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TECHNOLOGY IN CLINICAL TRIALS
AN EVOLVING INDUSTRY

The conclusion of the 2004 Drug Information Association (DIA) meeting provides an opportunity to reflect on the current status of technology in clinical trials. The content of the scientific sessions, as well as the number and distribution of technology companies in the exhibit hall, provides valuable insights into the state of our industry.

I continue to believe that the bio/pharmaceutical industry, and clinical drug development in particular, lags most other industry sectors in leveraging information technology (IT) to increase productivity. On the other hand, growing economic pressures within the industry are forcing more intense focus on improving processes. This year's showing of technology at the DIA evidenced signs of maturation. Some degree of consolidation was apparent, particularly in the electronic data capture (EDC) space. There were no new "disruptive" technologies apparent on the horizon. Instead, there was more of a focus on the practical application of technologies with considerably less hype than in some of the recent annual meetings.

PREVALENT TECHNOLOGIES

Some of the areas where technology companies were most prevalent included EDC, electronic document management systems (EDMS), clinical trial management systems (CTMS), safety/pharmacovigilance systems, electrocardiogram (ECG) processing, electronic patient reported outcomes (ePRO) solutions, interactive voice response systems (IVRS), medical imaging, and patient recruitment. Overall, there seems to be a trend toward practicality, with less "technology for the sake of technology." Buyers generally appear better informed and have clear drivers behind their technology decisions. All of the technology applications mentioned above are ones that are either readily justifiable by return-on-investment (ROI) analyses or where there are significant regulatory drivers. EDC, EDMS, ePRO, CTMS, IVRS, medical imaging, and patient-recruitment solutions all have strong business cases for how they can streamline clinical-trial conduct, improve efficiencies, support study workflow, and/or enable more effective decision making. EDMS, ECG processing, medical imaging, and safety/pharmacovigilance systems, among others, have important regulatory drivers.

While it is not possible in the scope of this brief commentary to provide a detailed analysis of the drivers for the use of each of these technologies, an example may be informative. Medical imaging is a technology application that falls into both categories. Regulatory authorities, such as the Food and Drug Administration, are increasingly accepting and/or requiring the results of medical imaging studies, such as X-rays, computed tomography (CT), and magnetic resonance (MR) imaging, to evaluate drug safety or efficacy as part of submissions. As a specific example, if a sponsor company wants to claim that a new drug has a disease-modifying effect on rheumatoid arthritis, FDA guidance requires that this be demonstrated using imaging. Historically, this has consisted mainly of conventional radiographs of the joints in the hands and feet. But it turns out that X-ray changes occur slowly in the hands and feet, perhaps over periods of one to two years. Using newer imaging modalities, such as contrast-enhanced MR imaging, it may be possible to demonstrate changes more rapidly, perhaps in a matter of weeks or months. While newer imaging approaches may be less acceptable to the FDA as surrogate endpoints, the results of such analyses may be used by companies for internal decision making. The ability to make better, earlier portfolio-management decisions offers the potential for significant cost savings; hence there is the potential for a compelling ROI independent of regulatory considerations.

GENERAL TRENDS

The trend toward practicality is indicative of an evolving and maturing industry. While technology features and functionality are clearly important, there is growing awareness of issues related to implementation, training, validation, and other aspects of deployment. Technology buyers are more closely attuned to total cost of ownership, and there is downward pressure on maintenance fees associated with software packages. In general, this appreciation for cost of ownership seems to be leading to greater degrees of software purchasing/outsourcing rather than internal development. On the other hand, for reasons that are not entirely clear, certain sponsor companies continue to undertake major internal software development activities. For certain technology-based services, such as IVRS, ECG, and imaging, sponsors have established specific outsourcing functions. This is indicative of the increasing use and importance of certain technology-based services.

Another trend is the increased appreciation for the importance and value of integrating the various technology solutions used within a bio/pharmaceutical company. This has the potential to increase efficiencies, improve trial management, and accelerate workflow. Presently, there is considerable redundancy in the data contained in the many systems within a bio/pharmaceutical company. As an example, the contact information associated with an investigator site may reside within an investigator database, CTMS, safety system, EDC/data-management system, and IVRS. But if these systems are maintained as independent silos, then corrections in one system will not be propagated to other relevant systems. The result is the need for repetitive data entry and cross-system reconciliation. Meaningful savings should be possible by eliminating redundant data entry and data-cleaning activities.

ELECTRONIC DATA CAPTURE

Of all the technologies, none causes more consternation for pharmaceutical companies than EDC. This can be attributed to a number of factors, including early unsuccessful experiences, unrealistic expectations, failure to consider implementation issues, technology shortcomings, and vendor challenges. Perhaps most importantly, many companies failed to modify their processes in a way that allows the potential of the technology to be beneficially leveraged. This has been the largest area of consolidation, not surprising given the rush of companies to exploit this opportunity several years ago. Nonetheless, several pharmaceutical companies claim significant success with broad implementations of EDC, Novartis among them. From a technology perspective, I believe that there will be a continued convergence between EDC and the core data-management systems that are used by pharmaceutical companies. If correct, this would imply a shrinking pie for pure play EDC technology/service companies.

VIEW TOWARD THE FUTURE

I believe that the penetration of technology into clinical-trial conduct will grow and that applications will continue to mature. Technology adoption cycles will be driven by regulatory and financial considerations, but it is likely that these cycles will be shorter in the future given the growing pressures on bio/pharma companies to increase efficiencies. Sponsor companies will seek greater levels of systems integration so that the return on technology investments can be maximized. One of the likely side effects of this focus on integration will be further consolidation on the technology provider side of the industry, as sponsors seek more fully integrated solutions. Systems will emphasize workflow as process improvements are more tightly coupled to technology innovations. If technology gets too far ahead of process modifications, then the risk of disappointment is greater. A more virtuous cycle is created when processes are analyzed and re-engineered in conjunction with technical innovations.

There continue to be significant opportunities for companies to leverage IT to improve their development processes. The result should be earlier identification of issues, faster interventions, better decision making, more efficient trial conduct, better informed portfolio management, and overall improvements in the time and cost required to bring a new product to market. There will undoubtedly continue to be novel innovations in the use of technology in trial design, conduct, and management. At present, however, there are numerous practical opportunities to take advantage of existing and proven solutions.

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