BioClinica Launches System for CLINICAL-TRIAL SUPPLY PLANNING

BioClinica Optimizer integrates planning and feedback loops with other e-clinical technologies, allowing companies to move beyond the current environment of spreadsheets and manual tools to plan and analyze clinical supply chains programmatically.

BioClinica Optimizer combines and enhances the features of the tcVisualize and tcOptimizer solutions developed by Tourtellotte Solutions, which was acquired by BioClinica in September 2009.

"Running out of critical supplies for clinical trials requires emergency shipments, potentially costing both time and millions of dollars," says Ed Tourtellotte, VP of product innovation for BioClinica. "We believe BioClinica Optimizer sets a new benchmark for the planning of clinical studies," adds BioClinica CEO Mark Weinstein.

As the complexity of clinical trials continues to increase, it's imperative that accurate clinical supply planning be a part of the process, says Ed Tourtellotte.

Optimizer provides customers the ability to streamline this vital process, potentially saving them hundreds of thousands of dollars per trial, says Mark Weinstein.

New Quintiles Tool Accelerates TRIAL RECRUITMENT

Every day lost in recruitment delays access to new and better medicines and is hugely expensive, says Dr. Chris Cabell.

Quintiles' latest solution, Quintiles Trial Enrollment Accelerator (QTEA), speeds patient recruitment by helping customers better manage the quality, consistency, and effectiveness of messaging and media outreach.

"On-time patient recruitment is the biggest challenge in clinical research today," notes Chris Cabell, M.D., senior VP, global access to patients.

QTEA allows biopharma companies to benefit from the effectiveness of a centralized patient outreach campaign without the usual high costs. It facilitates creation of consistent, branded recruitment materials for all sites, based on a full range of standard templates, helping users to capitalize on existing local media intelligence and increased negotiating power to reduce media costs by up to 50%. It also provides access to Quintiles proprietary opt-in patient database and referral network to drive highly efficient one-to-one marketing.

"Direct outreach has become a vital component of on-time patient recruitment with consistent evidence of breakthrough effectiveness," Dr. Cabell says. "But some biopharma companies are still reluctant to invest up-front in fully integrated, high-quality communication plans for their studies. This means that responsibility for creating and placing materials is typically left to individual sites, giving rise to inconsistency, poor returns on investment, and little to no visibility of program effectiveness."

Sidus Group Adds LIFE-SCIENCES HOSTING SOLUTION

Clients are able to take advantage of the cost savings of moving into a secure, fully validated, and scalable HIPAA-compliant hosting environment, says Jason Silva.

Sidus Group has launched Sidus BioData, an FDA- and HIPAA/HITECH-compliant data hosting solution that provides healthcare organizations and life-sciences companies with access to the latest data-center technology with a significant reduction in IT spending and a reduced regulatory risk profile.

"The national debate on managing healthcare costs, coupled with an increasing regulatory focus on security and privacy of electronic medical records, has left many healthcare organizations scrambling to reduce costs while at the same time meeting new compliance objectives," says Jason Silva, chief operating officer of Sidus Group.

Paragon, NextDocs Collaborate on CLINICAL OPTIMIZATION SOLUTIONS

Aligning Paragon's understanding of life-sciences processes and expertise in clinical optimization with NextDocs' industry-leading software modules allows for fast deployment of next-generation clinical solutions, says Zikria Syed.

Paragon Solutions has introduced solutions to optimize clinical operations incorporating the NextDocs product suite, combining the capabilities of the two partners to deploy accelerated solutions for life sciences built on the Microsoft Office SharePoint Server.

"With the growing adoption of SharePoint within life-sciences organizations, companies are looking for solution accelerators that leverage enterprise platforms to optimize the end-to-end drug development process," observes Ravi Shankar, VP of Paragon's life-sciences practice.

"Aligning Paragon's deep understanding of life-sciences processes and expertise in clinical optimization with NextDocs' industry-leading software modules allows for fast deployment of next-generation clinical solutions," adds NextDocs CEO Zikria Syed.

The clinical optimization solution portfolio from Paragon and NextDocs includes an integrated investigator portal that provides a collaborative environment for clinical sponsors and investigators to negotiate contracts.

It also provides a way to define communicating protocols; support site monitoring; manage grants; work with partners; and improve oversight and planning.

OmniConnect Enables Real-Time DATA INTEGRATION FROM MULTIPLE SOURCES

OmniComm Systems has added two products to its portfolio of applications aimed at more cost-efficient clinical trial data collection and management.

OmniComm's new application programming interface, OmniConnect, uses REST (representational state transfer) Web services based on an extended CDISC ODM dataset.

Chief Operating Officer Stephen Johnson notes that OmniConnect has already been deployed with customers to increase cost-effective management of ongoing clinical studies in the United States and Europe.

"Other uses include tracking and report enrollment, safety data, supply management, such as dispensation and reconciliation of study drugs, and exports to a CTMS, as well as imports of data from central labs, ECG, IVRS, and our newly released Phase I data collection and management system, TrialOne," Mr. Johnson adds.

The company has also launched TrialOne, a fully integrated Web-based solution designed to automate the Phase I clinical trial process. TrialOne provides all necessary Web-based tools used to recruit study volunteers, schedule screening appointments, collect screening data, directly capture real-time data, track sample transfers, and address the unique requirements of early-phase studies. TrialOne enables Phase I clinics to share data directly with other stakeholders via the Internet and provides a flexible ad-hoc reporting tool to help export and report data in various formats.

This flexible solution has many applications and has already been deployed with customers in ongoing clinical studies, both in the United States and in Europe, says Stephen Johnson.

ON-DEMAND INFORMATION MANAGEMENT SYSTEM Targets Smaller Labs

LIMS-on-Demand has built-in workflows, the ability to capture, store and analyze lab data, monitor resources, and integrate with instrumentation, says Dave Champagne.

LIMS-on-Demand, Thermo Fisher Scientific's software-as-a-service (SaaS), enterprise-class laboratory information management system, allows organizations of varying types and sizes to leverage the benefits of an LIMS solution without the time and cost associated with on-site software installation.

LIMS-on-Demand provides a more flexible alternative to conventional LIMS so that organizations can easily and cost-effectively adapt technology as needs change. The Web interface enables connectivity with a variety of internal instruments and systems as well as external facilities, partners, and regulatory agencies. The solution also helps organizations replace inefficient, error-prone manual processes with an automated data management solution. Customers can create workflows, map sample life cycles, and generate automatic updates while providing users with rapid access to up-to-the-minute data and information that impacts every phase of laboratory processes.

"LIMS-on-Demand delivers the benefits of an on-premise LIMS at a lower cost and with very little implementation time," says Dave Champagne, VP and general manager of Thermo Fisher Scientific's Informatics business. "With built-in workflows, the ability to capture, store, and analyze lab data, monitor resources, and integrate with instrumentation, more laboratories around the world can experience the competitive advantages of LIMS."

Kendle's BIOSTATISTICS INFRASTRUCTURE Increases Data Quality, Security

This investment allows Kendle to provide a more globally integrated solution to meet our customers' needs anywhere, anytime, says Dr. John Whitaker.

Kendle has implemented a new biostatistics infrastructure that enhances the analysis and delivery of quality clinical trial data for customers.

The centralized, SAS-based platform provides a virtual environment allowing for simultaneous access and analysis of clinical trial data by Kendle's global biostatistics and scientific programming teams from anywhere in the world, creating significant time savings and further enhancing data security.

"With this new environment, data are processed at the server level much faster than ever before, greatly improving the productivity of our teams around the world and expediting the delivery of quality data to our customers," says John Whitaker, Ph.D., VP, biostatistics and statistical programming.

In addition to improved efficiency, quality, and security, other benefits of the new infrastructure implementation include improved network performance and bandwidth availability; reduced licensing requirements; and simplification of the testing, production, and recovery environments.

Follow up

BIOCLINICA INC. is a global provider of integrated, technology-enhanced clinical trial management services. For more information, visit bioclinica.com.

KENDLE INTERNATIONAL INC. is a global clinical research organization that provides a full range of clinical development services. For more information, visit kendle.com.

NEXTDOCS provides Microsoft SharePoint-based document and quality-management solutions for life-sciences companies. For more information, visit nextdocs.com.

OMNICOMM SYSTEMS INC. provides customer-driven Internet solutions to pharmaceutical, biotechnology, research, and medical device organizations. For more information, visit omnicomm.com.

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