GREGG DEARHAMMER
Kendle International Inc.

Kendle is embracing the new standard format in a variety of ways. Most importantly, we are using CDISC standards as our programming defaults and have trained all relevant programming, statistical, and clinical data management associates on the CDISC standards.

KATHRYN ROY
Phase Forward

We are committed to promoting standards and incorporating CDISC data interchange models into the functionality of our product suite.

to manage multiple product types and will need to adopt a new business model that requires changes at every stage in the value chain. This model will not only affect their critical operations but it will also entail new ways of performing daily activities, such as accounting, human resources, and IT.

SHANAHAN. The industry should take lessons learned from other science-based industries, such as the semiconductor, automotive, and aerospace industries. Those science-based industries have adopted formal, modeling software applications, and the result has been a dramatic increase in collaboration, automated analytics, and more informed planning. The pharmaceutical industry still depends on paper notebooks, passive pictures of systems biology, and verbal communication of research goals and results. The complexity of the research problems and the development of new automated platforms will demand a revolution in scientific methodology.

SHEAIL. Roche has learned that a key to successful alliance management is to help our partners develop as entrepreneurial, independent companies. Today, biotech companies expect and deserve more of a role in the management of alliances. We encourage our partners to get involved at every stage of the alliance, from early development through clinical trials to the marketplace. By transforming our partnerships into true strategic alliances, we will continue to expand deals with existing and new partners ultimately bringing new drugs to market. Today, alliances between small biotech companies and large pharmaceutical companies are helping to balance the risks of drug discovery and are providing biotech companies with the resources as well as the expertise they need to advance projects aggressively.

CDISC STUDY DATA TABULATION MODEL

B. THOMPSON. We are carefully reviewing the new Study Data Tabulation Model (SDTM) to ensure that our company is doing everything possible to streamline submissions of data to the agency. It should be a goal of companies and the agency to find and implement greater efficiencies to shorten the time to market for important new therapeutics.

DEARHAMMER. Kendle is embracing the new standard format in a variety of ways to ensure the highest quality data management

THOUGHT LEADERS

centered marketing campaigns that focus on driving consumer behavior through educationally relevant strategies and tactics. For more information, visit healthed.com.

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solutions for our customers. Most importantly, we are using CDISC standards as our programming defaults and have trained all relevant programming, statistical, and clinical data management associates on the CDISC standards. Other efforts include working with our customers to accept or adopt CDISC, SDTM, and ADAM (active directory application mode) as their programming standards; working with clinical labs to transfer data using the CDISC LAB model; setting up a global work group with members from all relevant departments to review how well CDISC is working on current projects; and identifying, programming, and validating SAS programs to increase efficiencies.

ROY. We are committed to promoting standards and incorporating CDISC data interchange models into the functionality of our product suite. Phase Forward is a CDISC partner and is working closely with the organization. We have developed a CDISC compliant sample study protocol in our Clintrial Clinical Data Management System (CDMS) that can be used to facilitate CDISC compliance.

DRUG DEVELOPMENT

BOILY. Developing a drug is like walking on a tightrope blindfolded. Drug development takes between 10 years and 15 years and costs upward of $800 million per drug, yet only 8% of all drugs in development ultimately receive FDA approval, according to FDA Commissioner Lester Crawford. New financial models will be required to share the significant costs and associated risks involved in bringing new drugs to market.

CAUWENBERGH. The increased investment in R&D at the private and public side is an illusion. It is true that more money has been spent in those departments. The increased spending, however, primarily has covered increased overheads. Why is it that the fully loaded cost of a full-time equivalent (FTE) is about $100,000 per year lower in small pharma compared with big pharma? Watering the lawn and feeding the ducks in the pond also costs money and the overall cost of a heavy corporate overhead structure in big pharma contributes significantly to the difference. The increase in spending is in part also justified by the increased costs in areas such as regulatory, QA, compliance, legal costs, and IP protection. The FDA looks at fewer NDAs because big pharma submits fewer NDAs. That is because the financial machinations that go behind a development decision look at constantly increasing NPV requirements because of increasing internal costs: overheads. Drugs that take seven years to complete development and that have annual sales potential of $400 million don't make the cut in big pharma. To overcome these obstacles, companies need to question the relevance and validity of some of the regulatory interferences. They also need to stimulate controlled patent life extensions. Why is it that Mick Jagger (or his relatives) continue to get author right payments on "I Can't Get No Satisfaction" for a period of 50-plus years, whereas scientists see the time span they have to profit from their brain child reduced to less than 10 years as a result of extended development times? Patent life extensions could be considered in lieu of accepting price control measures after the initial patent

STRONG CLINICAL-TRIAL MANAGEMENT SYSTEMS MARKET OFFERS OPPORTUNITIES FOR SUPPLIERS, CLINICAL SPONSORS, AND CROS ALIKE

The U.S. clinical-trial management systems (CTMS) market is poised for steady growth through 2008, achieving a five-year compound annual growth rate (CAGR) of about 13%, a new research study from Life Science Insights reveals. Analysts expect the market for CTMS software licenses to grow during the same forecast period, from $193 million to $360 million.

While component technologies, such as EDC, play a major role in these markets, systems designed to manage multiple aspects of clinical-trial management will drive adoption of CTMS among pharmaceutical and biotechnology companies.

For similar capabilities, such as automating trial processes, increasing the efficiency of trials, and managing operations better, academic and government institutions will look to CTMS. According to the study, CROs will select applications providing a complete range of functions that these organizations can use to create greater efficiencies for outsourced clinical trials.

Life Science Insights' study, U.S. Clinical Trial Management System 2004-2008 Forecast and Analysis, illustrates that clinical-trial sponsors will increasingly seek to optimize the clinical-trial process by moving to fully functional CTMS. Successful providers will mature their systems with cross-functional features able to meet growing integration needs. Additionally, providers must offer sponsors the opportunity to save in management costs with a lower total cost of ownership compared with homegrown, disparate systems. Providers able to deliver these applications at lower prices could turn the tables on current market leaders.

Suppliers must offer sponsors the opportunity to save in management costs with a lower total cost of ownership compared with homegrown systems.

"The market for CTMS is still relatively immature," says Judy Hanover, research analyst. "Current market leaders cannot afford to become complacent as this market evolves because leadership and market-share positions remain in flux."

Source: Life Science Insights, an IDC company, Framingham, Mass. For more information, visit life-science-insights.com.

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