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CASE STUDY

PHARMACEUTICAL INDUSTRY

Introgen Therapeutics, Inc.

Generating process efficiencies and document access improvements in clinical research

CHALLENGE

- All clinical trial data related to new drug development must be captured and maintained according U.S. government regulations.
- High volume of case reports and lengthy scanning process generated a scanning backlog of up to one month.
- Field-based clinical research associates had difficulty accessing electronic files, causing them to wait until they returned to the office to view documents.

STRATEGY

- Microsoft SharePoint repository to securely store and share clinical trial data.
- Centralized scanning operation uses eCopy to capture clinical data and feed it directly into the Microsoft SharePoint repository from the MFP.

RESULTS

- Document processing time cut in half while scanning the same workload level, saving one full time equivalent staffer.
- Minimal learning curve drove fast user adoption.
- Document scanning cycle time reduced from one month to seven days or less, providing researchers with quicker access to data.
- SharePoint integration enabled case reports to be quickly and easily accessible through a Web browser, improving document access.

- Document handling efficiencies enabled Introgen to support a thirdparty pharmaceutical firm with Introgen's clinical research associates, creating a new revenue stream.

ABOUT INTROGEN THERAPEUTICS, INC.

Introgen Therapeutics is a biopharmaceutical company focused on the discovery, development and commercialization of targeted molecular therapies for the treatment of a wide range of cancer and other diseases. It is developing products that are designed to increase production of normal cancer-fighting proteins that act to overpower cancerous cells, stimulate immune activity, or directly kill cancer cells. Introgen also controls a broad intellectual property portfolio that includes more than 400 patent applications and issued patents.

"We implemented eCopy with a learning curve that was basically zero. eCopy's touchscreen interface is very intuitive, making it fast and easy for us to add documents to our Microsoft SharePoint repository."

— Sean McNelis
Associate Vice President, Operations
Introgen Therapeutics, Inc.

INTROGEN IS CURRENTLY IN CLINICAL STUDY PHASE WITH SEVERAL PRODUCTS...

Trial data is collected by Introgen's clinical research associates at treating physician sites throughout the world. Maintaining case report forms is mandatory under U.S. Federal Drug Administration (FDA) regulations, tracking which patients received what treatments by which physicians, along with maintaining background on all treating physicians and following patients' status.

This process generates extensive paperwork, commonly exceeding 300 new documents each week (ranging in size from one to 50 pages each). For quality assurance purposes, the FDA requires all these documents be scanned at a central location.

“eCopy has cut four steps out of our previous document scanning process. This means there is a decreased likelihood of errors, which can prove very costly in our highly regulated environment..”

— **Sean McNelis**
Associate Vice President, Operations
Introgen Therapeutics, Inc.

Previously, the Introgen Document Control Center utilized a less efficient method to process these documents. A standalone document scanner was used to capture clinical information; the scanned document was then appended to the associated case report, using Adobe Acrobat, and bookmarked. Once scanned, documents were stored using their computer network’s Microsoft Office folder system.

This process produced lag times of up to one month before new reports could be added to the system and made it difficult to search and retrieve documents later because they were only accessible by browsing by file name. For example, research associates -- who often need to review stored information when out in the field -- were frustrated by this cumbersome access, leading them to wait until they returned to the office to access documents.

INTROGEN TOTALLY REVAMPED ITS DOCUMENT SCANNING PROCESS...

by moving to an eCopy ScanStation connected to a Toshiba multifunction peripheral (MFP). Critical to process improvements was deployment of eCopy Connector for Microsoft SharePoint software. The Connector software integrates MFP- based scanning directly to Microsoft SharePoint. Now, as paper documents are captured they can be indexed and stored to the correct location in the SharePoint repository, making it as easy to store a scanned image as it is to store electronic documents, such as Microsoft Word or Excel files from the desktop.

THE PRIMARY BENEFIT TO INTROGEN WAS COMPLIANCE...

When a user goes to the Toshiba MFP, the eCopy touchscreen presents one-touch options to scan directly to three SharePoint sites (one for each drug type). Using the touchscreen, Introgen can quickly index the documents by drug name, treating physician, patient name, date entered and other factors. By ensuring that documents are maintained in the correct location in the repository, this process helps Introgen comply with CFR 21 Code of Federal Regulation Part 11, which is the FDA regulation that establishes requirements for the acceptance of electronic records. Additionally, leveraging SharePoint document security capabilities safeguards that documents are accessed only by authorized individuals.

All documents are stored in Adobe Portable Document Format (PDF) and are accessible via the Web through SharePoint, making it easy for Introgen research associates to retrieve clinical information later both in the office and when out in the field. Field researchers can access SharePoint using a Web browser to retrieve any clinical information they need to review how clinical trials are going, or update files with additional notes. By scanning documents directly to specified locations within the SharePoint repository, information is only accessible by individuals that have authorization to access that SharePoint site.

The efficiencies Introgen has built into its document processing has freed up field research resources and enabled the company to contract its data collection and scanning service to another drug company in clinical trials, treating a new revenue stream for Introgen.

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