Extracting Maximum Value FROM ELECTRONIC DATA CAPTURE

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Electronic data capture (EDC) has been employed for clinical trial data for many years and is encouraged by the FDA because it provides significant benefits to sponsors, investigators, and patients, including more accurate data that can be more easily shared and monitored, increased compliance with regulatory requirements, and lower overall costs. With the storage of protocols, assignments, and patient data in one central location for all sites in a clinical trial, cloud-based EDC software provides even more efficient data monitoring and reporting, enhanced communication and collaboration, and better budget forecasting.

As a result, cloud-based EDC systems are ideally suited for the more complex clinical trials studies being performed today. In addition, as EDC technology continues to evolve, it is further enabling pharmaceutical companies to improve the management of clinical trials and as importantly reduce clinical trial study times and costs.

A Clinical Trial Overview

Clinical trial costs have risen dramatically as studies have become more global and complex. Phase I, II, and III trials were estimated to cost on average $24 million, $86 million, and $61 million, respectively, in 2010. Trials are lasting longer because many new drugs are designed to treat chronic conditions and therefore must be studied for a longer period of time. They are also more global in nature so that efficacy can be demonstrated in many different patient populations.

Recent research has revealed that the use of lower-cost facilities/in-home testing and the increased use of mobile technologies and electronic data capture (EDC) could rapidly reduce clinical trial costs from 8% to 24% across all phases.

EDC Delivers Significant Efficiencies

As clinical trials are evolving and becoming more global and complex, communications between all involved parties, data management, record keeping, and regulatory compliance have become more challenging.

Fortunately, information technology has evolved as well, and advanced EDC solutions are helping clinical trial studies run more efficiently and effectively by providing convenient mechanisms for communication, increased efficiency and accuracy of data entry, organization, and monitoring, and optimization of workflows and team interactions.

Initial trial planning is simplified with the use of an EDC, because the full study can be first laid out on a general level and then details added, making it possible to establish timelines, determine the required number of sites, and define responsibilities for different staff members across multiple sites.

As a result, EDC tools can also be used to more rapidly design and launch trials. Elimination of the need to create paper case report forms (CRFs) is another advantage of using electronic data capture.

A COMMITMENT TO CONTINUOUS IMPROVEMENT IS A NECESSARY REQUIREMENT FOR ANY PROVIDER OF CLOUD-BASED EDC SOFTWARE AND SERVICES.

EDC software when appropriately implemented also provides for improved data management, because there are no longer thousands of pieces of paper to keep track of. Data are entered directly into the system, which has built-in checks designed to catch errors. In addition, data are available for access much more quickly when an EDC is used. Furthermore, the data can be readily organized and categorized for reporting purposes and easily searched and analyzed to detect patterns and significant outcomes.

EDC systems also keep track of required actions and monitor ongoing data entry and other activities, which leads to improved adherence to study protocols.

With EDC, communication between study managers, staff, patients, the custom manufacturer(s) of the drug being tested, and the trial sponsor is improved. As a result, delays are avoided, problems that do arise are caught and addressed early on before they become major issues, and everyone involved is kept up-to-date with the progress of the study. All of this leads to improved performance and potentially shorter study times. Plus, communications are documented in the EDC system and are searchable, as are updates and changes to the study.

Significantly, the U.S. Food and Drug Administration (FDA) encourages the use of electronic data capture for clinical trials. EDC systems help ensure that increasingly demanding regulatory data capture and reporting requirements can be met with confidence.

The benefits described above also add up to improved efficiencies and cost savings compared with those associated with conventional clinical trial management practices.

Cloud-based EDC is Even Better

While electronic data capture provides significant advantages over older systems based on paper record-keeping, data entry, and manipulation must still take place at each individual study site, and often significant time and effort are required to ensure that the data at all sites is current and in the correct format. In addition, IT equipment is required at each site for data storage.

With a cloud-based system, all of the data — eCRF data, electronic patient-reported outcomes (ePROs), images, PDF source doc-

uments, protocols, assignments, etc. — are stored in a central EDC system that is managed by a third-party service provider. The data are accessed through Web-based software using any type of Web-based device, and therefore trial managers can have real-time access to the data from all project sites. The data are automatically updated and collated for more rapid and efficient data monitoring and reporting, and often alerts can be built in to the system to notify users of changes and updates.

Furthermore, the high upfront investment costs required with conventional EDC systems are eliminated, because not only the cloud-based software, but the IT infrastructure is owned and maintained by a third party.

For more complex global clinical trials, cloud-based EDC systems provide not only data capture and management, but also help study managers track the drug supply, manage images, coordinate reporting, or even provide assistance with translation and patient education. The software typically is offered in different languages and translation features are often included.

In essence, the use of a cloud-based EDC system enables greater collaboration between sponsors, contract research organizations (CROs), contract manufacturers, investigators, and regulators because everyone has immediate access to the same data set, which is often more accurate.

This increased communication, combined with the facilitation of more efficient endpoint coordination and adjudication processes, results in shorter clinical trial times, which in turn leads to lower study costs and a reduced time to market.

It should also be noted that the data in cloud-based EDC systems for clinical trial management can be effectively used to achieve more accurate resource forecasting and budgeting.

The use of standardized forecasting and budgeting models and processes can also increase the efficiency and reduce the time required for the development and review of clinical trial budgets. Improving the accuracy of clinical trial budge forecasting is recognized as a significant need in the industry.

Introducing the Modular Approach

Effective cloud-based EDC systems are designed to be flexible so that the unique requirements of each clinical trial can be met regardless of company or study size.

THE DEVELOPMENT OF MORE EFFECTIVE AND EFFICIENT TOOLS FOR DATA MANAGEMENT AND COMMUNICATION ACROSS SITES AND BETWEEN VARIOUS INTERESTED PARTIES IS NECESSARY TO HELP REDUCE LENGTHENING TRIAL TIMES AND CLIMBING STUDY COSTS, WITH THE ULTIMATE GOAL OF ENABLING THE EFFICIENT DEVELOPMENT OF ADVANCED MEDICATIONS FOR PATIENTS IN NEED.

The best solutions are modular, scalable, platforms that can be custom configured to allow use of the specific tools that are needed for each unique study.

As a result, not only the databases, but study workflows and communications can be tailored to the site(s) and the trial from the outset.

Such modular EDC platforms offer core electronic data capture, management, and monitoring capabilities with optional add-on functionality from randomization and safety reporting to translation and endpoint adjudication.

When this type of system is combined with a pay-as-you-go approach — transparent pricing with payment based solely on what is used and for how long — savings can be further maximized, even for small pharmaceutical, biotechnology, and medical device companies.

Success Hinges on Continuous Process Improvement

Cloud-based EDC systems are designed to facilitate the commercialization of a new drug for the treatment of unmet medical needs. Therefore, they should not become burdensome or disrupt workflows. It must be realized, however, that the use of advanced cloud-based EDC systems or any technology alone is not sufficient to ensure success.

Users of cloud-based EDC systems must recognize that the adoption of new technology does not equate to improved efficiency and greater productivity without the simultaneous implementation of process changes.

Consequently, it is important for clinical trial managers to select an EDC system provider that is willing to be a strategic partner and truly commit to achieving the success of its clients.

Cloud-based EDC: Controlling Costs, Reducing Delays, Meeting Patient Needs

Continued increases in the complexity of clinical trials are expected in the coming years. At the same time, the number of clinical trials is growing dramatically, increasing approximately 33-fold since 2000, according to the National Institutes of Health.

An alarmingly high percentage of clinical studies conducted today experience delays, costing drug manufacturers tens of millions of dollars.

A commitment to continuous improvement is a necessary requirement for any provider of cloud-based EDC software and services.

The development of more effective and efficient tools for data management and communication across sites and between various interested parties is necessary to help reduce lengthening trial times and climbing study costs, with the ultimate goal of enabling the efficient development of advanced medications for patients in need. PV

Merge eClinical, *a division of Merge Healthcare Inc., develops and markets smart software that streamlines the clinical research process. The company is built on the belief that every study — no matter how large or small — deserves the benefits offered by information technology to improve safety, quality, and study outcomes.*

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