Merck KGaA

Merck KGaA Deutschland deploys the Adobe® Intelligent Document Platform to optimize clinical trials for new pharmaceuticals

Overview

The Merck group, based in Darmstadt, Germany, comprises 168 firms in the pharmaceutical and chemical industry in 56 countries. With over 28,000 employees, it is the oldest pharmaceutical and chemical company in the world, renowned for its traditional and progressive approach to science. In 2003, Merck revenues amounted to 5.0 billion euros, of which roughly 3.3 billion euros were derived from the pharmaceuticals business. Pharmaceutical operations include proprietary or patent-protected ethicals, generics, and self-medication products.

Challenges

Developing a new drug is a tedious and cost-intensive process. Before a product can be brought to market, its ingredients have to be scrutinized in a clinical trial. For this purpose, clinical researchers perform a series of tests on up to 10,000 patients over several years. Government regulations require that these clinical tests are documented in written, comprehensible, and auditable format. Allocating drugs to clinical investigators is particularly time-consuming and involves many forms. Therefore, Merck needed a system that accelerates the process using digital forms, enables the transfer of data from existing systems, and helps reduce costs and errors.

A medication request submitted to Merck by an outside clinical investigator can trigger up to four processes in addition to the actual order. These processes include the release, the shipping notice, the delivery, and the confirmation of receipt. All forms have to be submitted and signed, and the data from the forms has to be transferred reliably into a tracking table. Naturally, this workflow should include not only European but also Asian and American employees. Many of these processes are time-critical and require automatic email notification. "We needed a digital, intranet-based, workflow to coordinate and accelerate inter-departmental forms submission," explains Ines Höhne, international clinical IT coordinator at Merck.

Clinical trials are executed using various software systems, including a back-end trial management system connected to an Oracle database. Forms and workflows have to be able to transfer information to the system and process extracted data. Because the trial management system is deployed on a global scale, it has to be operated using a Web browser to ensure direct intranet access to forms for Merck employees and VPN access for external partners.

Solution

As early as 1998, Merck started implementing digital, HTML-based forms. Unfortunately, the company did not initially have a comprehensive document platform. Adobe server software provided all the solutions required to create and manage flexible form layouts and intelligent documents. The Adobe solutions also provided for flexible workflows and, above all, integration with back office systems and the intranet. In collaboration with Adobe's partner company, neeb & partner GmbH, Merck extended this platform using eForms to build its "Merkur" system and connected it to its trial management system and existing databases.

MERCK KGAA

www.merck.de

MERCK

INDUSTRY

Pharmaceuticals and chemicals

CHALLENGES

- Optimize processes with intelligent documents
- Implement a digital workflow
- Increase the value of existing enterprise systems

SOLUTION

- Electronic process management
- Digital workflows

  Merck KGaA is leveraging the Adobe Intelligent Document Platform for a flexible eForms system connected to its clinical trial management and existing database systems.

RESULTS

- Intelligent documents helped reduce forms processing time from five minutes to one minute
- Digital workflow helps ensure reliable document delivery, shortening time for processes by several days
- Tracking tables optimizes project control

IN PARTNERSHIP WITH

- neeb & partner GmbH, a software and consulting firm specializing in Enterprise Content Management (ECM) and Archival

  www.np-gmbh.com

Adobe

Merck clinical trial forms and documents are accessed by 300 internal and external users worldwide via the company intranet. The XML-based Adobe architecture enables the transparent integration of existing applications and documents and paves the way for the connection to SAP systems as well as the EMC Documentum platform.
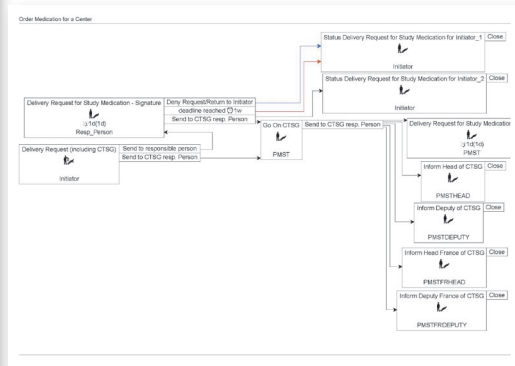
"By deploying the Adobe Intelligent Document Platform, we can conduct clinical trials far more efficiently than before."

Ines Höhne,
International clinical IT coordinator,
Merck KGaA

Merck has created more than 100 intelligent forms over the last 4 years which are accessed by 300 authorized internal and external users worldwide via the Merck intranet. The XML-based Adobe architecture enables the transparent integration of existing applications and documents and paves the way for the connection to SAP systems as well as the EMC Documentum platform.

"Using Adobe Designer, we can develop forms, integrate plausibility checks, or connect to a database quickly," says Alexander Tryba, managing partner at neeb & partner GmbH. The major challenge of global projects is usually the workflow organization. "With Adobe's workflow solutions, process design can easily be visualized and realized as a series of activities in a flowchart on a graphical interface."

Results

More efficient studies due to more efficient processes
Working with digital documents enables Merck to deploy standardized processes and achieve considerable cost savings, although the improvement of the internal processes is of even greater significance. Merck succeeded in reducing the amount of time required for form processing from five minutes to one minute by connecting the forms to its databases. Input errors are as good as non-existent thanks to the integrated plausibility checks. Even changes to the mandates set by the U.S. Food and Drug Administration (FDA) can easily be transmitted to the Merkur system in less than a day.

The ability to control the project status in tracking tables is one of Merck's major requirements. Using the Adobe interface, data can easily be exported into the corresponding Microsoft® Excel structure for further processing. As a result, even external employees without direct access to the system can use the data. The Merkur system has become indispensable. As Ines Höhne concludes, "By consistently deploying the Adobe Intelligent Document Platform, we have managed to implement a forms solution for the pharmaceutical business sector that enables us to conduct clinical trials far more efficiently than before."