ClinChain Updates **CLINICAL SUPPLY-CHAIN SOFTWARE**



Clinical supply-chain professionals need new, flexible systems to meet the challenges of constant change. short timelines, and regulatory compliance, within the realities of shrinking budgets and implementation time limits, says Patti Isaacs-Hansen. President and CEO of ClinChain Inc.

ClinChain Inc. has launched Plenish version 3.2, the latest version of its clinical-supply inventory tracking and documentation software.

A fully validated, 21 CFR Part 11 compliant software, ClinChain Plenish facilitates all clinical-trial drug-supply activities, such as material receipts, manufacturing requests, primary and secondary packaging requests, site distributions, drug returns, and destructions. Sophisticated data inheritance rules and interrelated drop-down menus are used to minimize user input and ensure data integrity.

The system is designed to be configured within a few days to accommodate client-specific tasks, data fields, and reports. The system architecture also allows new functionality to be added or changed quickly to address special needs, such as user-specific privileges, automatic assignment of initial statuses. drug-shipment restrictions based on

expiration dates, unique data-integrity checks, and automatic e-mail generation.

ClinChain Plenish provides enterprise features, including multi-user client/server architecture, genealogy tracking across any level of conversion, flexible data-querying capabilities, and a reporting

Since the system uses a standardized database, security and data integrity are well established. Integration with other databases and third-party software can also be set up as needed, and on-site personnel can maintain and configure the system.

GE Healthcare Launches LABORATORY ASSETS SYSTEM

GE Healthcare has introduced Scientific Asset Services, a laboratory asset services offering that can save pharmaceutical and biotechnology companies up to 20% of their total service costs and optimize service operations.

Scientific Asset Services provides R&D labs with single-service coverage and advanced tracking technology of assets that are manufactured by a variety of companies

As pharma and biotech firms face mounting cost pressures, this offering helps drug developers save money by

enabling them to use R&D assets with the maximum effectiveness and costefficiency. By working with one service provider — instead of with perhaps

up to 100 — lab managers simplify their service operations and enable their staffs to focus on the core business. Also, proprietary GE technologies help lab managers track maintenance costs in detail, finetune service practices, and support sound equip-



Ours is a total asset management approach. Service management is centralized, allowing the customer to access critical data instantly and use it to maximum advantage, says Nick Padula. General Manager of Services for the Life Sciences Business of GF Healthcare

ment purchasing and replacement decisions.

GE's Scientific Asset Services includes the following technologies:

- · AssetPlus asset and maintenance management, which records maintenance activity, condition, operating history, and other data from all devices on a single database, enabling easy access to key management metrics.
- IntelliMotion asset tracking, which uses radio-frequency identification (RFID) to monitor the location and maintenance status of individual devices.
- · BiolnSite remote monitoring, by which GE tracks equipment over secure broadband connections, detecting and often fixing issues without a service technician visit.

"Ours is a total asset management approach," says Nick Padula, general manager of services for the Life Sciences business of GE Healthcare. "We inventory all equipment, set it up in a database, and help laboratory man-

agers keep detailed maintenance records. In the long run, they get a clear picture of the total cost of ownership for each device. Service management is centralized, allowing the customer to access critical data instantly and use it to maximum advantage."

IFPMA Upgrades CLINICAL-TRIALS PORTAL

To improve public access to pharmaceutical industry clinical-trial data, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has launched the second stage of the IFPMA Clinical Trials Portal, at ifpma.org/clinicaltrials. Developed in conjunction with IBM Corp., the portal is the first Internet search engine constructed to link to online information about ongoing and completed clinical trials sponsored by research-based pharmaceutical companies worldwide.

In line with the pharmaceutical industry's commitment to increase the transparency of clinical trials, this latest development focuses on helping more people to use the IFPMA Clinical Trials Portal and making it an easier unique locator for them to use. IFPMA and IBM have made it possible for users to input search criteria for clinical trials in German, French, Japanese, and Spanish, as well as English. Additional languages will be considered later.

"We have improved the search facility so that it suggests synonyms for medical conditions and helps to correct misspelled words, including the names of medicines," explains Dr. Harvey E. Bale, director general of the IFPMA. "With the Stage 2 development, the Portal's reach is greatly extended, because it now searches for trials corresponding both to the term entered by a layperson and its synonyms."

The upgraded portal also makes it easier to perform multiple criteria searches and allows searches to be qualified by geographical area.

The amount of clinical-trial information accessible via the IFPMA Clinical Trials Portal has increased significantly. The Stage 1 Portal, launched in September 2005, indexed about 26,000 individual pages. The Stage 2 Portal already indexes more than 88,000 pages. The number of sites that post clinical-trials information to which the Portal links also has increased, from 10 sites when launched to 15.



IFPMA's Clinical Trial Portal allows users to more easily find trials in the area where they live and in the disease that interests them, says Dr. Harvev E. Bale. Director General of the International Federation of Pharmaceutical Manufacturers and Associations.

3i Infotech Introduces ELECTRONIC PEDIGREE SOLUTION FOR PHARMACEUTICAL SUPPLY-CHAIN COMPLIANCE

Through its modular design, Orion
Pedigree can cater to a diverse set of business scenarios and is fully compatible with current RF and RFID technologies.

3i Infotech Ltd. has launched the Orion Pedigree solution for the pharmaceutical industry.

The new solution enables pharmaceutical companies to comply with the pedigree requirements as mandated at the

federal and state levels.

A stand-alone, off-the-shelf solution, Orion Pedigree delivers rapid compliance without major modifications to current systems and offers a scalable foundation to enable companies to address future legislative requirements. By implementing this application, participants in the pharmaceutical supply chain can track drug information and provide quality assurance to customers, ensuring the authenticity of their drug products.

Through its modular design, Orion Pedigree can cater to a diverse set of business scenarios and is fully compatible with current RF and RFID technologies.

This comes at time when Florida state has mandated that drug pedigrees will become effective later this year and as the FDA is currently undergoing a phased-in approach to RFID and electronic pedigree by 2007.

"3i Infotech is pleased to be one of the first few select software vendors to offer pedigree compliance for the pharmaceutical industry," says Sharad Vajpayee, VP of 3i Infotech.

iAdvantage Releases CLINICAL-STUDY SOLUTION

iAdvantage Software Inc. has released its Web-based eStudy management software as a hosted solution.

"Small to midsized pharmaceutical companies and contract research organizations want to transition to electronic study management (eSM) systems to improve data communications and increase productivity, but at their own pace," says Dr. Fate Thompson, president and CEO of iAdvantage. "All want full functionality with global access 24/7."

Hosted eStudy clients have full access to a Web-based study-management solution that includes study design, e-notebook design, data collection, data analysis, and data reporting.

Additionally, pharmaceutical companies and CROs are supported by globally recognized back-end training and network operation centers to manage data storage, security, redundancy, and auditable validation with training and full help-desk support.

"Hosted eStudy offers clients a fully integrated solution under a monthly service plan eliminating up-front software site-license fees, software installation, additional IT hardware, and personnel expense, yet includes secure off-site hosting, support, and training on all of the functionality of eStudy," says Larry Laws, VP of sales and marketing for iAdvantage.

In related news, the company also has launched ePublisher, a report generator from its Web-based eStudy management solution, as a stand-alone product.

Customized, on-demand, ad-hoc, and comprehensive reports can be generated with ePublisher from synthesis and discovery through preclinical/clinical and throughout the manufacturing process.

Reporting has long been a stumbling block in the life-sciences industry. Most tools are cumbersome to use, limited in capability and flexibility, or are under IT rather than user control for creation of and changes to report templates.

With ePublisher the user has on-demand control to design templates and to generate reports directly into the word processing or spreadsheet software of their choice. Report templates are available for reuse and sharing. ePublisher extracts data from Oracle and SQL databases.

"The ePublisher tool is a milestone advancement in a critical bottleneck confronting life-science research and development," Dr. Thompson says. "Ease of use, user control, and speed of reporting are hallmarks of this powerful tool, of which the ultimate benefit is real-time business intelligence and the reduced time-to-market impact it can have on the drug-development life cycle."

According to Mr. Laws, the tool reduces report generation from weeks to minutes. Users simply point ePublisher to the data source, select the data set of interest, select the desired report template, and click generate report. The report may contain single data points, text, tables, and images.

"The creative look and feel of the report includes all the functionality of the output source selected," Mr. Laws says. "Reports are generated to software that users are familiar with, including Word, Word Perfect, or other word-processing software; Excel; or PDF for review, and revisions can be sent directly to a document management system."



The hosted eStudy solution was created to empower small to midsized pharmas and CROs with the same functionality, security, and support our larger clients are used to, says Dr. Fate Thompson, President and CEO of iAdvantage Software Inc.

Skyscape Launches MOBILE VERSION OF THE HARRIET LANE HANDBOOK

Skyscape Inc. has launched an updated mobile version of The Harriet Lane Handbook, featuring exclusive interactive flowcharts, built-in medical calculators, and integrated pediatric drug dosing tools.

For more than 50 years, The Harriet Lane Handbook has been the pediatrician's reference book of choice, offering diagnostic and management guidance, recommended tests, and comprehensive therapeutic and drug formulary information.

The new Skyscape version, for use on handheld PDAs and smart phones, integrates a host of interactive tools that help ensure healthcare providers

make accurate and confident decisions at the point of care.

The new tools, available exclusively in the Skyscape version of the handbook, include almost 600 built-in, weight-based drug dosing calculation tools. There are also new interactive flowcharts that transform complex algorithms and protocols from static images into dynamic step-by-step decision support tools, more than 100 full-color images to illustrate and bring content to life, built-in medical calcula-



Mobile technology is revolutionizing the medical field, enabling medical-care professionals to provide better quality care for more patients while reducing the opportunity for errors, says Sandeep Shah, Founder and CEO of Skyscape Inc.

tors that provide instant access from within relevant topics, and Skyscape's patented smARTlink to easily cross-index handbook entries with any of its more than 300 medical-reference titles.

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Skila Introduces COMPETITIVE INTELLIGENCE SOLUTION



We feel that iIntelligence can give pharmaceutical companies a strategic and competitive advantage in a rapidly changing global market, says Moish Tov, CEO of Skila.

Skila has launched iIntelligence, a next-generation solution for optimizing sales and marketing effectiveness. Developed specifically for the pharmaceutical and life-sciences industries, iIntelligence enables global organizations to effectively manage competitive intelligence and more quickly leverage data for more strategic decision making.

ilntelligence helps organizations proactively monitor competitive intelligence, collecting information from external sources and from an organization's own internal network.

Skila's pull-through services help to facilitate communication and collaboration among individuals and teams, pushing relevant information in front of key decision makers. Intelligence briefs and red alerts delivered with brand implications allow managers to quickly assess situations and transform information into action. By integrating competitive intelligence into brand-management workflows, stakeholders at every level of the organization can make informed, strategic decisions.

The early-warning mechanisms that ilntelligence employs enable even large organizations to remain flexible. iIntelligence also provides the necessary infrastructure and support services to capture and retain organizational knowledge and promote best practices on both a local and global scale.

"Research shows that 70% to 80% of competitive intelligence can be found within one's own organization," says Moish Tov, CEO of Skila. "We feel that ilntelligence can give pharmaceutical companies a strategic and competitive advantage in a rapidly changing global market."

S&R Releases E-MAIL MANAGEMENT SYSTEM



iRelate integrates seamlessly with clients' current marketing initiatives and lets them track the results of their interactions, says Steve Friedman, Senior Director of New Services at S&R Communications Group.

S&R Communications Group has unveiled iRelate, a new offering in its online communications portfolio.

iRelate is a permission-based e-mail management system for group mailings, allowing clients to

customize messages and target them to specific market segments. The service is designed to create a one-to-one relationship between a company and its client base, enabling e-mail distribution management, advanced e-mail tracking, and real-time delivery statistics.

"iRelate gives our clients better management of their customer communications, and its advanced targeting capabilities help to create better quality relationships," says Steve Friedman, S&R's senior director of new services.

GeneGo and XB TransMed Provide INTEGRATED SOLUTIONS FOR TRANSLATIONAL RESEARCH

GeneGo Inc. and XB TransMed Solutions have integrated their flagship products, MetaCore and XB-BioIntegration Suite, to launch XB-BIS. XB-BIS fulfills the need in translational medicine for efficient data capture, management, analysis,

Mutual customers can capture, manage, and mine integrated clinical, preclinical, and molecular data in its various forms.

and reporting in an intuitive workflow that resembles the natural translational path from early hypothesis generation to validation and application in the areas of clinical diagnostics and intervention. In addition, customers can functionally analyze the associated results in the context of biological pathways, networks, cellular processes, and disease networks.

"Understanding the differences of drug effects on individual patients is a very challenging task, which requires state-of-the-art tools in both translational medicine and functional data mining," says Julie Bryant, VP of business development at GeneGo. "Over the past year, we have witnessed an increased demand for systems biology solutions from the clinical-trial market. We are very pleased to join forces with XenoBase inventors Dr. Craig Webb and Dr. Jerry Miller at the Van Andel Institute to develop analytical workflows for the clinical environment."

Follow up

31 INFOTECH LTD., Edison, N.J., is a global provider of information-technology solutions. For more information, visit 3i-infotech.com.

CLINCHAIN INC., New Castle, Del., provides clinical-supply software and management services to the pharmaceutical industry. For more information, visit clinchain.com. **GE HEALTHCARE**, Chalfont St. Giles, United Kingdom, is a unit of General Electric Co. that provides transformational medical technologies to enable healthcare providers to better diagnose and treat cancer, heart disease, neurological diseases, and other conditions. For more information, visit gehealthcare.com.

GENEGO INC., St. Joseph, Mich., develops systems biology technology for life-sciences

research. For more information, visit genego.com.

IADVANTAGE SOFTWARE INC., Cary, N.C., provides electronic study management software for development and preclinical life-sciences studies. For more information, visit iadvantagesoftware.com.

THE INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS (IFPMA), Geneva, is a global nonprofit, nongovernmental organization representing research-based pharmaceutical, biotech, and vaccine companies, as well as national industry associations in developed and developing countries. For more information, visit ifpma.org.

S&R COMMUNICATIONS GROUP, Durham,

N.C., is a full-service healthcare marketing and communications company. For more information, visit srcomgroup.com. **SKILA**, Morris Plains, N.J., develops best-in-class, knowledge-driven management solutions for the

management solutions for the pharmaceutical industry. For more information, visit skila.com.

SKYSCAPE INC., Marlborough, Mass., offers a library of trusted, evidence-based decision-support tools for handheld devices. For more information, visit skyscape.com.

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