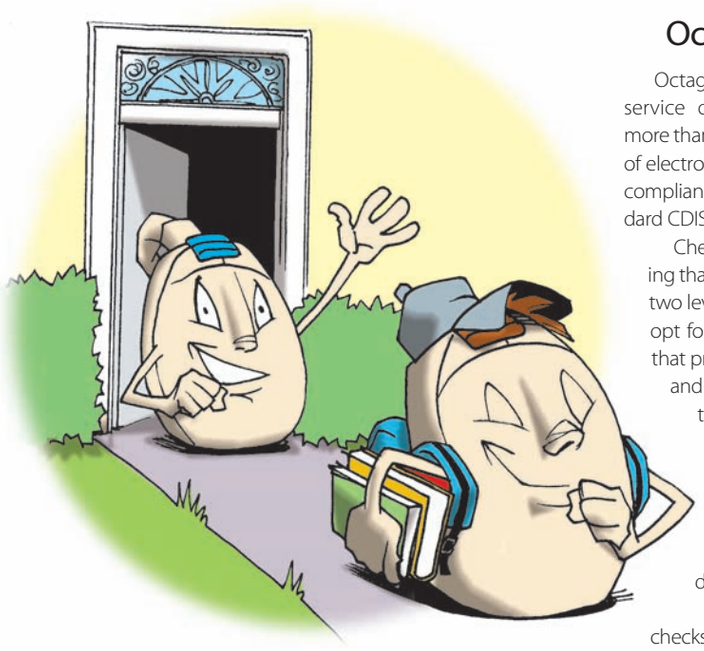


Octagon Research Provides SYSTEM FOR SUBMISSIONS

Octagon Research Solutions' latest service offering, CheckPoint, provides more than 300 separate validation checks of electronic clinical study data to ensure compliance with the open industry standard CDISC SDTM.

CheckPoint is a three-tiered offering that enables clients to choose from two levels of validation services and to opt for additional consulting services that provide guidance on compliance and process issues. The basic validation service includes the same 105 validation checks that the agency runs once submission data are received, as well as an additional four checks for the open-source data model JANUS.

Enhanced validation includes the basic checks plus an additional 200 checks that confirm SDTM compliance.

Compliance is key to a successful electronic submission. We want to provide visibility into data-compliance issues before submission, says Dave Evans, Chief Information Officer at Octagon.

"Electronic submissions enable agency reviewers to navigate to supporting data more quickly and efficiently," notes Dave Evans, chief information officer at Octagon.

In other moves, Octagon has released ViewPoint Quantum, the latest version of its enterprise process management solution that helps organizations manage the drug-development life cycle. ViewPoint Quantum includes enhanced data, document, and submission publishing functionality that connects the industry's most widely used content repositories to the ViewPoint Quantum environment. These repositories frequently hold in-process documents, legacy documents, and datasets that are eventually used to support an electronic regulatory submission.

Safe-BioPharma Activates ELECTRONIC IDENTITY LINK

Crossing the Federal Bridge allows Safe-BioPharma to streamline business and regulatory transactions between industry and the government, says Dr. Peter Alterman, Chair, Federal PKI Policy Authority. It is a major step toward improving productivity in both the private and public sectors.

Safe-BioPharma Association has introduced the first electronic bridge enabling trusted transactions between many of the world's largest pharmaceutical companies and key U.S. government agencies, including the Food and Drug Administration, the Department of Health and Human Services, Department of Defense, Homeland Security, and the U.S. Patent and Trademark Office.

The legally binding digital identity and signature standard created and managed by Safe-BioPharma provides users with a secure, enforceable, and regulatory-compliant way to verify identities of parties involved in electronic transactions and to apply their digital signatures to electronic documents. By using Safe-BioPharma digital signatures, companies are able to dispense with paper originals and other cumbersome forms of backup.

"Crossing the Federal Bridge allows Safe-BioPharma to streamline business and regulatory transactions between industry and the government," says Peter Alterman, Ph.D., chair, Federal PKI Policy Authority. "It is a major step toward improving productivity in both the private and public sectors."

FDA inspectors have received training to recognize electronic documents signed with Safe-BioPharma digital signatures, and Safe-BioPharma plans to initiate educational programs to help personnel within other federal agencies become more familiar with the signatures.

Targetbase Introduces CUSTOMIZED DIRECT-TO-PATIENT SOLUTIONS

Targetbase has launched a proprietary approach that delivers best practices in customer relationship management (CRM) for the healthcare space. Targetbase XACT Direct-to-Patient offers a modular suite of solutions that helps pharmaceutical companies make better use of patient intelligence to more effectively address patient prospecting, adherence and retention, and lifecycle management. These solutions strategically target and acquire patient audiences to drive brand growth and database building and maximize patient value by promoting patient compliance, persistency, and loyalty; and fuel new product launches.

Effective and efficient patient marketing is a critical need for healthcare marketers as they look for ways to cut costs and make better use of patient intelligence, says David Scholes, CEO of Targetbase.

According to CEO David Scholes, effective and efficient patient marketing is a critical need for healthcare marketers as they look for ways to cut costs and make better use of patient intelligence.

Visual i|o Launches PORTFOLIO MANAGEMENT SYSTEM

By leveraging the new technologies available with the advent of Web 2.0, we are able to "mash up" applications from various sources to present information in compelling new ways, says Angela Shen-Hsieh, President and CEO of Visual i|o.

Visual i|o has launched DecisionIris for Project Portfolio Analysis in the pharma industry. The solution provides intuitive and detailed views of projects across pharmaceutical portfolios, arming key decision makers with the information necessary to make educated, strategic decisions in a timely manner.

By manipulating a number of variables — such as time, expenditure, risk, and value — portfolio managers can see at a glance how the company's investment is aligned with the portfolio and quickly gauge each project's value and risk relative to other projects.

"DecisionIris for Project Portfolio Analysis is designed to allow ordinary business users to find patterns, distributions, correlations, and anomalies across multiple data types," says Angela Shen-Hsieh, president and CEO of Visual i|o.

"By leveraging the new technologies available with the advent of Web 2.0, we are able to 'mash up' applications from various sources to present information in compelling new ways," Ms. Shen-Hsieh adds.

E-UPGRADES AND ENHANCEMENTS

- **Advanced Clinical Software (ACS)**, a privately held Seattle-based developer of clinical-trial management software, **has introduced StudyManager 13.5**, an upgrade to its end-to-end solution for research sites, universities, and hospitals. StudyManager streamlines clinical research, providing real-time access to key enrollment and financial metrics. The latest version provides scheduling improvements, allowing coordinators to quickly assess patient schedules for protocol compliance and schedule all patient appointments with one click. StudyManager 13.5 also provides integration with Allscripts' Touchworks EHR (electronic health records), allowing customers to add patients to StudyManager from TouchWorks with the click of a button, establishing a link between the two programs. Linked patient records are then synched in both applications.

  For more information, visit studymanager.com.

- **ClearTrial**, Chicago, **has released version 2.4 of ClearTrial** clinical-trial software, which helps biopharmaceutical companies and CROs more effectively plan, budget, outsource, and optimize the operational design of clinical trials.

  Among the key enhancements in ClearTrial v2.4 are support for mixed-monitoring strategies; a customizable milestone payment schedule and cash-flow chart for an accurate cash-flow status for each month of the study; greater flexibility to set resources and rate per-plan or per-task; and the ability to upload service provider rates into the software. In addition, the new version broadens the already considerable array of clinical, cost, and resources reports available in the software.

  For more information, visit cleartrial.com.

- **CSS Informatics**, Cambridge, Mass., the clinical and safety data-management consulting services and proprietary e-technologies division of PPD, **has released an enhanced version of its specialized software product, eLoader**, which enables pharmaceutical, biotechnology, and medical-device companies to load external patient response, vendor and laboratory data, trial protocol information, and electronic data capture (EDC) system data into Oracle Clinical and Oracle Thesaurus Management System (TMS).

  Version 4.0 of eLoader allows users to load data into a study's test area and map to provisional objects within Oracle Clinical. Users can also perform eLoader dataset table management and show potential updates before loading data into Oracle Clinical or TMS. The product also offers File Format Independence, which generates multiple source formats directly as files are loaded.

  For more information, visit cssinformatics.com.

- **Simulations Plus**, a Lancaster, Calif.-based provider of simulation and modeling software for pharmaceutical discovery and development, **has made available version 4.5 of its ClassPharmer software** for analysis of chemical libraries and design of new molecular structures. The updated version incorporates several significant improvements to further enhance the pharmaceutical research chemist's ability to design new drug molecules faster and with greater insight.

  ClassPharmer 4.5 includes integration with Simulations Plus' ADMET Predictor software, which helps researchers assess whether newly discovered molecules are likely to have desirable properties. Another new feature, Pair SAR, rapidly identifies pairs of molecules that are nearly the same, but that have very different activities, enabling the chemist to separate the particular small structural changes that produce large changes in activity from those with little or no effect.

  For more information, visit simulations-plus.com.

- **Target Health**, a New York-based contract research organization, **has made available the newest release of Target Document**, a secure, regulatory-compliant document sharing, distribution, and management system that allows users to post, share, electronically sign, search, and archive any electronic document within a Web browser. The solution is ideal for CROs and sponsors who want to transparently communicate among themselves, as well as with vendors, study sites, and other third-party entities.

  Target Document allows for a paperless Trial Master File (TMF) and is part of Target Health's paperless eClinical toolbox of products.

  For more information, visit targethealth.com.

- **Velos**, a Fremont, Calif.-based provider of clinical trial management information systems for large investigator sites and sponsors, **has launched a new version of Velos eResearch**, its Internet-based clinical-study management platform. Velos eResearch Version 8 offers enhancements that improve the product's flexibility, configurability, and interoperability. A significant number of enhancements also focus on financial-system needs, as well as day-to-day patient and research management.

  For more information, visit velos.com.

Qforma Tool Optimizes **MANAGED CARE STRATEGIES**

We created iQMCO to provide quantitative insights that effectively prioritize the payers best positioned to deliver on specific goals, says CEO Kelly Myers. The results help them optimize rebate strategies.

Qforma has developed a managed care optimization model, iQMCO, to help pharmaceutical managed-market executives create informed contracting and pull-through strategies.

iQMCO quantitatively scores and ranks more than 2,100 payers who are most effective at implementing formulary decisions based on modeling outcomes of both qualitative and quantitative data.

"Managed market professionals expressed a need to make objective contracting decisions for their product portfolios," says Kelly Myers, CEO of Qforma.

"We created iQMCO to provide quantitative insights that effectively prioritize the payers best positioned to deliver on specific goals," he says. "The results help them optimize rebate strategies."

Verticals onDemand Introduces **ON-DEMAND MOBILE APPLICATION**

With MaaS applications, customers benefit from a fast and flexible mobile application that is self-updating and self-maintaining, says Peter Gassner, President and CEO.

Verticals onDemand has launched the first in a new category of on-demand mobile applications, mobility-as-a-service (MaaS). Its VMobile MaaS application provides users with offline access to their VBioPharma customer relationship management (CRM) system anytime, anywhere, enabling life-sciences companies to deploy mobile applications without incurring additional maintenance costs or support efforts.

The VMobile application runs on any Microsoft Windows XP or Vista-based laptop or Tablet PC. Like other multitenant software-as-a-service (SaaS) applications, all VMobile users run the same version of the underlying software code, enabling back-office upgrades. VMobile also automatically reads the VBioPharma metadata, allowing for one-time configuration of the application for deployment both online and offline.

Similar to the user synchronization sessions employed in traditional mobile applications, VMobile sends all new data to the server and downloads all relevant data updates for the user. But unlike other mobile products, any software updates, new versions of the application, and metadata are also included in the same synchronization session.

"For the very first time, customers do not have to choose between end-user satisfaction and overall maintenance costs," says Peter Gassner, president and CEO. "With MaaS applications, customers benefit from a fast and flexible mobile application that is self-updating and self-maintaining."

SciQuest Adds **SUPPLY MANAGEMENT SOLUTION**

Supplies Manager was developed to tackle an important area for savings and efficiency — understanding current inventory levels allows companies to strategically manage their resources and make prudent purchases, says Jamie Duke, Chief Operating Officer of SciQuest.

SciQuest has added Supplies Manager to its full suite of strategic procurement solutions that automate the entire purchasing process from sourcing to settlement.

Problems with lack of visibility to inventory levels and duplicate purchases of items already in stock are common at research organizations. Supplies Manager allows clients to integrate e-procurement systems with inventory management and internal supply centers — including storerooms, supply closets, and lab freezers — to quickly locate in-stock supplies for faster acquisition.

"Supplies Manager was developed to tackle an important area for savings and efficiency — understanding current inventory levels allows companies to strategically manage their resources and make prudent purchases," says Jamie Duke, chief operating officer.

Supplies Manager allows users to shop for the materials they need and compare the vendors that offer them. Supplies Manager notifies stockroom managers what and how much to order for supplies replenishment when inventory reaches predetermined levels. It also enables stockroom personnel to quickly create pick lists as well as packing slips, and buyers can check the status of their orders online. Biometric systems and log-in identifications can be used to ensure security.

PharmaPros Introduces **DATA MANAGER FOR CLINICAL TRIALS**

PharmaPros has launched Dataflow Manager, a data-driven, integrated technology platform.

PharmaPros has launched Dataflow Manager, which empowers clinical-trial sponsors and CROs to rapidly and effectively harmonize trial-wide operational data despite disparate systems, different formats, multiple vendors, and far-reaching geographical parameters.

Dataflow Manager is configured to map trial data through an expected data schedule. The platform executes context-intelligent queries against the data agents and presents the in-stream operational status of a trial through a central interface.

Dataflow Manager is delivered as software-as-a-service (SaaS). Configuration, hosting, and validation are performed by PharmaPros to eliminate the negotiation and setup of data access to these external disparate systems where these source data of interest reside.

Total Learning Concept Offers **CUSTOMER RELATIONSHIP TRAINING PROGRAM**

Physicians are no longer focused solely on the clinical benefits of products; they are now interested in how products can help them meet nonclinical needs, says Suzanne Burrell, VP and Director of Total Learning Concepts.

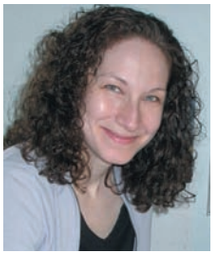
Total Learning Concepts is offering a training program that provides sales representatives with the skills, knowledge, and practice they need to build long-term relationships with their customers.

Designed for both new hires and seasoned professionals, the program was developed based on the concepts and theories of conflict resolution, personality profiles, buying cycles, and consultative selling. The program teaches pharmaceutical sales representatives how to analyze doctors' needs and work with them to better manage their medical practices.

"Physicians have become more than just healthcare providers; they have become businesspeople," notes Suzanne Burrell, VP and director. "Today's doctors are concerned with the challenges of running their practices efficiently and keeping costs down without sacrificing the quality of patient care."

Total Learning Concepts' customized customer relationship training program is highly interactive and immersive.

TCN e-Systems Offers **CLINICAL-TRIAL RECRUITMENT SOLUTION**



For a clinical trial to succeed, all stakeholders must understand what it takes to drive timely patient recruitment and have easy access to the information necessary to make it happen, says Jaime Cohen, Data Management Lead at TCN e-Systems.

TCN e-Systems has released Center of Excellence, a product designed to establish secure, Web-based infrastructures that support in-house recruitment capabilities for clinical-trial sponsors.

TCN e-Systems' Center of Excellence is designed to institutionalize patient recruitment expertise by establishing an easy-to-use infrastructure for creating, collecting, standardizing, and disseminating institutional knowledge throughout a given life-sciences company.

"As pressure builds for clinical-trial sponsors to assume full accountability for patient recruitment outcomes, acquiring all of the knowledge necessary for successful study enrollment poses a variety of operational challenges," says Jaime Cohen, data management lead.

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WK Health Introduces **FORMULARY ANALYTICS TOOL**

Our goal was to provide more insight for account management teams and marketing departments so that pull-through programs or contracting approaches could be revisited, says Bob Jansen, VP of Managed Markets and Brand Analytics.

Wolters Kluwer Health has introduced Formulary Facts, an automated, Web-based analytics tool designed to help pharmaceutical companies better manage their products in the managed-care sector.

Rather than making assumptions using projections or surveys, Formulary Facts used data from Source Dynamic Claims, Wolters Kluwer Health's real-time analytics tool for claims data, to provide a real-world view of how drugs are performing in the managed-care marketplace.

Formulary Facts captures actual patient out-of-pocket expenses that occur at the point of sale, providing a more accurate view of what consumers are really paying. Real-time data capture also allows pharmaceutical companies to detect when managed-care organizations change the formulary status for their own or competitors' pharmaceutical products, regardless of whether the company was notified of the change.

"Companies can use Formulary Facts to assess the true positions of their products on plan formularies and then use the analysis to react to market opportunities or challenges in real time," says Bob Jansen, VP of managed markets and brand analytics.

Formulary Facts uses a user interface that simplifies the research process and employs a series of preset, user-selectable report templates designed to address specific questions relating to key formulary issues. Users are able to select any of more than 40,000 drugs they wish to research and compare from the Dynamic Claims database.

TranSenda System Provides **CLINICAL TRIAL MANAGER**

TranSenda International has introduced Office-Smart Clinical Trial Manager, a clinical trial management system (CTMS) that addresses clinical-trial professionals' need to integrate study software with the 2007 Microsoft Office System.

With Office-Smart Clinical Trial Manager, users can leverage their favorite Office tools, such as Excel and Outlook, within the regulated environment of a CTMS. This eliminates problems such as mismatched data from separate workaround spreadsheets, extra data entry, and CTMS application interfaces that do not communicate with study professionals' e-mail or spreadsheets. In addition, the TranSenda solution allows traveling CRAs to remotely access Word documents, create site-visit reports, and trigger work flow for an approval process, all through Outlook's familiar environment.

"We all know there is a great need to improve clinical trial productivity," says Robert Webber, president and CEO of TranSenda. "We believe the best prospects for progress start with the basics of improving office productivity and focusing on the business-process side of conducting clinical trials."

There is a great need to improve clinical trial productivity. We believe the best prospects for progress start with the basics of improving office productivity, says Robert Webber, President and CEO of TranSenda.

Follow up

OCTAGON RESEARCH SOLUTIONS INC., Wayne, Pa., offers a suite of regulatory, clinical, process, and IT solutions to optimize drug development. For more information, visit octagonresearch.com.

PHARMAPROS CORP., Cambridge, Mass., is a technical consulting and solutions provider specializing in data and workflow management for clinical trials. For more information, visit pharmapros.com.

QFORMA INC., Santa Fe, N.M., is an advanced analytics and predictive modeling company specializing in solutions for the healthcare industry. For more information, visit qforma.com.

SAFE-BIOPHARMA ASSOCIATION, Fort Lee, N.J., is a nonprofit association that manages the SAFE-BioPharma digital identity and digital signature for the pharmaceutical and healthcare industries. For more information, visit safe-biopharma.org.

SCIQUEST INC., Cary, N.C., provides specialized knowledge and on-demand software solutions to help research-centric organizations realize the potential of strategic procurement. For more information, visit sciquest.com.

TARGETBASE, Dallas, part of Omnicom Group Inc., is a direct marketing agency with expertise in direct-to-consumer campaigns. For more information, visit targetbase.com.

TCN SYSTEMS LLC, Newton, Mass., provides patient recruitment management systems for the clinical-trial market. For more information, visit tcnesystems.com.

TOTAL LEARNING CONCEPTS, Lawrenceville, N.J., a Publicis company, is a pharmaceutical and biotech sales training provider that specializes in e-learning. For more information, visit tlconline.com.

TRANSENDA INTERNATIONAL LLC, Boston, provides integrated modular software solutions for clinical-trial professionals based upon Microsoft's .NET technology. For more information, visit transenda.com.

VERTICALS ONDEMAND, Pleasanton, Calif., provides software-as-a-service CRM applications to the pharmaceutical and biotechnology industries. For more information, visit verticalsondemand.com.

VISUAL I|O, Newton, Mass., develops interactive visual analysis solutions that provide comprehensive views into the state of business operations to maximize organizational decision-making. For more information, visit visual-io.com.

WOLTERS KLUWER HEALTH, Conshohocken, Pa., provides information for professionals and students in medicine, nursing, allied health, pharmacy, and the pharmaceutical industry. For more information, visit wkhealth.com.