Clinical Ink Launches WEBSITE, PLANS PRODUCT RELEASE
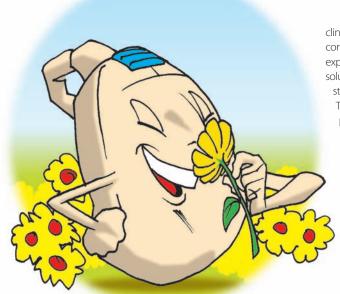
Clinical Ink has introduced clinicalink.com, a Website that provides corporate information and detailed explanations of the Clinical Ink eSource solution for the electronic capture and storage of data during clinical trials. The company also has announced plans to release in June version 1.0 of its eSource solution.

Clinical Ink's eSource consists of tablet PCs running proprietary software that allows data entry on customized documents that retain the look and feel of paper data-collection forms, as well as a Web portal accessible from any Internet-connected computer.

Our system eliminates multiple data entry, increases accuracy and ultimately saves money by reducing the time to market, says Clinical Ink CEO Doug Pierce.

"Our system eliminates multiple data entry, increases accuracy and ultimately saves money by reducing the time to market," says CEO Doug Pierce. "It also allows customers to manage, view, and store the data and forms on our secure Web portal."

To create this technology, Clinical Ink entered into an exclusive worldwide license with Datasci, owner of a patent regarding the collection and validation of clinical trial data over the Internet. In return, Mr. Pierce says, Datasci has subsequently invested in Clinical Ink and is an integral part of its success. To date, Datasci has been granted six non-exclusive patent licenses in the electronic data capture marketplace.

BridgeNet Releases SUPPLY-CHAIN MANAGEMENT TOOL

Xonar enables supply-chain professionals to perform a quick analysis and assessment of their global transportation costs and service requirements.

Xonar, a new Web-based global visibility tool from BridgeNet Solutions, allows healthcare and life-sciences professionals to manage their global supply chains from anywhere in the world. The network-spend data analytics and planning solution uses advanced optimization technology to manage complex supply chains and includes an executive dashboard, 360-degree logistics performance-monitoring capabilities, exception/event management capabilities, and real-time reporting, analysis, and a global communications tool.

Xonar enables supply-chain professionals to perform a quick analysis and assessment of their global transportation costs and service requirements, as well as the calculation of the optimal network configuration for different cost and service objectives. Solutions from the model can be viewed, compared, and easily exported to tables and graphs for presentations and further analysis.

The system provides Phase IV cost visibility and compliance. All modes of transportation imported into a central repository database, providing a dashboard with advanced features: exceptions/event management, compliance, internal alignment with all business entities, trends analysis, forecasting and demand planning, and business process management for proactive cost initiatives.

Intrasphere Launches CONTENT MANAGEMENT TOOL

Intrasphere Technologies has launched PharmaCM, a comprehensive content management solution designed to help clients more effectively manage drug information critical to patient safety, including the content for drug labels, clinical-trial protocols, and drug-safety reporting.

PharmaCM, which is powered by Microsoft Office SharePoint Server 2007 (MOSS), is a seamless, user-friendly system that enables organizations to overcome inefficient content authoring, management, and distribution processes in a cost-effective manner. The solution provides an intuitive and familiar interface for generating a series of regulated documents, including protocol disclosure forms required for registration on clinicaltrials.gov, as well as the structured product labels (SPL) required by the U.S. National Library of Medicine's DailyMed Website.

PharmaCM also includes a submissions management and authoring module to help clients create content and easily prepare for NDA submissions following electronic common technical document (eCTD) standards. Users can now manage the complex process of planning, authoring, reviewing, approving, and releasing submission content from a common portal.

"It is critical for life-sciences organizations to have the ability to create and manage content such as product labels, clinical protocols, and study reports while at the same time staying in compliance with the latest regulations, including the recent FDA Administration Act," says Woo Song, cofounder and chairman of Intrasphere. "PharmaCM makes it possible for them to easily manage this process in a familiar Microsoft environment."

It is critical for life-sciences organizations to have the ability to create and manage content while at the same time staying in compliance with the latest regulations, says Woo Song, Cofounder and Chairman of Intrasphere.

ClinPhone Offers INTEGRATED TRIAL MANAGEMENT SOLUTION

ClinPhone's newest addition to its clinical technology portfolio integrates its electronic data capture (EDC) and randomization and trial supply management applications into one product, offering clients a comprehensive solution for managing clinical data.

ClinPhone EDC combines the functionality of paper data entry with the flexibility of EDC into an electronic clinical data management platform based on Microsoft connected technology and servers. Both ClinPhone Randomization and ClinPhone Trial Supply Management use interactive voice response (IVR) and interactive Web response (IWR) technologies to provide centralized management of clinical trial randomization and supply chain logistics.

ClinPhone's newest addition to its clinical technology portfolio integrates its electronic data capture (EDC) and randomization and trial supply management applications into one product.

E-UPGRADES AND ENHANCEMENTS

■ **Advanced Clinical Software (ACS),** Seattle, has expanded upon its flagship **StudyManager clinical trial management software (CTMS).** StudyManager Sponsor Edition (SE) provides clinical data collection, study management, and real-time interaction among study administrators, monitors, and site users.

For more information, visit studymanager.com.

■ **Almac Clinical Technologies,** Yardley, Pa., has **expanded its Express Suite** to incorporate the company's iTrial EDC electronic data capture and IXR Express interactive voice and Web response capabilities. Employing Almac's fully integrated, cost-effective IXR/iTrial EDC Express Suite, sponsors benefit by reducing study start-up times, eliminating data entry redundancies, and streamlining overall study timelines.

For more information, visit almacgroup.com.

■ **BioWizard,** Wayne, Pa., has **added a set of personalization utilities** to its online information and communications platform for the biomedical research community. Known as myBioWizard, or myBW, these personalization tools enable BioWizard users to develop a customized homepage. BioWizard has also added PubMed search enhancements to its life-sciences platform. Furthermore, myBW offers syndicated news feeds from more than 70 life-sciences universities.

For more information, visit biowizard.com.

■ Contract research organization **Beardsworth Consulting Group,** Flemington, N.J., **has released BNet3,** the newest version of its clinical trial management system (CTMS) for providing clinical trial data to its pharmaceutical clients. BNet3 improves upon previous versions by integrating real-time data into the clinical trial process. Its modular approach allows real-time tracking and updating of metrics from the field and provides users with quick, accurate data in the required format.

For more information, visit beardsworth.com.

■ **Datatrak International,** a Cleveland-based technology and services company focused on global electronic solutions, **has announced the release of Datatrak eClinical.** Enhancements include VisualArchitect, a drag-and-drop interface for designing clinical trials; eTrain, an online training tool for data-collection and investigator review, as well as a new trial-management workflow tool that allows virtual teams to set up and deploy clinical trials through a Web browser.

For more information, visit datatrak.net.

■ **Liquent,** a Thomson Scientific company, has **announced the availability of InSight Publisher 3.6.** InSight Publisher enables pharmaceutical companies to create, manage, and publish regulatory submissions in both paper and electronic format using a single software application. This newest version adds intuitive hyperlinking and cross-reference management to InSight Publisher's enhanced functionality set.

For more information, visit liquent.com.

■ **Medidata Solutions,** New York, **has released Medidata Rave 5.6.2,** the newest version of its electronic data capture (EDC) solution for clinical trials. With this version, Medidata has incorporated its e-learning module directly into the Rave system. Upgrades include a publish-in-

place function that allows immediate updating of CRF versions during development and a custom function development utility that assists in development and testing of custom edit checks.

For more information, visit mdsol.com.

■ **Octagon Research Solutions,** Wayne, Pa., **has added a number of new features to its StartingPoint** suite of submission documents authoring templates. Tools incorporated into StartingPoint 3.0 include a document validation button, document information for field codes, keyboard shortcuts, improved table functionality, and additional content templates for the United States and Europe.

For more information, visit octagonresearch.com.

■ **Pedagogue Solutions,** Princeton, N.J., **has released version 9.0 of its Pedagogue Assessment Management System.** Pedagogue AMS9 offers enhancements to the online assessment system's delivery, authoring, reporting, and administration platforms. New features include testing by learning objective, more flexible scoring and test-delivery options, e-mail notification, and individualized remediation plans.

For more information, visit pedagogue.com.

■ **Phase Forward,** Waltham, Mass., **has announced Central Coding for InForm 2.0,** a new release of a Web-based application for updating clinical-study data to reflect the terms for adverse events and medical coding from the latest industry-standard dictionaries. The latest version is optimized to code clinical data using these dictionary terms within Phase Forward's InForm Integrated Trial Management (ITM) electronic data capture (EDC) product.

For more information, visit phaseforward.com.

■ **Phoenix Data Systems (PDS),** King of Prussia, Pa., **has added randomization and clinical supply management capabilities within its PDS Express** electronic data capture (EDC) application. EDC Randomization encourages sites to immediately enter qualified patients into the EDC system and randomize them as they are enrolled, improving the sponsor's visibility regarding enrollment. PDS Express' clinical supply management capability allows sites to use either the EDC system or PDS IVR to record the use of clinical trial supplies.

For more information, visit phoenixdatasystems.net.

■ **Systech International,** Cranbury, N.J., **has introduced version 8.0 of its Systech TIPS Engine** packaging execution system. Its new interface employs icons to visually represent components and functions of the packaging execution system, allowing packaging line engineers to easily assemble and realign these icons as they implement and modify their packaging lines.

For more information, visit systech-tips.com.

■ **Verticals onDemand,** Pleasanton, Calif., **now offers a primary care version of its VBioPharma CRM** application. VBioPharma Primary Care Edition CRM is a CRM solution pre-validated for PDMA and FDA compliance. The solution provides out-of-the-box call reporting and sampling system with complete IQ and OQ documentation.

For more information, visit verticalsondemand.com.

Roska Healthcare Introduces
CORPORATE WEBSITE

The site makes robust use of imagery, video segments and logic-based navigation that enable visitors to engage with Roska Healthcare, says Chris Matsinger, VP, Digital Services of Roska Healthcare.

Roska Healthcare Advertising's new Website, roskahealthcare.com, offers visitors a virtual tour of the agency's people, clients, and category experience. Intuitive navigation allows viewers to explore information by disease category, product life cycle, or audience, providing a personalized, productive experience tailored to their specific needs.

"The site makes robust use of imagery, video segments, and logic-based navigation that enable visitors to engage with Roska Healthcare to gain a true sense of what it is like to work with the agency," says Chris Matsinger, VP, digital services. "A good example is a streaming video of the firm's president, Jay Bolling, offering some insightful perspective on DTC advertising and the value of touchpoints, varied media, and engaging the consumer."

Manhattan Research Introduces
CONSUMER RESEARCH SERVICE

Manhattan Research has introduced ePharma Consumer, a service that provides subscribers with insight into the way U.S. consumers are using pharmaceutical information online based on an online study generating more than five years of trended data. Topics explored by ePharma Consumer include online pharmaceutical information resources; DTC advertising; utilization and trust of online prescription information; pharmaceutical company and product Websites; and use of search engines, blogs, Podcasts, Wikis, and social networking.

"ePharma Consumer provides our agency and pharmaceutical clients with insight into how consumers are using branded and unbranded pharma properties online today," says Meredith Abreu Ressi, VP of research for Manhattan Research. "Combining this research with server and usage data is critical to painting a complete strategic picture of the online consumer marketing and media landscape."

> **ePharma Consumer provides our agency and pharmaceutical clients with insight into how consumers are using branded and unbranded pharma properties online today.**

Pharma companies and agencies use ePharma Consumer for budget planning, product-site development, market sizing, and ROI measurement for online initiatives. The research and advisory service helps planners and marketers:

- Examine consumer use of pharmaceutical information online and trends over time.
- Determine the impact of Web 2.0 on consumer pharmaceutical marketing strategy.
- Identify utilization trends for more than 30 corporate and more than 150 branded product sites.
- Determine the profile of online visitors by brand (Rx status, caregiver, or information-seeker).
- Assess the actions taken offline after visiting product sites compared with competitor sites.
- Features and tools desired by consumers visiting product sites.

Publicis Selling Solutions Introduces
WEB-BASED CONTACT MANAGEMENT TOOL

> **SFA Sidekick offers sales reps, sales managers, and home-office operations personnel a collaborative tool.**

Publicis Selling Solutions, a Publicis Selling Solutions Group company, has developed SFA Sidekick, a Web-based target management tool that allows field sales representatives and home-office staff to make prescriber-profile and call-plan changes more easily and efficiently.

SFA Sidekick offers sales reps, sales managers, and home-office operations personnel a collaborative tool in which each stakeholder has input into their territory changes. The solution is customized to incorporate each client's specific business rules so that reps are immediately aware of the impact of any recommended changes, and its Web-based interface allows users to access the planned changes along with an intuitive approval workflow from any Internet-enabled computer or device. SFA Sidekick can also be integrated with all SFA systems, regardless of the platform being used.

"SFA Sidekick can turn these routine, large-scale salesforce automation (SFA) edits from a painful process into one that is infinitely easier and more efficient," says Rick Keefer, chief operating officer.

He says SFA Sidekick mirrors the information in the sales representatives' SFA system. This allows changes to take place in a 'safe' environment that is flexible enough to incorporate collaboration from the sales managers and the home office.

MDS Unveils Web-Based STUDY-MANAGEMENT SYSTEM

MDS Pharma Services has launched Apollo, a unified, Web-based study-management tool that provides clients with secure, transparent tracking of study samples and results and real-time, worldwide virtual access to their study data. The new solution provides customers with significant benefits in terms of efficiency and standardization in study management. The system provides for global standardization of requisitions, reports, kits, barcode labels, as well as scientific information.

The Apollo system, developed for MDS Pharma's Global Central Lab business, strengthens the chain of custody from specimen collection, to central lab receipt, to testing and sample storage.

Apollo provides a single interface for all aspects of protocol management, including protocol specifications, kit building, sample reception and test ordering, query identification and resolution, customizable results flagging, report distribution, frozen sample management, data extraction and invoicing. Apollo improves the efficiency and quality of MDS Pharma-managed studies and enables the company to respond quickly to changes in client needs and study requirements, regardless of where the client is or where the work is being done.

"A single global system with increased transparency of processes and data across all our sites will help us consistently deliver on our brand promise of quality, on-time results," says President David Spaight. "The Apollo system, which is exclusive to MDS Pharma Services, will help to redefine the customer experience, allowing studies to start on time, run smoothly, and end on time."

A single, global system with increased transparency of processes and data across all our sites will help us consistently deliver on our brand promise of quality, on-time results, says MDS Pharma President David Spaight.

The new system is built on an Oracle database and provides client study teams a host of features that enable greater control over all aspects of the study.

These features include:

- A dashboard for high-level overview of a trial, including automated kit-expiration and test-cancellation notification, alert/exclusion reports, and query notices regarding pre-programmed escalations.
- Automatic detection of late or missing batch samples, third-party shipping list templates, automatic recall site notification, recall of frozen samples from affiliate laboratories, and global frozen sample inventory reports.
- Kit-building support, including latest bills of material, kit component inventories with specific lot numbers and expiration dates, and pre-labeled tubes for delivery to study sites.

DrugLogic Adds **RISK-MANAGEMENT SOLUTION** for Smaller Firms

> **DrugLogic has unveiled Qscan-RM, an extension of its Qscan-ERM workflow-management product line.**

DrugLogic has unveiled Qscan-RM, an extension of its Qscan-ERM workflow-management product line that provides rapid implementation of a risk-management solution to small and mid-sized organizations, giving them the benefits of workflow and data interface functions without the hassle of a custom implementation.

The Qscan-RM solution expedites and eases the implementation of a major system. In addition, migration to full Qscan-ERM in-house operations will be facilitated.

"Companies with fewer work steps and departments still require total regulatory compliance," says Victor Gogolak, president and CEO. "What we offer is an easily tailored process — a starter set workflow, standard alert definitions — and the ability to map proprietary data based on years of experience in risk and event management. Over time, the workflow model can be adapted to growth and drug numbers." Qscan-RM consists of three core components:

- A DrugLogic-hosted secure application and data-storage system, with all client-specific data segregated on dedicated servers.
- A set of 'templates' for workflow, coding, alerting analysis, and reporting that can be adapted, changed, refined, and saved by the users.
- A system of load facilities with a maximum client data mapping time of one week.

Qscan-RM is designed for secure hosting in an application services provider (ASP) mode and is available for application to public or internal data. The service is being offered in subscription and license form, with full value applied when upgraded to an in-house solution.

The company also has released an integrated vaccines offering of Qscan-ERM. Vaccine data are available in both the Vaccine Adverse Event Reporting System (VAERS) and the Adverse Event Reporting System (AERS) databases, allowing researchers to access and cross-compare data from both sources. DrugLogic is updating the AERS data on a quarterly basis, while the VAERS data are being updated monthly. In addition, the release of data to subscribers, which had been on a two-month schedule, is now occurring as the data are released by the U.S. Food and Drug Administration.

ISI, EMC Create **REGULATORY SUBMISSION SOLUTION** for Midsize Companies

Image Solutions (ISI) has extended its relationship with EMC, enabling the company to co-sell ISI's integrated regulatory suite with EMC's Enterprise Content Management solutions.

The Compliance-in-a-Box (CiB) Submission Edition is a prepackaged, integrated regulatory compliance solution that gives organizations the flexibility to submit using paper or the electronic common technical document (eCTD) format. The combination of a document management solution packaged with a publishing system allows midsized companies to achieve enhanced content creation and management, eCTD generation, and true document life-cycle management in a simple, cost-effective manner. The backbone of the CiB solution is EMC's Documentum Compliance Manager (DCM) combined with Impact Systems' accelerator configuration package.

"The decision to target the mid-market is fueled by our belief that these companies have the same sophisticated needs as their market-leading counterparts," says Paul Chung, executive VP of ISI.

The decision to target the midmarket is fueled by our belief that they have the same sophisticated needs as their market-leading counterparts, says Paul Chung, Executive VP of ISI.

OCEG Seeks **COMMENTS ON DATABASE**

The Open Compliance and Ethics Group (OCEG) has launched the public exposure draft of the Pharmaceutical Sales and Marketing Supplement, an interactive database designed to assist the pharmaceutical industry in understanding legal and regulatory requirements, as well as core business practices, of the Pharmaceutical Sales and Marketing Compliance Program.

Understanding and implementing the requirements for a company's compliance program can be a daunting task for any executive, says Scott Mitchell, CEO of OCEG.

"Understanding and implementing the requirements for a company's compliance program can be a daunting task for any executive," says Scott Mitchell, CEO of OCEG. "The Pharmaceutical Sales and Marketing Supplement public exposure draft gives executives an opportunity to provide commentary on guidelines that are intended to be the gold standard for compliance issues in the pharmaceutical industry."

OCEG worked with Ernst & Young and the law firm of Hogan & Hartson in writing the supplement. They were supported by an advisory board of experts who offered comments in the initial scoping of the supplement structure, and reviewed drafts.

Oracle Partners Introduce **LIFE-SCIENCES SOLUTIONS**

Oracle and its partners have introduced nine new Oracle Accelerate solutions tailored to meet the needs of the life-sciences industry. These solutions, offered by Oracle Certified and Certified Advantage Partners worldwide, feature prepackaged application bundles and a wide range of industry-specific functionality designed to help rapidly growing life-science organizations quickly and affordably implement Oracle applications.

"Emerging life-sciences organizations face the same clinical trial and regulatory requirements as larger, more established players in the field," says Torsten Adam, managing director of pharmasol. "They also require enterprise-class applications to manage these functions effectively, but frequently face significant time and resource constraints."

Pharmasol is an Oracle partner based in Europe that has launched an Oracle Accelerate for Oracle Clinical Solutions product.

Since August 2007, Oracle partners have launched a total of 15 Oracle Accelerate solutions dedicated to the life-sciences industry. Oracle Accelerate is Oracle's strategy for helping Certified Partners and Certified Advantage Partners provide midsize businesses and government entities with the most complete, easy to own, industry-focused solutions. Oracle Accelerate solutions combine Oracle's enterprise-class applications with partner expertise and rapid implementation tools in industry-tailored solutions that are specifically packaged, priced, and designed by partners for easy ownership by midsize businesses and government entities. Fundamental to the Oracle Accelerate program is pre-packaged application bundles that allow for rapid, best-practice implementations. Partners who participate in the Oracle Accelerate program are provided with Oracle Business Accelerators, rapid implementation tools, templates and process flows.

"Fast-growing life-sciences organizations require robust, affordable, and easy-to-implement solutions to help them meet industry-specific requirements, ranging from streamlining management of complex clinical trials to ensuring efficiency of supply chain, manufacturing, and sales processes," says Dennis Constantinou, senior director, life-sciences, at Oracle. "Oracle Accelerate solutions for life sciences meet these needs by allowing partners to provide bundled and pre-configured applications and services tailored to industry best practices."

> **Oracle and its partners have introduced nine new Oracle Accelerate solutions tailored to meet the needs of the life-sciences industry.**

Follow up

BRIDGENET SOLUTIONS, Chicago, specializes in helping companies achieve supply-chain cost reductions through data analytics software. For more information, visit bridgenetsolutions.com.

CLINICAL INK, Winston-Salem, N.C., provides electronic data capture (EDC) solutions for clinical trials to pharmaceutical and medical device companies. For more information, visit clinicalink.com.

CLINPHONE, East Windsor, N.J., is a specialist clinical technology organization working with global biotech and pharmaceutical organizations. For more information, visit clinphone.com.

DRUGLOGIC, Reston, Va., develops analytical tools for managing risks related to drug-safety issues. For more information, visit druglogic.com.

IMAGE SOLUTIONS (ISI), Whippany, N.J., provides submissions solutions, process services, and consulting to life-sciences companies as a way to improve clinical and regulatory processes that bring new medicines to market. For more information, visit imagesolutions.com.

INTRASPHERE TECHNOLOGIES, New York, is a technology-consulting firm with a core focus on the life-sciences industry. For more information, visit intrasphere.com.

MANHATTAN RESEARCH, New York, is a healthcare market research and services firm that helps healthcare and life-sciences organizations adapt, prosper, and explore opportunities in the networked economy. For more information, visit manhattanresearch.com.

MDS PHARMA SERVICES, King of Prussia, Pa., a business unit of MDS Inc., offers a full spectrum of resources to meet the drug discovery and development needs of the pharmaceutical and biotechnology industries. For more information, visit mdsps.com.

OPEN COMPLIANCE AND ETHICS GROUP (OCEG), Phoenix, is a nonprofit organization that helps organizations drive principled performance by enhancing corporate culture and integrating governance, risk management, and compliance processes. For more information, visit oceg.org.

ORACLE, Redwood Shores, Calif., is an enterprise software company that manages, shares, and protects information. For more information, visit oracle.com.

PUBLICIS SELLING SOLUTIONS, Lawrenceville, N.J., a Publicis Selling Solutions Group (PSSG) company, offers a range of strategic selling solutions to the pharmaceutical, biotech, and medical-device industries. PSSG is part of the Publicis Healthcare Communications Group of companies. For more information, visit psellingsolutions.com.

ROSKA HEALTHCARE ADVERTISING, Montgomeryville, Pa., is a full-service advertising and communications agency with strategic focus on disease awareness, brand advertising, and relationship marketing. For more information, visit roskahealthcare.com.