Zelta

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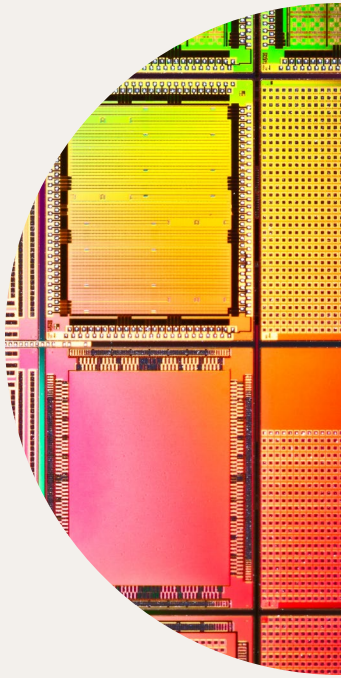
Getting to market faster

Find out how ProTrials is accelerating processes across the development life cycle



ProTrials conducts high-quality clinical trials for all study phases and across multiple therapeutic categories — including cardiovascular, central nervous system and infectious diseases; oncology; and ophthalmology. Its offerings range from standalone clinical support services to full-service, international clinical trial management, delivered with expertise and integrity and aligned to meet each customer's specific project requirements. Founded in San Jose, California, in 1996, the company operates in the US and Canada and also engages professionals in Europe and other countries.

Business challenge

To improve its data management services — and facilitate audits — ProTrials Research, Inc. sought to replace its existing electronic data capture (EDC) system and paper-based reporting processes.

Transformation

A contract research organization (CRO) focused on quality, ProTrials needed to more thoroughly document clinical studies for sponsors, regulatory authorities and other auditors. Now, with Merative's cloud-based, unified Zelta™ clinical trials platform, the CRO can quickly create accurate digital records of every action taken, including granting users access and updating study protocols.

Results

30 minutes to perform a minor study change to in-progress studies, complete with the customer's digital approval form.

Around-the-clock user activation and training with novel safeguards created using the Zelta platform's integrated workflows.

Improved the company's audit readiness and competitive advantage with newly digitized processes and documents.

“From the start, we saw that the Zelta platform operates on the leading edge. The difference was night and day.”

Justin Quilliam
Manager of Clinical Data Management
ProTrials Research, Inc.

A patchwork of clinical paperwork

ProTrials consistently tops the go-to list of many sponsors who need a high-quality CRO to help cost-effectively conduct their clinical trials. The US-based, midsize CRO helps pharmaceutical, biotechnology and medical device companies worldwide efficiently progress new drugs and devices from conception to regulatory approval with exceptional attention to detail. Founded more than 20 years ago, the company continues to grow its customer base while maintaining high rates of repeat business and employee retention.

It's up to the data management team at ProTrials to oversee data quality, integrity and security throughout the course of each clinical trial. During study build and launch phases, for example, the team must grant sponsors, patients and other stakeholders access to clinical data according to industry- and customer-specified protocols and also ProTrials' own standard operating procedures (SOPs). This process requires clinical investigators to submit an accurate, up-to-date electronic delegation of authority log, which lists the individuals permitted to access trial data and each person's authorized role, such as for data entry or drug dispensation. Before activating a user in the system, the ProTrials team must also verify that each individual is certified to perform the assigned duties.

In addition, as the study progresses, the team must be able to update study protocols as requested by customers and outlined in the study's case report form (CRF). For each update, the team must conduct user acceptance testing (UAT) and go live with the new version of the CRF. Similarly, the team must often make minor, customer-initiated study changes, such as modifications to user roles, and that do not require CRF updates.

Given the limitations of its EDC system, the data management team struggled to rapidly execute and record each action. The system had several separate, siloed workflows, each with its own login, and the team relied heavily on manual, paper-based processes and spreadsheets to document each step. The system also came with an expensive, rigid cost structure.

The disparate processes threatened the company's ability to track compliance with US Food and Drug Administration (FDA) regulations; Good Clinical Practice (GCP) and other guidelines developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); and its own SOPs. "In the regulatory environment, we need to have documentation to support actions taken in our electronic system, and it has to

be ready and on file for any auditors," explains Justin Quilliam, Manager of Clinical Data Management at ProTrials.

The team also could not readily show a systematic audit trail to prospective customers. "Their quality assurance inspectors want to investigate us at a deeper level than done in the bidding phase, with a heavy emphasis on understanding our internal SOPs, including our user activation processes and version controls on every document," says Quilliam.

To help ProTrials maintain its long-standing reputation for quality, the data management team needed to increase the speed and accuracy of its clinical data capture, management and reporting. The team sought a highly secure, cost-effective solution with integrated, automated workflows; a user-friendly interface and excellent support; and the scalability to handle distributed teams and huge data volumes.

Every action digitally documented

ProTrials selected the Zelta clinical trials platform as its system of choice for data management. Now, the team has a unified platform that centralizes all clinical study data and documents in an advanced EDC system, which fully integrates with other key solution capabilities covering management of the entire study lifecycle. Authorized users can access the system through a password-protected, single sign-on interface — from anywhere in the world, including on mobile devices. In addition, the solution's around-the-clock support helps ProTrials deliver excellent onsite customer service.

After rapidly deploying the solution using a software-as-a-service (SaaS) model, the ProTrials team began to build newly customized CRFs using the intuitive user interface and clear step-by-step process. "From the start, we saw that the Zelta solution operates on the leading edge. The difference was night and day. This system didn't have the same stale, cookie-cutter EDC features," says Quilliam. "Fast forward to today, and we still see continual innovations."

The team capitalized on the solution's randomization and trial supply management functions to create a system of automated checks for the study startup process. Employing a novel approach, the process prevents ProTrials data managers from activating new users until they receive an electronic delegation of authority log.

"The delegation of authority log becomes the trigger point by which we electronically activate that account in the EDC. Then, we give the appropriate credentials to that role and click Go. Essentially from there, and what we love about the Zelta EDC, the system provides participants with self-service training," explains Quilliam.

The electronic delegation of authority log, kept in the study's master file, then records each user's training, including the date and time of completion. Through careful review of the logs, ProTrials' data managers become empowered to work with customers to proactively resolve any user-related issues that might otherwise impede study startup.

The team also designed a new workflow that documents every minor change made to the study with a comprehensive electronic audit trial. For each change, the clinical team must now electronically sign a one-page form that verifies they reviewed and approved the requested change. "It's something so simple, but now we have full documentation that the customer approved the change and we aren't arbitrarily changing things. Everything is being tracked," says Quilliam. The Zelta system also tracks changes resulting from mid-study updates to electronic CRFs (eCRFs).

Faster and audit ready

With a unified data management platform, the team can now work with not only greater efficiency but also increased confidence in its ability to display its meticulous attention to detail, especially during audits. “As data managers, we might be able to build studies quickly, but are we still maintaining quality? Are we taking our processes to the next level so that we’re still audit ready at any point in time?” asks Quilliam. “With the Zelta platform, we can answer ‘Yes.’ We are fast and audit ready.”

For example, given the ease with which the Zelta system accommodates updates, the team can now make a minor study change—and fully document the customer’s approval—in under 30 minutes. Previously, the team could make a change but struggled to document it within the same timeframe.

Using a SaaS delivery model with flexible pricing options, ProTrials now has a cost-competitive system customizable for each customer’s specific trial needs. In addition, the company receives seamless product updates and can rapidly scale its services to accommodate globally distributed users and large data volumes.

Ultimately, with tighter data management processes supported by a user-friendly platform, ProTrials has a stronger competitive advantage when it comes to winning new business and helping enable clinical studies with successful outcomes. “The core focus in our organization is on quality,” says Matt Smith, Chief Revenue Officer for ProTrials. “What it comes down to is that with the Zelta system, we can efficiently drive data integrity for our customers’ clinical trials.”

About Merative

Merative provides data, analytics, and software for healthcare and government social services. With focused innovation and deep expertise, Merative works with providers, employers, health plans, governments, and life sciences companies to drive real progress. Merative helps clients orient information and insights around the people they serve to improve decision-making and performance.

Learn more at www.merative.com

Produced in the United States of America
March 2024

MCD-3061988659 Rev 4.0