merative™

Worldwide Clinical Trials

375+ successful studies with cloud-based clinical trial-management software

Worldwide chose the Zelta™ clinical trials platform by Merative to design and manage complex clinical trials, including a recent multinational oncology study. The solution's user-friendly design, scalability and flexibility allow Worldwide to quickly add protocol revisions and manage multiple sites with ease.

Business challenge story: Behind the scenes of a clinical trial

Business challenge

As a global leader in clinical trial research, Worldwide Clinical Trials (Worldwide) wanted to focus on its core competence, not on designing and programming the databases that support clinical trial management.

Transformation

Worldwide chose the Zelta™ clinical trials platform by Merative to capture, manage and analyze the vast and varied data from today's complex, multisite trials.

RESULTS

Managed 375+ clinical trials using the Zelta platform

Generated custom reports quickly and easily without advanced programming skills

Added protocol updates and revisions with ease thanks to the solution's cloud-based scalability

Worldwide manages all phases of complex clinical trials for its customers around the globe. Until 2012, it used an in-house clinical development software solution to set up clinical databases to record and analyze trial data. Modifying or updating the system required personnel with coding and development skills. In addition, implementing revisions — amended versions of the clinical database — to trial protocols took time that could interrupt data input and reporting, and slow down trial completion.

Desiring to keep its focus on its core competence, senior management at Worldwide sought a clinical development solution that would not require a large programming team to manage. It wanted a versatile system that it could use for all trial phases, and for complex, multinational and multisite trials.

Worldwide found the answer in the Zelta clinical trials platform. In 2012, the company began using the software for electronic data capture (EDC) and to manage clinical trials. When it embarked on a very complex, multi-country oncology study in 2014, the solution offered the clear choice for designing and managing a study that included a complicated patient visit schedule, multiple tracks within the study groups, and an open-ended and variable patient participation timeline.

"Despite the trial's level of complexity, our sites have been able to conduct it successfully, thanks to the Zelta platform."

— Program Clinical Data Manager, Worldwide Clinical Trials

Transformation story: Complex trial design requires flexibility

Worldwide chose Zelta software to design and manage its oncology clinical study. Using the software-as-a-service (SaaS) EDC solution allows the company to manage each step of the clinical trial, from design to revision to reporting, with no in-house infrastructure. The intuitive and easy-to-use solution requires no advanced programming expertise. Users access pages, reports and data through a password-protected web interface.

The solution enables Worldwide to take a customized approach to building each study database. According to Amanda Cross, Vice President, Biometrics at the company, "We use the core system for the EDC, and we add on different modules depending on the sponsor's requirements."

Merative-trained designers built the database based on the sponsor's protocol design. Because the solution is designed to allow easy implementation of protocol amendments at country and site levels, adding multiple sponsor revisions for the complex oncology project was relatively straightforward. Once implemented, personnel using the solution to enter clinical data automatically see the correct database version for their site. Because this study has two groups, each with multiple treatment tracks, Worldwide needed its design to be simple and intuitive for the study sites' use. "The sites want the system to think for them as much as possible," said an experienced Program Clinical Data Manager at the company. The design team used the Expression Editor module to trigger the display of the next relevant question, page or visit based on user input.

Because the study includes a variable patient visit schedule and multiple treatment regimens, Worldwide used features of the EDC solution to provide as much guidance as possible to the study sites. "There's quite a lot of thought that has to happen for the sites to know where they have to go in the system each time they see the patient and to report the required data," explains the Program Clinical Data Manager. "We've provided additional help text guidance that pops up based on certain data entries, so that the sites know which page to access next."

The solution also enables Worldwide to use APIs to import data from its interactive response technology (IRT) system. These imports include screening data to add patients to the system and open their case report forms (CRFs), randomization data, information about investigational medicinal product (IMP) or study medication kits assigned, and subject-status updates such as screening failures or discontinuations. This process adds data to the electronic case report form (eCRF) in real time so that the IRT and eCRF are always in sync.

Worldwide also uses the API functionality to import laboratory data. The central lab vendor provides a monthly data transfer, which Worldwide Data Management then uploads using the API. The imported data is set to read-only so it cannot be amended by study site users — only a subsequent import from the lab can change the data. Data entry fields are configured on the same page to keep site-level data entry requirements to a minimum, making it faster for sites to report results. Finally, a report of all lab results and a CS/NCS assessment is available to the sponsoring medical team at the patient, site and study levels.

Results story:
User-friendly design facilitates success

To date, Worldwide has used the Zelta platform to manage more than 375 clinical trials. The cloud-based software is versatile enough to use for any trial phase, and for the simplest to the most complex studies. It was the perfect fit for this ongoing particularly complex, multiphase, multisite oncology trial.

Even when the study sponsor added new protocols and revisions, Worldwide responded quickly to satisfy new requirements. “Despite the trial’s level of complexity, our sites have been able to conduct it successfully, thanks to the Zelta platform,” says the Program Clinical Data Manager.

Worldwide attributes its successful use of the Zelta platform to the software’s flexibility and ease of use. “The interface doesn’t require special programming skills like Java or any other complex language,” says Kevin Oldham, Senior Director, Data Management. “It doesn’t take long at all when a lead data manager needs a spec update. It’s translated into the system quite quickly.”
The solution’s user-friendly design makes it simple for Worldwide to import lab data without complicated programming. Using the Site Management – Import Sites functionality enables quick upload of site detail updates, including changes to the CRF revision number used. Using the solution also helps the company track study medication kits at the site level for drug accountability during the study.

Clinical research organizations such as Worldwide Clinical Trials need clinical development software that adapts with the changing study landscape. For example, as clinical trials and drug studies become increasingly complex, with ever-growing requirements for separate country protocols, Worldwide must add protocols quickly, without slowing down the overall study. Using the cloud-based Zelta platform not only lets the company add new protocols, but it can also adapt the solution using different modules, connect APIs and import external data, create custom reports and integrate revisions with ease to ultimately meet and exceed its sponsors’ expectations.

About Worldwide Clinical Trials

Founded in 1986 by physicians dedicated to advancing medical science, the mission of Worldwide is to bring better medical products to market and improve patients' lives through its clinical trial services. Headquartered in Morrisville, North Carolina, Worldwide Clinical Trials lives up to its name, with approximately 1,600 professionals conducting clinical trials in more than 60 countries around the globe. The company boasts therapeutic expertise in several critical areas, including central nervous system, cardiovascular and metabolic, immunology, rare disease and oncology and hematology, and combines proactive insights with rigorous operations.

Learn more about the Zelta clinical trial platform

www.merative.com/clinical-development

About Merative

Merative is a data, analytics and technology partner for the health industry, including providers, payers, life sciences companies and governments. With trusted technology and human expertise, Merative works with clients to drive real progress. Merative helps clients reassemble information and insights around the people they serve to improve healthcare delivery, decision making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022. Learn more at www.merative.com

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