



Acurian Launches NEW VERSION OF RECRUITMENT MANAGER



The real power of Recruitment Manager lies in the simplicity and elegance of its design, which removes any need for user training or support, says Roger Smith, Acurian's Chief Technology Officer.

Acurian Inc. has launched the latest version of Recruitment Manager, a Web-based application that enables sponsors to track patient-recruitment campaigns and investigator performance.

This version includes enhanced views of project data to provide project managers with a comprehensive analysis of their investments in patient recruitment and investigative sites. These views include current data on recruitment vendor performance, recruitment source comparisons, site status and information, and patient ineligibility breakdowns.

"Recruitment Manager is the direct result of customer demand for an online, real-time system that tracks every recruitment asset, be it vendor, patient, or site," says Mark Eisenach, Acurian's CEO. "Over time, this information becomes a knowledge base that the sponsor can reference and use to make decisions based on fact rather than memory or other subjective data."

Recruitment Manager is a hosted solution that requires only a standard Web browser, Internet connection, and secure login. Sponsors and CROs can manage multiple projects by assigning administrators, managers, and users within and outside the enterprise. It can scale from one user to hundreds of users to meet the needs of any size organization.

AXIS Healthcare Communications Launches ONLINE RESOURCE CENTER

AXIS Healthcare Communications LLC has launched Nucleus, an online life-cycle resource center for the pharmaceutical and biotechnology industries. The resource was developed through a strategic partnership between AXIS Healthcare Communications and Econium Inc., a provider of collaborative and knowledge management solutions.

Nucleus is a browser-based resource-management tool that provides real-time access to core product assets, competitive information, project management, status reporting, and action management to global product development and commercialization teams.

"A pharmaceutical product is not just a molecule; it is a vast compendium of clinical and preclinical data, publications, market research, competitive intelligence, key-opinion leader information, and more," says Neil Matheson, president and CEO of AXIS. "These pieces of information are the key prod-



Successful global pharmaceutical companies agree that bridging the gap between clinical development and marketing teams, as early as Phase II in the drug-development process, is essential to successful commercialization and maximizing the company's investment in the product life cycle, says Neil Matheson.

uct assets and the building blocks of pharmaceutical brands."

With Nucleus, brand teams gain access to core assets through an intuitive browser-based interface. The product is a dynamic suite of tools that help global product teams keep close tabs on the brands and their competitors' development. Because of its modular design, Nucleus can grow to accommodate a global team's changing needs. The Asset Library holds science, education, training, and promotional assets of all file types. Its navigation and search features make it easy to locate previously developed assets or those in draft stage.

The Publications Module encourages real-time monitoring of project status and assets. Supporting studies, messages, calendars, and reports are closely integrated and are complemented by a comprehensive database of journals and meetings. The Strategic Module holds research that supports the commercial plan, including market research reports, and competitive-intelligence tracking.

Dendrite Offers NEW-GENERATION CRM TECHNOLOGY

Dendrite International Inc. has launched a technology framework that will serve as the core architecture for a new generation of pharmaceutical customer-relationship management (CRM) systems.

The framework is a flexible technology architecture that enables cost-effective integration and a streamlined configuration process for a best-of-breed approach to pharmaceutical CRM software applications, including salesforce automation, sample management, customer management, call center, marketing, and data-management solutions.

"Pharma's approach to CRM primarily has been focused on two components: SFA and call center, or a combination of the two," says Dave Escalante, director of North American marketing, Dendrite. "Pharma companies have not tackled what we call the enterprise customer integration problem. A single view across the enterprise, or of the customer interaction across that enterprise, does not exist today within pharma."

He says many pharma companies have had to sacrifice existing capabilities and functionality as a result of upgrading to SFA.

"Pharma companies are adopting stringent strategies and standards as they relate to integration," Mr. Escalante says. "This is going to have a huge impact on their ability to pick solution providers in the future."

Featuring a set of pharmaceutical-oriented Web and integration services and common objects, Dendrite's framework helps ensure interoperability with other leading software providers and strategic partners. The framework is built on Microsoft .NET to take full advantage of the inherent integration and future expansion of Web services.

Dendrite's new framework will form the core of all new application development and be incrementally incorporated into the company's existing solution portfolio. Using the framework's configuration tools, the latest version of Dendrite's flagship sales-effectiveness suite and home-office products will be released later this year and be among the first applications to use the new platform.



Big-suite technology applications may not have the flexibility to satisfy pharma's needs from a business perspective, and this can result in the total cost of ownership being more than originally planned for, says Dave Escalante, Director of North American Marketing at Dendrite.

Phase Forward Releases NEXT-GENERATION SAFETY SOLUTION

Phase Forward has introduced Clintrace 4, a next-generation safety solution leveraging Web-based technologies. It has the scalability, reliability, and security to meet the needs of global safety organizations.

Clintrace 4 enables pharma, biotech, and medical-device companies to meet key challenges by speeding adverse event processing by electronically linking all safety personnel; boosting the productivity of safety personnel through an easily configured workflow and user interface; and reducing IT expense with Web-based software that is easy to install, maintain, and support.

The architecture allows user access via a standard Web browser. In addition, since there are fewer software modules to install, the validation process is streamlined, and the overall validation effort can be reduced by about 20%.

The Clintrace 4 solution electronically links all



We have re-engineered the Clintrace solution to incorporate a scalable and reliable Web-based architecture, leveraging leading-edge workflow capabilities that enable safety organizations worldwide to meet their global challenges, says Steve Rosenberg, VP of Development at Phase Forward.

safety personnel — those in-house as well as at CROs, partners, and affiliates. Linking all safety users electronically speeds the delivery of information for faster case processing, while preventing delays due to misplaced paperwork. With an extensive library of standard reports, managers have instant visibility into all work in process, including assigned tasks and their statuses, deadlines, and coding accuracy to help drive the timely submission of reports.

Case workflow expedites case movement among team members from data entry through approval. The default workflow is easily configured to organization-specific requirements. User interface enhancements in the Clintrace 4 product assist in processing cases more efficiently.

All default forms and screens are easily configured to meet organizational standards and keyboard accelerators speed common steps.

Veritas Research Introduces TOOLS FOR MONITORS

Veritas Research Inc. has introduced CRAtoolbox, a PDA-based application geared to the pharmaceutical/biotech industries.

Designed to assist clinical monitors with calculations and conversions for onsite case report form (CRF) review, CRAtoolbox is a customized calculator, converter, and data/process confirmation tool.

The functions of CRAtoolbox can be customized to match the various clinical-research needs within the industry. It allows for imperial or metric units for height, weight, and temperature, U.S. or European date styles, and either 12-hour or 24-hour time formats.

"We all know the high cost of query resolution, monetarily, as well as the time lost toward database lock," says Stacey Lense, executive VP of Veritas Research. "CRAtoolbox helps eliminate the common errors found onsite in CRFs and streamlines a sponsor's query resolution process in-house."

CRAtoolbox is a customized calculator, converter, and data/process confirmation tool.

Constella Group and SAS Provide Integrated DRUG-DEVELOPMENT SOLUTION

Constella Group Inc. and SAS Institute Inc. are providing an integrated offering that allows life-sciences companies to merge the day-to-day planning and execution of clinical trials with powerful data integration and analysis.

The joint offering — Constella Orion Powered by SAS Drug Development — works through an ASP platform to provide U.S.-based customers with direct visibility into the total clinical project through a single, intuitive interface.

The joint offering provides companies with the ability to actively monitor the progress of clinical trials and take action to address problems, such as delays in overall patient enrollment, instead of waiting until a paper report is issued at a predetermined milestone.

Licensed on a per-trial basis to pharmaceutical, biotechnology, and medical-device companies



With the integration of SAS Drug Development and Constella Orion, customers will not only manage, but truly collaborate around life-sciences research programs through a secure, Web-based environment that provides the regulatory support that is required, says Kecia Serwin, General Manager of SAS' Health and Life Sciences Group.

engaging in Phase II through Phase IV clinical trials, it provides a cost-effective approach to implementing and managing new technologies.

Customers can analyze the collected clinical-trials data for regulatory submission and explore their research for new market opportunities, product line extensions, and safety issues, all within a controlled and secure collaborative framework designed for life-sciences research industries.

"Together with SAS, we are creating a seamless, end-to-end drug development platform unlike any other on the market," says Donald A. Holzworth, CEO of Constella. "This highly affordable platform is designed to increase R&D efficiency, improve collaboration and information exchange among study teams and sponsors, and accelerate time

to market with excellent regulatory support and direction."

Omnicare Clinical Research Offers TRIAL-MANAGEMENT SYSTEM

Omnicare Clinical Research has released a new version of its clinical-trial-management system, OmnieTrack v6.0. This tool enables users to streamline process and enhance communication and reporting by providing upgraded modules for clinical investigators, clinical research associates, and clinical-trial-management activities from site recruitment through close of the site.

OmnieTrack v6.0 is a Web-based program providing secure access for all members of the global project team to clinical-trial activities, status reports, and updates. CTMS systems hold the potential to streamline studies through efficient management.

OmnieTrack enables information to be tracked through customized reports, providing secure, real-time project updates around the world. This system provides key data for study management, including information on site and subject enrollment status to facilitate deployment of resources.



This achievement places Omnicare Clinical Research on the leading edge of pharmaceutical electronic clinical-trial activities, says David Morra, CEO of Omnicare Clinical Research.

DataLabs Offers PRODUCTS AND SERVICES FOR CROs



Because CROs conduct more than half of all clinical trials, we feel it is important to offer a compelling program that provides tangible benefits for all industry stakeholders, from CROs and sponsors to regulatory agencies and consumers, says James Langford, President of DataLabs.

DataLabs Inc.'s CRO Partner Program — a suite of software, services, and benefits — is designed to help contract research organizations (CROs) expand their services and improve the clinical-development process.

The DataLabs CRO Partner Program includes the DataLabsXC CRO Edition software suite for clinical-study design, electronic data capture, and data management, which can be privately labeled to the CRO partner and is configurable to meet the various processes of the CRO's pharmaceutical clients.

Through the program, CROs have access to specialized services to support the growth of their businesses and to form libraries and validation support. DataLabs

also provides documentation and training materials customized for CRO clients and dedicated support. The program also features flexible pricing options (from leasing to owning unlimited licenses), as well as the opportunity for charter members to join the DataLabs CRO advisory board, which provides feedback for product and services advancement.

The DataLabsXC CRO Edition software suite can be branded specifically for the CRO partner. Based on Microsoft platform technology, XML Web services, and the CDISC ODM standard, the CRO Edition is able to adapt to each sponsor's established operating procedures and integrates easily with existing technology systems. DataLabsXC was developed using the Microsoft .NET Framework, an architecture designed to support XML Web services. Applications built using the .NET Framework can connect with existing systems and packaged applications regardless of the underlying platform.



We're pleased to now offer our customers a solution that enables them to capture important quality-of-life data from patients during scheduled clinic visits, says Doug Engfer, Founder and CEO of invivodata.

invivodata Inc. has unveiled SitePRO, an in-clinic patient reporting system for collecting patient-reported outcomes (PRO) data in clinical trials. Specifically designed for conducting on-site quality-of-life assessments and patient screening, SitePRO is currently being used in a global

Fast Track Systems Introduces SOFTWARE FOR PROTOCOL DEVELOPMENT

Fast Track Systems has introduced TrialSpace Designer, an enterprise solution to enable efficient and consistent trial protocol design. The software was developed based on the findings from an extensive beta program with four of the world's largest pharmaceutical organizations.

Based on economic analyses performed on the results of numerous protocol quality engagements, Fast Track estimates that protocol errors cost the industry \$710 million per year in direct costs and more than \$7.5 billion per year in lost potential revenue. Many of these errors originate from poor or incomplete protocol design, resulting in development delays, document inconsistencies, long review times, and excessive procedures.

TrialSpace Designer offers a first-in-class approach to developing protocol designs by combining unique industry data with sophisticated modeling technologies to create more accurate, consistent, and efficient protocols. TrialSpace Designer embeds the Fast Track Intelligent Clinical Protocol technology within Microsoft Word, resulting in a familiar user-friendly, data-driven environment for medical researchers designing protocols and for professional teams that review, finalize, and implement protocols.

"Together with our TrialSpace solution suite, TrialSpace Designer enables the industry to execute clinical development plans more effectively over the entire clinical development life cycle for remarkable gains in time, cost savings, and resource allocation," says Dr. Michael Kahn, VP and chief medical officer, Fast Track Systems.



Our technology opens the door for pharmaceutical and biotech companies to achieve substantial breakthroughs in trial performance, as well as major reductions in operational costs, says Dr. Michael Kahn, VP and Chief Medical Officer of Fast Track Systems.

Medidata Solutions Introduces NEW CLINICAL DATA SOLUTION

Medidata Solutions Inc. has introduced RAVE 5.0, a unified platform for electronic clinical-data management (eCDM). The RAVE 5.0 environment features the same ultra-thin client architecture available in previous Medidata RAVE electronic-data capture (EDC) systems. It provides a complete range of clinical-data management and EDC capabilities within a single technology platform for pharmaceutical, biotech, and medical-device companies.

By deploying a single system instead of employing an integration approach, companies can eliminate significant redundancies in processes and data.

Medidata's RAVE 5.0 allows companies to flexibly implement eCDM solutions at a pace that suits their business goals, offering a smooth transition from traditional processes to eCDM through integration with existing CDM systems, support of CDISC data import and export, and the ability to easily upgrade existing installations with additional RAVE modules.

"Our approach is to provide technology with the flexibility to map to and evolve with our clients' varying requirements and protocols, eliminating the burden of ongoing software customization," says Glen de Vries, cofounder and chief technology officer of Medidata. "Instead of adapting processes to accommodate new technology, we believe customers should be able to use our technology both with their existing data management methodologies and as a foundation for innovative new processes."



We're delivering on our vision of a single technology platform that can provide value in all facets of clinical trials, including building and deploying studies, capturing and managing data, coding and submitting to agencies, as well as reporting on and optimizing business processes driven by the data itself, says Glen de Vries, Cofounder and Chief Technology Officer of Medidata.

invivodata Provides SYSTEM FOR COLLECTING PATIENT DATA AT SITE LEVEL

Phase IIB trial involving hundreds of sites and thousands of patients.

SitePRO features a screen three-and-one-half times wider than a standard personal digital assistant (PDA) display and can present complex text-based questions on an easy-to-use touch-screen interface without reformatting.

Merging the practicality of a PDA with the functionality of a Tablet PC, SitePRO is an easy-to-use sys-

tem to help patients provide accurate in-clinic reporting. It scores patient assessments automatically, expediting the process and eliminating data entry errors.

SitePRO was developed through an exclusive licensing agreement between invivodata and AlphaSmart Inc., a provider of technology solutions for education and productivity. invivodata holds the rights to use the product in clinical studies.

Churchill Communications Offers **PUBLICATION-PLANNING TOOL**

Churchill Communications has introduced the latest version of its Clinical Edge publication-planning services. New competitive benchmarking and proforma planning tools allow clients to make the best use of their time and resources.

The new version of Clinical Edge includes expanded reporting features and opinion-leader tracking modules that help to keep publication-planning team members abreast of the latest developments.

"Clients have a lot more riding on the success of a publication plan than they did 15 years ago," says Frank Rodino, founder and president of Churchill Communications. "Our new editorial services and database features let clients test assumptions before going live. This helps to save time and money."



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New Clinical Edge features include:

- Detailed competitive benchmarking to determine precisely where and to what degree publication efforts should be targeted;
- Proforma planning tools that allow clients to test publishing variables before deciding on a final course of action;
- Comprehensive opinion-leader modules for vetting prospective authors or speakers; and
- Custom reporting features that allow clients to tailor communications activity reports to their specific needs.

"Publication-planning needs often differ between product teams within a company," adds Bill Matthews, director of information services at Churchill Communications. "Clients now have the flexibility to choose the editorial services, database modules, or delivery methods that meet their specific needs."

Follow up

ACURIAN INC., Horsham, Pa., a full-service provider of clinical-trial patient and investigator recruitment solutions for the life-sciences industry, is able to identify, contact, prescreen, and refer study candidates and profile and recruit investigators. For more information, visit acurian.com.

AXIS HEALTHCARE COMMUNICATIONS LLC, Yardley, Pa., provides a full spectrum of services to support the life cycle of products, including strategic consulting, analysis and planning, medical communications, medical education, sales training, and healthcare advertising and promotion. For more information, visit axis-healthcare.com.

CHURCHILL COMMUNICATIONS, Millburn, N.J., offers professional advocacy, publication planning, and medical-education programs. Clinical Edge is the company's strategic communications planning service, a publishing database that contains detailed profiles of journals, associations, key opinion leaders, and clinical studies. For more information, visit churchillcommunications.com.

CONSTELLA GROUP, Durham, N.C., is a provider of professional health services worldwide, dedicated to enhancing human health through innovative science, technology, and knowledge solutions. For more information, visit constellagroup.com.

DATALABS INC., Irvine, Calif., is a developer of Internet-based applications for clinical development that help the biopharmaceutical industry accelerate clinical trials with software for study design, data capture, and data management. For more information, visit datalabs.com.

DENDRITE INTERNATIONAL INC., Morristown, N.J., develops and delivers solutions that increase the productivity of sales, marketing, and clinical processes for pharmaceutical and other life-sciences clients. For more information, visit dendrite.com.

ECONIUM INC., Totowa, N.J., is a provider of business solutions whose capabilities include strategic technical and business process consulting, solution development and design, and deployment and hosting, as well as data repositories for presentations, business workflow solutions, document life cycle management, and digital asset management. For more information, visit econium.com.

FAST TRACK SYSTEMS, Fort Washington, Pa., a clinical-development optimization company, provides a data-driven systems approach to expediting clinical-trial design, setup, and execution. For more information, visit fast-track.com.

INVIVODATA INC., Pittsburgh, combines behavioral science, information technology, and clinical expertise to capture clinical-trial data directly from patients. invivodata.com's solution provides real-time access to study data, giving researchers and sponsors visibility

into study progress and improving trial efficiencies. For more information, visit invivodata.com.

MEDIDATA SOLUTIONS INC., New York, is a provider of Web-based data-management solutions for clinical trials and offers applications that streamline the process of collecting, verifying, and consolidating clinical-research data. For more information, visit mdsol.com.

OMNICARE CLINICAL RESEARCH, King of Prussia, Pa., is a division of Omnicare Inc. and provides clinical-research services for the pharmaceutical and biotechnology industries in 29 countries. For more information, visit omnicarecr.com.

PHASE FORWARD, Waltham, Mass., is a provider of integrated enterprise-level software products, services, and hosted solutions for use in the clinical-trial component of its customers' global research and development initiatives. For more information, visit phaseforward.com.

SAS INSTITUTE INC., Cary, N.C., is a market leader that provides a new generation of business intelligence software and services that create true enterprise intelligence. For more information, visit sas.com.

VERITAS RESEARCH INC., North Massapequa, N.Y., is an independent contract research organization that has been serving the pharmaceutical/biotechnology industry since 2000. For more information, visit veritas-cro.com.