



SUITE OF TECHNOLOGY SOLUTIONS Addresses Safety Issues



Pharmaceutical executives know that technology is a major component of addressing safety and pharmacovigilance. As a result, they are demanding advanced IT solutions and services, says Mark Loudon, Director of Regulatory Compliance at ArisGlobal LLC.

Life-sciences organizations face increasing scrutiny from consumers, healthcare professionals, regulatory agencies, and legislators. As a result, it is critical that they take a proactive approach to the way adverse-event cases are received, processed, tracked, analyzed, and reported at all stages throughout the entire product life cycle. With this in mind, ArisGlobal LLC has developed Total Safety, a comprehensive suite of applications designed to meet the broad spectrum of drug safety, pharmacovigilance, and risk-management needs of pharmaceutical, biotechnology, medical-device, and contract research companies.

Total Safety is comprised of integrated, complementary applications that can be implemented as a complete suite or on a stand-alone basis. Each component is designed to support integration with legacy systems and is compatible with the most commonly used technology infrastructures in the industry.

The suite includes: ARISg for global adverse event reporting; agXchange for secure electronic submission of safety case information to regulatory agencies and among partners; SafetyMart for implementing a proactive safety, pharmacovigilance, and risk-management plan; SafetyComposer for meeting ever-changing regulatory periodic reporting requirements and internal reporting needs; and ClinicalConnect for supporting the connectivity and transfer of information from CDMS to ARISg, or other safety systems.

THOUGHT-LEADER MANAGEMENT DATABASE System Launched

InsiteResearch has launched the Keystone System, a platform database for managing and tracking all critical data related to key influencers, authors, speakers, advocates, investigators, and association officers for the pharmaceutical and medical industries. The system enhances the benefits of traditional key opinion leader databases by including expanded research capabilities, in-depth thought-leader profiles, and the ability to create and implement thought-leader development plans.

"Because pharmaceutical companies can more accurately identify, track, and manage their key influencers, the Keystone System enables them to maximize the return on investment of their thought-leader programs and ultimately impacts their bottom lines," says Eric Johnson, senior VP of InsiteResearch.

The Keystone System offers an integrated and detailed data repository that organizes all information into a single, central location. Pharmaceutical marketers, medical science staff, and sales personnel gain vital information on key industry leaders and can align marketing activities to the leaders according to their strengths.



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ONLINE CME Part of Strategic Partnership

MedPage Today LLC and Intellisphere LLC have forged a marketing and editorial alliance that extends the reach of MedPage Today's real-time, medical-news reporting, including continuing medical education (CME) programs.

Unlike didactic medical subject reviews, MedPage Today offers medical professionals the opportunity to receive CME credits as part of its news reporting. The combination of medical news with



An increasing number of physicians are embracing online CME, says Paul Greenberg, M.D., President of MedPage Today LLC.

CME provides physicians with the ideal content to meet their needs.

Under this partnership, MedPage Today's online content will be integrated into Intellisphere's *MD Net Guide*, a print publication distributed to more than 250,000 physicians. Intellisphere also has integrated MedPage Today's real-time news feed into its professional healthcare Website, mdnetguide.com.

ONLINE QUALITY IMPROVEMENT PROGRAM Addresses Coronary Artery Disease

The American Academy of Family Physicians (AAFP) has launched a second METRIC module, Coronary Artery Disease: Improving Patient Care.

AAFP's METRIC (Measuring, Evaluating, and Translating Research Into Care) is an online quality improvement program. The first module, Diabetes: Improving Patient Care, was launched in January 2005.

The program was developed to provide members with an opportunity to participate in the new practice-based continuing medical education (CME) pro-

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cess, while at the same time fulfilling the American Board of Family Medicine's requirements for Maintenance of Certification for Family Physicians (MC-FP) Part IV.

"Programs such as METRIC are key to life-long learning and developing a sus-

tainable 'quality improvement' culture," says Bruce Bagley, M.D., AAFP medical director of quality improvement. "Our goal is to teach family physicians how to do these types of interventions on an ongoing basis."

PATIENT-RECRUITMENT TOOL Introduced by (Pi) Patient Interaction



Better patient targeting means better results, increasing the likelihood that a clinical trial will enroll on time resulting in moving a product to market more quickly and with less expense, says Ron Drenning, President of First Marketing.

(Pi) Patient interaction has introduced Precision Patient Insights, a proprietary profiling tool that enables clinical-trial sponsors to learn as much as they can about patients with a specific therapeutic condition and helps them target the most likely prospects for enrollment in a specific clinical trial.

The goal is to provide sponsors with predictive information based on an analysis of individuals who have self-reported having a given therapeutic condition.

Patient details include socioeconomic and behavioral characteristics, such as income, age, occupation, neighborhood surroundings, household composition, and lifestyle habits.

Precision Patient Insights blends lifestyle and behavior patterns (psychographic) to better understand what motivates a specific group, as well as their media preferences for better targeting of print, radio, and broadcast advertisements. It also links to a large network of consumer research on media behaviors, such as newspaper, radio, and television usage.

"With a more complete picture of the patient-recruitment target, our strategic team can prepare recruitment materials such as posters, brochures, and ads that reinforce themes, images, and messages that truly motivate response," says Ron Drenning, President of First Marketing, Patient interaction's parent company.

INDUSTRY TECHNOLOGY COUNCIL Formed Through Merger

The Compliance Consortium has merged with the Open Compliance and Ethics Group (OCEG), forming the OCEG Technology Council to provide information and best practices on using technology to manage areas of compliance, ethics, and corporate governance.

The Compliance Consortium's nine member companies are the charter members of the Technology Council, with current OCEG members eligible to join immediately.

Ted Frank, chairman of the Compliance Consortium advisory council and president of Axentis, joins OCEG's overall Leadership Council and leads the newly formed Technology Council.



The Compliance Consortium is excited to continue its work with OCEG's membership to define a comprehensive enterprise governance, risk, and compliance management reference architecture and associated deliverables, says Ted Frank, Head of OCEG's Technology Council.

"The Compliance Consortium has been focused on the important topic of identifying best practices for applying technology to governance, risk, compliance, and ethics management processes," says Scott Mitchell, president and CEO of OCEG. "We are delighted to incorporate and leverage the Compliance Consortium's work and its membership to further OCEG's broader charter to help organizations align their information-technology activities to drive business performance and promote integrity."

One of the OCEG Technology Council's first objectives is to expand membership to include commercial organizations and other technology providers.

Customized Messages AVAILABLE FOR TABLET PCS

Proscap Technologies and Blue Diesel have joined forces to develop customizable messaging for Tablet PC-based sales materials.

Proscap currently offers a solution that enables pharmaceutical sales teams to manage sales and marketing content, including visual aids, case studies, clinical reprints, POA materials, opinion leader videos, managed-care information, and training materials to be distributed via the Web to reps in the field using Tablet PCs.

Blue Diesel is developing



Tablet PC-based sales aids are flexible, easy to update, and allow pharmaceutical sales reps the ability to customize their presentations, says Kelly Gratz, President of Blue Diesel.

the content and managing the information flow of online sales materials for its pharmaceutical clients.

"Not only is the online format more flexible and easier to update with new information, it also gives sales reps the ability to customize the presentation for the specific physician they are calling on," says Kelly Gratz, president of Blue Diesel. "We are expanding our interactive focus by taking on direct-marketing projects that include both online and offline components."

Electronic Records Compliance INFORMATION CENTER WEBSITE

AXS-One Inc. has launched the Electronic Records Compliance Information Center (ERCIC). ERCIC provides a single destination for anyone in IT, legal, compliance, records management, or the media attempting to navigate the complex and ever-changing issues of electronic records management. ERCIC is a free resource that can be accessed at axsone.com/form_resource_ctr.shtml.

"Electronic records management is often seen through a very narrow lens; organizations tend to view it as the responsibility of one department to meet a few of their requirements or regulations," says Bill Lyons, CEO of AXS-One. "The reality is that successful electronic records management is a much broader issue that affects the entire organization and requires executive sponsorship to be successfully implemented and enforced."

ERCIC includes comprehensive cross-functional information on topics such as records compliance management (RCM), e-mail and instant messaging management, e-discovery, data retention, and U.S. regulations segmented by industry, as well as links to other public-information sources. In addition, it contains archived presentations, case studies, FAQs, white papers, interviews, tips, checklists, and Webinar transcripts from AXS-One.

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E-TRAINING SOLUTIONS to Improve Site Performance



Lance Converse

We help companies improve efficiencies and site satisfaction, which can, in turn, reduce trial timelines and increase subject compliance, says Lance Converse, CEO of ePharmaLearning.



Phil Lee

Our experience demonstrates that effective training is an essential component of a successful ePRO solution, says Phil Lee, President and CEO of PHT Corp.

ePharmaLearning Inc. and PHT Corp. have formed a partnership to offer advanced e-training solutions to improve clinical-trial site satisfaction.

Through the agreement, ePharmaLearning is delivering online training for sites on PHT's e-source applications, including LogPad, StudyPad, and StudyWorks.

The e-learning modules, which address topics ranging from setting up a LogPad to running subject compliance reports in StudyWorks, are fully animated and narrated. They are available on-demand throughout the study to supplement the training sessions delivered at the initial investigator meeting. The interactive modules include simulation exercises, a training certification test, and complete training records for each user that completes the online tutorial.

ePharmaLearning's customized training educates site personnel on the details of the LogPad or StudyPad system and improves the site coordinators' ability to help subjects unfamiliar with e-diaries, thereby enabling sponsors to better leverage their investment in ePRO. Clients also benefit from the added efficiency

of online training, which typically costs 80% less than traditional in-person training and can achieve equivalent learning outcomes in one-third of the time.

Website Offers SOLUTIONS-ORIENTED RESOURCES FOR DTP MARKETERS

MTI Information Technologies has relaunched its Website, offering visitors a selection of important information categories, including real-life case studies backed by simplified navigation keys, to assist in the formulation of marketing communications plans across all product categories and life-cycle stages.

Key among the site's features is the eXtendRx sales optimization program, which is designed to drive incremental sales in a competitive marketplace by delivering just the right message to the right physician at the right time with the right frequency.



With competition constantly increasing and sales resources decreasing, alternative media solutions need to be part of the pharmaceutical marketing mix, says Betty Michelson, Senior VP of Business Development at MTI.



SelectSite Express delivers savings by improving productivity and empowering spend management, says Stephen Wiehe, President and CEO of SciQuest.

Midmarket E-PROCUREMENT SOLUTION Reduces Time and Costs

In response to demand from midtier organizations, SciQuest Inc. has launched SelectSite Express, a Web-based e-procurement solution that delivers significant savings by improving productivity and empowering spend management.

"Current market conditions are putting pressure on time resources as well as budgets," says Jamie Duke, chief operating officer at SciQuest. "Mid-sized organizations are particularly constrained. The solution can help save time and money, allowing organizations to reallocate more resources to their strategic initiatives."

Users can search and shop from hosted catalogs and supplier Websites; create electronic requisitions; send requisitions through electronic approval routing; distribute orders to suppliers automatically; gain visibility into order status, from requisition to receipt; as well as aggregate all requisitioning activity and spend data in one place.

In addition, the solution comes completely preconfigured, allowing quick implementation with minimal IT support.

Unified Platform MANAGES CLINICAL DATA

Medidata Solutions Worldwide has introduced Medidata Rave 5.4, a user-friendly tool to help pharmaceutical, biotechnology, and medical-device companies streamline clinical-trial processes, offer early insight into study bottlenecks, and leverage an intuitive interface for widespread site adoption.

By making tasks such as site data entry, surveillance data capture, local lab data integration, study configuration, and system administration faster and more efficient, the system promises increased user acceptance.

Medidata Rave 5.4 also provides a highly scalable platform for global trials and offers integrated dictionary coding functionality and automated data migration for CRF revisions. For the sponsor, Rave 5.4 provides the earliest visibility into critical data to drive better decision-making, increase return on investment, and lower overall risk.



Rave 5.4 was designed to appeal to sponsors wanting to increase ROI and for end-users whose focus is on intuitive improvements, says Tarek Sherif, CEO, President, and Cofounder of Medidata Solutions Worldwide.

WEB-BASED SYSTEM Improves Study Management

iAdvantage Software Inc. has launched a Web-based system designed by scientists for scientists that integrates study design, e-notebook design, data collection, and data reporting.

"By eliminating paper systems and islands of automation, e-Study Manager's unique reporting tool allows critical business decisions, such as product-go/no-go, to be made at any point in the study life cycle, preventing the waste of critical resources," says Fate Thompson, Ph.D., president and CEO of iAdvantage.

By automating data collection, the software allows scientists from the same or separate sites to access the study, record their findings, and pull supporting data into one secure database. Designated team members can collect, access, share, analyze, and report the information quickly and easily. Patent-pending technology provides on-demand document generation, reducing final report creation time from weeks to minutes.



By eliminating paper systems and islands of automation, e-Study Manager improves communication, increases productivity, and reduces time to market, says Dr. Fate Thompson, President and CEO of iAdvantage Software.

ENTERPRISE CONTENT MANAGEMENT Solution Enhances Process Capabilities

First Consulting Group Inc. (FCG) has released FirstDoc 3.3, the latest version of its enterprise content management (ECM) solution for the life-sciences industry.

FirstDoc 3.3 includes enhanced XML capabilities and a re-architected enterprise object model to enable more flexible content sharing and better business process harmonization across functional areas.

With new organizational mandates around speeding submissions, reducing time to market, and cutting costs, the life-sciences industry is moving to a new model and metrics for measuring content management effectiveness.

FCG officials say by incorporating XML into FirstDoc 3.3 and leveraging its content reuse capabilities, product content development costs can be reduced by at least 20%. The program also ensures compliance with new labeling regulatory standards set by the FDA and European Medicines Evaluation Agency, both of which have XML-based standards.



We estimate that companies can reduce the cost of product-content development by at least 20% based on reuse of common content and safety regulations among products, says Jeffrey Klein, VP of Product Strategy for FCG's life-sciences practice.

Follow up

THE AMERICAN ACADEMY OF FAMILY PHYSICIANS, Leawood, Kan., is the only medical specialty society devoted solely to primary care and represents more than 94,000 physicians and medical students nationwide. For more information, visit aafp.org.

ARISGLOBAL LLC, Stamford, Conn., develops pharmacovigilance and safety-registration information management, clinical-trials management, and medical communications software solutions for the pharmaceutical, biotechnology, medical-device, and CRO markets. For more information, visit arisglobal.com.

AXS-ONE INC., Rutherford, N.J., provides high-performance records compliance management solutions. For more information, visit axsone.com.

BLUE DIESEL, Columbus, Ohio, is an interactive communications company that blends direct marketing, interactive technology, and creative design to provide evidence-based marketing solutions. For more information, visit bluediesel.com.

THE COMPLIANCE CONSORTIUM, Cleveland, was formed by software, content, and services firms with the goal to promote effective enterprise governance, risk, and compliance management. For more information, visit thecomplianceconsortium.org.

EPHARMALEARNING INC., Conshohocken, Pa., provides clinical services that improve the way sites are selected, trained, and activated to commence clinical trials. For more information, visit epharmalearning.com.

FIRST CONSULTING GROUP INC., Long Beach, Calif., provides outsourcing, consulting, and systems integration for healthcare, pharmaceutical, and other life-sciences organizations throughout North America, Europe, and Asia. For more information, visit fcg.com.

IADVANTAGE SOFTWARE INC., Cary, N.C., develops electronic study management software that supports development and preclinical life-sciences studies by improving data communication, productivity, real-time business intelligence, and time to market. For more information, visit iadvantagesoftware.com.

INSITERESEARCH, Union, N.J., is a market research company and a division of Advanced Health Media. For more information, visit insiteresearch.net.

INTELLISPHERE LLC, Plainsboro, N.J., is the publisher of MD Net Guide journals and e-mail newsletters, which explore the ongoing convergence of technology, the Internet, and healthcare. For more information visit, mdng.com.

MEDIDATA SOLUTIONS WORLDWIDE, New York, helps the world's leading pharmaceutical, biotechnology, and medical-device companies realize the maximum potential value from their clinical-research investments. For more information, visit mdsol.com.

MEDPAGE TODAY LLC, Little Falls, N.J., provides real-time medical news for physicians, clinicians, and other medical professionals. For more information, visit medpagetoday.com.

MTI INFORMATION TECHNOLOGIES, Langhorne, Pa., offers pharmaceutical marketers proprietary, demand-generating products that use sophisticated, data-driven technologies. For more information, visit mtiinfotech.com.

OPEN COMPLIANCE AND ETHICS GROUP (OCEG), Scottsdale, Ariz., was formed in 2002 by a multi-industry, multi-disciplinary coalition that recognized the need to integrate the principles of effective governance, compliance, risk management, and integrity into the practice of everyday business. For more information, visit oceg.org.

PHT CORP., Charlestown, Mass., provides electronic patient reported outcome (ePRO) solutions in worldwide clinical trials. For more information, visit phtcorp.com.

(PI) PATIENT INTERACTION, Pompano Beach, Fla., a division of First Marketing, offers a full-service approach to facilitate, accelerate, and enhance the clinical-trial enrollment and retention process. For more information, visit patientinteraction.com.

PROSCAPE TECHNOLOGIES, Horsham, Pa., develops face-to-face sales and marketing effectiveness software for the pharmaceutical industry. For more information, visit proscapetechnologies.com.

SCIQUEST INC., Cary, N.C., provides supplier management and procurement automation solutions that help customers gain greater visibility and control over their spend. For more information, visit sciquest.com.