Trends and Issues in an Electronic Clinical Data Management World

The Internet, Pharma, and Electronic Data Capture
In the pharmaceutical industry, the emergence and acceptance of Internet-enabled technologies such as electronic data capture (EDC) have transformed clinical development practices, efficiently supporting faster, larger, and more complex trials.

Current industry projections estimate that EDC is now used in approximately 50% of all clinical trials (see Figure 1). Companies are increasingly leveraging EDC and other tools to power global trials and benefit from the ability to analyze incoming data and performance metrics in real time. The availability of such data supports more rapid decision-making and provides the agility to make necessary adjustments during ongoing trials.

With increased adoption of EDC, market expectations for the technology are high. A more technology-fluent user base is demanding richer features, ease of use, and flexibility within trial settings. Global usage also requires high availability and scalability. Furthermore, there is a growing acknowledgement that EDC represents only a subset of the critical aspects of the overall data value chain, highlighting the need for a fully integrated eClinical ecosystem. Such an integration of EDC and other eClinical systems will provide a holistic view across trials and data sources and minimize process and infrastructure redundancies.

In this dynamic environment, EDC and other clinical trial technologies can deliver real fundamental benefits but also continue to introduce new challenges as the eClinical evolution continues. Some of these issues are discussed below.

Changing Roles for Data Management
Data management organizations in particular are front and center in this bold new world. Due to the increasingly prevalent use of EDC coupled with industry outsourcing trends, the role of an ‘in-house’ data manager has changed considerably. Further removed from the daily discrepancy resolution routine, these individuals are now charged with program-level oversight responsibilities, including tracking progress of work being conducted by third-party contract research organizations (CROs), and sometimes across multiple organizations on several studies. While skills in the core data management systems are still vital, better tools are necessary to provide oversight-level data in real time, and productivity and performance metrics are paramount to understanding and measuring this new environment.

Globalization and New Challenges
While ongoing global expansion of trials presents new opportunities, it additionally increases the pressure and demands placed on EDC and IT infrastructure and support resources. The growing prevalence of global site users and outsourcing practices have transformed clinical trials into an around-the-clock operation. This ‘always on’ business model creates a technical support dilemma. Given the 24/7 availability requirements to support the global trial environment, there is no opportune time to schedule maintenance and perform repairs.

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Furthermore, in the event that a technical problem that affects EDC system availability does occur, all sites using the technology platform can potentially be affected. For example, a pharmaceutical company running 300 trials concurrently might, in the worst-case scenario, have to suspend workflow on all trials until access to the system can be restored. Given the staggering implications of this example, companies are focusing on issues such as infrastructure/server redundancy, backups, and failover. With EDC, there is an absolute dependency on IT support and service levels to ensure business continuity running clinical trials. This reality has been an internal hurdle for some organizations seeking to implement EDC, and some organizations have opted to outsource.

Similarly, since EDC use extends to site staff as well as CROs and business process outsourcing providers, the exponential growth of user populations has led many organizations to rethink their EDC support strategies. Both end-user training and ongoing helpdesk support is critical to success with EDC. Vendors are coming into this space specifically to handle initial training, arrange Internet connectivity around the world, negotiate Internet service provider agreements, provision and track hardware when necessary, and provide all-hours helpdesk services in multiple languages.

The advent of EDC enables much earlier data review, and it has also helped advance new trial designs that rely on such early data availability. Complex trials are also being leveraged strategically to optimize resources and productivity given the constrained financial climate, budget cuts, and pressure to run fewer trial programs.

Trial Complexity

Trials have evolved significantly over the past several years. Historically, the traditional trial model followed a natural, sequential pattern in which companies would collect data over the course of the trial, and when completed would lock the database, carry out analyses, and assemble a candidate submission. Clinical trials today, however, are much more complex. The advent of EDC enables much earlier data review, and it has also helped advance new trial designs that rely on such early data availability. Instead of a single analysis after the trial completes, trials today require multiple sophisticated data cuts and ongoing analyses. Availability of data from EDC helps to facilitate such ‘soft-lock’ processes, effectively simulating a subset of the traditional end-of-study procedures with interim data.

This mid-study process can occur multiple times during the trial for safety monitoring boards, submissions, or interim reviews. However, utilizing this sort of rolling lock system consumes more resources than the traditional process. So, while EDC enables resource savings for traditional discrepancy management activities (as projected), this trend for more complex trials and process changes introduces added complexity and new resource demands to support a study.

The use of adaptive trials is also increasing, which requires support for real-time insights and a variety of mid-trial modifications for dynamic response to changing circumstances.

Complex trials are also being leveraged strategically to optimize resources and productivity given the constrained financial climate, budget cuts, and pressure to run fewer trial programs. To meet trial quotas while fulfilling project needs, companies can opt to run multiple studies within a single trial. For example, within a single oncology trial, there may be six separate study populations each based on a different tumor type.
**Data Integration and Interoperability**

EDC is just one aspect of the eClinical ecosystem. There are many systems employed throughout the clinical development process for data acquisition, data analysis, trial management, and reporting. As the volume of data from all sources increases, the need for an intelligent aggregate data storage environment becomes imperative. Oracle has introduced one such system, the Life Sciences Data Hub, that enables access to all trial data from a single location, thus greatly reducing the time and effort required for study reporting milestones while providing the ability to accurately track and reconstruct complete reporting data sets and outputs.

While there are a multitude of available software platforms designed to manage various aspects of clinical trials, most of these disparate systems work independently of one another, unable to communicate or share information. Additionally, sponsor companies may use separate, independent vendors for each IT system, particularly if they seek to employ ‘best-of-breed’ options for every product type. When overlap does exist between applications but identical data must be entered into them independently, the issues of redundancy and inefficient use of both time and resources are compounded.

Going forward, interoperability will be a key factor in realizing maximum possible results using eClinical systems. While there are a multitude of available software platforms designed to manage various aspects of clinical trials, most of these disparate systems work independently of one another, unable to communicate or share information. Additionally, sponsor companies may use separate, independent vendors for each IT system, particularly if they seek to employ ‘best-of-breed’ options for every product type. When overlap does exist between applications but identical data must be entered into them independently, the issues of redundancy and inefficient use of both time and resources are compounded.

Going forward, interoperability will be a key factor in realizing maximum possible results using eClinical systems, allowing records to be linked and shared, and eventually improving efficiency and reducing overall costs. Industry standards will evolve to make disparate platforms interoperable and less proprietary. Oracle is working toward this objective by developing the Health Sciences Suite platform, a fully integrated suite of best-in-breed eClinical applications that will also be able to extend to applications from other vendors.

**The Road Ahead**

The industry is changing more rapidly than ever before and organizations across the pharmaceutical spectrum are dealing with many of the issues discussed herein. This report features contributions from leaders of some of the organizations working at the forefront of the EDC movement. These authors describe their organizations’ experiences of working with Oracle’s EDC solution, Remote Data Capture (RDC), and provide insights into related challenges, successes, and lessons learned.

Robert Goodwin, Pfizer

As the world’s largest pharmaceutical company, the way in which Pfizer implements and handles the running of full-scale EDC will be a touchstone for other companies in the industry. Robert Goodwin, Vice President of Global Clinical Data Services, talks about the role of technology when working with many different kinds of partners, including investigators, technology vendors, and CROs, in collaborating to run complex, global clinical trials.

James Streeter, PPD

The CRO is now a critical link enabling pharmaceutical firms to run large, intricate clinical trials as efficiently as possible in many locations around the world. James Streeter, Executive Director of EDC, talks about the pressures on a CRO to ensure that staff are properly trained and supported to keep pace with the high-pressure, fast-moving clinical trial environment.

Dave Hanaman and Rob Vollkommer, C3i

Technology is the enabler, but who empowers people to use it? Step forward technology service company C3i, which works to ensure that clinical trial staff have access to the right equipment when they require it, have the requisite knowledge to get the most out of it, and have support on hand for when they need it.

We extend our sincere appreciation to our contributors for sharing their valuable insights and experiences in this report. The eClinical transformation offers a chance to maximize the value of clinical trials, improving pharmaceutical development efficiencies and ultimately providing patients with timely, new, and improved treatment options.

We have seen significant progress to date and tremendous opportunities lie ahead. Companies of all types and sizes must respond to the pressures the industry is facing, trim operating expenses, and establish cost-effective and efficient working practices. It is critical to weigh technology investments against both short- and long-term objectives. Oracle is committed to the health sciences market and is uniquely positioned to deliver a full-spectrum, comprehensive solution.

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Although there will be short-term challenges to overcome in the process of continuously adapting to new technologies and gaining acceptance of new ways of working, we hope that this report will resonate with those professionals who are helping to lead the way through the eClinical landscape toward a complete, open, and integrated clinical trials ecosystem.

We look forward to your thoughts and feedback.