E-MEDIA

NEW ELECTRONIC AND WEB-BASED APPLICATIONS, SITES, AND TECHNOLOGIES

FDA, NIH Launch ELECTRONIC SAFETY REPORTING PORTAL

We are now able to analyze human and animal safety-related events more quickly and identify those measures needed to protect the public, says the FDA's Margaret Hamburg.

The FDA and the National Institutes of Health are developing a website to provide a mechanism for the reporting of pre- and postmarket safety data to the U.S. government.

The Safety Reporting Portal (SRP) site provides greater and easier access to and online reporting of safety problems related to foods and animal drugs, as well as adverse events occurring on human gene transfer trials. Clinical-trial sponsors can use the portal to prepare a report, print it, and send it to the agency to satisfy reporting requirements for investigational new drugs. In the future, the system will encompass other types of clinical trials and, eventually, safety problems arising from products regulated by a broad array of federal agencies.

The SRP is a first step toward a common electronic reporting system that will offer one place for individuals to file a single report to multiple agencies that may have an interest in the event. The portal also enhances the government's systematic analysis of safety information, which will benefit public health.

"The portal is a key detection tool in improving the country's nationwide surveillance system and strengthens our ability to protect the nation's health," says FDA's Commissioner of Food and Drugs Margaret Hamburg.

Insurance Documentation System Helps PREVENT STUDY DELAYS

Chubb WORLDcert is a new online system from the Chubb Group of Insurance Companies that allows drug and medical device developers to quickly secure the required insurance documentation for clinical trials around the globe, helping them to deliver lifesaving products to market faster.

Life-sciences companies and contract research organizations cannot secure approval from a medical institution's ethics committee to begin a clinical trial without accurate documentation that appropriate insurance has been secured.

"A seemingly minor mistake, such as producing a certificate of insurance with a typographical error, insufficient insurance limits, or an incorrect number of participants, could set a clinical trial back for months," observes Frank Goudsmit, VP and life-sciences international manager, Chubb Commercial Insurance. "Complicating the process further, key details about a trial are frequently a moving target right up to the ethics committee meeting, and such gatherings happen infrequently at many institutions."

A seemingly minor mistake could set a clinical trial back for months, says Frank Goudsmit.

Since WORLDcert provides instant certificates of insurance in 149 countries, sponsors of clinical trials in these countries no longer need to wait for an insurance agent or broker to communicate trial information to an insurance company and for the insurer to complete manually intensive back-end processes.

The resulting efficiency allows the innovator company to focus their efforts on delivering lifesaving or life-extending therapies.

"If a clinical trial is delayed because a certificate of insurance is not available, inaccurate, or incomplete, it also shortens the time frame during which a life-sciences company enjoys patent exclusivity," Mr. Goudsmit adds.

GSW Worldwide Unveils NEW WEBSITE AND BLOG

GSW Worldwide's revamped website, gsww.com, features a new 3-D design and a multimedia marketing blog, Brand Liberators, that discusses what it takes to propel brands to the next level.

The website includes links to video interviews, testimonials, client work, capabilities, and agency offerings. Readers of Brand Liberators can find examples of innovative healthcare marketing, new ideas on how to knock down roadblocks, and out-of-category examples of successful strategies.

"We're excited to establish a presence where we can invite participation and connect within a community to broaden the conversation, elevate ideas, and hopefully generate value through collective sharing," says Phil Deschamps, president and CEO of GSW Worldwide.

This is a welcome way for us to show what it means to truly live our brand and join with other like-minded brand liberators, says Phil Deschamps.

Derycz Scientific Offers Solution for ELECTRONIC ARTICLE REUSE

Derycz Scientific's Reprints Desk subsidiary has launched ePrints NRx, a new scientific article collection service that simplifies the reuse of PDFs by medical marketers, brand managers, and sales professionals through its copyright-compliant, plug-and-play licensing solution.

Through ePrints NRx, subscribers can use multiple articles from multiple content sources in online portals, physician detailing and e-detailing, and digital marketing initiatives. The service is deployed through a closed-loop marketing (CLM) solution and an online portal for healthcare consumers and includes components such as publisher relationship management and collaboration; annual or transactional licensing, workflow, and technical requirements determinations; and electronic content delivery or hosting for on-demand PDF downloads.

"ePrints NRx can help medical marketers and brand management professionals who want to incorporate e-prints into their program, but have run into various licensing, technical, and budgeting challenges," says Derycz President and CEO Peter Derycz.

ePrints NRx can help medical marketers and brand management professionals who want to incorporate a group of scientific article e-prints into their program or campaign, says Peter Derycz.

Accelrys' Biological Registration System Enables SHARING OF KNOWLEDGE

The recently launched Accelrys Biological Registration application is a multientity, enterprise-scalable registration system for biological entities that can significantly reduce the risks associated with non-registration and enable knowledge-sharing among research scientists.

The difficulties associated with an information management system for registering and relating biological materials are a particularly acute challenge for knowledge management.

"The previous lack of such a system has limited the potential reuse of these materials to drive innovation," observes Frank Brown, Ph.D., senior VP and chief science officer of Accelrys.

The Accelrys application integrates with existing infrastructure and comes with out-of-the-box templates for eight major biological entities: yeast, cell line, DNA, protein, plasmid, vaccine, antibody, and siRNA. Using a flexible and extensible knowledge model, with automatic relationship cross-referencing, organizations can configure the solution to support their scientific research and development processes, supported by the underlying business rules and workflows in Accelrys Pipeline Pilot.

Accelrys Biological Registration is the result of a three-year collaboration with several leading biopharmaceutical companies under the special interest group (SIG) model.

"We are proud that through this industry consortium, a state-of-the-art biological registration system has been developed," Dr. Brown says.

In other moves, Accelrys has updated its Pipeline Pilot scientific informatics platform. Accelrys Pipeline Pilot 8.0 allows research organizations to use a single informatics platform across their entire R&D enterprise, enabling scientists to work more efficiently and collaboratively, automating scientific workflows, and capturing institutional best practices, all while reducing associated operating costs.

This new system meets a broad spectrum of needs across the biopharmaceutical industry, while also providing the foundation for tomorrow's challenges in biological sciences, says Dr. Frank Brown.

Thomson CompuMark Reduces RISK OF COSTLY BRAND CONFLICTS

With so many drug names on the market, pharmaceutical brand owners face particularly complex challenges when developing new trademarks, says Martin Burke.

Thomson CompuMark has added more FDA content to its Pharmaceutical XC Search tool that helps companies protect their investment in creating, clearing, and registering drug trademarks.

Pharmaceutical XC Search now includes proprietary FDA drug sources, as well as authentic FDA phonetic orthographic computer analyses (POCAs) of potential marks, both of which reduce the risk of pharmaceutical brand conflicts. Endorsed by the FDA, POCAs help clients identify potentially problematical names early in the clearance process, before FDA submission, by assessing the similarity of the mark in writing and speech, thereby reducing the risk of name rejection because of potential confusion.

"Expanding the coverage offered by Pharmaceutical XC Search helps keep brand owners, and the IP professionals who advise them, ahead of the curve, providing the most complete information to help them make better decisions and reduce their business risk," says Martin Burke, group managing director of Thomson CompuMark.

Pharmaceutical XC Search offers exclusive search coverage of Thomson Reuters Micromedex, including international and FDA-approved drugs, as well as the Natural Medicines Database, the gold standard for natural medicines product information. Additional FDA-recommended sources include Drugs@FDA, AERS (adverse event reporting system), and VAERS (vaccine adverse event reporting system).

Aris Global and Medidata Offer INTEGRATION OF EDC, SAFETY REPORTING

The combined use of ARISg and Medidata Rave addresses the time-sensitive process of alerting regulatory agencies to potential safety events, says Aris Global's Jeffrey Yablon.

Medidata Solutions and Aris Global have made available an integrated solution that provides rapid data-sharing between the Medidata Rave system for electronic data capture (EDC), management, and reporting, and the ARISg solution for pharmacovigilance and clinical safety.

The solution leverages Medidata's Rave Safety Gateway, a configurable EDC-to-safety system interface to automatically transmit safety-related patient data collected in Medidata Rave directly into ARISg, reducing redundant data entry and eliminating the costly and time-sensitive burden of collecting and reconciling safety data.

This partnership is further proof that one-size-fits-all or multiple legacy systems approaches are no longer valid in our market, says Medidata's Glen de Vries.

"To achieve optimal efficiencies across clinical research processes, sponsors require, and are demanding, the ability to easily implement the most advanced technologies in alignment with their strategic goals," says Medidata President Glen de Vries. "Sponsors are savvier, the pressures on operations are greater, and there is no excuse for integrations that are less than seamless."

"Like Medidata, Aris Global has long subscribed to the approach of supporting customer choice in best-of-breed clinical trial technology," says Jeffrey Yablon, VP, sales Aris Global.

Sentrx Offers CRO CHANNEL-PARTNER SUPPORT SOLUTION

Sentrx's CROplus provides comprehensive channel partner support for CROs and is a comprehensive channel partner solution for growth-oriented clinical research organizations.

CROplus addresses those critical areas CROs have targeted in a pharmacovigilance channel partner through highly configurable adverse event management services, enabling CROs to customize workflow, support global regulatory reporting, and integrate both proprietary and third-party signal detection tools.

The solution incorporates fully integrated PV implementation plans, including prequalification audit support, SOP development, and systems assessment.

Our channel partner solution provides an easy-to-use set of pharmacovigilance capabilities, knowledge, and expertise for CROs, says Charles Saldarini.

"It's clear the needs sponsors have to seamlessly integrate pharmacovigilance with global clinical development are producing new opportunities for CROs," says Charles Saldarini, Sentrix's CEO.

IntraLinks Incorporates **DIGITAL IDENTITY CAPABILITIES** with Life-Sciences Solutions

IntraLinks is providing Safe-BioPharma's digital identity and signature standard with its document-sharing solutions, helping to meet the pharmaceutical industry's objective to move toward completely paperless clinical trials.

The Safe-BioPharma digital identity credential provides additional security and speed for signing documents, increasing clinical trial efficiency and eliminating the need to print hard copies of case-books and other documents. Users of IntraLinks' SaaS-based document-sharing platform have the opportunity to securely upload and use their Safe-BioPharma digital identities on the IntraLinks platform, ensuring that their credentials are available anytime and anywhere via the Web. IntraLinks is also enabling documents signed with Safe-BioPharma signatures to be stored and shared on its existing platform.

"Incorporating Safe-BioPharma's digital identity and signature standard into IntraLinks' platform is very significant for our clients and the community who rely on IntraLinks to manage their clinical trial communication and document exchange," says Alison Shurell, VP, life-sciences product marketing, IntraLinks.

"Our mission is to facilitate the transformation of the pharmaceutical and healthcare communities to a fully electronic business environment by 2015," notes Mollie Shields-Uehling, president and CEO, Safe-BioPharma. "The incorporation of the community's digital identity and signature standard into the IntraLinks platform helps professionals further simplify and manage compliance and security within a paperless environment."

This new capability helps life-sciences professionals simplify and manage compliance and security within a seamless, paperless environment, says Safe-BioPharma's Mollie Shields-Uehling.

Sponsors, CROs, and investigators are now able to eliminate the need to print or physically store the numerous documents that require signatures during a trial, says IntraLinks' Alison Shurell.

PPD's Expert Community Encourages **SHARING OF IDEAS AND OPINIONS**

PPD has added to its corporate website an online, interactive area where company and other industry professionals can engage in a robust exchange of ideas and opinions regarding important clinical research topics and trends.

PPD's Expert Community presents concepts and insights from PPD leaders on important, timely topics such as patient safety, globalization, biologics in drug development, and advanced technologies for managing clinical trials. Experts and professionals are invited to comment on the featured topics and respond with their own views about these important industry issues.

The biopharmaceutical industry continues to face significant scientific, regulatory, and economic challenges that require new ideas, expertise, and innovation, says Mike Wilkinson.

"Expert Community fosters an online exchange of viewpoints where experts can gain insights and understanding from peers," says Mike Wilkinson, executive VP of clinical development for PPD. "It is an important venue for sharing opinions about how we can work together toward a common goal of advancing global drug discovery and development."

Follow up

ACCELRYS INC. develops scientific business intelligence software and solutions for the life-sciences, energy, chemicals, aerospace, and consumer products industries. For more information, visit accelrys.com.

ARIS GLOBAL is a provider of integrated software solutions for pharmacovigilance and safety, regulatory affairs, clinical research, and medical information. For more information, visit arisglobal.com.

THE CHUBB GROUP OF INSURANCE COMPANIES provides property and casualty insurance for personal and commercial customers worldwide. For more information, visit chubb.com.

DERYCZ SCIENTIFIC INC. develops solutions that facilitate the reuse of published content. For more information, visit deryczscientific.com.

THE FOOD AND DRUG ADMINISTRATION is the federal agency responsible for ensuring the safety of foods, cosmetics, human and veterinary drugs, biological products, and medical devices. For more information, visit fda.gov.

GSW WORLDWIDE, an inVentiv Health company, is one of the world's largest healthcare advertising agencies. For more information, visit gsw-w.com.

INTRALINKS provides on-demand solutions for businesses to collaborate, communicate, and exchange information. For more information, visit intralinks.com.

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

NATIONAL INSTITUTES OF HEALTH, part of the U.S. Department of Health and Human Services, is the primary federal agency for conducting and supporting medical research. For more information, visit nih.gov.

PPD INC. is a global contract research organization. For more information, visit ppdi.com.

SAFE-BIOPHARMA ASSOCIATION is a nonprofit consortium that manages a digital identity and signature standard for the pharmaceutical and healthcare industries. For more information, visit safe-biopharma.org.

SENTRX provides safety technology systems and adverse event management and medical affairs solutions. For more information, visit sentrx.com.

THOMSON COMPUMARK, part of Thomson Reuters, delivers solutions for global trademark research and brand protection. For more information, visit compumark.thomson.com.

E-UPGRADES AND ENHANCEMENTS

- **CEGEDIM DENDRITE** has announced the availability of its flagship Mobile Intelligence customer relationship management (CRM) suite for iPad and iPhone users. Mobile Intelligence enables sales teams to have anywhere access to their CRM solution, giving them the ability to obtain real-time data, updated customer profiles, and leverage map location capabilities.

  For more information, visit cegedimdendrite.com.

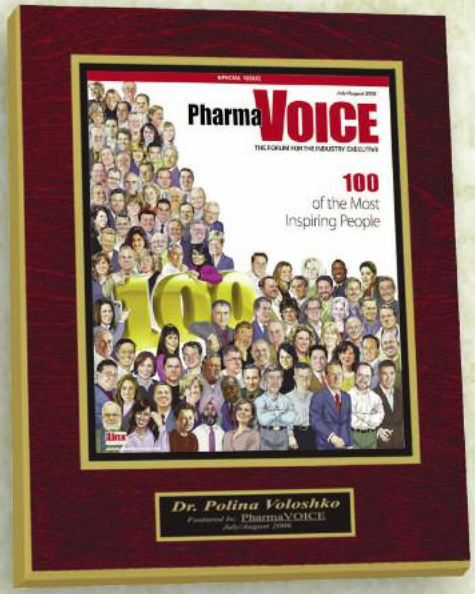
- **KIKA CLINICAL SOLUTIONS** has upgraded its Veracity electronic data capture platform to offer an improved user experience and additional operating system support. Key features of Veracity 3.9 include enhanced signature and manual queries workflow interaction, new filtering options for export, and extended options for e-mail notifications.

  For more information, visit kikaclinicalsolutions.com.

- **MEDICAL MARKETING SERVICE (MMS)** has released an enhancement to its Med-E-Mail service, Mult-E-Mail, that gives clients the option to deploy messages to multiple physician e-mail addresses. Clients using Mult-E-Mail deployments can increase response rates because it delivers a second or third touch to busy physicians checking different e-mail addresses at home, at work, or on the go via their mobile devices.

  For more information, visit mmslists.com.

A Pat On The Back You Can Hang On The Wall!



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