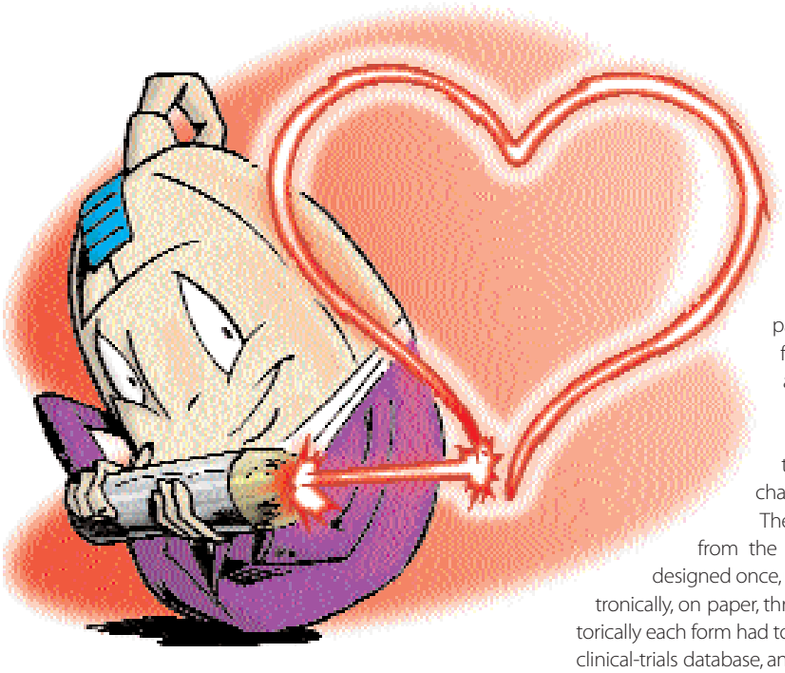

Oracle's RDC to **SPEED DATA COLLECTION IN CLINICAL TRIALS**

Oracle's latest release of Clinical Remote Data Capture (RDC) features advances in usability, form design, and support for clinical trials. It provides the staff at doctors' offices and hospitals with an integrated Web interface for entering patient data directly into a complete clinical-trials database.

The release extends the solution's capability by integrating Adobe Portable Document Format (PDF) forms technology, allowing the data to be collected in page layouts that are identical to the conventional paper forms. As each page of data is submitted, it is validated against Oracle Clinical Data Management system, and the user is notified immediately of any data problems. Any problems can then be corrected quickly and electronically, with the system keeping a full audit trail of any changes, as required by the FDA's CFR Title 21 Part 11.

The solution's integrated layout tool presents a change from the earlier version in that forms for data collection are designed once, regardless of whether the data are to be collected electronically, on paper, through batchload, or any combination of the three. Historically each form had to be defined three times — once on paper, once for the clinical-trials database, and once for the RDC tool. Once a study is complete, the data may be converted to PDF, providing both a certified copy of the data for the doctor and a record of the source data for the eventual submission. This is a critical feature because all original clinical data must be included in regulatory submissions, and the FDA expects submissions in PDF.

The RDC application also includes the ability to design and deploy adobe PDF forms in Japanese and to translate the Japanese data into English.

Pfizer, which cosponsored the development of this new release, has taken a license for use with future clinical trials.

"The new release of Oracle Clinical RDC automates study design, data collection, data management, and regulatory submissions, using an architecture that can scale to handle hundreds of studies per year," says Keith Howells, VP of Oracle's pharmaceutical applications group.

Lilly Enhances **E-DETAILING WEBSITE**

Eli Lilly has added more robust content and a more user-friendly format to LillyConnect.com, a multibrand, interactive Website with e-detailing capabilities that gives healthcare professionals instant access to in-depth product and disease information.

LillyConnect.com delivers information by integrating the Internet with traditional sales activity for Strattera, Evista, Prozac Weekly, Humalog Mix75/25, Humalog, and Humulin. Information about other Lilly products is expected to be added to the site in the future.

To access LillyConnect.com, healthcare professionals register with the site to receive personalized Lilly product and disease-state information for their area of interest and specialty. All content is password protected.

The reformatted LillyConnect.com offers improved navigation and content areas for product and disease-state information, assessment/diagnostic tools physicians can use with their patients, as well as interactive, self-directed informational presentations that describe a product's use and efficacy.

The Website also provides access to additional product and disease-state Webcasts and audio presentations.

In addition to clinical, product, and disease-state information, the site also offers patient-education materials that healthcare professionals may print to give to patients during office visits, Lilly product safety and prescribing information, Lilly patient assistance information, links to professional meetings and continuing medical-education courses, and access to clinical-trial information and medical society Websites.

Insightful Upgrade Provides Platform **FOR VALIDATED STATISTICAL DATA ANALYSIS**

Insightful has released S-PLUS 6.2, an upgrade to the company's statistical data-analysis software. The latest release provides users with enhanced performance, reliability, and validation capabilities for analysis of data in production environments.

The upgrade's new batch processing and verbose logging capabilities provide a platform for validated statistical data analysis in production and regulated environments. These capabilities will benefit data managers in the pharmaceuticals industry who require validated statistical software support systems for researchers and decision-makers to comply with regulations, such as 21 CFR 11.

The upgrade's batch processing and verbose logging capabilities provide a platform for validated statistical data analysis in production and regulated environments.

Verbose logging gives users comprehensive logs of computational processes providing a detailed audit trail. New XML-based reporting allows developers to build predefined reports in HTML, PDF, or RTF formats to meet regulatory specifications.

"Demand for business analytics is growing as business leaders demand better intelligence to make more profitable decisions," says Dan Vesset, research manager, analytics and data warehousing at Insightful. "Companies are integrating business analytics into their information systems to improve the quality of information delivered to key decision-makers making essential risk/reward decisions. Insightful is well-positioned to meet this demand with the launch of S-PLUS 6.2 with greater integration, industry-leading analytics, and better reporting capabilities."

The upgrade can be fully integrated with the S-PLUS product family, including S-PLUS server products for deployment of analytics to large numbers of users; Insightful Miner, a data analysis workbench; and vertically-focused modules such as S+ArrayAnalyzer for statistically robust microarray data analysis in the biopharm market, and S+Finmetrics for advanced econometrics aimed at the financial market.

Camstar Extends Life-Science Manufacturing Execution System **TO PHARMACEUTICAL INDUSTRY**

Camstar has released an edition of its integrated manufacturing and quality solution specifically designed for global pharmaceutical companies. The InSite Pharmaceutical Edition includes a visual master batch record (MBR) process modeling environment that allows process specialists to create, modify, and validate new process specifications in single or multiplant environments.

Camstar's patented revision management capability allows multiple revisions of a single base MBR to be simultaneously active in production.

Camstar's patented revision management capability allows multiple revisions of a single base MBR to be simultaneously active in production. In addition, the system automatically compiles an electronic batch record (EBR) that provides traceability of the final product back to every plant, machine, batch, order, operator, supplier, ingredient, and operating condition encountered or consumed in production. The integration of Camstar's enterprise corrective and preventive action (CAPA) functionality coordinates the company's response to deviations and ensures that a fully auditable record of corrective actions is also included in the EBR. In addition, Camstar provides prebuilt integration adapters for SAP, JD Edwards, Oracle, and PeopleSoft ERP systems for rapid implementation and return on investment.

MRO Software and Stelex Alliance to **HELP MANAGE PRODUCTION COMPLIANCE SOLUTIONS**

An alliance between Stelex and MRO Software is expected to provide industries subject to FDA regulation with a cost-effective, risk-based validation approach to managing production and compliance.

Through the alliance, the companies will provide a complete solution for FDA-regulated customers based on MRO Software's strategic asset management solution, MAXIMO 5 Pharmaceuticals, and Stelex's Common Sense Compliance Approach. The combination of Stelex's domain expertise and MRO Software's services and solutions will help customers implement solutions to improve business processes and help to meet the regulatory requirements of the life sciences and other industries regulated by the FDA.

MRO Software currently provides asset management solutions for the top 13 pharma companies.

Follow up

CAMSTAR SYSTEMS INC., Campbell, Calif., provides enterprise manufacturing performance management systems for life sciences, semiconductor, electronics, and other global industrial manufacturers. For more information, visit camstar.com.

INSIGHTFUL CORP., Seattle, provides enterprises with scalable data-analysis solutions that drive better decisions faster by revealing patterns, trends, and relationships. For more information, visit insightful.com.

ELI LILLY AND CO., Indianapolis, is an innovation-driven corporation that is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. For more information, visit lilly.com.

MRO SOFTWARE INC., Bedford, Mass., is a provider of e-business solutions for strategic asset management. For more information, visit mro.com.

ORACLE CORP., Redwood Shores, Calif., is an enterprise software company, whose life-sciences division offers solutions for discovery, clinical trials, manufacturing, and sales and marketing. For more information, visit oracle.com.

STELEX, Bensalem, Pa., a subsidiary of Vital Signs Inc., is a consulting firm providing enterprisewide compliance solutions to regulated industries in the pharmaceutical, medical-device, diagnostic, and biotechnology sectors. For more information, visit stelex.com.