

> Areas of Impact: How Sponsors and CROs
Benefit from EDC Efficiencies

+ *The intense competition in the prescription drug market is driving pharmaceutical companies to expedite their drug discovery and development processes. Pharmaceutical companies understand the value of being the first to bring a new drug to market and it is this knowledge that is leading them to streamline their clinical trial process.*

The question used to be how can a pharmaceutical company conduct efficient and effective trials, but it has evolved to include process improvements such as better data collection and cleaning, streamlined process monitoring/query resolution, improved process management and reporting, as well as expedited FDA approval for new drugs. Pharmaceutical companies also want the ability to access study information in real time, as it is occurring in order to make better decisions regarding the viability of a drug as the study is conducted.

Given the changing face of clinical trials, there is a unique opportunity for CROs and EDC vendors to join forces to better serve the pharmaceutical industry.

With the goal of helping sponsors bring new drugs safely to market, CROs have much to gain from using EDC. The benefit to implementing EDC is that it provides an expedited clinical trial process through efficient study design and deployment as well as access to real time data. And with EDC, the control of the study is in the hands of the sponsors and CROs.

Typically, when the benefits of EDC are discussed the most common advantage is time to database lock. While quick database locks are important, of greater importance is the immediate access to clean data. If the data is not clean, the entire process of locking the database is in jeopardy.

There are many elements of trial information for which EDC offers improved process management: trial design and compliance, safety, clean data, deployment and time to database lock as well as trial management information.

Trial Design and Compliance

The key aspects to managing clinical data are: trial design, compliance, safety and interim reviews. With any clinical trial, there is the possibility that the protocol is not in its final form or has not been fully validated. Early data collection can provide critical input to determine necessary protocol amendments to ensure a successful trial. The flexibility of EDC allows for immediate and cost effective mid-study changes.

In addition to having immediate access to clinical data to validate or modify the protocol design, EDC allows monitors and project managers to determine whether sites clearly understand the protocol. Also, sponsors and CROs can through an automated process to query sites electronically to clarify questionable data Safety.

One of the most compelling reasons to use EDC is immediate access to safety data both on an individual patient basis and for an entire study. An EDC-based study can automatically generate FDA safety data forms and notify study personnel via automatic reporting or email.

Some studies, such as critical care, may require regular safety and efficacy reviews by internal or external committees, such as the Data Safety Monitoring Board. In a paper-based trial assembling, cleaning, and reviewing data is a logistical nightmare. Additionally, the lag time on the data may range from six to eight weeks whereas EDC presents that timeline in real time.
Clean Data.

There are three primary factors that contribute to cleaner more accurate data. In eCRFs, dropdown menus and code lists are used in order to eliminate the most common data entry and transcription errors. Edit checks can be programmed into the eCRF, thus providing sites with immediate feedback to correct the most common of errors such as missing or out of range data. More complex edit checks based on cross panel logic are also easily programmable.

Typically the data cleaning process occurs in the later stages of a trial. However with EDC, the data cleaning process is moved to the front-end and is maintained on a timely basis through the duration of the trial. Given the ongoing data cleaning process, sponsors and CROs are guaranteed access to the most accurate data as well knowing they are viewing the same data.

This enables CROs to conduct their jobs more efficiently as they can handle most issues and concerns from the convenience of their office.

Deployment

A common misconception is that whatever time may be saved on the back-end by quickly locking the database is offset by the time needed on the front-end for study setup.

This is a dated line of thinking in that significant improvements have been made to study design tools. An eCRF can be developed in a few days and, more importantly, the database is developed automatically as a by-product. Sites have the ability to begin entering data within a few weeks from the start of the design process. And if an eCRF needs to be modified, it is possible to deploy a new eCRF quickly without delaying a study. This is important to CROs, as they are ultimately responsible for driving the study and hitting timelines. An additional benefit to EDC is that edit checks are in place to automatically force data cleaning.

Although the specifying, programming and testing of edit checks can take additional weeks, the eCRF can be deployed with or without edit checks in place in order to expedite deployment. The majority of edit checks are null checks, which engage if there is missing data, or range checks which require data to fall within a predetermined range of acceptable values (for example, a body temperature of 112 degrees would trigger an out of range message that the site would be forced to correct). To expedite study start up, it is possible to deploy with those easily developed edit checks in place and then develop the more complex cross panel and logic checks as the study progresses.

Database Lock

Although faster database locks are not the most compelling reason for a sponsor or CRO to choose EDC, it is a real and valuable result. With EDC, database lock can happen earlier and more efficiently, because the data cleaning process occurs as the study progresses and is not a back-end task to complete as the last step before database lock.

Another benefit to the ongoing data cleaning process is that any interim analysis of data will be far more complete and reliable and more accurate conclusions can be drawn. The expedited database lock in the short-term can influence both the submission of NDAs and in the long-term can maximize the patent life of a new drug

Trial Management

The major elements to effective trial management are enrollment status, accurate forecasting, timely protocol amendments, efficacy and safety and site payments.

Key enrollment information is available to program managers and monitors immediately as patients are enrolled. And enrollment report generation is an automatic by-product of using EDC.

In addition, crucial clinical data related to patient screening failures can also be included in automated reports that, when combined with other enrollment data, allows more accurate enrollment rate projections to be quickly generated. And when armed with reliable enrollment data, sponsors and CROs can proactively modify protocols to help ensure that the best possible patients are being included in a trial. It also enables the efficient adding and replacing of sites to expedite enrollment rates. With EDC, protocol amendments can easily be deployed since sites are automatically updated to the most current version for their site upon login. In addition, to the standard efficacy and safety reporting, any key data that sponsors wish to view can be summarized into automatically generated management reports that are updated daily.

A study is only as successful as the sites that manage it. EDC gives sponsors a unique tool that motivates sites to speed data collection while eliminating the majority of the administrative burden. Site payments can automatically be linked to data entry and data cleaning activities.

Automatic payment reports can be generated and exported into a variety of user friendly formats such as Excel in order to automatically calculate and generate site payments. As a result, sites are motivated to complete the entry of data into the eCRF in order to ensure prompt payments and sponsors have a cost effective and easy way pay sites based on the actual work completed.

21 CFR Part 11 Compliance

With EDC, the clinical trial data resides in a regulated

environment that is in compliance with FDA guidelines. Furthermore, the FDA has approved the release of drugs to market whose clinical trials were conducted using EDC. The system has been validated so the risk to CROs and sponsors is eliminated.

Conclusion

As a Gartner Analyst so aptly commented, "Although efficient and effective clinical trials are important, that is not the overarching goal of pharmaceutical and biotechnology companies. Instead, their objective is to discover, market and launch novel and profitable therapeutics as quickly as possible."

With the competitive nature of the prescription drug industry, a clinical solution that combines an experienced CRO expert in using best-in-breed EDC systems can offer an extremely powerful advantage sponsors. Especially with a sponsor that values not only being first to market, but also knowing that they got there with accuracy of data

and efficient use of resources.

About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at www.merge.com.

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