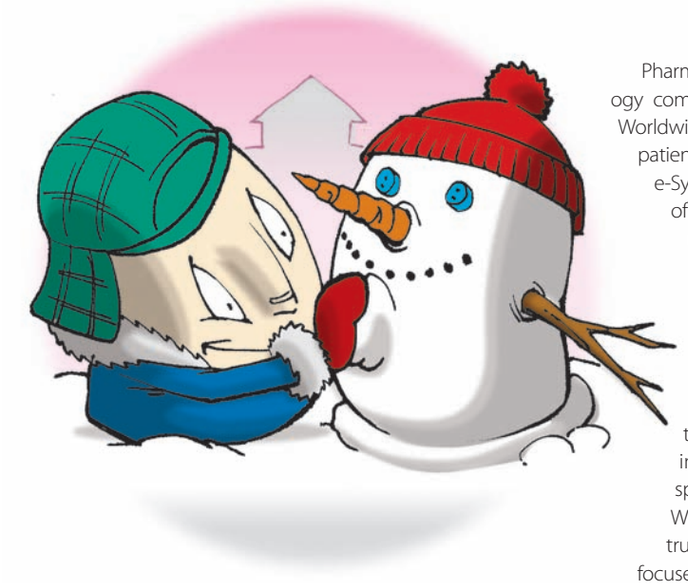

BBK Launches **E-BUSINESS SUITE OF TOOLS FOR PATIENT RECRUITMENT**

Pharmaceutical, medical-device, and biotechnology companies can now take advantage of BBK Worldwide's TCN e-Systems, a licensable e-business patient-recruitment solutions offering. With TCN e-Systems, study sponsors have greater control of their clinical trials, whether they want to manage and/or deploy efforts for an entire therapeutic category, a specific protocol, or a single study site.

Throughout the life-sciences industry, clinical-study sponsors are becoming increasingly aware that on-time trial enrollment depends on the early integration of patient-recruitment considerations into the study-planning process. Correspondingly, the need for a rapid and efficient Web-based study communications infrastructure, as well as for innovative, Internet-focused physician and consumer outreach techniques, is rapidly becoming paramount.

TCN e-Systems is highly compatible and flexible. It is a breakthrough technology platform that forms the basis for a suite of e-business products and elective services.

Each product and service is part of one of six distinct system modules, which correspond to one of the six key risk areas for patient-recruitment intervention.

The six modules of TCN e-Systems are:

- Study Forecaster, which allows planning, reporting, monitoring, and redeployment activities, displayed in easy-to-evaluate charts and graphs.
- Site Optimizer, which allows for the selection of the most appropriate sites and ensures the sites are adequately trained.
- Patient Generator, which allows users to conduct efficient and effective patient recruitment outreach and tracking.
- Materials Manager and Approval Tracker, which enables users to develop, gain, and track regulatory approvals for study materials.
- Retention and Compliance, which maintains study participation and compliance with the protocol.
- Study Message Center, which facilitates study community training and communication.

BBK has already deployed the technology platform and now has organized its infrastructure to support the sales and deployment of TCN e-Systems so that other e-business products and services can be wrapped around it.

"All the decades-old challenges of maximizing a study's enrollment potential — enrollment projection modeling, effective site selection, investigator and site staff training, accurate measurement of site performance, gauging the pace of patient recruitment, and even CRO assessment and how to identify and control clinical-trials costs — can now be addressed," says Joan F. Bachenheimer, Founding Principal, BBK Worldwide.

Oracle Introduces **NEXT-GENERATION EDC SYSTEM**

"The environment at many clinical sites is unpredictable, with patients coming in for unplanned visits that require on-the-spot data collection," says Mychelle Mowry, VP for Global Health Industries at Oracle.

To help life-sciences organizations accelerate and simplify clinical-trial data collection, Oracle has introduced Oracle Remote Data Capture Onsite. The EDC system is designed to accelerate and simplify the collection of clinical data and the deployment of EDC studies at clinical-trial investigative sites, helping to improve site personnel productivity and trial data accuracy.

Individuals at clinical-trial sites tasked with collecting data must be able to locate and enter patient case report form (CRF) data quickly.

Time wasted searching through records takes away from site personnel's primary task: collecting timely and accurate patient data.

Oracle Remote Data Capture Onsite, a new interface that can be applied on top of Oracle Remote Data Capture v4.5.1, streamlines navigation to CRFs for accelerated data display and/or update.

The tool provides an intuitive data entry interface, allowing site personnel to interact with CRFs electronically as if they were working in a native paper environment.

The system also performs robust online edit checks instantaneously in the data entry environment, invoking a discrepancy management module from the CRF to capture, route, and resolve discrepancies, when necessary.

Thomson Scientific Extends **ONLINE LEARNING FOR REGULATORY TRAINING**

Thomson Scientific has expanded its online learning library to include three new modules to optimize success in regulatory affairs. Provided by IDRAC, a global regulatory intelligence database, the online learning modules include training related to: ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use); how to prepare for an FDA advisory committee meeting; and orphan drugs in Europe, the United States, and Japan.

The modules cater to three levels: introductory, practical, and strategic. Users can choose either to follow the entire course as a complete guide to regulatory affairs or select modules to meet their specific training needs. Each module provides expert instruction and is continually updated to reflect the latest developments.

"Industry resources indicate there is currently a shortage of knowledgeable regulatory affairs professionals," says Claude Basset, Managing Director of IDRAC, Thomson Scientific.

An e-testing capability is also available to assess knowledge acquired after each module.

Six additional regulatory online learning modules are scheduled for launch later this year, with further modules planned for 2007.

Thomson Scientific has also launched Liquent InSight Publisher 3.5, which is designed to accelerate the publishing process for drug submissions to the world's regulatory authorities.

This version provides step-by-step wizards for eCTD and study reports that comply with ICH and other specifications, as well as templating capabilities that let companies predefine the structure of content.

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Princeton Brand Econometrics Launches **NEW WEB-BASED INFORMATIONAL SERIES**

PBE's series of articles was developed to challenge conventional wisdom about corporate marketing.

Princeton Brand Econometrics (PBE) is offering answers and new insights into brand profitability and other marketing subjects of interest in a new "Do You Know?" series of articles available on the company's Website www.pbeco.com. Currently available articles include: What is the Hidden Factor of Brand Profitability?, How Marketing Communications Succeed for an Established Prescription Brand, Which Doctors Are Most Often Over-Sampled, and Where Your Prescription Drug Will Be At Equilibrium.

Kent Stephan, CEO of PBE and author of the articles, developed this series to challenge conventional wisdom about corporate marketing and to provide new insights into reasons why marketing strategies succeed or fail.

"Even if you're an experienced and very successful marketer, it's never a good idea to trust solely your judgment, unless you have no alternative," Mr. Stephan says.

Take Solutions Releases **UPDATED PHARMAREADY TOOL**

"By incorporating a training records management system with SPL/PLR and eCTD modules, our PharmaReady product represents a regulatory compliant and fully integrated software suite," says Ram Yeleswarapu, President and CEO of Take Solutions.

Take Solutions has released its PharmaReady V3.0 Document Management System (DMS) with a fully integrated training records management system (TRMS). In addition, the company is planning for the launch of PharmaReady V4.0, which includes fully integrated structured product labeling (SPL/PLR) and electronic common technical document (eCTD) modules.

PharmaReady V3.0, which is fully integrated with the DMS, addresses a significant requirement of the regulated life-sciences industry.

Additionally, PharmaReady V3.0 users now benefit from active directory authentication, e-mail reminders, expanded reader assignment features, and advanced PDF publishing capabilities.

TrialStat Releases **BROWSER-SIDE ENCRYPTION MODULE FOR EDC**

TrialStat has released a browser-side encryption module for hosted EDC. The new patent-pending encryption module for ClinicalAnalytics 3.0, the company's on demand EDC platform, consists of a customer-managed security key that is used to encrypt and decrypt specified data fields before they are sent from a Web browser to a hosted server. It is an integrated Web and handheld EDC solution that enables users to design, configure, and manage clinical research projects.

The module's encryption process, which is transparent to researchers entering data, completely obscures highly sensitive data elements, such as health card numbers, so that only users who created them and colleagues at different research sites can view their details. This enables researchers to capture highly sensitive data elements, such as patient names, while satisfying the privacy and security requirements of regulatory and ethics bodies for such data. TrialStat's encryption module goes beyond standard security practices by ensuring that data in specified fields are fully encrypted before leaving the browser.

"The browser-side encryption module is a significant evolution in data security and has been driven by the needs of our customers to create a more secure operating environment," says Peter O'Blenis, VP, Product Management, TrialStat.

The module has user-administered electronic security keys to ensure that only researchers who create the data can access it in a decrypted format. The module provides end-to-end encryption because there is no point during the transmission or storage of the data where the information is ever readable without the key that was used to encrypt it.

I-many Updates **VALIDATA AND MEDICAID SOLUTIONS**

A new version of I-many's Validata leverages seamless integration with I-many's CARS to deliver functionality that minimizes rebates paid and cuts costs associated with rebate operations.

Enhancements to the latest version of I-many Validata leverage its tight integration with I-many CARS to ensure that rebate requests conform to market share requirements specified in original contracts.

I-many Validata scrubs script-level data submitted to pharmaceutical manufacturers, eliminating the need for high-priced third-party validation services whose fees increase substantially with escalating data volumes, and home-grown systems that are expensive and time-consuming to develop and maintain.

Enhancements to the latest version of I-many Validata leverage its tight integration with I-many CARS to ensure that rebate requests conform to market share requirements specified in original contracts and to enable priority-based management of duplicate rebate requests across multiple commercial and government rebate programs. The solution now also flags rebate requests for transaction quantities that exceed preset levels.

"I-many Validata is the only solution available off the shelf that cost-effectively combines the full range of data scrubbing capabilities pharmaceutical companies need to control rebate payments," says David Gelhar, senior director of life-sciences products at I-many. "This latest version increases the parameters that can be applied when validating transaction data to include information stored in I-many CARS,"

In other company news, a new version of I-many's Medicaid solution features enhancements that support monthly reporting of pricing information as mandated under the Deficit Reduction Act (DRA). The solution also supports other customized data exports required for state-specific reports.

In addition, the latest version of I-many Medicaid offers increased flexibility in the way state-specific Medicaid supplemental programs are managed, as well as an interface to I-many Government Pricing. The government pricing tool calculates best price (BP) and average manufacturers price (AMP), which are key elements in accurately determining the rebates pharmaceutical manufacturers must deliver to states under the federal Medicaid program.

"With its latest enhancements, I-many Medicaid ensures that these manufacturers will remain compliant with evolving regulations while also optimizing the efficiency of their rebating processes," says David Blumberg, executive VP of fulfillment.

Flexibility has also been enhanced for presentation of Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statements (PQAS) reports.

In addition to delivering these reports in hard copy, the solution now supports submission of these reports to states electronically.

The new version also streamlines processing of payments for Medicaid supplemental programs.

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HCL Launches **E-COMPLIANCE SUITE**

The suite features HCL's eCTD Compliance Manager for creating, publishing, and managing eCTD submissions.

To help pharmaceutical companies manage the complex regulatory submissions process, HCL Technologies Ltd. has launched an e-compliance product suite, a first-of-its-kind complete submissions and labeling solution that facilitates global regulatory compliance. The suite features HCL's eCTD Compliance Manager for creating, publishing, and managing eCTD submissions as per the specifications laid out by the International Conference on Harmonization (ICH), as well as Easy Labeling, a global drug labeling solution that addresses the FDA's Structured Product Labeling (SPL) standard, the Physician Labeling Rule (PLR), and European Medical Agency's Product Information Management (PIM) compliance.

The drug dossier approval process is an iterative and time-consuming process, often resulting in delays because of erroneous or noncompliant data and content that might creep in, given the manual nature of the dossier submission process. HCL's new e-compliance suite can help companies remove errors relating to content compliance and manage this complex process, ultimately reducing the regulatory approval cycle.

"HCL's eCompliance suite takes our compliance offering to the next level," says Pradep Nair, VP, global life-sciences and healthcare practice, at HCL.

Symfo Unveils **NEW E-DIARY PRODUCT**

"The release of the SymPhone product is a definitive step in the implementation of our product strategy, which will allow Symfo to participate in a broader range of clinical studies throughout the world," says Serge Bodart, Symfo's CEO.

Symfo has recently released SymPhone eDiary, a handheld Java (J2ME) smartphone supporting Unicode and capable of recording patient data the same way as the SymQuest eDiary.

This smartphone-based system uses secure GSM (Global System Mobile) wireless technology for data transfers and is suited for use in countries where the mobile telecommunications network is more readily available than the landline infrastructure. GSM is the most popular standard for mobile phones today.

To transmit data, patients use the GSM data call feature integrated in the SymPhone eDiary. After the information is entered, the SymPhone connects automatically to a preprogrammed number and the data are sent immediately to Symfo's central server, where sponsors and site personnel log in to view patient data and monitor patient compliance.

HealthiNation Releases **FREE TO CONSUMER WEBSITE WITH INTERACTIVE VIDEO**

HealthiNation has launched video programming at www.healthination.com. The network, spelled with an "i" for independence, was created to provide an in-depth and entertaining health learning experience through short-format videos covering topics such as cholesterol, diabetes, cancer, women's health, and health insurance.

The Internet launch complements the HealthiNation video on-demand service on select digital cable channels.

"We developed our videos so people can learn about important health topics easily and at their own pace," says Raj Amin, President and Cofounder of HealthiNation.

The network takes an innovative approach to health education by explaining medical conditions in familiar terms and featuring 3-D bio-animation sequences of how the body works. HealthiNation's videos are produced independently and reviewed by a medical advisory team that includes respected physicians from a variety of fields of medicine, many of whom have been featured on major national TV outlets.

HealthiNation's programming also centers on everyday people who share their personal experiences about what helped them manage their medical condition, as well as celebrities who are connected to certain conditions. One segment features baseball pitcher Curt Schilling and his wife Shonda, who give a personal account of her successful battle with skin cancer.

In addition to its growing library of health topics, HealthiNation also focuses on monthly awareness campaign.

Follow up

BBK WORLDWIDE, Newton, Mass., is an e-business solutions company for the clinical R&D and product marketing segments of the pharmaceutical, biotechnology, and medical-device industries. For more information, visit bbkworldwide.com.

HCL TECHNOLOGIES LTD., Sunnyvale, Calif., is an India-based global IT services company, providing software-led IT solutions, remote infrastructure management services, and BPO. For more information, visit hcltech.com.

HEALTHINATION, New York, is a health-education network that combines a community of people and the power of interactive media to help improve health. For more information, visit healthination.com.

I-MANY INC., Edison, N.J., is a provider of advanced contract life-cycle management solutions for managing corporate commitments. For more information, visit imany.com.

ORACLE, Redwood, Calif., is an enterprise software company. For more information, visit oracle.com.

PRINCETON BRAND ECONOMETRICS, Princeton, N.J., is a marketing engineering consultancy. For more information, visit pbeco.com.

SYMFO, Boston, is an international organization specializing in electronic patient diary solutions. For more information, visit symfo.com.

TAKE SOLUTIONS INC., Princeton, N.J., is a technology enabled business solutions company with expertise in life sciences and supply-chain management. For more information, visit pharmaready.com.

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