



Healthcare Company Expects Online Collaboration to Save Millions of Euros

OVERVIEW

Country or Region: France
Industry: Healthcare—Pharmaceutical

CUSTOMER PROFILE

Headquartered in Paris, France, sanofi offers a portfolio of pharmaceutical products and is a world leader in producing vaccines for humans. It employs more than 100,000 people in 100 countries.

BUSINESS SITUATION

Sanofi wanted to replace a manual, paper-based clinical trial process with a streamlined digital signature-compliant document management solution operating in a global, web-based collaborative framework.

SOLUTION

The company deployed the Clinical Trial Portal, which is based on Microsoft portal and collaboration technologies. Global stakeholders will use it to share information efficiently throughout a trial.

BENEFITS

- Improves trial management
- Drives productivity
- Reduces costs
- Builds competitive advantage

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Fabien Jolly, Vice President, Technology and Information Management, sanofi

Sanofi is a multinational pharmaceutical company engaged in the research and development, manufacturing, and marketing of prescription drugs, vaccines, and over-the-counter healthcare products. Sanofi relied on time-consuming, paper-based processes to manage global drug trials. To introduce efficiencies and reduce costs, sanofi deployed a digitalized version of its previous method. Called the Clinical Trial Portal, the solution is based on the Clinical Portal solution from NextDocs that uses Microsoft portal, collaboration, and content management technologies. The new solution will accelerate time-to-market for new drug therapies and is expected to save an estimated 10,000 working days—costing €6.4 million (U.S.\$9 million) in time wasted managing documents—when it is deployed to more than 3,000 internal and 40,000 external stakeholders over the next few years.

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The Situation

Sanofi has an extensive portfolio of prescription drugs, vaccines, generics, and consumer healthcare products targeting traditional markets and emerging countries. Sanofi addresses fundamental health issues and makes major therapeutic solutions available in its areas of expertise: oncology, diabetes, thrombotic and cardiovascular diseases, and central nervous system disorders. Sanofi Pasteur, the vaccines division of sanofi, offers vaccines protecting against 20 infectious diseases. Sales in 2010 for sanofi were €30,384 million (U.S. \$43,967 million).

Goal to Streamline Drug Trials

To enable its strategic goals and build a more agile, adaptable organization, sanofi is improving efficiencies in its key business processes. The company began by focusing on how it brings its drugs to market. For sanofi, bringing a drug to market is a multiyear, complex process of global proportions. Expediting this process depends on the successful completion of clinical drug trials. At any given time, the company has dozens of trials in progress. For any trial, sanofi international clinical trial managers (CTMs) could be collaborating with affiliate hospitals or health facilities in as many as 50 countries, where clinical research associates (CRAs) at hundreds of local sites manage trial data from primary investigators, or physicians, administering the drug to many thousands of patients.

A Paper-Based Process

At sanofi, managing clinical drug trials was primarily a paper-based process. “Each clinical trial can generate more than 25,000 documents,” says Denis Cardinal, Domain Manager, Clinical Information and Collaboration, at sanofi. “These are collected during the course of the trial in a trial master file [TMF].”

At the beginning of a trial, when sanofi determines the feasibility of working with a local hospital and verifies that investigators have all the equipment and expertise to proceed, many documents travel between research sites and sanofi locations. However, there’s also a steady stream of documents sent back and forth in the intervening months or years of a trial. From start to finish, each document, and every subsequent revision to that document has to be collected locally, printed, signed, and sent to sanofi. There, sanofi quality control employees compile the TMF and store the documents in boxes to ensure that the company has an audit trail that shows how it complied with standard procedures every step of the way.

The logistics of managing this paper-based process for dozens of concurrent trials was daunting. Faxing, sending by courier, and emailing documents to sanofi was expensive and time consuming. Before participating in a clinical trial, physician investigators must sign a 1572 form required by the Food & Drug Administration (FDA). In addition, signed contracts and confidentiality agreements are required from CRAs at affiliate hospitals. Obtaining the original signatures on paper documents could take weeks. During the course of the trial, CTMs had to locate the right documents and ensure that they were up-to-date, which also incurred delays in the process.

Manual data gathering and file processing opened up the increased possibility of error; missing documents had to be found and entered into the TMF before the study



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could be officially closed. Also, with a paper-based document management system, it was very difficult to use and store metadata, such as authors, dates and other important contextual information. In the context of a long-term clinical trial, metadata is very important because it provides irrefutable evidence of who authorized, revised, and signed documents, and when. This information helps sanofi to follow industry regulations for clinical document management.

CTMs wanted an easy way to gain visibility into a trial’s progress instead of searching through the TMF or tracking down documents that might still be in transit. With trial documentation located in various places, it was difficult to ensure that clinical milestones were reached according to schedule and to communicate accurate progress reports to the team. Similarly, sanofi executives did not have an up-to-the minute, global view of all trials underway.


“We needed to replace an outdated paper-based process and align ourselves with the health industry’s push towards electronic data exchange that adheres to the latest regulations on security and privacy,” says Cardinal. “We envisioned a web-based portal solution that would encompass sophisticated document management capabilities, including digital signatures, and a global framework to enable internal and external stakeholders to collaborate and communicate efficiently on clinical trials. The solution had to provide easy access to clinical trial documents and applications and a global view of each study’s progress.”

Solution

After evaluating different document management and collaboration solutions on the market, sanofi narrowed its decision down to two vendors: Microsoft and a leading competitor. As part of its evaluation, sanofi invited Microsoft Managed Partner NextDocs to visit the Paris headquarters and conduct a proof-of-concept (POC). NextDocs has expertise in building SharePoint-based compliance solutions that address regulatory requirements in the healthcare industry. Sanofi was interested to see how the NextDocs Clinical Portal solution worked with Microsoft Office SharePoint Server 2007 to fulfill the company’s requirements for an easy-to-use health portal and compliant document management solution.

“When we saw SharePoint Server in action with the NextDocs Clinical Portal solution, which ensures industry regulatory compliance, we were won over by the ease of use, adaptability, and additional functionality of the technologies,” says Cardinal. “SharePoint Server offers much more than document management capabilities: it’s a scalable, user-friendly portal and collaboration platform with additional features such as subscriptions, notifications, shared calendars, and message boards. We had already deployed Office SharePoint Server 2007 for a few internal collaboration sites and we appreciated the value of taking advantage of existing IT capabilities.”

Sanofi also chose Office SharePoint Server 2007 because it could easily interoperate with existing line-of-business solutions, including the Clinical Trial Management System (CTMS) and an Oracle-based solution that tracks employee permissions to access corporate network resources. Also, the company liked the product’s familiar, easy-to-use interface. The interoperability between Office SharePoint Server 2007 and Microsoft Office desktop productivity software would ensure a ready adoption of the solution for clinical research associates and investigators because they could access and store documents within the familiar Office business applications that they rely on to create and modify content.



Requirements Gathered

Beginning in June 2009, sanofi began gathering high-level requirements from CTMs, hospital staff, doctors, and CRAs around the world. This tremendous undertaking was necessary to ensure the creation of a digital system that improved upon the manual process. At the height of the project, there were 40 people from sanofi involved in different project areas such as trial contact management, integration with external systems, and building standardized taxonomy and metadata.

“With our new clinical trial portal, we were determined to design and implement optimized processes and to standardize document metadata,” says Cardinal. “We defined 650 different document types. All documents are tagged with clinical keywords defined by the team so we can use SharePoint search functionality instead of looking through paper files. All the document templates were set up using the same phrases and keywords throughout the company so that documentation will be standard and familiar to everyone.”

Instead of sending paper documents to be filed in the TMF in boxes at sanofi locations, internal and external stakeholders will upload documents to the Clinical Trial Portal to create an electronic Trial Master File, (eTMF) that stores documents and all associated updates online. The difference is that now, based on user access and permissions, internal and external international team members will be able to see the contents of the eTMF and watch carefully as documents are added and milestones are reached.

Security Concerns Addressed

As sanofi makes the transition to a digital clinical trial management process and electronic text documents replace paper records, it must comply with government and industry regulations that govern the flow of digital information. Working with NextDocs, sanofi added electronic and digital signature capabilities and new workflows that comply with Title 21 CFR Part 11 containing FDA guidelines on electronic records. Now an investigator can file a 1572 form online using a digital signature, which is a coded message unique to both the document and the signer. Sanofi has 30 days to process these forms, so in order to stay on schedule a SharePoint-based workflow sends a reminder email message to the correct recipient’s Microsoft Office Outlook inbox or mobile phone using Microsoft Exchange ActiveSync technology.

NextDocs used SharePoint Timer jobs to ensure that the Clinical Trial Portal module interoperates with the CTMS to synchronize portal data with the information contained in the CTMS and an Oracle-based permissions system. This makes it easy for sanofi staff to share appropriate study and management data from the CTMS system with trial participants around the world. For example, trials with an affiliate hospital must include a signed confidentiality agreement that resides in the CTMS. For the link to the permissions system, NextDocs developers simply replicated existing permissions when assigning users to the Clinical Trial Portal, which ensures that everyone continues to access the information for which they have permission, according to responsibility and position.



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Designed to Scale

Sanofi is in the final stages of deploying the Clinical Trial Portal based on Office SharePoint Server 2007, running the solution in the test and development environment to correct any last-minute issues. The company released the first live version of the Clinical Trial Portal in April 2011 and by May 2011 two new studies were using the system. Another two new studies are also scheduled to start using the system in May 2011. NextDocs offers a version of its clinical health portal that takes advantage of Microsoft SharePoint Server 2010 and sanofi will be upgrading its Clinical Trial Portal to SharePoint Server 2010 at the beginning of 2012.

While the first live studies will focus on two small trials, sanofi designed the Clinical Trial Portal to scale to thousands of users and has high expectations for performance and reliability. “When we are fully deployed, we’re expecting to reach approximately 3,000 internal users, including affiliate staff at up to 10,000 hospital sites, where between 30,000 and 40,000 doctors will be gathering and uploading clinical trial data into the portal,” says Cardinal. “We worked with Microsoft to complete two performance tests to ensure our SharePoint environment is well-configured and scalable. We’re confident that the clinical portal solution will perform well. Using the system requires little training, encouraging a quick adoption rate and positive user response.”

“With the new Clinical Trial Portal, we leverage best-in-class portal and document management technologies to produce a rich user experience and enable efficient global collaboration,” adds Fabien Jolly, Vice President of Technology and Information Management at sanofi.

Benefits

Thanks to Microsoft collaboration technologies, sanofi is poised to experience a paradigm shift in clinical trial management and operational efficiency. Replacing a manual, paper-intensive process with a web-based digital solution was a daunting project. However, the company benefitted from the Microsoft partner ecosystem by taking advantage of NextDocs’ expertise in extending SharePoint technologies to meet its needs. The end result combined health portal capabilities with compliant document management to deliver an innovative solution that will speed time-to-market, improve productivity, reduce costs and risk, and drive a competitive advantage.

“In a networked, open source environment, the Clinical Trial Portal leverages the capabilities for integrated technologies, improves the productivity, speed, and quality of our trials, and liberates the investigators to focus on the care of the patients,” says Ji Zhang, Vice President, Head of Clinical Sciences and Operations Worldwide, sanofi.



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*Marie Sebille, Vice-President of Trial Operations,
sanofi*

Increased Insight Improves Trial Management

Instead of waiting until the end of a trial to ensure that all required, signed documentation is included in the trial master file, CTMs will be able to monitor which documents are added and when, taking steps along the way to submit the proper documentation to applicable regulatory agencies on time and to ensure that nothing is missing before going to the next step.

“With real-time document submission to the Clinical Trial Portal, trial managers can measure the performance of their teams to see if they are providing the right information,” says Cardinal. “And with aggregate trial data available, sanofi executives will gain a new level of insight into global operations.”

Seamless Collaboration Drives Productivity

The Clinical Trial Portal provides easy access to one platform so that all internal and external stakeholders will be able to collaborate and communicate efficiently on drug trials no matter where they are in the world. The solution not only delivers streamlined information sharing for clinical trial data, but also facilitates access to data from back-end clinical management and user permission applications.

If one team member adds a document, or updates a file, everyone else on the team will be instantly aware of the change and can work with the most recent draft. With everything located in one easily accessed location, sanofi estimates that document versions will be reduced by 30 percent.

“Instead of phoning and emailing clinical trial team members, our stakeholders will be able to work together more efficiently, responding to issues and delivering results more quickly,” says Cardinal. “When an investigator connects to the portal, he or she will see all the documents in the electronic Trial Master File and all contact information for his or her colleagues throughout the trial. Easy communication and collaboration builds teamwork and improves productivity all around.”

Digital Collaboration Reduces Costs

After sanofi rolls out the Clinical Trial Portal globally, the company will be saving a significant amount of money on long-distance phone bills and fax, courier, and paper costs. “It’s easy to imagine the savings in labor costs if you think about the time and effort required to manage 25,000 documents, and that’s just for one trial,” says Cardinal. “Even if we take into account the cost of maintaining the new system, we still expect to experience a positive return on investment within the first 2 years.”

As an example, for a single study the average trial master file contains up to 25,000 documents. Conducting 100 trials per year requires the creation, review/approval, and management of up to 2,500,000 documents per year. “If we consider that for each document lifecycle we could save only 2 minutes—a very conservative example—in searching, processing, and posting documents, it adds up to 5,000,000 minutes, or approximately 10,000 person-days of time savings per year,” says Cardinal.



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Faster Time-to-Market Improves Public Health

The Clinical Portal Solution provides a communication forum for users to share their views about a clinical trial in real time. It used to take several weeks to obtain signed contracts before launching a trial, but now this step will be accomplished in minutes, thanks to the digital signature function in the Clinical Trial Portal. And CTMs and quality assurance staff will no longer be spending days sorting through the TMF to make sure it contains all of the documents required by regulatory agencies: this task will be accomplished at regular intervals as documents are uploaded during the course of a trial, saving a significant amount of time.

“The Clinical Trial Portal will simplify the day-to-day activities of thousands of people that work in our clinical trials,” says Marie Sebillé, Vice President of Trial Operations at sanofi. “This will help us gain time during the startup and completion of a trial, which is one of our major challenges.”

“We expect the Clinical Trial Portal to help us bring drugs to market faster,” adds Cardinal. “That’s because everyone will be working in a secure, compliant environment where it’s easy to create, store, and find the documents they need, when they need them. “

Regulatory Compliance Features Reduced Risk

The Clinical Portal Solution will make it easier for sanofi to satisfy regulatory compliance requirements by providing audit trails, electronic signatures, strict access control, accurate copies, and proper storage of all document versions.

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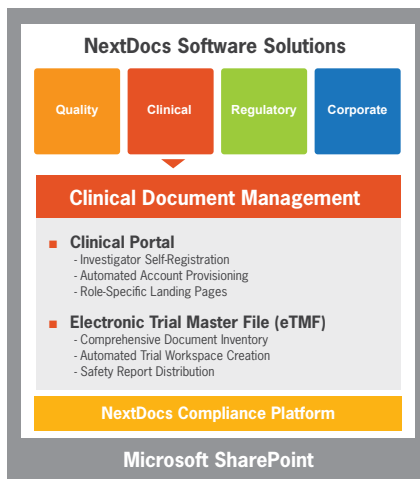
Innovation Builds Competitive Advantage

With its Clinical Trial Portal based on Microsoft technologies, sanofi has moved to the forefront of drug trial management innovation. When it rolls out the solution worldwide, sanofi expects positive feedback from clinical research associates and investigators working in the field. “We appreciate that for our investigators this is additional work to caring for their patients, so we want to make it as easy as possible to work for sanofi,” says Cardinal. “The Clinical Trial Portal will be an important tool that we can use to differentiate our company and keep our investigators happy, because they are essential to the process.”

Eventually, sanofi could use the Clinical Trial Portal to forge partnerships with other organizations, a key element of the company’s evolving business model. “This portal is truly welcomed by the clinical study units,” adds Mark Travers, Vice President, Clinical Study Units at sanofi. “We see it as a strategic vehicle where sanofi and our partners can exchange information in real time and as the interface of our organization with the clinical research community.”

“The Clinical Trial Portal built on Microsoft technologies enables efficient global collaboration that directly supports our ambition to be a sponsor of choice for clinical trials and to sit among the top clinical development performers,” concludes Jolly.





The NextDocs Clinical Collaboration Platform

NextDocs' collaborative solution for clinical trials, built on Microsoft SharePoint provides an integrated platform that streamlines processes, automates information exchange, and dramatically reduces administrative overhead associated with running clinical trials. Our clinical portal allows clinical teams to work together in an effective and efficient manner by keeping trial personnel connected, informed and on task – providing access to everyone at any time, from anywhere. NextDocs Clinical Document Management solution is based on the NextDocs compliance platform, which includes a comprehensive set of features that address all ICH, FDA, EMEA, and MHLW regulatory requirements.

Key Features and Benefits:

- » Collaborative platform for managing all clinical trial documentation
- » Workflow-driven processes ensure consistency and increase efficiency
- » Advanced metadata dictionaries manage trial site and personnel information
- » Data-driven creation of key site-level documents such as the FDA 1572
- » Electronic alerts and notifications communicate key information to trial personnel
- » Real-time visibility into each trial site file to assess completeness and compliance
- » Automated distribution of critical product safety information saves time and money while meeting regulatory obligations
- » Comprehensive eTMF document inventory that is based on the DIA Reference Model



NextDocs Corporation

500 N. Gulph Road, Suite 240, King of Prussia, PA 19406
Tel: 610.265.9474 Fax: 610.265.9478

NextDocs is the global leader in providing Microsoft SharePoint-based document and quality management solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs. NextDocs customers include Pharmaceutical companies, Bio-Techs, Medical Device companies and CROs.

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