



Perceptive Informatics Introduces E-CLINICAL SUITE



To further simplify workflow and enable users to perform activities using whichever system is best suited to their preferences, we are continuing to blur the boundaries between our EDC and RTSM solutions, says Dr. Bill Byrom.

New functionality in Perceptive Informatics' DataLabs EDC solution creates advanced interoperability with ClinPhone Randomization and Trial Supply Management (RTSM) technologies, allowing the use of either system for randomizing patients and dispensing medication.

"Fueled by the next version of Perceptive's EDC solution, this latest achievement in true convergence represents a radical shift in the way technologies can be used together to accelerate clinical trials," explains Bill Byrom, Ph.D., senior director, product strategy for Perceptive Informatics.

The convergence between the EDC and RTSM solutions in Perceptive's eClinical Suite simplifies work flow, making it easy for clinical site personnel to use both technology solutions seamlessly within a single clinical trial. The DataLabs EDC system can be used as an interface to the ClinPhone RTSM technologies so that clinical sites can randomize and dispense medication in real time. Users can perform these activities without logging into a second system, eliminating the need to enter data via phone or online, then reconcile within the EDC system at a later time. This approach increases efficiency and productivity for sponsors and sites and ultimately reduces the costs associated with clinical research.

Elsevier has established a new online resource center for American Recovery and Reinvestment Act (ARRA) updates and initiatives accessible via Elsevier's Clinical Decision Support Web site (clinicaldecisionsupport.com).

The resource center and accompanying blog provide users with updates on ARRA progress and actions, as well as insightful commentary on emerging trends and issues from top Elsevier executives, including Jonathan Teich, M.D., Ph.D., chief medical informatics officer; Michelle Troseth, R.N., MSN, DPNAP, executive VP and chief professional practice officer; and Swati Abbott, M.S., president of Elsevier's MEDai subsidiary.

Meaningful clinical decision support (CDS) is a key tenet of healthcare reform and ARRA goals for quality improvement. Designed to assist physicians and other care providers with decisions at the point-of-care, CDS systems assimilate data on a variety of conditions and diagnoses and can flag potential issues, such as unsafe medication interactions, that may end up being harmful to patients as well as costly to the entire healthcare system.

Elsevier Launches Online RESOURCE CENTER FOR ARRA UPDATES



The blog will be a way to facilitate discussions on many topics relevant to the market today, including the role of CDS in the national healthcare environment, says Dr. Jonathan Teich.

"Elsevier's CDS blog and ARRA portal are designed to be a solution to the challenge of keeping current with national quality initiatives, meaningful use updates, and other significant new policies and programs that affect providers, payers, and patients," Dr. Teich says.

In other news, Elsevier has relaunched Embase, its comprehensive biomedical database of more than 20 million indexed records from more than 7,000 active, peer-reviewed journals. This new version of Embase can now be used by all biomedical and pharmaceutical scientists and clinical and regulatory professionals and includes new retrieval tools and the addition of indexed articles-in-press and conference abstracts.

Thomson Pharma Database Integrates TRIAL PROTOCOL, OUTCOME INFO

Thomson Reuters' Thomson Pharma drug pipeline database is now available with fully integrated, detailed clinical trial protocol and outcome information.

Thomson Pharma offers drug-related clinical trial intelligence from registries, publications, press releases, conferences, and other sources across all therapeutic areas. The database includes some of the most advanced searching capabilities on the market, enabling identification of trials based on

more than 20 criteria individually indexed by experts. These include trial criteria such as drug, phase, and recruitment status; and scientific criteria such as mechanism of action, target, and biomarker.

"We are proud to be the first to integrate drug pipeline content with robust clinical trial content in a single competitive intelligence solution," says Wendy Hamilton, VP of product strategy at Thomson Reuters. "This addresses our customers' needs for increased efficiency and new competitive insights."

Take Supply Chain Releases MULTI-TENANT SAAS PLATFORM

OneSCM, the latest software as a service (SaaS) platform from Take Supply Chain, is designed to deliver online supplier management to medium and large enterprises, enabling them to facilitate supplier response transactions to function against the purchase order schedules.

OneSCM is the company's first release featuring a multi-tenant SaaS architecture and serves as the foundation for Take Supply Chain's growth toward becoming a multienterprise, collaborative network provider. This release enables manufacturers and distributors to provide shipment execution functionality such as part tracking numbers (PTNs), barcode label printing, and shipments.



Brand owners, goods and services providers, distributors, and customers will each realize unique value from OneSCM, says Warren Sumner.

"OneSCM is a platform and a set of integrated applications that industry-specific ecosystems will use to perform supply chain activities across all of their value-adding partners," observes Warren Sumner, chief operating officer and general manager of Take Supply Chain.

Medidata Solutions Provides SAFETY REPORTING CAPABILITY



The single source of data maintained through this end-to-end e-clinical process reduces the reconciliation efforts between safety and clinical databases during the life cycle of a study, says Glen de Vries.

Medidata Solutions' Rave Safety Gateway provides clinical research sponsors and contract research organizations (CROs) with a more efficient and accurate solution for collecting and transmitting serious adverse events (SAEs) and related data from sites to safety reporting systems.

Global regulatory agencies enforce stringent guidelines for timely reporting of SAEs by sites and sponsors during clinical trials.

Rave Safety Gateway, an extension to the Medidata Rave electronic data capture (EDC) and clinical data management (CDM) solution, addresses these inefficiencies by providing built-in functionality that automatically transmits safety case data entered at sites to sponsors' safety reporting systems using the International Conference on Harmonization industry standard E2B file format. By doing so, both sites and sponsors can leverage efforts already put forward in entering safety related data into the EDC system, thus significantly reducing the burden of collecting and reconciling safety data.

"The introduction of Rave Safety Gateway offers our clients the opportunity to achieve significant efficiency improvements by streamlining their safety data collection and transmission processes," says Medidata President Glen de Vries.

Follow up

ELSEVIER is a publisher of scientific, technical, and medical information products and services. For more information, visit elsevier.com.

MEDIDATA SOLUTIONS WORLDWIDE is a provider of hosted clinical development solutions. For more information, visit mdsol.com.

PERCEPTIVE INFORMATICS, a subsidiary of Parexel, provides e-clinical solutions. For more information, visit perceptive.com.

TAKE SUPPLY CHAIN provides real-time supply chain and reverse logistics software solutions. For more information, visit takesupplychain.com.

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E-UPGRADES AND ENHANCEMENTS

▶ **DATATRAK INTERNATIONAL's** eClinical 9.0 software release introduces two new mechanisms for facilitating Datatrak One's Knowledge offering. The Datatrak Learning Center delivers tutorials, guides, manuals, and FAQs in a package that employs screenshots, images, and video, while the Datatrak Learning Manager e-learning solution provides Datatrak and its partners with greater flexibility in creating content and managing access to available courses and training records.

For more information, visit datatrak.net.

▶ StudyOptimizer 4, the latest version of **DECISIONVIEW's** Web-based solution, now includes advanced historical analysis and templates capabilities, as well as enhancements to its predictive analytics technology. The solution provides clinical trial managers with a comprehensive view of their organization's clinical trial patient recruitment performance with past enrollment patterns and metrics, present enrollment actual performance compared with plans, and future forecasted end dates of trials based on performance to date.

For more information, visit decisionview.com.

▶ **OCTAGON RESEARCH SOLUTIONS** has updated its global product suite to support recently updated European Union requirements for electronic common technical document (eCTD) submissions. Octagon's ViewPoint v.3.12.0, eCTD Viewer v.2.6.0, and eCTD Validator v.2.6.0 all include support for the updated attributes, naming conventions, and checksum information detailed in eCTD EU Module 1 Specification, version 1.4.

For more information, visit octagonresearch.com.

▶ **PHARMAVIGILANT** has released an enhanced version of its I-Builder solution that eases the electronic data capture (EDC) study-build process and technology transfer for sponsors. I-Builder 2.0 provides an enhanced, intuitive user interface that can support multiple users for building all phases of clinical research studies.

For more information, visit pharmavigilant.com.

▶ **PHH ARVAL** has made an enhancement to its mobile application, PHH Connect, that makes it easier for pharmaceutical salespeople to report mileage. Reps using PHH Arval fleet vehicles can now enter odometer information anytime, anywhere using their smartphones, rather than having to log on to their computers or make phone calls to report odometer information.

For more information, visit phharval.com.

▶ **SPARTA SYSTEMS** has made additions to its TrackWise Electronic Regulatory Reporting (eReporting) solution to support specific U.S. and European reporting protocols. The addition of ClinicalTrials.gov reporting to TrackWise enables companies conducting clinical trials to streamline protocol registration and trial results reporting in accordance with FDA requirements. The solution also supports Medical Device Vigilance reporting to European health authorities that are becoming a mandate in the first quarter of 2010 for the German BfArM.

For more information, visit spartasystems.com.

▶ **SYMIX TECHNOLOGIES** has released Symyx Notebook 6.4., which offers scientists improved support for method development, validation, and execution in regulated and non-regulated analytical labs. The latest release of Symyx's electronic lab notebook (ELN) offers new cross-experiment referencing and reporting capabilities that improve collaborative workflows for multidisciplinary teams working in the life-sciences, chemicals, energy, and consumer products industries.

For more information, visit symyx.com.

▶ **THOMSON REUTERS** has linked its drug-discovery database, Prous Science Integrity, with its Web of Knowledge research platform, enabling scientists to quickly and easily draw together research findings and analyze, visualize, and organize information.

Thomson Reuters also has released a new version of its Micromedex clinical information system. Micromedex 2.0 features a new interface based on clinician workflow patterns, enhanced search capabilities, special tabs for high-usage tools, and compatibility with smartphones and other mobile devices.

For more information, visit thomsonreuters.com.