

DOV Pharmaceutical adds global reach, cuts costs, lowers risks with advanced clinical trial management system

Solution from IBM and Winchester Business Systems improves collaboration, communication among researchers and managers



Overview

The Challenge

To quickly achieve global capabilities in managing complex clinical trials for new drug therapies

The Solution

IBM Lotus Domino Express 6.5.4, IBM Lotus Notes 6.5.4, IBM Lotus Sametime 6.5.1, IBM eServer xSeries, plus Protocol Manager, Version 7 and adWATCH-AE, Version 7 from Winchester Business Systems

The Benefit

Customer achieved immediate leap forward in global operational capabilities, with anticipated cost savings of \$3 million by year-end 2006

Let's say your company is a growing U.S. biopharmaceutical and has potential drug therapies in development that may have strong applicability in overseas markets. Suddenly you're looking at managing clinical trials with patients, doctors and researchers at 50 different sites across the globe, in places like India, Israel and Guatemala, as well as in the United States.

A domestic clinical trial by itself (without global sites), is a complex and delicate process—keeping track of a host of activities and milestones, keeping them on time and in compliance with the stringent oversight of the U.S. Food and Drug Administration. A report by the Tufts Center for the Study of Drug Development has cited clinical trials as the main contributor to the upward cost

spiral in bringing a new prescription drug to market in the United States. The cost to bring a new drug to market now averages more than \$880 million and extends over 10 to 15 years.

You've managed previous clinical trials using basic IT support and paper-based documentation: spreadsheets, conventional e-mail, faxes, overnight mail and the like. Now, the global coordination will be vastly more complicated, and any misstep could have costly consequences in delaying FDA approval.

“The extraordinary robustness of Lotus Notes and Domino and the IBM hardware once again justified our choice of this strategic solution platform.”

Mike Regentz,
managing director,
Winchester Business
Systems, Inc.

IBM PartnerWorld Industry Networks makes for tighter integration with Winchester for further evolution of specialized solutions

Benefits

- Rapid improvement in global management capabilities while lowering development and operational costs
- Improved internal and external coordination of delicate clinical trial processes
- Risk of human error lowered through automation of critical steps
- Reduced need for time and travel to collaborate, evaluate, and report

Decisive wins

That was the challenge facing DOV Pharmaceutical, Inc., of Hackensack, New Jersey, in late 2004. DOV chose Protocol Manager™, a clinical trial management solution (CTMS) from IBM and Winchester Business Systems, Inc., an IBM Business Partner specializing in the healthcare and life sciences industry. Winchester, which was founded in 1989, is headquartered in Woburn, Massachusetts.

Meeting the challenge demonstrated how IBM and Winchester brought exactly the right focus to a customer problem and also led to marketplace wins for IBM and Winchester. IBM Lotus Domino® Express, Lotus Notes® and Lotus Sametime® have been implemented, and in the second quarter of 2006, Lotus Domino and Lotus Notes mail will replace Exchange and Outlook from Microsoft. Winchester's clinical software suite, Protocol Manager, Version 7 and adWATCH-AE, Version 7 were chosen by DOV over competitors, signifying that Winchester was able to provide a more complete solution.

The new CTMS was implemented in the spring of 2005, and after only a few weeks DOV managers were confident they were on track toward a positive return on investment by year-end 2006, with the ultimate goal of trimming \$3 million off corporate operational and drug development costs in the same timeframe.

AnnMarie Dodson, DOV director of information technology, said, "The \$3 million in anticipated savings derives from improved productivity among people collaborating more effectively across a variety of corporate operations and clinical trial processes. The automation and workflow improvements are obvious even at this early stage."

"Missed arrivals and past expiration dates are costly.....What we've basically done is eliminate many of the opportunities for human error."

AnnMarie Dodson,
director of information technology,
DOV Pharmaceutical, Inc.

Pull versus push

"Pull" technologies are the heart of those improvements. As explained by Mike Regentz, Winchester managing director, "Conventional e-mail is an example of 'push' technology, where nothing happens until someone sends a message—pushes it down the line—to someone else. With 'pull' technologies, everybody in an organization can pull up the same trial documents at the same time and have collaborative online discussions."

Regentz continued, "Groupware may involve shared workspaces in which information can be created and used by all members of a group. Various groupware capabilities may maintain security and document integrity and, for everybody in the group, keep track of any changes, comments, to-dos, reminders, and so forth."

IBM Lotus Domino is also a rapid application development platform for new collaborative applications. Regentz said IBM Lotus is "the most robust, stable and scalable groupware there is," so Lotus Notes and Domino became the strategic platform on which Winchester would build and evolve its products.

The solution Winchester designed for DOV is a Domino-based clinical trials management system, called Protocol Manager. It helps manage time-critical information, regulatory documents, budgets and schedules about investigators, patients, clinical-trial staff and all related components of a clinical trial. The main components reside on three IBM eServer xSeries 346 systems.

Other important steps in the clinical trials process are case management and the tracking of adverse events (i.e., any negative or dangerous effect that may be experienced by a patient and caused by a drug or medical device). These steps are managed by adWATCH-AE from Winchester. adWATCH-AE is integrated into the clinical trial management process and automatically ensures that any adverse effect is noted and filed with the appropriate regulatory agency and the FDA. In the system previously used at DOV, adverse-effect reports had to be done manually in a time consuming process always subject to human error.

Instant messaging proves itself

More benefits of the Lotus Notes and Domino product set emerged during the application development and deployment phase. As Dodson explained, "We saw the Winchester team using Lotus Sametime instant messaging for quick communications and the Web conferencing capabilities to collaborate and demonstrate how everything worked. We were impressed. Obviously this same tool could be used for collaboration among DOV employees and our contractors around the world. It's secure and amazingly effective."

Then there was e-mail. As Regentz explained, "It quickly became evident that the DOV applications and business model would need a more robust e-mail solution. That would entail replacing Microsoft Outlook and Microsoft Exchange with IBM Lotus Notes and Domino, and that's what we're doing now as we close out 2005."

The decision to implement new technology and change existing technology is not made lightly. So what are the benefits that DOV saw? Dodson cited a few in particular:

- By enabling DOV internal staff to better manage far-flung clinical activities, the new solution reduces DOV reliance on more expensive contractual arrangements with outside vendors for coordination and reporting tasks.
- By harnessing the instant messaging and Web conferencing power of Lotus Sametime, DOV managers and operational experts now conduct training, provide updates, and collaborate with researchers in the field faster, cheaper and just as effectively as they would in face-to-face meetings without leaving Hackensack headquarters. Time and dollar costs of travel, hotels and out-of-town meetings are avoided.
- Through the automated monitoring and reporting of Winchester Protocol Manager and the adverse-event alerts from Winchester adWATCH-AE, DOV improves the timing and coordination of critical trial events. These are often simple things, like ensuring that a fresh drug delivery gets to a remote research site precisely when the patient and clinician are ready to use it. "Simple? Yes," said Dodson, "but missed arrivals and past expiration dates are costly, as anybody in the biopharm business can tell you. What we've basically done is eliminate many of the opportunities for human error."

Key Components of the DOV Solution

Software

- IBM Lotus Domino Express 6.5.4
- IBM Lotus Notes 6.5.4
- IBM Lotus Sametime 6.5.1
- Winchester Protocol Manager, Version 7
- Winchester adWATCH-AE, Version 7

Hardware

- IBM eServer xSeries 346

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Mike Regentz,
managing director,
Winchester Business Systems

Dodson first became aware of Winchester capabilities when she visited its booth at a Drug Information Association Conference in 2001. As Winchester's Regentz recalled, "Apart from our own capabilities, clearly our IBM relationship and the fact that our products were built on the IBM Lotus platforms had also made a favorable impression."

The choice is made

By 2004, Dodson had narrowed her options on the clinical trial management system to a choice between a comprehensive IBM and Winchester solution and two competitive solutions – each of which would have addressed a different subset of the overall requirements. By year-end 2004, the IBM and Winchester proposal had won.

After that, things moved fast, first with a two-week consulting engagement in which Winchester worked with Dodson's project team to lay out implementation plans. DOV launched informational campaigns for the benefit of the 50 DOV personnel who would be most intimately involved with the new system.

Equally involved were the 75 to 100 people at DOV's outside contractor organizations around the world—those who would be coordinating and reporting from the field. By August 2005, Regentz said, "Protocol Manager was running smoothly and adWATCH-AE was kicking into gear. The extraordinary robustness of Lotus Notes and Domino and the IBM hardware once again justified our choice of this strategic solution platform."

IBM Business Partner benefits

The success of the solution and deployment are directly related to the strength of the teaming between Winchester and IBM. The breadth of IBM offerings and the industry expertise of Winchester combined to provide several winning solutions for DOV.

Winchester Business Systems, Inc., an advanced IBM Business Partner, is also an industry optimized member of the healthcare and life sciences industry. That means it has developed further specialization by optimizing its applications with IBM on demand technologies, achieving success with its own on demand solutions and other criteria.

For more information

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