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In the past several years, eClinical technologies have become a more widely-used asset in clinical trials due to their effectiveness compared to paper processes. With the elimination of paper CRF books and, in some cases, clinical data management systems, technologies such as electronic data capture and electronic patient-reported outcomes have proven to be more cost-effective, timely, and easier to use.

However, the area of data analysis still may have some room for improvement. On one hand, eClinical technologies provide real-time access to data entered by the site or patient regarding a clinical trial. On the other hand, there are still mounds of other critical data that is not integrated within a singular technology, which can hinder the clinical trial process.

To say that eClinical technologies address all of the issues related to clinical data analysis would be naïve — there are still obstacles to overcome to integrate all sources of clinical data. However, vendors are in the process of developing ways to fully integrate all types of data involved in a trial to further streamline the clinical trial process. Full integration of data can be a benefit and a hindrance if used incorrectly. And some vendors are hesitant to embrace technology that alerts of every "trend" emerging from the data, because too much data analysis may cause unnecessary delays and challenge the integrity of a trial sponsor and/or contract research organization.

In an environment that has developed over the past several years regarding patient safety issues, addressing ways to better identify problems within a trial has become a paramount issue with technology vendors. However, when does efficient data analysis become overwhelmed with too much external data to skew and/or negate trial outcomes?

Trends in Data Analysis

Many different technologies have emerged to assist in streamlining the clinical trial process. Some have succeeded, as is evident by the many technology options available today, and many have failed. The industry is dictated by the needs of the customers, and it appears that the vendors who have persevered have adapted to these changing requirements: faster data analysis, robust reporting capabilities, compliance with consortium standards, and integration capabilities.

All eClinical technologies available on the market today provide sponsors access to more timely data regarding a clinical trial. This not only results in faster trials and speed to market, but ultimately affects the bottom line — faster trials are more cost effective. As many pharmaceutical corporations have embraced eClinical technologies such as electronic data capture, this is becoming an accepted reality of the industry. As technologies inevitably evolve, at exponentially faster rates, vendors are finding newer, more efficient ways to analyze data and provide their customers with the most robust software applications available.

Currently, the landscape is scattered with technology vendors that offer “solutions” for electronic data capture, clinical trial management systems, clinical data management systems, electronic patient reported outcomes, and safety reporting tools. Their offerings are broad, few are very deep. Sponsors and CROs must still collect data from multiple sources — slowing processes, decreasing productivity. An inevitable result, data is not analyzed as “real-time” as originally perceived. This includes the integration of other external data sources, such as device data, lab data, etc.

Moving into the future, technologies need to evolve to allow data analysis from multiple sources all in one software application. This is including, but certainly not limited to, adding clinical trial management system functionalities, supply chain management, and safety reporting. Integrated data is capable of being analyzed at much faster rates then the current models dictate. This real-time analysis can provide sponsors with crucial trial information that will positively affect patient safety, and ultimately, trial results.

Multiple source integration

Of the 25% or so of the industry currently using electronic data capture software applications for their clinical trials, almost 100% of them are still utilizing some form of outside software for data analysis and reporting. Granted, this is not true of all organizations, and there is a lot of analysis available with current eClinical technologies. However, few have the capabilities to integrate multiple sources of data that warrant centralized analysis.

There are technology vendors leading the initiative to integrate all sources of clinical trial data. Recent additions to many eClinical software applications include Bluetooth technology for device data, laboratory data, clinical trial management systems data, and even enterprise-wide data. If the past is an indication of the future, then it is only a matter of time that most all eClinical vendors will offer some more robust data integration of technologies within their applications. The competitive nature of the industry indicates that vendors follow in the footsteps of the market leaders. It is up to sponsors and responsible technology vendors to dictate how much integration is necessary for successful, efficient trials.

Identifying trends in data

In a recent trial, lab data was successfully integrated into electronic data capture for a hematology study. Using the information available, a trend in adverse-event data was determined that would have gone unnoticed for several months had the information not been integrated into the electronic data capture application. The investigators were able to immediately react to the data, and the study was halted, saving the sponsor millions of dollars in trial costs. Had the data not been integrated, these patients’ long-term health would have been seriously jeopardized, and the integrity of the sponsor would have been questioned.

Not all situations will result as that example did. A sample population of males ages 30 to 40 may be having headaches not due to a trial drug, but because they are stressed during the holiday season. In this case, as in many others, this may cause delays, over-analysis of data, unnecessary micro-management of every aspect of the study, and ultimately long-term impact on a sponsor’s bottom line. To alleviate these issues, it is necessary to understand how integrated data and trends in the data will most effectively be utilized within an eClinical solution, as well as the outcomes of this data. Technology applications should be offered to provide solutions to a problem – with buy-in and agreement from both

the vendor and sponsor. Without a clear-cut plan before the commencement of a trial, snafus are inevitable.

Developments in technology will continue to advance, and with them, issues regarding their efficacy and cost-efficiency. As with all innovations, it is necessary to understand the benefits and the costs. Having a candid conversation with your technology vendor regarding the needs and capabilities of a technology solution is the first step to your next successful trial.

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