The Volunteers Direct Network provides access to CenterWatch clinical trial listings on the NCERx lifestyle

Thomson CenterWatch and NCERx Service Provides CLINICAL-TRIAL INVITATIONS to Research Volunteers

Thomson CenterWatch and NCERx have established the Volunteers Direct Network, a collaborative Internet-based service for patients interested in participating in clinical research studies. The service, volunteers direct.net, reaches a large and highly motivated group of patients with targeted invitations for them to participate in disease-specific clinical trials. The new service also assists clinical-research professionals in augmenting their subject recruitment efforts.

"Looking at the evolution of the biotechnology and pharmaceutical industry over the next five years, we see the rate of discovery accelerating the need for ever more targeted candidates for trials of increasingly specialized compounds and chemical entities," says Colin Lucas-Mudd, president and CEO of NCERx. "We are delighted to be collaborating

with CenterWatch, the clinical-trial market leader. The Volunteers Direct

Network is a first step in a collaboration that addresses clinical-trial recruitment needs in this dynamic research environment."

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accelerating the need for ever more targeted candidates for trials of increasingly specialized compounds and chemical entities," says Colin Lucas-Mudd.

MedManage/MD Consult Partnership **HELPS PHARMACEUTICAL CUSTOMERS**

With Drug-Sample Program

MedManage Systems and MD Consult have partnered to link physicians and pharmaceutical companies using MedManage's eMedSample Online Drug Sampling Platform. MD Consult is expanding its physician services by providing its community of 285,000 physicians and other healthcare professionals with easy, online access to prescription drug samples and related information powered by

MedManage. Based on the options defined by pharmaceutical companies, qualifying physicians are able to request and obtain specified quantities of samples for delivery via mail, by pharmaceutical representatives, or by downloading sample vouchers.

MD Consult subscribers have complimentary access to the Med-Manage eMedSample Platform through MD Consult's Clinical Knowledge System, an integrated family of online medical information services. More than 1,000 healthcare organizations and more than 90% of North American medical schools license the service.

The solution includes physician targeting and recruitment services, alternative drug sampling systems, and marketing informatics services. The solution captures data on the frequency and manner in which physicians use the platform, as well as promotional response analytics and ROI analyses.

through CenterWatch. **Qumas Introduces Life-Sciences Repository-Neutral**

COMPLIANCE SOLUTION

and healthcare network. Currently, the NCERx network receives more than 10 million monthly visitors seeking

health-specific information. The proprietary NCERx platform includes protocol-specific filtration, messaging, and

online screening components. Research sponsors, CROs, and investigative sites can use this large and growing

network to direct prospective volunteers to newly initiated and ongoing clinical trial descriptions maintained by CenterWatch. Use of the Volunteers Direct Network is available exclusively to clinical research professionals

E-DocCompliance for the Oracle platform, recently launched by Qumas, is a ready-to-validate, Webbased application that manages the full life cycle of regulatory-controlled documentation without the need for customization. The application manages the full life cycle of regulatory controlled documentation in compliance with FDA (including 21 CFR Part 11), EMEA, ISO, and other international regulations.

The application manages the full life cycle of regulatory controlled documentation in compliance with FDA regulations.

routing, review, approval, and archival of regulatory documents. The application integrates with existing technology infrastructures and the entire suite of Qumas Enterprise Compliance Management solutions. E-DocCompliance features full administrative functionality, an enhanced audit trail, and critical compliance management features.

In addition, the company has released Qumas Visa to help pharma-

ceutical, medical-device, and biotechnology corporations comply with the latest international regulations.

E-DocCompliance incorporates the latest Web technology, including J2EE, to facilitate the electronic

LIFE-SCIENCES COMPANIES' RESPONSES to Product-Related Inquiries

First Consulting Group's FIRSTDOC MEDINFO STREAMLINES

First Consulting Groups FirstDoc MedInfo centralizes and streamlines the critical task of responding to product-related inquiries for life-sciences and biopharmaceutical companies. First Doc MedInfo provides an end-to-end customer relationship management answer to manual processes of medical information services departments.

FirstDoc MedInfo integrates the company's domain knowledge with the technologies of Siebel and Documentum, leaders in call center and content management. Medical-information services departments can capture inquiries, build responses, and distribute them efficiently, while complying with federal and global regulatory requirements. The product's features include quick automatic response identification and assembly based on inquiry information and seamless automatic distribution of the response via e-mail, fax, or mail; reference management that links standard responses to internal study reports and/or external journal articles; workflow that automates the review and approval process; on-demand and scheduled management reporting; automatic assignment based on workload within the medical information services department and triaging of adverse events to pharmacovigilance; optional healthcare professional self-service Website; and online help and end-user training.



Bill Haines, VP of product development and marketing for MD Consult, says busy physicians now have easier access to the drug information and samples they want.

Major Pharmaceutical Companies Adopt Thomson PDR WEB-BASED INFORMATION MANAGEMENT SYSTEM FOR LABELING

Thomson PDR has entered into agreements with four leading global pharmaceutical companies to manage its product labeling submissions with the Web-based PDRxpress system. Launched in June 2002, PDRxpress permits online submission and management of official drug product labeling that PDR collects, maintains, and disseminates in both print and electronic formats.

When pharmaceutical manufacturers electronically submit new product labeling and labeling updates using PDRxpress, the information is reformatted exactly as it will appear in PDR and posted on a secure Website for the manufacturer's review and final approval. The approved entries are then available for electronic distribution via pdr.net and PDR on CD-ROM. Printed versions of the entries will appear in the annual edition of PDR and its supplements.

PDRxpress also is a key element in a paperless labeling system that Thomson PDR has proposed at the request of a special task force within Pharmaceutical Research and Manufacturers of America. The system is designed to electronically deliver the most current drug labeling to every dispensing site in the United States and its territories. Following an alpha test in 2002, Thomson Healthcare emerged as one of two finalists to establish such a system.

"Ultimately PDRxpress will provide an end-toend XML-based solution for the electronic management and delivery of the latest prescribing information to healthcare professionals," says Mukesh Mehta, VP for Thomson PDR. "Pharmaceutical companies will upload their labeling documents in XML. PDRxpress will maintain an archive of each document and provide each participating company with a complete history of changes in their labeling."

PDRxpress also is designed to accommodate recently proposed amendments to the regulations governing the format in which pharmaceutical companies submit product labeling to the Food and Drug Administration. Under the amended regulations, electronic copies of the labeling in PDF format must accompany new drug applications, biological license applications, abbreviated new drug applications, supplements, and annual reports.



Mukesh Mehta says
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information to healthcare
professionals.

QUOVADX TOOLSET

Helps Companies Cut Development Cycles, Increase Productivity, and Eliminate Errors

Quovadx Inc. has introduced its Life Sciences Adaptive Framework, which can help pharmaceutical organizations to shorten development cycles, quickly respond to new business requirements, comply with government mandates, and leverage and extend existing systems. The framework is a set of reusable interoperable components that complement its business process management and integration platform, QDX Platform V. This flexible approach is expected to result in faster time-to-market as well as reduced training time, support costs, and likelihood of error.

"The proven components that comprise our framework deliver tangible bottom-line results, including improved process compliance and documentation, expedited task completion, and increased staff productivity," says Dr. Ken Macrae, senior VP and chief medical officer at Quovadx.

The Life Sciences Adaptive Framework consists of a suite of core components that organizations can reuse to get up and running quickly, enhancing return on technology investment. For example, rolebased access control ensures security by providing access to specific systems and data based on an individual's role. Government mandated features support 21 CFR Part 11 and HIPAA compliance. Personalized and dynamically updated action and to-do lists, based on automated standard operating procedures, ensure processes are completed according to organizational guidelines. Automated escalation provides functionality to keep projects on track and eliminate roadblocks that can impede completion through a succession of customizable alerts, reminders, and action steps.

Follow up

FIRST CONSULTING GROUP INC., Long Beach, Calif., is a leading provider of consulting, technology, applied research, IT, and business-process outsourcing services for healthcare, pharmaceutical, and other life-sciences organizations throughout North America, Europe, and Asia. For more information, visit fcg.com. MD CONSULT, St. Louis, helps physicians answer clinical questions and stay abreast of recent developments online. MD Consult is a part of health science publisher, Elsevier. For more information, visit mdconsult.com.

MEDMANAGE SYSTEMS INC., Bothell, Wash., offers comprehensive prescription drug-sampling solutions for the pharmaceutical industry. For more information, visit medmanagesystems.com.

NCERX LLC, Oceanside, Calif., is a healthcare information technology company providing a unified solution for clinical-trial recruitment, consumer messaging, and market research needs to the pharmaceutical and biotechnology sector. For more information, visit ncerx.com.

QUMAS, Florham Park, N.J., and Cork, Ireland, develops, markets, and supports a suite of integrated compliance

management products designed to help life-sciences companies ensure regulatory compliance. For more information, visit qumas.com.

QUOVADX INC., Englewood, Colo., provides end-to-end business infrastructure software and services, including consulting, transaction hosting, and operations management for business-critical applications. For more information, visit quovadx.com.

THOMSON CENTERWATCH, Boston, a business unit of The Thomson Corp., is a publishing and information services company that provides business journalism, reference databases, accredited training manuals, original research and analysis, and market intelligence services to assist organizations in managing and implementing clinical research strategies and operational initiatives. For more information, visit centerwatch.com.

THOMSON PDR, Stamford, Conn., part of The Thomson Corp., publishes The Physicians' Desk Reference, as well as several other annual titles and offers numerous professional educational program sponsorship opportunities to the pharmaceutical industry. For more information, visit thomson.com.