APPLIED CLINICAL TRIALS

Employing existing CTMS technologies now can head off potential problems in the future.

New Risks Require New Solutions

David Grace

A clear and present danger has emerged for the pharmaceutical and medical device industry that threatens its very core. After a wave of criticism about the way federal drug regulators are performing their duty, a Supreme Court majority handed down a decisive endorsement of lawsuits in state courts to address deficiencies at the national level. Specifically, lawsuits that claim drugmakers have not given doctors and patients sufficient warnings about side-effects. The six Justices who upheld a verdict of nearly $6.8 million against a major pharmaceutical company have sent a warning to the industry, and to the Food and Drug Administration. The Court has asserted that the FDA, among other measures, needs to police the industry more closely.

Clearly the FDA will likely want to see more transparency in the clinical trial management process.

The life sciences industry faces tough choices for both clinical trial data management and the post marketing studies regarding the development of new drugs and therapies. The future scrutiny of the clinical trial process could lead to a decline in research and development by industry and pulling existing drugs from the market for fear of legal ramifications. At this pivotal moment, the industry can choose either to shy away from innovation, or to take control of its destiny.

The good news, for those who choose to move forward, is that right now, the industry can employ existing technologies to head off potential problems and dramatically reduce risk. By using EDC (electronic data capture), especially in concert with CTMS, companies stand a better chance at discovering hazards as they arise and avoiding costly lawsuits, after the fact. EDC offers protection against future lawsuits over severe adverse reactions or possible complications by empowering both sites and drug companies to view data in real time, at any time, during the study.

Taking Control.

The industry must now conduct research differently to successfully navigate through this new environment. No longer can we hide behind the “we didn’t know” argument. Conducting research differently means achieving a new level of accountability. It means taking control. The Agency holds us accountable, thus our data must remain inviolable.

If we give away too much operational control of a study and the data, we open ourselves to risk. Now, sponsors can take ownership of the data and eliminate the need to rely entirely on CROs. Integrated EDC and CTMS provides complete transparency and control at all times**.**

Real-time EDC provides critical and comprehensive data at all times during the study. Red flags get identified as they arise, not after the fact. Sites can then enact change at the site if necessary, leading to clarifications and/or modifications of protocol as needed, better execution of the study, and improved safety.

Reducing the Risks of Paper-based Methods.

Tracking progress at investigator sites with paper visit monitoring trip reports is time consuming and delays access to critical status information about how the study is progressing. This is information that, if known as it occurs, can prevent adverse results. In this new environment, excuses for missing safety data because of trip report delays will no longer be accepted. EDC with CTMS empowers the site and company to address potential and actual risks as they occur by streamlining and reporting in real time.

Risks of Paper-based methods include:

- Loss of data.
- Risk of paper being physically destroyed, lost, and/or damaged.
- Legibility issues.
- Archival degradation.
- Increase human error.

EDC significantly reduces human error by reducing human interaction with data collection. Paper systems, due to their inherent nature, simply cannot provide the necessary assurances that EDC delivers.

Organizations reticent to the move to EDC need to understand that the required upfront investment is more than offset by the potential damage awards should it be proven that a paper-conducted trial was flawed and missed critical information or that critical information was lost or unattainable.

EDC with CTMS: How it Works.

Employing a synchronized EDC/CTMS system provides a level of transparency that will already be far ahead of anticipated FDA requirements in this new climate. It's important to match a carefully designed CTMS system with an EDC system that has robust functionality. Functionality that helps sponsors to manage, analyze and report many different aspects of a clinical trial.

The synchronicity of EDC properly integrated with CTMS produces a result that is greater than the sum of the parts. These parts include customized databases, eCRF design/review, data validation/verification programming, comprehensive data management planning, ongoing data review and logic checks, laboratory data management, data encoding, reconciliation of serious adverse events, database lock and finalization budgeting, patient management, compliance with government regulations.

The result is a real time, "multi-angle" visualization that enables both the site – and more importantly- the sponsor to gain a holistic awareness of the study as it happens. It is this more complete and novel awareness that nearly eliminates risk, and increases profitability through cost containment and reduced liability. Which, in the end, creates a safe harbor for innovation.

What are the Obstacles?

Obstacles for employing an EDC system are largely based on inaccurate perceptions.

• Perception I: High cost.

Due to the upfront investment required in some EDC systems, many view it as cost prohibitive. In truth, EDC cuts costs through the inherent efficiencies realized at every stage of the study. For example, EDC that allows a study to lock 3-6 months earlier can more than pay for itself. EDC with CTMS can also help to significantly contain costs. For example, if diagnostic budgets are determined and paid based on whether testing actually took place, EDC can verify if tests were actually performed. Differences between stated testing and actual tests completed can be reconciled, resulting in significant cost reduction.

• Perception II: Difficult user experience.

EDC is actually very user friendly - the right EDC system will utilize data entry screens that have the look and feel of traditional CRFs, yet all warnings, including complex cross-panel edit checks fire instantly upon data entry. Site users enjoy the ease of use and speed of eCRF screens.

• Perception III: Painful transition.

Most users find the transition seamless due to the familiarity and ease of use of a thoughtfully constructed, Sponsor-configured EDC system. The key to successfully employing an effective EDC system is focused leadership in training and management. Migration to EDC is successfully navigated only under the experienced leadership of the right dedicated team. This is a key factor, as an EDC system without dedicated management will fall short of optimal functionality.

• Perception IV: Conflicts and/or complications integrating with CTMS.

In actuality, CTMS and EDC, both digital in nature, “talk to each other” very well. Whereas paper-based methods cause a disconnect between the CTMS and the traditional system. A critical disconnect that can lead to missed safety issues. Configured correctly, EDC and CTMS sync seamlessly together, realizing dynamic efficiencies in data analyzation/collection, trial management and budget management.

Take Control.

In a new, volatile environment the pharmaceutical and medical device industry faces a pivotal moment. Now is the time to stand up and take control by continuing to embrace emergent technological innovation and progress.

By moving to 100 percent EDC, companies will better track data, manage study information and, at the end of the day, be better protected against future law suits proclaiming that the study process failed to account for any severe adverse reactions or possible complications. While no system can ensure that new drugs and therapies will be without risk to the patient, EDC is the most available and proven insurance policy organizations can use to go beyond regulations and protect themselves in the future. ◙