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Product

Industry

Country/Region

Organization Name

Partner Name

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RSS

Case Study

Merck & Co., Inc.

Merck Determines Microsoft Windows Rights Management Services Improves Confidentiality of Clinical Trial Information

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Information confidentiality is of critical importance to pharmaceutical firms. During clinical trials, Merck & Co., Inc., a leading world-wide pharmaceutical products and services company, exchanges sensitive information with participating partner physicians. This poses a security challenge because Merck must make every effort to protect the confidentiality of the information during transmission as well as after it is in the physicians' possession.

Microsoft Windows Rights Management Services (RMS) for Microsoft Windows Server 2003 offers the perfect solution to meet Merck's challenge. Without RMS, Merck delivers only hardcopy documents via express couriers to physicians. Even then, it is difficult for Merck to ensure that the information remains confidential after it has been received by the physician. With RMS, documents continue to be protected even after delivery.

Situation

New medicines must undergo extensive clinical trials before receiving regulatory approval and being introduced to consumers. These trials require the exchange of confidential contracts, sensitive data, and other regulated information between pharmaceutical companies and physicians before, during, and after the trial. Document confidentiality is mandated by government regulations and must be kept out of the hands of competitors. Keeping the content of the documents private is essential, no matter what the cost.

Today, confidential communications between Merck and the physicians are carried out by using hardcopies to reduce the chance of accidental distribution. To provide accountability for the receipt of sensitive documents, Merck relies on overnight delivery via express couriers.



“ Windows Rights Management Services helps to enforce existing corporate security policies governing intellectual contents.

Hong L. Choing
Manager Applications
Development, CDR



The current process requires a minimum of 2 days of valuable clinical trial time for documents and agreements to be signed and returned. The delay is compounded when even the smallest changes are needed, raising overall drug development costs.

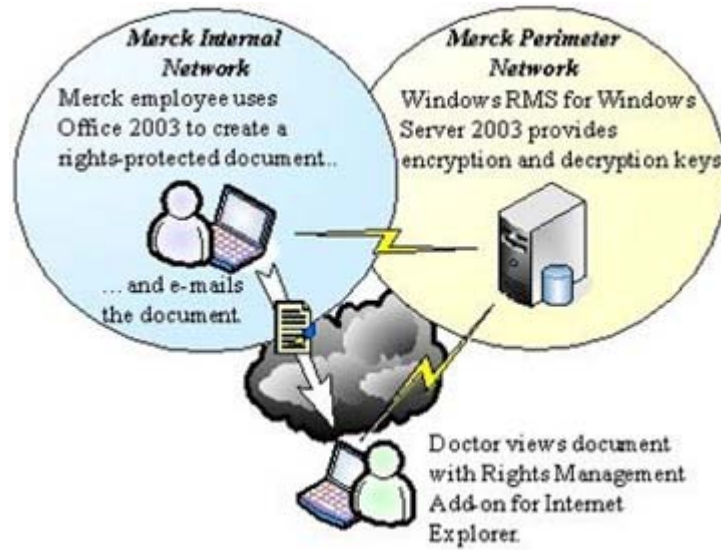
Information confidentiality remains critical even after the clinical trial has been completed, as Merck is required to archive

Technology
Management
Merck & Co., Inc.

results for several years. If the files are retrieved for reference, access to the information is limited only to authorized employees.

Solution

Merck determined that Microsoft® Windows® Rights Management Services had the potential to improve the confidentiality of its clinical trial information and communications, grant more control over document lifecycles, and improve the efficiency of clinical trials.





To validate this, the Clinical Development Program (CDP) Technology Management Group established a separate Active Directory® directory service forest to support the Merck RMS users representing both Merck employees and partnering physicians. Creating a separate environment eliminated the possibility of affecting the existing environment. CDP installed Microsoft Windows Server™ 2003 operating system and RMS on a server and configured RMS to use an existing Microsoft SQL Server™ to store configuration and licensing information. All servers are protected by a firewall running Microsoft Internet Security and Acceleration Server.

Using an RMS-enabled application, such as Microsoft Office Word 2003 Professional, Merck employees create documents as they normally do. After clicking a button on the toolbar and providing the authorized recipients' names and rights, RMS encrypts the documents using AES-128 cryptography and creates a specific publishing license delineating the usage rights of the file. Merck employees can now distribute these rights-protected documents to the physicians by using any method, including email and ftp.

“ The ability to persist and change rights throughout the lifecycle of the document and into the archiving period is a big win.

Hong L. Choing
Manager Applications
Development
CDP Technology
Management
Merck & Co., Inc.

Upon receiving the file, physicians can view rights-protected documents in trusted RMS-enabled applications such as Word 2003 or Internet Explorer (IE) 6.0 with the Rights Management Add-on (RMA). RMS-enabled applications enforce the usage rights defined in the usage policy template while decrypting and rendering the content. Physicians with IE can install the RMA to view the rights-protected information.

When an authorized physician receives a rights-protected document, the

RMS-enabled application sends a request to Merck's RMS server for a use license that is required to decrypt the file. When the RMS server receives the request, it validates the physician's credentials and the usage rights granted by the document owner as prescribed by the publishing license. RMS provides the RMS-enabled application with a user-specific and machine-specific use license that enables the RMS-enabled application to decrypt the document. The application will then enforce the permissions assigned by the document author. These communications use Secure Sockets Layer (SSL)-encrypted Web services requests. Because all communication with the RMS server occur using a single, encrypted protocol, only a single port (e.g., TCP port 443) needs to be opened in the firewall.

Solution Overview

<http://www.merck.com/>

Customer Size: 2500 employees

Organization Profile

Merck & Co., Inc. develops, manufactures, and markets innovative products to improve human and animal health. Its Clinical Development Program evaluates leading-edge technologies for opportunities to improve the development process' efficiency and information security.

Business Situation

Merck ships confidential documents regarding its late-stage clinical drug trials to physicians around the country during the trials' course. Merck relies on the physicians to protect the documents' confidentiality after delivery.

Solution

Merck evaluated Microsoft® Windows® Rights Management Services combined with the Microsoft Office System to determine if both the confidentiality of sensitive communications and information and the efficiency of clinical trials improved.

Benefits

- Improved information confidentiality
- Information protection throughout the lifecycle
- Increased clinical trial efficiency

Software and Services

- Microsoft Windows Rights Management Services
- Microsoft Windows Server 2003 Datacenter Edition
- Microsoft Windows Server 2003 Enterprise Edition
- Microsoft Windows Server 2003 Standard Edition

Healthcare and Healthcare
Insurance

Country/Region

United States

Merck also created custom use policy templates for each of the document types exchanged during the clinical trial

process. For example, early in the process Merck must send an agreement to each physician detailing the physician's participation in the clinical trial. While rights could be applied individually to each document, using a policy template such as "Physician Agreement" increases both efficiency and consistency. The policy template not only reduces the time required to define the permissions, but it also helps to maintain that rights are assigned uniformly.

Benefits

Replacing paper communications with the transmission of rights-protected digital files improves confidentiality and efficiency. RMS uses technology to grant access only to authorized recipients, which reduces the risk of information leakage. The use policies stay with the document, providing persistent protection throughout the document's lifecycle. Additionally, rights-protected documents have features not available with paper communications, such as restricting users from opening a document after a certain date. Using RMS also enabled Merck to provide an easy way for users to apply uniform security policies via templates, reducing the risk of policy misinterpretation among users. Finally, the efficiency of a clinical trial is improved by decreasing the time spent waiting on paper deliveries.



“ The Windows Rights Management Services (RMS) infrastructure built on Windows Server 2003 provides Merck a means to control the distribution of our mission critical information with persistent usage policies. Furthermore, it also provides an infrastructure to expire Microsoft Office System documents while managing distribution, thereby ensuring

Improved Confidentiality

The existing method of authorizing internal users to access documents is file-level security and a Microsoft SharePoint™ Portal Server. This allows only authorized users on a given access control list the right to retrieve a document. However, it does not provide protection for the document after an authorized user has retrieved it. Specifically, once the file is removed from the protected share, the file is in the clear and can be forwarded to another user who should not have access or posted on the Internet for public viewing.

Human error presents a significant risk. While RMS does not prevent all human errors, all rights-protected documents are encrypted, and rights-protected documents can be decrypted only when RMS validates the credentials of an authorized user and issues a use license. Therefore, even if unauthorized users receive a rights-protected document, the document will be encrypted, preventing it from being viewed.

Protection Throughout the Document Lifecycle

The confidentiality requirements of clinical trial documentation can change over time. RMS use policy templates allow Merck to centrally manage its confidentiality policies for clinical trial documentation. If a requirement changes, Merck would need to change only the centrally managed clinical trial template, rather than re-train the end users in the system.

RMS-enabled applications can enforce Merck's complex business rules, which require use rights to documents to change over the document's lifetime. RMS can enable a use license to expire on a

that we maintain information relevance as well as appropriate access.

Jim King
Group Manager,
Technology
Management CDP
Technology
Management
Merck & Co., Inc.

”

given date. For Merck's purposes, this expiration should happen after the work on the drug trial has been completed. If employees attempt to view a file after the expiration date, they will not be able to open the document. Naturally, the author can extend the right to view the document's contents.

RMS provides the option to designate an individual or group of individuals to have full control over all rights-protected information. For example, if a legal team member needs to review a rights-protected document relating to a particular clinical trial and the author no longer works for the company, a designated individual with full control will be able to grant the legal team member rights to that document. The administrators responsible for managing the RMS environment and the administrators responsible for retrieving the documents from archive do not have rights to view the document, unless specifically granted by the document owner.



Improved Clinical Trials Efficiencies

Without RMS, Merck makes a costly trade-off to ensure confidentiality—clinical trials are lengthened by several days while documents are being delivered. Merck has been unable to collaborate digitally on clinical trials because of the potential risk of information leaking. The common scenario of accidentally forwarding an email poses too great a risk for clinical trial related information.

Consider the following scenario: Merck sends a document to the physician, and the physician revises the document and returns it to Merck. Relying on paper communications and overnight deliveries, this process would take a minimum of 2 days: 1 day for Merck to send the original document to the physician and at least 1 day for the physician to respond and return the revised document. Thanks to RMS, the entire process can be completed much more efficiently while still meeting Merck's confidentiality requirements. Merck can transfer the original agreement to the physician and obtain the revised agreement almost instantly by emailing the rights-protected document. RMS protection stays with the document even if the message is forwarded or intercepted.

RMS improves information confidentiality, provides protection of the information throughout its lifecycle, and increases the overall efficiency of clinical trials.

Microsoft Windows Rights Management Services (RMS) for Windows Server 2003 is information protection technology that works with RMS-enabled applications to help safeguard digital information from unauthorized use—both online and offline, inside and outside of the firewall. RMS augments an organization's security strategy by providing protection of information through persistent usage policies, which remain with the information, no matter where it goes.

For more information about RMS, go to:

<http://www.microsoft.com/rms>

Microsoft Windows Server System is a comprehensive, integrated, and interoperable server infrastructure that helps reduce the complexity and costs of building, deploying, connecting, and operating agile business solutions. Windows Server System helps customers create new value for their business through the strategic use of their IT assets. With the Windows Server™ operating system as its foundation, Windows Server System delivers dependable infrastructure for data management and analysis; enterprise integration; customer, partner, and employee portals; business process automation; communications and collaboration; and core IT operations including security, deployment, and systems management.

For more information about Windows Server System, go to:

<http://www.microsoft.com/windowsserversystem>

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For more information about Merck Co., Inc. products and services, call (908) 423-1000 or visit the Web site at:

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