Has EDC Kept Up With Changes In Clinical Trials?

In just a few decades, clinical trials have changed dramatically. Twenty years ago, most of the data used in clinical research was entered on paper, but today it can come from sources as varied as sensors, smartphones, and electronic health records (EHRs). The COVID-19 pandemic has brought even more changes as pharmaceutical companies rush to adapt remote methods for collecting data and conducting visits so that patients can be kept safe. In addition, trials for new COVID-19 vaccines and treatments must be set up very quickly and be able to adapt to mid-study changes in near real time.

Pharmaceutical companies are realizing that new digital approaches are not only possible but can bring real benefits to running clinical trials. As they take a serious look at the best ways to design and implement clinical trials that incorporate virtual components and new types of data, it is becoming clear that traditional electronic data capture (EDC) systems aren't equipped to handle the complex data collection and integration required in today's environment.

In response, new platforms for data collection and clinical trial management are emerging that can support the volume and variety of data that results from incorporating virtual components into clinical trials. Additionally, clinical trial processes that used to be supported by separate systems are now being supported in the same environment, making it faster, easier, and cheaper to set up and run clinical trials. These advancements in the technology supporting clinical trials give study teams more realistic information about how well a drug is working so they can make better decisions. Not only does this help bring new treatments to patients faster, but it also helps pharmaceutical companies focus efforts on drugs that are most likely to be successful.

How Was EDC Developed?

In the late 1990s and early 2000s, the internet was becoming a viable way of creating software applications, but clinical trial data was still collected on forms. These forms were filled out by the patients themselves or clinical staff and then faxed or mailed to a central location. If a correction was needed, a correction form had to be filled out.

Around this time, leaders in the industry realized that the internet could be used to allow electronic data capture in clinical trials, creating what would become known as "EDC." EDC turned paper forms into electronic forms, greatly reducing the time required to enter data. In 2004, two events served as inflection points and helped quicken the adoption of EDC: Quintiles started charging less for trials using EDC rather than paper, and GSK announced its clinical trials would only use EDC. Eventually, EDC standards were formed, and federal agencies also began to accept electronic submissions. At that point, there was no turning back. EDC would soon become the norm.

During this time, EHRs were also becoming more common. Although there has been much discussion about replacing EDC with EHRs, the systems each serve different purposes and come with different levels of scrutiny. EHRs are designed to help doctors provide care to patients and bill appropriately, while EDC systems are designed to collect data for research involving people. EHRs don't have the full ability to capture all types of data needed for clinical trials, but they can contain information that is valuable for them.

Is EDC Working For Today's Clinical Research?

Although EDC was a huge improvement over paper-based forms, since its development, clinical trials have become much more complex and the volume and types of data collected have increased significantly. Mobile phones and wearable devices – collectively known as mHealth – provide around-the-clock data that comes in various forms. For example, a clinical trial participant might enter daily food intake into an electronic diary while a sensor measures activity 24 hours a day. Other information might come from blood tests or vital signs taken in the clinic or by a visiting nurse.

This wide variety of data sources and data types puts an incredible burden on a clinical team trying to use the EDC systems in place now. Most EDC systems were designed to support electronic forms, which are structured. These systems were not built to handle unstructured data, like the data that comes from wearables and sensors. They also weren't designed to collect large volumes of data or to handle various data

sources and compile the data in one place. Although integrations have been built to allow EDC systems to collect other types of data, trying to make new types of data fit into old systems is not without problems.

These challenges around using EDC systems make it very difficult and time-consuming to get clinical trial data organized in a useful way. Because the approaches to collecting and organizing data need to be set up early in the clinical trial design process, it can be quite a barrier to getting clinical trials up and running quickly.

EDC is just one of many systems with which a clinical trial team may be working. A single trial can involve up to 30 different systems, all with separate credentials, training, interfaces, support, validations, upgrades, and builds. Getting these systems to all work together is extremely inefficient and makes it difficult to effectively use the data to get a complete picture of a patient.

Another challenge is that EDC systems, and the many other systems used in clinical trials, were developed in isolation to support specific elements of the clinical trial process. These "point solutions" were not built to work together and inevitably introduce redundancies for clinical trial teams that slow down clinical research.

Even after selecting what seem to be the best systems for a trial, it is a fact of life that software gets old quickly. Software even 1 year old is considered outdated, meaning that a clinical trial running for years will inevitably go through upgrades and new releases that may require validation, training, process changes, and more, which is disruptive, time-consuming, and costly. Keeping EDC systems up-to-date and integrated with other systems is very difficult. In fact, 70 to 85 percent of the total IT budget for a clinical trial can be spent on maintaining EDC software and other systems.

How Do EDC And Other Systems Need To Change?

In the past, vendors offered clinical trial software that operated in a certain way, and clinical trial teams had to figure out how to adapt their protocols to fit these systems. This approach makes it extremely laborious and expensive to set up a clinical trial.

It's time for a drastic change in the eClinical environment that allows clinical trial teams to focus on medical needs and designing the best protocols rather than on system maintenance and integration. It sounds like a tall order, but it can be done by approaching the technology as a unified platform with capabilities that enable study teams to do whatever they need to do, instead of rigid point solutions that only support a certain process in a certain way.

Ideally, such a system would come with the ability to understand when to grab a piece of data from a medical device or when data needs to be collected from a home nurse visit. Then, it would effortlessly bring data from these very different collection techniques into a central location where it can be utilized to its fullest capacity. Additionally, the system would keep track of how the data was collected, who collected it, and how that data can be used.

Mining EHRs for useful data is another powerful approach that can help clinical research but isn't very easy to implement with today's clinical trial systems. EHRs can be used to find patients that meet inclusion criteria for a specific trial and see where these patients are located. They can also be used to compare certain drugs that are already in use. In a few cases, EHR data has even been used to gain drug approval for an indication that was previously off-label. EHRs hold a great deal of data that is useful for clinical trials, if it can be captured and analyzed in a useful way.

Can New Technology Platforms Help?

To meet the changing needs of clinical trials today and in the future, Oracle developed a truly unified single eClinical platform called Clinical One. With Clinical One, study teams simply enable the functions needed to run a specific trial instead of having to figure out which systems are necessary to run a trial, which vendor is going to provide which software, and how to integrate all the systems. With a unified system, you build a study once, enter data once, and do everything from one place.

The platform brings together data collection with randomization and trial supplies management – which were previously always separate systems – to create seamless integration and a unified clinical trial workflow. This essentially eliminates the time and costs of integrating these systems.

Clinical One enables effortless data collection from paper forms, EDC and EHR systems, wearable mHealth devices, and even genomics tests. The clinical trial team can select when and where the data is coming from, how it will come, and then configure it themselves. The platform even has built-in features for managing wearable devices, which can be a challenging process for large clinical trials. These capabilities can help advance the use of more virtual approaches, greatly reducing the number of clinic visits required of patients. This could significantly increase the number and diversity of people willing to participate in clinical trials while also upping retention.

Thanks to the unification of processes on a single platform, Clinical

One has shortened the time for trial setup to an average of three weeks or less. For COVID-19 studies, the platform has been used to get some clinical trials running in even less than 10 days. If mid-study protocol changes are needed, they can be deployed in minutes by dragging and dropping out old protocols and replacing them with new ones.

Oracle's Clinical One takes the complexity out of clinical trials and data collection processes while supporting the collection of more complex data, allowing clinical trials to run faster and smarter. By embracing new technology, pharmaceutical companies can streamline their efforts to bring life-saving treatments to the patients who need them most.

About Oracle Health Sciences

As a leader in life sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the life sciences industry to improve patient outcomes.

Build a study once,
enter data once,
do everything in
one place.

CONTACT

+1 800 633 0643

healthsciences_ww_grp@oracle.com

www.oracle.com/healthsciences

CONNECT

blogs.oracle.com/health-sciences

facebook.com/oraclehealthsciences

twitter.com/oraclehealthsci

linkedin.com/showcase/oracle-health-sciences