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 IBM® Clinical Development solution from IBM Watson Health™ 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.

Results

Managed 300+ clinical trials
using the IBM Clinical Development solution

Generates custom reports
quickly and easily without advanced programming skills

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

Worldwide Clinical Trials

300 successful studies with cloud-based clinical trial-management software

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.

"Despite the trial's level of complexity, our sites have been able to conduct it successfully, thanks to the IBM Clinical Development solution."

—Program Clinical Data Manager, Worldwide Clinical Trials

Share this

Behind the scenes of clinical trials

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 IBM Clinical Development solution from Watson Health. In 2012, the company began using the IBM Clinical Development 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 IBM Clinical Development 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.

Complex trial design requires flexibility

Worldwide chose IBM Clinical Development 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 Katie Jarvis, Associate Director, Data Management at the company, "We use the core system for the EDC, and we add on different modules depending on the sponsor's requirements."

IBM Clinical Development-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.

User-friendly design facilitates success

To date, Worldwide has used the IBM Clinical Development solution to manage more than 300 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 Clinical Development solution,” says the Program Clinical Data Manager.

Worldwide attributes its successful use of the IBM Clinical Development solution 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 the Executive Director, Data Management Vanessa Jeffrey. “It doesn’t take long at all when I need 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 IBM Clinical Development solution 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.

Solution component

- IBM® Clinical Development

Take the next step

To learn more about the IBM solution featured in this story, please contact your IBM representative or IBM Business Partner.

About Watson Health

IBM Watson Health is a business unit of IBM that is dedicated to the development and implementation of cognitive and data-driven technologies to advance health. Watson Health technologies are tackling a wide range of the world’s biggest health care challenges, including cancer, diabetes, drug development and more.

Please Recycle

02030102USEN-00