



Contract Researcher Cuts Costs by 35 Percent with FDA-Compliant System

Overview

Country or Region: United States

Industry: Healthcare services

Customer Profile

Clinilabs, based in New York City, is a contract research organization that provides early phase and specialty clinical drug development services to the pharmaceuticals industry.

Business Situation

Clinilabs wanted a way to grow its business by managing the documentation of clinical trials faster and less expensively—while also increasing the quality of its service.

Solution

The company adopted a document management system for clinical trials based on Microsoft Office SharePoint Server 2007.

Benefits

- Cuts clinical trial costs by 35 percent
- Speeds time-to-market
- Makes users happier
- Enables higher-quality service

“In addition to increasing our revenue and building our brand, [our Microsoft-based solution enables] us to offer even higher-quality service to our customers.”

Dr. Gary Zammit, President and Chief Executive Officer, Clinilabs

Clinilabs, a contract research organization that serves the pharmaceuticals industry, wanted a way to compete effectively against much larger competitors. It focused on the development of a product to improve clinical trial source-document management, a time-consuming and inefficient process that drives up the cost of clinical trials. After considering and rejecting an EMC Documentum solution, Clinilabs turned to a custom solution it calls Clinical InSite, which is based on Microsoft Office SharePoint Server 2007 and has been fully validated for compliance with 21 CFR Part 11 FDA regulations. The solution sped to market in just six months. Clinilabs now reduces clinical trial monitoring costs by 35 percent, saving customers up to U.S.\$465,000 per study. This makes customers happier and is boosting business, brand value, and overall quality.



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Situation

The pill that cures your infection or other illness may be smaller than a pea. But the thousands of documents generated by the clinical trials for that pill likely created a small mountain.

Keeping track of all of those documents is the responsibility of the contract research organizations (CROs) that conduct or oversee trials on behalf of the pharmaceutical companies. Tracking the documents is not just a business or contractual obligation. CROs must adhere to strict regulations set by the United States Food and Drug Administration (FDA). A system that manages those documents must be validated to be in compliance with Part 11 of Title 21 of the United States Code of Federal Regulations (21 CFR Part 11), which determines the rules for electronic records. These rules cover system access authorization, document audit trails, electronic signatures, and validation requirements for computer systems.

Clinilabs is a CRO that needs to adhere to the requirements of 21 CFR Part 11. The company provides early phase and specialty clinical drug development services to the pharmaceuticals industry. Since 2001, Clinilabs has worked for nine of the top 20 pharmaceutical companies in the world, and five of the top 10 CROs, to conduct more than 170 trials and contribute to nine successful new drug applications.

As part of its clinical trials, Clinilabs must ensure that the flow of documentation is smooth, prompt, and accurate. Many of the documents it handles are created by clinical investigators whose research sites are located anywhere around the globe. Those investigators create source documents (for example, patients’ medical records) at their own sites, typically on paper. Data from

these documents is rekeyed into Web applications known as electronic case report forms (eCRF), a time-consuming and laborious process. The pharmaceutical companies then have to send monitors to the research sites to conduct reconciliations and confirm that the eCRF data matches the original paper source data.

“That’s a hugely expensive problem for the pharmaceuticals industry and the CROs who serve them,” says Dr. Gary Zammit, President and Chief Executive Officer of Clinilabs.

Clinilabs and companies like it face many other document management issues. Customers are hardly the only ones needing to conduct audits. The CROs themselves conduct internal audits, and they can be audited by external entities, such as the FDA. The failure to store medical records in digital form and in a single location increases the cost of those audits significantly.

A related concern is the way documents are distributed when they are in electronic form. There is opportunity for error when documents are saved to hard drives, or “file share” computers, and are distributed through e-mail systems, creating multiple copies of files and potential version-control problems. Security is a related concern when documents can be sent freely across the organization’s borders.

Zammit saw a business opportunity for Clinilabs in addressing these document management concerns. “We’re a small company competing against much larger CROs, so we had to innovate,” says Zammit. “The time and expense of dealing with documentation is a major expense. If we could address that problem by digitizing and centralizing documentation to reduce the time and cost of reconciliations and

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audits, we could cut travel time and cost for monitors and auditors, and reduce expenses for our customers—making us a much more attractive alternative in the marketplace.”

Solution

Clinilabs considered a range of options for its electronic document management solution. Commercial hosted document management services for the pharmaceuticals industry, because of the massive numbers of documents generally stored and managed, are prohibitively expensive for a smaller company seeking an edge over larger competitors. Products such as EMC Documentum were also too expensive—and that was only part of the problem.

“Documentum didn’t fit our business model,” says Dr. Yu Ding, Vice President of Operations for Clinilabs. “We didn’t want to force clinical investigators to change workflow or give them additional document management responsibilities. We wanted researchers to be able to use our application as a part of their natural workflow. Documentum was just too difficult to use for that to happen.”

Instead, Clinilabs turned to a solution based on Microsoft Office SharePoint Server 2007. “Like other Microsoft Office products, SharePoint Server doesn’t change the way people work. It enables them to work with the icons and folders and other interface elements with which they’re familiar,” says Ding.

Ding says that Clinilabs was also impressed that Office SharePoint Server would be up and running with minimal configuration and development, cutting the time and cost to market, and then minimizing the need for user training because of its familiar interface. “We’re a small company,” she

says. “This definitely fit our business model.”

To create its Office SharePoint Server–based solution, Clinilabs turned to Perimeterwatch, a Microsoft Gold Certified Partner. “Perimeterwatch had a keen understanding of how we operate—and how we want to operate. They also offered expert service at a highly competitive rate,” says Karina Palafox, Project Manager at Clinilabs.

The solution, now dubbed “Clinical InSite,” was designed over a period of three months, and then developed and deployed only three months later. One of the most important parts of the process was validating Clinical InSite for 21 CFR Part 11 compliance. For this, Clinilabs turned to an outside firm that specializes in validation. The validation process tested both the installation and operation qualifications of Clinical InSite and returned a report of full compliance with the FDA regulations regarding clinical document management systems.

A three-computer solution includes one computer running Office SharePoint Server 2007 and a pair of computers running Microsoft SQL Server 2005 data management software (Figure 1); the company plans to upgrade to SQL Server 2008. The computers running SQL Server are clustered for redundancy, providing both greater reliability and availability. Clinicians at remote research sites access the solution through a secure Web-based logon interface; internal users log on over the intranet.

Both sets of users access Clinical InSite through a firewall and perimeter network (also known as a DMZ or demilitarized zone), providing security for the highly confidential research data contained in the

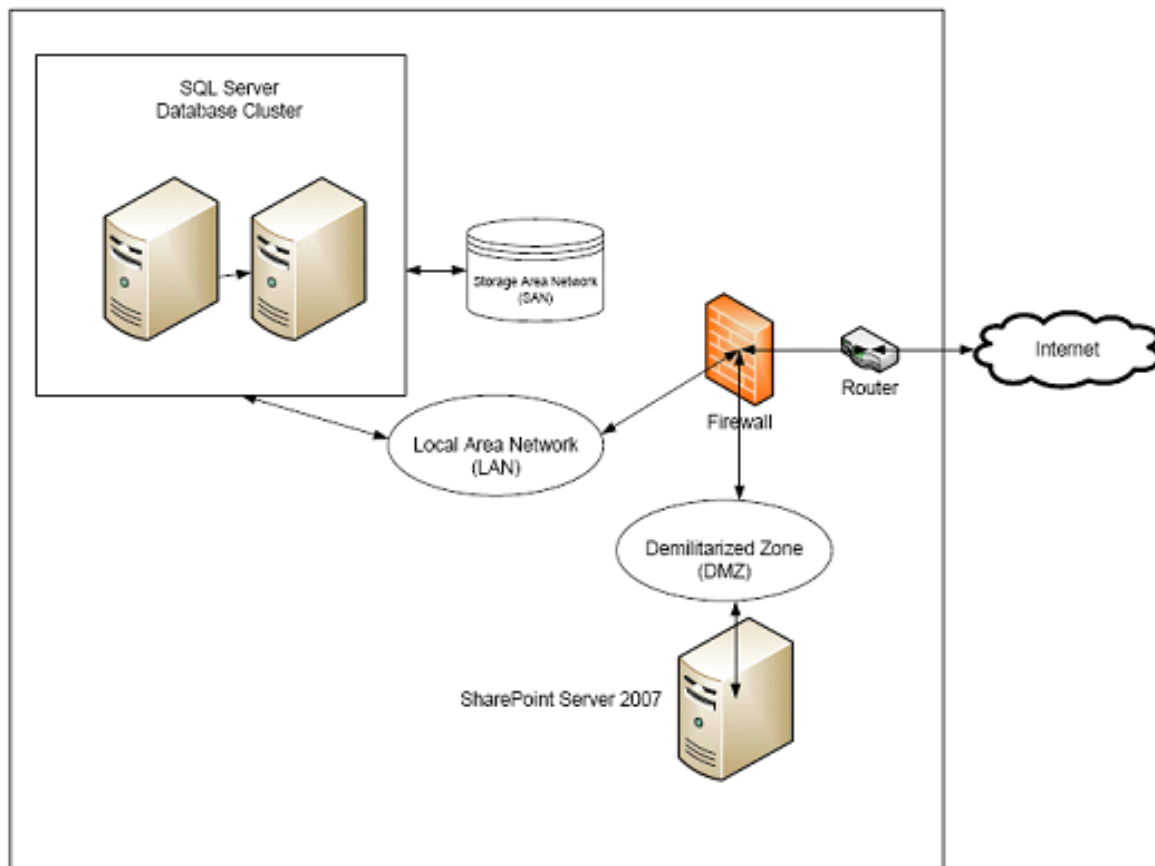


Figure 1. Both internal and external users access the Clinilabs solution, based on Office SharePoint Server, through a firewall and perimeter network, promoting security of sensitive information.

solution. User-based permissions ensure that users see only the information that is required for their jobs. Executive-level users, for example, can see corporatwide data as well as information on the status of clinical trials. Clinical trial personnel see folders related to their specific projects. Permissions are set within Office SharePoint Server by a "super user," a business user who is trained to administer the solution.

Clinical investigators and their staff who submit documents to the central database have a streamlined window in which to do so, replacing the decentralized system on which Clinilabs formerly relied (Figure 2).

The document check-in and check-out system in Office SharePoint Server ensures that as documents are revised or updated, the latest version is always available, without the creation of "version control" problems.

Benefits

By building its clinical trial documentation solution on Office SharePoint Server 2007, Clinilabs has cut trial costs by 35 percent, saved customers up to U.S.\$465,000 per trial, boosted the quality of its service, and made its customers happier—all with a solution that sped to market in just six months.

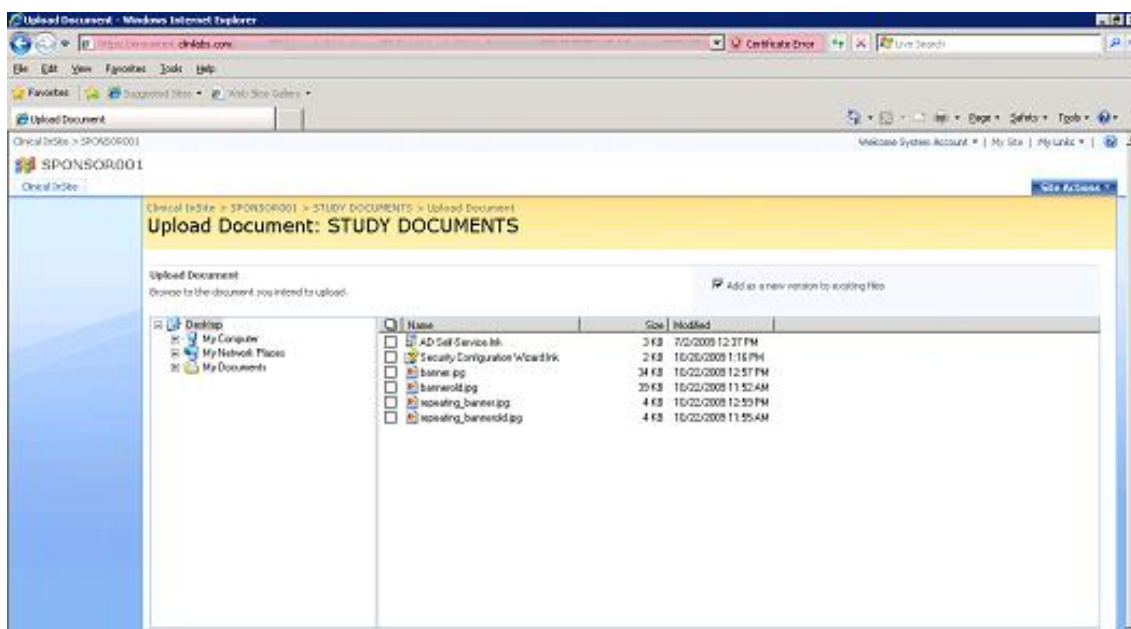


Figure 2. Users upload clinical and other documentation through a streamlined interface to the SharePoint Server–based document repository.

Cuts Clinical Trial Costs by 35 Percent

The central management of clinical documents will change the economics of clinical trial management, significantly reducing costs for Clinilabs and its customers, according to Ding.

One of the biggest areas of savings results from the customers' not having to send monitors or auditors to remote research sites as frequently. This expense has always been high but has risen with the globalization of clinical trials. Clinilabs estimates the number of on-site visits can drop by 50 percent when customers use Clinical InSite. Customers typically make a dozen or more such visits per study, so the savings can be substantial. Overall, Clinical InSite lowers costs by reducing monitoring time, decreasing visit costs (such as travel time, hotel accommodations, transportation costs, and per-diem expenses), and reducing employee burnout

that results in staff losses and leads to the expense of recruiting, hiring, and training new personnel.

While many clinical monitoring visits will no longer be necessary, customers and Clinilabs will gain real-time access to remote researchers' clinical data. That will enable them to query researchers more quickly regarding clinical questions or issues, eliminating the bottleneck of queries that typically comes at the end of a study. The use of built-in workflow capabilities in Office SharePoint Server, which Clinilabs is now beginning to use, will further speed communications between researchers and administrators regarding documentation.

"Any group activity related to a research document is faster and easier with Office SharePoint Server," says Ding. "Any document needing editing or approval, for example, will receive that editing and

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approval faster and easier with SharePoint Server notifications, rather than sitting and possibly getting lost in an e-mail inbox.”

In all, Clinilabs expects to reduce the cost of a typical clinical study by about 35 percent, for a savings of \$175,000 to \$465,000 on the studies it manages.

Speeds Time-to-Market

Once Clinilabs developed its user specifications (a three-month process), it took Perimeterwatch only three months to develop the application. “Beyond the expertise that Perimeterwatch brought to the project, we were able to deliver our product to market so quickly because of the flexibility and comprehensiveness of Office SharePoint Server,” Palafox says. “We used the solution largely out of the box, with the configuration of standard features, rather than having a massive project of coding new features.”

Customized features Palafox points to include the integration of SQL Server Reporting Services to provide standard reports and dashboards on clinical trial status information, as well as features that enable authorized users to post comments on submitted research without changing the original documents themselves.

Makes Users Happier

Another key benefit of the system is equally important but less quantifiable, according to Ding. “Our employees and our customers are happier,” she says. “The response we’ve received is that the system is very simple to use, very user friendly, and very accessible to every authorized user.”

To prove her point, Ding points to the outside consultants used to validate the solution for 21 CFR Part 11 compliance. “When we brought them in and they saw the system we wanted them to validate,

they asked if they could be users themselves—if we could sell the system to them for the management of their own customers,” she says. “That’s how attractive this system is.”

Enables Higher-Quality Service

The overarching goal of Clinilabs in adopting the Office SharePoint Server-based solution was to create a tool that would enable the company to compete on an equal footing with much larger organizations. That’s what Clinilabs now has, according to Zammit.

“Our mission as an organization is to help develop new drugs and to do so in the most responsible way,” Zammit says. “Clinical InSite supports that. While it expedites the process of clinical trials, it also introduces high levels of quality assurance and creates a backup system that we never had before. It gives our data the integrity our customers and regulatory authorities require. In addition to increasing our revenue and building our brand, we see Clinical InSite as a technology solution that fundamentally improves clinical trial workflow, enabling us to offer even higher-quality service to our customers—and that’s the most important benefit of all.”

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