Alfresco Case Study

eResearch Technology streamlines compliant records management with Alfresco.

A global provider of health outcomes research services, eResearch Technology (ERT) supports biopharmaceutical sponsors, contract research organizations, medical device manufacturers and healthcare organizations around the globe achieve their drug development and healthcare objectives.

Headquartered in Philadelphia, and with additional offices in the US, UK, Japan and Germany, the company integrates its solutions within a rigorous scientific and regulatory framework to collect, analyze and deliver data critical to the approval, labeling and commercialization of pharmaceutical products and new medical treatments.

Challenge

One of the world's leading providers of high quality patient safety and efficacy endpoint data collection, every year ERT facilitates the collection, analysis and delivery of data from tens of thousands of sites worldwide for use in clinical development and healthcare scenarios.

Instrumental in leading the shift from conventional paper-based collection methods to streamlined electronic data collection in the 95 countries it serves, ERT wanted to digitize the creation, management and storage of all client agreements and related documentation, including project approvals and change requests. Operating in the highly regulated life sciences field, records need to be held for a minimum of 15 years following the closure of a clinical trial or observational study.

An enterprise content management system that was fully compliant with the FDA's 21 Part 11 guidance for electronic signatures and electronic records would enable ERT to move to paperless working, centrally managing and securely storing thousands of documents generated each year relating to its data collection projects around the globe. The ability to support the collaborative exchange of digitally signed documents between staff, business partners and clients, would eradicate the cost and complexity of coordinating the worldwide delivery of its services. This would make it easier to expedite client contracts and initiate new projects faster.

"Protecting key assets and compliance with all regulatory requirements was a priority. We needed an ECM solution that could support e-signature authentication, eradicating the risk, time delays and cost involved in printing and dispatching documentation beyond organizational boundaries," explains Kurt Palmer, Senior Director, Information Technology at ERT.

Solution

Having evaluated a number of potential solutions, including SharePoint and OpenText, Alfresco was selected as the ECM system that best met ERT's diverse requirements.

"Alfresco offered the greatest flexibility and extensibility of all the solutions we reviewed," confirms Kurt. "Alongside meeting the FDA's requirements on records management and security standards relating to the creation, classification, protection and record retrieval, it delivered integration with our CoSign digital signature solution." Implementation was undertaken by Alfresco's Platinum Partner, Zaizi, who developed

> Today we operate and collaborate as one, having eliminated the information disconnect that previously existed between our global sites when we operated islands of file servers. Now our people can access documents quickly and with confidence, taking advantage of unified workflows that streamline how they work.
>
> — Kurt Palmer, Senior Director, Information Technology

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specially customized workflows and engineered the CoSign integration with Alfresco, combining the two so that workflows for multiple, parallel and sequential signatures can be managed. Today Alfresco currently manages over 400,000 documents and the process of migrating thousands of legacy documents from Windows file servers continues apace.

"Thanks to Alfresco we've been able to eliminate the silos of data that previously existed across our global operations", explains Kurt. "Now, regardless of where they're located, our staff can instantly access the most current version of documents and instantly retrieve or route documents from our central repository at the press of a button."

Alfresco's deep integration with CoSign will streamline the approvals process for external sponsors, enabling ERT to maintain a complete electronic workflow within the organization while seamlessly connecting external stakeholders. Digital signatures can be applied and verified in one simple step, ensuring ERT can demonstrate client cognizance and approval of operational agreements and change orders.

Results

- A standardized platform for the collaborative exchange of digitally signed documents among staff, partners and customers
- Secure central repository for over 400,000 documents relating to clinical studies, with full traceability of record modifications, versions and all user actions
- Introduction of digital signature approvals and verification that meets stringent life sciences industry regulatory requirements, including FDA 21 CFR Part 11
- Fully electronic workflows have streamlined business processes, enhanced productivity and delivered faster decision-making and approvals while mitigating risk
- User controls and access rights for defined tasks and individual documents enforces secure records management, process compliance, and accountability to FDA standards
- Comprehensive audit trail meets stringent regulatory and reporting requirements.

Today Alfresco is generating significant efficiency and cost savings for ERT and its clients thanks to a fully automated project approvals and logistics process that is now fully automated and inherently secure and compliant.

"We've moved from printing and shipping out copious amounts of information on a daily basis," confirms Kurt. "We now have a secure document exchange and FDA compliant e-signature process in place that eliminates the delays, costs and low-level security associated with paper-based documentation," confirms Kurt. Centralized document management has generated additional benefits, enabling ERT to achieve a newfound organizational cohesion that is boosting the productivity of its globally dispersed teams.

The future-proofed flexibility and extensibility of Alfresco has also proved beneficial as ERT progresses on its journey to optimize operational dexterity. "We're committed to bringing together Microsoft Dynamics, Salesforce and Google Apps to achieve further efficiencies and Alfresco, with its peerless integrations, will act as the engine behind the scenes that brings everything together," concludes Kurt.

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