KOFAX

SUCCESS STORY FOR PHARMACEUTICALS

Large Global Pharmaceutical Company

Required by law to keep all documents related to clinical trials ready for inspection, this global pharmaceuticals company used to spend an inordinate amount of time photocopying, scanning and classifying documents. With a mobile capture application from Kofax, the company has cut time taken to process documents from three months to 15 minutes, ensuring complete compliance with safety regulations.

Challenge

Committed to helping people heal their conditions, this global pharmaceuticals company dedicates a great amount of time, money and energy to research and development. The company runs 20-40 large-scale clinical trials a year to test new products, which provide scientists with insight into the efficacy of its medicines.

"Medical research is key to finding better, more effective treatments," said a company spokesperson. "To capture the information needed to improve medicines, develop new products and meet strict safety regulations, every stage of our clinical trials is documented to the nth degree—from patient consent forms and doctors' qualifications to the temperatures that products must be stored at. If we do not ensure complete compliance with the regulations set by national authorities, we would not be allowed to market new products. All pharmaceutical companies are therefore obliged by law to keep electronic 'trial master files' that must contain every single document related to each clinical trial."

Previously, the company relied on manual processes to collate data for the trial master files. On-site clinical research associates (CRAs), who act as the company's contact to clinical sites involved in the testing of products, would have to photocopy every document related to a clinical trial, then send the photocopies back to a local office. There, administrative staff would scan and upload the documents into a file sharing system and output them as PDFs, load each

This leading global pharmaceuticals company develops and manufactures medicines to treat serious health issues, helping people around the world to achieve a much higher quality of life.

Products in Use:

- Kofax Capture™
- Kofax Mobile Capture™
- Kofax Transformation™

Solution Area: Regulatory Compliance

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>
> **Spokesperson**, Global Pharmaceuticals Company

individual PDF into a document management system and then manually classify them. Documents had to be individually classified into one of 570 different types, each with their own indexing fields, before being passed into the document management system—a huge undertaking.

"Our existing process was difficult, time-consuming and highly inefficient," a company spokesperson recalled. "It was ludicrous that CRAs had to send paper copies of relevant documents to the local company office by courier in order for them to be scanned and processed. We knew that there had to be a better way to capture and handle this information."

> ***"We are inspection-ready in a much more controlled way than before, as the Kofax solution guarantees an extremely high quality of documentation."***
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Solution

Looking for a way to streamline the trial master file documentation process without compromising on compliance, the company turned to Kofax Enterprise Software for help.

"We wanted CRAs to be able to scan documents on-location at clinical trials and make that data available to the local team without the hassle of having to photocopy at the clinical sites, carry documents to the CRA's office and then send them to local company offices for scanning using couriers. A much better way had to be found," said a company spokesperson. "We were offered a fantastic solution that ticked all the boxes."

Mobile document capture became available for the company's CRAs in January 2016 following extensive quality assurance work, which ensured that the solution delivered the expected functionality and was fully compliant with all GxP validation standards.

"We worked closely with Kofax partner ScanSolutions to set up the solution and to configure the app to capture all the relevant documents from clinical sites," said a company spokesperson. "Now, rather than laboriously photocopying documents, CRAs can quickly and easily capture content using their mobile devices. The capture process typically takes about 30 seconds per page, meaning that it only takes a couple minutes to process a standard document—much faster than the two to three months this process took in the past.

"Thanks to the Kofax solution's advanced OCR technology, we have been able to dramatically reduce the number of data fields that the backend processing team need to enter by hand. In fact, CRAs now perform very little data entry; they simply have to select a document type in the application interface and fill out just four data fields, such as the document date and site personnel names. The OCR engine then automatically retrieves the remaining 25 indexing fields required by the document management system. Automating the document classification process has accelerated processing times and enabled staff to focus on more value-added tasks."

Results

Today, around 60 CRAs use Kofax Mobile Capture™ and feedback has been overwhelmingly positive.

"We are onboarding more and more users every week as demand for the app grows," said a spokesperson. "CRAs are delighted with the solution, as they no longer have to photocopy and carry around lots of paper documents, fill out courier forms and make sure that everything is shipped correctly. Being able to capture documents using their mobile phones or iPads is much easier.

"What's more, users are amazed at how fast the entire process now is. Because captured documents are automatically classified, they can be processed and put on file in the document management system in a matter of minutes. Previously, it would take more than three months before a document was actually filed in the document management system. Today, the same process takes as little as 15 minutes, provided that the documents do not require manual quality control checks.

> ***"The solution has significantly accelerated our document collection procedure, making closing trial master files a much simpler, smoother process—while still ensuring compliance with safety regulations."***
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"There was a learning curve when it came to making the CRAs aware that they are responsible for the quality of the documents that they supply and the properties entered. It can be difficult to manage a mobile device to ensure good quality document capture, so it is important to be patient with users as they get to grips with the solution. We currently enforce random quality checks of incoming documents by the backend validation team. This helps us to ensure professional integrity and maintain high standards around data quality and accuracy."

With the solution, the company can also be sure to maintain compliance with stringent regulations.

"We are inspection-ready in a much more controlled way than before, as the solution guarantees an extremely high quality of documentation," explained a spokesperson. "We are regularly inspected by national authorities. During inspections, we want to present our trial master file as complete as possible—nothing should be missing, meaning that we can have anywhere from 10,000 to 100,000 documents on file for a single clinical trial. The Mobile Capture app gets us much closer to being compliant than we ever could have expected to be without it.

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