wbsnet.com

For more information on Cubist Pharmaceuticals, visit www.cubist.com

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