



Merck Optimizes a Reporting System for Clinical Trials

Overview

Country: United States
Industry: Pharmaceutical

Customer Profile

Merck & Co., Inc. is a global, research-driven pharmaceutical company with fiscal year 2002 sales of more than U.S.\$51 billion. Based in Whitehouse Station, New Jersey, Merck discovers, develops, manufactures, and markets a broad range of innovative products to improve human and animal health, directly and through joint ventures.

Business Situation

Merck wanted to optimize business processes, enhance workflows, and integrate systems more closely through the use of the latest XML-based technologies. Merck identified a pilot opportunity in the clinical development division, which runs late stage clinical trials.

Solution

Merck and Microsoft Consulting Services have developed a pilot application using Microsoft® Office InfoPath™ 2003 and a set of Web services running on Microsoft Windows Server™ 2003 to replace a paper-based system for reporting on patients participating in clinical trials.

Benefits

- Prepopulation of data fields reduces user input and time to complete form
- Field-level validation reduces user error and improves information quality and accuracy
- Capture and transmission of report data as XML code make it easy to use and reuse information among many different systems

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Jim Karkanias, Executive Director of Operations, Clinical Development Program, Merck & Co., Inc.

Technologists at Merck & Co. Inc. have developed a pilot solution with Microsoft Office InfoPath 2003 to optimize the creation, transmission, and collection of information associated with late stage clinical trials. InfoPath is helping expedite the creation and completion of these reports and helping improve the quality of data captured in the critical databases—both of which improve Merck's ability to compile and analyze critical data and its ability to increase operational efficiencies. As Merck technologists put the information gathering program's use of XML, Web services, business rules, and powerful validation tools to the test, they are also determining how other processes at Merck can be optimized by an InfoPath-based solution.

Situation

Late stage clinical trials are a critical step in bringing new pharmaceutical products to market. They must prove the experimental product safe and effective. But what happens when a participant in a human clinical trial experiences unwanted effects? Whitehouse Station, New Jersey-based pharmaceutical giant Merck & Co., Inc. requires that field investigators notify the trial sponsor within 24 hours of learning of a problem. Additionally, the Merck clinical monitor must file a formal report within 48 hours (2 working days) with the department at Merck that manages this data.

For years, Merck met these requirements using a system that relied on telephone calls from investigators, followed up by reports faxed in from the field. When the field report arrived, Merck personnel rekeyed the information from the report form into a Microsoft® Word document, which they would then e-mail to the appropriate department, where personnel would enter the information into the official Merck database.

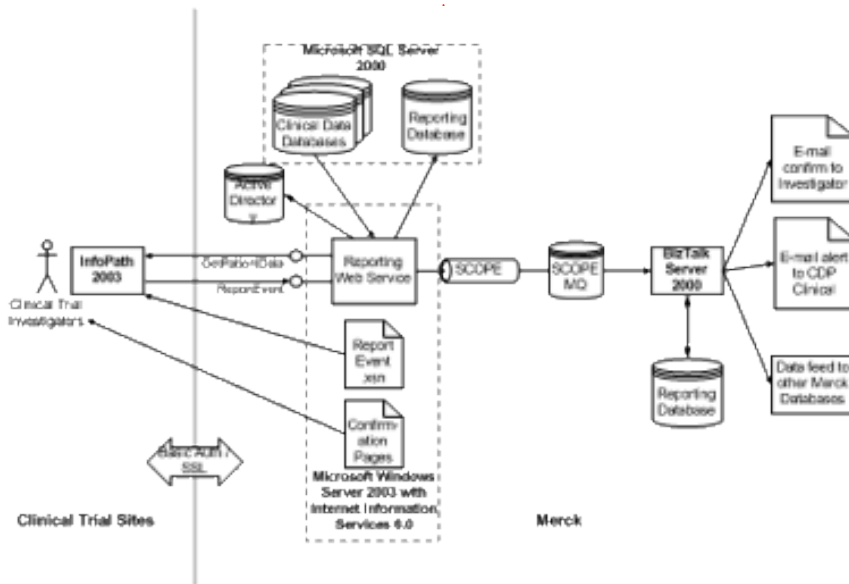
Officials in Merck's technology management group, the organization that provides IT and infrastructure support for the Clinical Development Program, recognized that this approach was time and labor intensive, as well as subject to communication and transcription errors. If the group could create an electronic workflow and introduce a measure of automation into the process, they reasoned, they might be able to support the process more efficiently and effectively. An electronic process could accelerate the movement of data, ensuring compliance with Merck's 48-hour reporting requirement. Moreover, by capturing information once up front and avoiding the confusion that sometimes arose from poor-quality faxes and rekeying errors, the quality of the information retained in the database would likely be higher than ever.

But how best to create an electronic version of this reporting system? For the technology management group, the answer became clear as soon as team members heard about Microsoft Office InfoPath™ 2003 information gathering program, a new tool in Microsoft Office Professional Enterprise Edition 2003 that makes it easy to gather and communicate information flexibly and efficiently with rich, dynamic, XML-based forms.

Solution

Merck worked with Microsoft Consulting Services to develop an electronic reporting system using InfoPath 2003 forms. The system makes InfoPath-based forms available to investigators participating in late stage clinical trials. If an investigator needs to report unwanted reactions, the investigator calls up the InfoPath form on a local desktop, laptop, or Tablet PC. He or she identifies the participant and then clicks a form button that prompts a Web method to retrieve relevant patient information from a Microsoft SQL Server™ 2000 database and populate key fields in the InfoPath form with information about the trial participant and the trial itself. The investigator then fills in the remaining InfoPath fields with pertinent information.

Upon form completion, the investigator clicks the Send button, and InfoPath submits the form as an XML-based message to the reporting Web service, running on the Microsoft Windows Server™ 2003 operating system with Internet Information Services (IIS) version 6.0. The Web service then passes the XML message into a message queuing system at Merck (called SCOPE, which is based on Microsoft Message Queuing version 3.0), which in turn passes the message to a workflow system running Microsoft BizTalk® Server 2002. The BizTalk-based system saves a copy of the report in a central reporting database and sends a



Merck's new reporting system uses Microsoft Office InfoPath 2003, Windows Server 2003 with IIS 6.0, SQL Server 2000, and BizTalk Server 2002 to report adverse effects with greater speed and data integrity.

message to the investigator confirming receipt of the report; it also sends an alert to a medical coordinator who reviews the report in the reporting database. If the coordinator has any questions, he or she can contact the investigator using e-mail; if not, the coordinator can approve the report, which initiates another message to BizTalk Server. BizTalk Server then can release the report for inclusion in the official Merck database.

"We are focusing on the InfoPath component of Microsoft Office Professional Edition 2003 because we're trying to improve the efficiency with which we record events in our clinical trials," says Hong Chong, Applications Development Manager for the Technology Management Group at Merck. "InfoPath appears to be a good blend of technologies to enable us to do that."

Benefits

Merck believes that InfoPath will help it manage its reporting systems more efficiently and effectively than before. Even more exciting to Merck executives are the implications of the InfoPath pilot on other

workflows and processes within the company. What Merck is learning from the pilot may ultimately make it easier to move application development closer to the business units that need information, may streamline and automate data collection and dissemination, and may reduce costs and improve operating efficiencies at many levels throughout the organization.

Optimized Business Processes

A streamlined reporting system built on InfoPath can optimize the process of reporting an unwanted reaction at several levels. Instead of requiring trial physicians or investigators to fill out a paper-based form with 80 or more fields, InfoPath enables the same individual to work with a computer-based form that can populate many data fields automatically through a database lookup. This immediately reduces the amount of time it takes an investigator to complete a form and ensures that the data is clear and correct.

The investigator then fills in the appropriate fields with a detailed description. Merck's pilot implementation of InfoPath provides field-level validation, which helps eliminate data entry errors at the source, thereby reducing the need for post-submission contact with the investigator for clarification. Moreover, because investigators now have access to Microsoft Office Outlook® 2003 messaging and collaboration software as part of their Office 2003 Edition configuration, any post-submission clarification can happen through e-mail, rather than a telephone call. This further expedites the ultimate submission of the report to the Merck database.

"Anywhere we can save time within Merck's 48-hour reporting window is a tremendous benefit for us," says Chong. "Doing things electronically with InfoPath helps to eliminate some lag time. Eliminating the fax, for

Patient Demographics

First Name Or Initials:

Last Name:

Allocation Number:

Baseline Number:

Age (in years):

Sex: Male Female Unspecified

Weight:

Weight Units: Lbs. Kgs.

Pregnant:

Weeks Gestation:

Primary Merck Therapies

Therapy	Formulation	Route	Indication	Strength	Frequency	Total Daily Dose

Suspect Secondary Therapies

Therapy	Formulation	Route	Indication	Strength	Frequency	Total Daily Dose

Microsoft Office InfoPath 2003 enables field investigators to enter information quickly and easily, using forms that are already familiar.

example, can speed things along because with the fax there's a lot of room for error—if nobody checks the fax machine, or if the fax gets lost. We also eliminate the issue of rekeying information from the fax into another system within Merck."

Ease of Adoption

Choing and other members of Merck's Technology Management Group appreciate the flexibility of InfoPath to design the data collection interface, as well as its instant familiarity as a member of the Microsoft Office System. This ease of use is expected to make for easy adoption in the field.

"Everybody is used to dealing with paper and forms," says Jim King, Group Manager of the Technology Management Group. "InfoPath lets business users set up forms in the way that they're already used to doing it. The major difference to the investigator or physician is that they can now prepopulate

some of the form with information from the database."

"These users are familiar with Microsoft Office and how to interact with those products," King says. "If we can build a system around an interface with which they are already comfortable, it's going to be easier for them to participate in our trials."

Increased Operational Efficiencies

The new solution is expected to deliver another benefit to both the users at the trials and Merck: increased operational efficiencies. Physicians and investigators in the field can spend less of their critical time filling out forms. Also, that familiarity reduces training time for both participants and Merck.

More efficiencies may be gained if Merck's pilot shows that the clarity and accuracy decreases the number of post-submission contacts with the investigators.

Linking of People, Processes and Business

While the reporting system project is still in its pilot phase, the outcome of the pilot may affect far more than the manner in which some clinical data is reported at Merck. For Choing, King, and many others at Merck, the pilot also is an exploration of key new technologies that may be able to play an important role in many other areas within the company.

According to Choing, the ability of InfoPath to manipulate XML-based data and to interact with Web services makes it a powerful tool for interacting with not only Merck's extensive installation of Windows®-based systems but also its extensive legacy system infrastructure. It could be used to engage many different kinds of systems and facilitate the flow of information across many different business processes. The ease with which individuals can create InfoPath forms holds the potential to create dramatic

improvements in the way applications are developed at Merck.

"The capabilities that InfoPath brings to our organization are revolutionary," says Jim Karkanias, Merck Executive Director of Operations. "This application enables us to push tasks into the hands of the process owners rather than the technologists, which breaks the traditional time-consuming cycle of application development and approval"

In addition, couple the easy-to-build forms with field-level validation, and the result is an easy-to-use form that proactively reduces data entry errors, therefore increasing the likelihood that business users will want to adopt the form. "When you take that," says King, "and factor in automation and the fact that you can build a business rule infrastructure that can clean the data coming in so that your data starts to become cleaner across the board, then you begin to see ways to use automated processes in situations that were previously quite unlikely.

"There's a potential here," King continues, "to drive benefits all the way across the board, well beyond the pilot application. It might be possible to use InfoPath for financial requests, for report generation, for managing report requests using internal executive information portals—things like that. We've talked about many different kinds of scenarios. As our Web service and business rule infrastructures mature and as we standardize implementation of InfoPath forms, we could conceivably push form generation out to the businesses and make it almost a self-service operation."

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