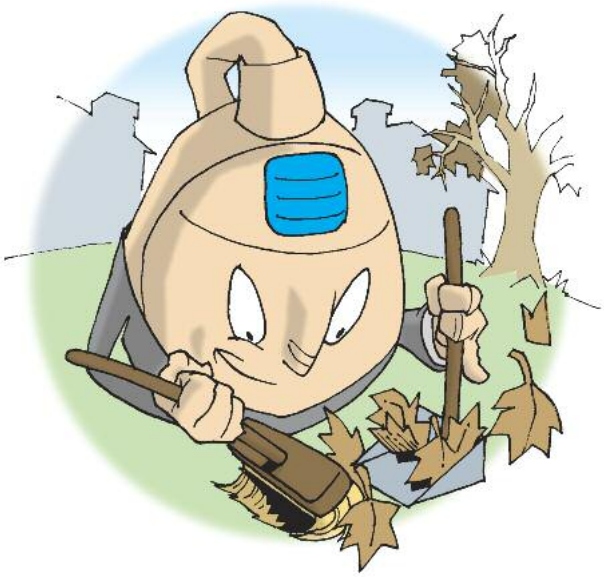
# E-MEDIA

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



## M|C Communications Partners with Accela on INTERACTIVE VIDEO PROGRAMMING

*Working with Accela Communications to bring additional rich media content to pri-med.com will provide added value to our existing community of clinicians, says Pri-Med's Alisa Wilke.*

*Together, we have a powerful combination to bring to the market, says Accela's Bob Whiting.*

M|C Communications, owner of the Pri-Med brand, and Accela Communications have joined forces to offer healthcare communications companies the opportunity to post interactive video and rich media programming for the physician audience on the Website pri-med.com.

Through its Pri-Med brand, M|C Communications offers both educational solutions for physicians and allied healthcare professionals and non-CME product information sharing and exhibit opportunities for the industry.

Through M|C's collaboration with Accela, Pri-Med hosts and markets the content, while Accela's AccelaCast manages the usage tracking and reporting. As a result, clients gain greater reach and clinicians gain more dynamic content.

The agreement also authorizes Accela to deliver their interactive video production and platform and measurement services on pri-med.com.

"We are excited to expand the pri-med.com platform to include third-party content," says Alisa Wilke, group director, new media strategy and business development, Pri-Med.

"I am very proud of the relationship we have with Pri-Med," adds Bob Whiting, VP/healthcare solutions group for Accela Communications.

## KMR Group Adds Site-Level Module to PATIENT ENROLLMENT SYSTEM

*We are providing biopharma companies with a solution to address their most important recruitment questions, says Linda Martin.*

SiteView is the latest module in KMR Group's Enrollment Metrix application, which helps companies plan more effectively and reliably when setting recruitment targets and timelines, saving them millions of dollars in costs that can result from delays and nonconformance. SiteView users can examine enrollment KPIs derived from site-level data and use the information for planning and forecasting recruitment in clinical trials. The new module allows users to anticipate the expected number of patients to be recruited from any given site, as well as the time it takes any given site to complete recruitment, thus giving companies a more nuanced view when it comes to planning for any region or country.

"Our enhanced Enrollment Metrix application satisfies biopharma companies' need for reliable data, flexible criteria, and robust viewing options," says KMR Principal Linda Martin.

## Moonbay Technology Enters LIFE-SCIENCES INDUSTRY WITH EDM SYSTEM

*Pipeline EDM reduces the total cost of system ownership, as the only IT requirements are an Internet connection and a browser, says Jill Iacopi.*

Moonbay Technology has made its life-sciences debut with the launch of Pipeline EDM, a regulatory document management and electronic submission system aimed at alleviating the IT support burden and cost from resource-strapped companies. Based on a SaaS model, Pipeline EDM complies with 21 CFR Part 11 and covers regulatory document management, e-publishing, compliance, and clinical management.

"Moonbay understands the financial positions of many emerging life-sciences companies and offers subscription-based pricing," says Jill Iacopi, founder and CEO.

## ParagonRx Website Includes Hub for ASSISTING IN FDA COMPLIANCE

*In many ways, risk management, including REMS, is becoming its own new discipline, says Jeffrey Fetterman.*

ParagonRx's new Website, paragonrx.com, includes a REMS Hub for pharmaceutical and biotech companies that need information and assistance in complying with new FDA requirements to ensure the medical benefits of a drug outweigh its risks and dangerous side effects. The hub addresses the related but varying needs of pharma and biotech companies working with risk management and REMS in any of a product's key stages: development, peri-approval, launch, and post-marketing. It also explains how a science-based approach to REMS development can assure safer product use and often broader product use as well.

"REMS requires a whole new mindset for many professionals in the industry, in that patient safety is no longer merely a statistic that is passively measured for regulatory compliance," says CEO Jeffrey Fetterman.

## Sparta Systems Adds CLINICAL QUALITY MANAGEMENT TOOL

*Companies and CROs need to maintain the same high level of quality expected by global regulators, says Mike Jovanis.*

Sparta Systems' TrackWise product, TrackWise Clinical Quality Management Solution, provides an end-to-end system that streamlines the oversight of business-critical clinical-trial processes and helps ensure compliance with global regulatory standards.

According to Mike Jovanis, VP, product management, this extension of the TrackWise enterprise quality management system drives organizational efficiencies beginning with pre-clinical activities through manufacturing and post-market operations.

## E-UPGRADES AND ENHANCEMENTS

- TrialCentralNet (TCN) 5.0, the latest version of **BBK WORLDWIDE'S** patient recruitment management system, incorporates recent advances in technology, BBK's evolving institutional knowledge, and extensive user feedback to optimize patient recruitment planning and accelerate patient enrollment for multinational trials. The new version, developed by BBK partner company TCN e-Systems, features instantly customizable reports, streamlined tracking of patients from prescreening to study completion, and a strengthened architecture to bring together the entire study community.

  For more information, visit bbkworldwide.com.

- **MEDNET SOLUTIONS** has announced Enlighten as the new name for its EDC/e-clinical technology solution. The company also has made a number of enhancements to Enlighten that target study workflows, honoraria management, and advanced reporting.

  For more information, visit mednetstudy.com.

- **PREMIER RESEARCH GROUP** has announced the implementation of Oracle Remote Data Capture Onsite 4.5.3, the enhanced version of Oracle's EDC application featuring new functionality to meet the needs of trial sponsors as well as investigative site personnel. The system's zero-footprint deployment allows sites to rely solely on a Web browser without loading or maintaining additional software streamlining system and site management.

  For more information, visit premier-research.com.

- **TARGET HEALTH** has released version 1.4 of Target Document, an enhanced version of its software that provides the pharmaceutical industry and CROs with a cost-effective, highly sophisticated, Web-based document management system. The new version includes enhanced project templates, routing for electronic signatures, and automatic e-mail alerts.

  For more information, visit targethealth.com.

## Cegedim Dendrite Solution Detects **COUNTERFEIT PRODUCTS**

***Drug counterfeiting is a concern in the pharmaceutical industry with estimates indicating that upward of 8% of pharmaceutical medicines worldwide may be counterfeit, says Bill Buzzeo.***

Cegedim Dendrite's most recent offering, Counterxfeit Detect, is designed for pharmaceutical companies that need to identify and determine the source of counterfeit, contaminated, or adulterated product.

Through Counterxfeit Detect, Cegedim Dendrite coordinates the purchase of noncontrolled, finished drug products from contract manufacturers or distributors, using an independent pharmaceutical buyer. The product is then shipped to a testing facility or the pharmaceutical company's analytical lab, where the product is analyzed.

Cegedim Dendrite's independent purchasing of finished drug product takes the burden off the pharmaceutical company's internal resources. Counterxfeit Detect is fully secure and includes appropriate audit trail documentation that provides insight into the full acquisition chain associated with the independent pharmacy's purchase.

"As part of their anti-counterfeiting programs, pharmaceutical companies should acquire finished drug products within the supply chain for analysis and testing to ensure their quality," says Bill Buzzeo, VP and general manager, compliance solutions and OneKey. "We seamlessly facilitate that process. If an independent party is making the purchase, pharmaceutical companies can better show that they had a random sample for testing and that the process was not tainted by anyone internally with false motive."

## Adair Greene McCann Revamps **AGENCY WEBSITE**

***The central theme for the Website grew out of the realization that healthcare marketers are looking for help to combat the ever-increasing competitive pressure they face, says Mark Perlotto.***

Adair Greene McCann's redesigned Website, adairgreene.com, showcases the agency's body of work with pharmaceutical, biotechnology, medical device, and diagnostic clients.

"Our philosophy has always been to find the most effective and creative solutions, with the belief that those ideas yield the best results for our clients," says Mark Perlotto, executive VP, managing director.

## Aris Global Provides **CLINICAL TRIALS MANAGEMENT SOLUTION**

***Companies benefit from having a proven EDC solution that has been deployed worldwide in hundreds of sites and studies and is interoperable with third-party clinical and pharmacovigilance systems, says Simon Sparkes.***

Aris Global's integrated EDC software-as-a-service (SaaS) solution, agCapture, offers life-sciences organizations a cost-effective alternative for capturing, managing, and reporting clinical research data.

Based on software developed by Aris Global and InferMed, the agCapture solution seamlessly integrates with Aris Global's ARISg pharmacovigilance system, enabling pharmaceutical companies and their clinical partners to reduce the efforts required for SAE reconciliation and immediately take the necessary steps for case processing.

Simon Sparkes, VP, corporate strategy and marketing, says with agCapture, pharmaceutical companies are able to conduct all data management activities electronically and seamlessly integrate with other systems and departments, such as safety and CTMS, helping to eliminate duplicate data entry functions and prevent delays and inefficiencies in adverse event reporting.

## DDW Offers **PATIENT EDUCATION MARKET-RESEARCH TOOL**

***The traditional top-down marketing paradigm is being replaced by a more comprehensive approach that recognizes the increasing influence patients have in their care, says Chip Lister.***

Patient-360, a new market-research tool from Data Development Worldwide (DDW), allows pharmaceutical marketers to identify, prioritize, and optimize all touch points in the patient pathway, resulting in high-impact patient education programs that produce quality interactions and build lasting relationships.

The patient pathway starts at the point a medical issue becomes apparent and continues through to diagnosis/treatment and then resolution.

Patient-360 identifies and prioritizes these touch points, allowing pharmaceutical marketers to leverage the most valuable communication opportunities and audience segments.

"For communications efforts to be completely optimized, it is essential to understand and prioritize the patient pathway," says Chip Lister, managing director.

## ERT Portal Improves **CARDIAC SAFETY DATA MANAGEMENT**

***This system provides a comprehensive toolset for monitoring cardiac safety and delivers significant enhancements to clinical teams, says Julie Nelson.***

ERT has introduced an online Web interface, My Study Portal, aimed at enhancing the accuracy and efficiency of cardiac safety data management in clinical trials.

My Study Portal, which replaces the previous Digital ECG Community, provides users with secure 24/7 access to a centralized environment to view and to manage vital data from anywhere in the world, on demand, in real time.

The portal is designed for use by both sponsor personnel and investigator sites and can be used by a wide range of study personnel to track the progress of their clinical trials.

Key cardiac information is continuously updated, including ECG findings and interpretations, ECG quality, abnormalities, query resolution, and other key study metrics.

The portal is powered by ERT's proprietary Expert Technology Platform, a secure and validated clinical-research workflow-processing technology that powers centralized electronic data collection, data management, and information exchange.

"With the advent of site-specific tools to view and respond to queries, order ECG-related supplies, and create reports with up-to-the-minute information, this product drives cost savings across the entire cardiac safety management process," says Julie Nelson, director of online reporting services.

## Cutting Edge Unveils **NEW WEBSITE**

Cutting Edge Information's redesigned Website, cuttingedgeinfo.com, features the consulting firm's new corporate logo and an interface that better enables users to quickly access the latest business management information of value to the life-sciences industry.

Visitors to the new Website can find Cutting Edge's consulting services and research reports readily available on the home page. Product pages are now formatted to make finding important details more convenient, and contact information appears throughout the Website to enable direct communication links to the company's team of experts.

***Our hope is that the Website continues to grow as a decision-making toolkit for our clients, says Jason Richardson.***

"When we redesigned the Website, our No. 1 priority was to incorporate client feedback into the final product," notes Cutting Edge President and CEO Jason Richardson.

In conjunction with the Website's launch, Cutting Edge has rolled out a new corporate logo. The logo incorporates conversation bubbles to reflect the company's renewed focus on bringing together clients, research partners, journalists, and collaborators to produce the best possible business intelligence.

## New Website Provides Access to **PHARMA-RELATED CONTENT**

Pharma-Marketer.com is a Website designed to provide users with the benefits of attending a top-rated pharmaceutical industry conference without the travel or related costs.

The site provides pharmaceutical marketing professionals with convenient access to a wide range of industry-related content in the form of industry-respected blogs, original authored articles and best practices from thought leaders, and up-to-the-minute news. It also features an Ask the Experts section for Q&A directly with users, as well as virtual vendor booths for companies to showcase their services.

As a peer-driven site, users can rate vendors, share their experiences, and submit reviews to aid their peers in evidence-based decision-making.

Future planned features include a comprehensive research database where users can submit campaign stats to feed an ongoing arsenal of relevant data, conference listings, and whitepapers.

## Phase Forward Enhances **GLOBAL EDC CAPABILITY**

***InForm GTM provides an integrated, unified environment for use in regional and multilanguage global trials, says Bob Weiler.***

The latest addition to Phase Forward's portfolio of e-clinical solutions, InForm Global Trial Management (GTM), offers enhancements that increase the speed and efficiency of EDC and expand its capacity for trials conducted across different countries.

"Widespread adoption of InForm in real-world implementations has given us the benefit of extensive experience in helping customers maximize EDC solutions for clinical trials on a global basis," says Bob Weiler, chairman and CEO.

InForm GTM offers a redesigned interface that simplifies navigation and helps users reach conclusions quickly, reduce errors, quickly discern the most important pieces of information, and streamline workflow. It also provides a single environment that enables study sponsors to streamline the management of clinical-trial data from design through submission, all within a single environment for use in regional or global trials.

Phase Forward also has unveiled Empirica Study, formerly the Clinical Trials Signal Detection product (CTSD), as part of the company's Empirica Suite of solutions. Empirica Study helps clinical and safety teams improve their understanding of a product's emerging safety profile during clinical development by facilitating the timely detection, review, and analysis of safety issues in clinical trials data.

In addition, the company has announced the availability of WebSDM Release 3.0, which validates and reviews submission data in CDISC Study Data Tabulation Model (SDTM) format. The latest version of WebSDM includes support for checking data submitted in CDISC SDTM version 3.1.2 format and updates to edit checks for earlier SDTM versions, as well as the ability to generate define.xml files from SDTM datasets.

## eClinical Suite Combines **PERCEPTIVE INFORMATICS PRODUCTS AND SERVICES**

Perceptive Informatics, a subsidiary of Parexel International, has launched eClinical Suite, a combination of Perceptive products and services designed to provide seamless integration and access to data across multiple technologies throughout the clinical-trial process.

***By enabling the core functionality of one solution to be accessed from another, this convergence of solutions is a dramatic shift in the way that technologies can be used together to streamline workflow, says Bill Byrom.***

Key components featured in the integrated suite include the Perceptive Portal, an enterprise portal solution that provides trial communities with secure, central access to essential study documentation and materials; a combined electronic data capture-integrated voice response (EDC-IVR) system that allows users to perform real-time randomization and dispensation activities within Perceptive's DataLabs EDC solution; and a clinical technology integration platform (CTIP) that provides seamless, automated exchange of data across different systems without having to modify applications on connected systems.

***More than ever, our customers need to make better, faster, and more informed decisions about their compounds in development, says Steve Kent.***

"In the past, clinical data were simply moved between applications to reduce the need to reconcile independent databases," says Bill Byrom, Ph.D., senior director, product strategy. "Perceptive has made integration scalable by implementing cutting-edge integration middleware focused on simplifying processes to create highly optimized experiences for users."

"We expect our customers to benefit noticeably from this suite of integrated technologies and services that are aligned to help achieve their development goals," says Steve Kent, president.

In other moves, Perceptive Informatics has introduced a new reporting solution as part of its ClinPhone Randomization and Trial Supply Management (RTSM) technologies.

The reporting solution features a universal suite to monitor trial management performance, RTSM dashboard with trending and forecasting functionalities, and self-service module with customizable search criteria for power users who are focused on in-depth data analysis.

# CIS Launches **COMPLIANCE EXCHANGE FOR R&D PROFESSIONALS**

Compliance Implementation Services (CIS) has developed a clinical R&D version of its Pharma Compliance Exchange (PCX) Website, with the goal of bringing accessibility and order to the continually expanding laws, regulations, and guidelines governing pharmaceutical clinical research.

The new Website, clinical.cis-pcx.com, contains regulations and guidelines for the United States, European Union, and International Conference on Harmonization, as well as archived topics such as clinical trial application, clinical trial conduct, study sites, and IRB/EC drug safety and marketing authorization. In addition, it provides weekly updates and a hot topics section listing the newest regulations posted to the Website.

**The new Website, clinical.cis-pcx.com, contains regulations and guidelines for the United States, European Union, and International Conference on Harmonization, as well as archived topics.**

"We saw an industry need for a single online reference for regulations and guidelines governing clinical research and development activity," notes Annette Horner, senior director, clinical compliance. "We recognize the struggle and importance of keeping up to date with these regulations, so having this information organized and in one location is an easy solution for our subscribers."

# Datatrial Launches **REDESIGNED CORPORATE IDENTITY**

Datatrial has announced an updated corporate identity, including a new logo and tagline, intended to convey the company's ability to serve as a virtual extension of customers' teams.

To complement the branding initiative, Datatrial CEO Adam Black says the company has introduced version 2.0 of its nowEDC software-on-demand application, which features enhancements to the underlying architecture to speed up access, augment the user interface, and provide flexibility in study structure.

***The redevelopment of nowEDC aims to make it even easier for customers to use and even faster to get real-time data from their clinical research, says Adam Black.***

## Follow up

**ACCELA COMMUNICATIONS** creates opportunities for market and audience engagement through its rich-media platform and data acquisition, measurement, and delivery systems. For more information, visit accelacommunications.com.

**ADAIR GREENE MCCANN** provides strategic and creative marketing excellence to drive the success of brands across the pharmaceutical (Rx and OTC), medical device, diagnostic, and biotechnology marketplaces. For more information, visit adairgreene.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.

**CEGEDIM DENDRITE** provides compliance technology solutions and services to the pharmaceutical industry. For more information, visit cegedimdendrite.com.

**COMPLIANCE IMPLEMENTATION SERVICES (CIS)** is a consulting firm specializing in compliance strategies for pharmaceutical companies. For more information, visit cis-partners.com.

**CUTTING EDGE INFORMATION** provides research and consulting to the pharmaceutical industry and the financial services industry. For more information, visit cuttingedgeinfo.com.

**DATA DEVELOPMENT WORLDWIDE (DDW)** uses proprietary market-research tools to provide insights for global marketers in categories including pharmaceuticals, consumer products, financial services, communications, and traditional/new media. For more information, visit datadw.com.

**DATATRIAL** is a boutique clinical data organization specializing in custom approaches to study delivery. For more information, visit datatrial.com.

**ERT** provides centralized ECG and e-clinical technology, ePRO, and other services designed to support clinical trials. For more information, visit ert.com.

**KMR GROUP** provides benchmarking, analytics, and performance management services with an exclusive focus on biopharmaceutical R&D. For more information, visit kmrgroup.com.

**M|C COMMUNICATIONS LLC** provides medical education event management solutions for healthcare professionals and others around the globe. For more information, visit mc-comm.com.

**MOONBAY TECHNOLOGY** provides regulatory document management applications and services that help life-sciences companies with efficiency, due diligence, and compliance. For more information, visit moonbaytech.com.

**PARAGONRX** provides risk mitigation and appropriate use programs. For more information, visit paragonrx.com.

**PERCEPTIVE INFORMATICS**, a subsidiary of Parexel International Corp., provides e-clinical solutions to the life-sciences industry. For more information, visit perceptive.com.

**PHARMA-MARKETER.COM** provides pharmaceutical marketing professionals access to a wide range of industry-related content. For more information, visit pharma-marketer.com.

**PHASE FORWARD** is a provider of integrated data management solutions for clinical trials and drug safety. For more information, visit phaseforward.com.

**SPARTA SYSTEMS INC.** provides global quality and compliance management systems. For more information, visit sparta-systems.com.

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# Pharmaceutical Market Access 2010: Strategic Developments Impacting the US, EU, and Emerging Markets

**DATE AND TIME**
Wed., Sept. 30, 2009
12 PM - 1 PM ET

**GUEST SPEAKERS**

**Lee Blansett**
Senior Vice President
Oncology Market Access
**MattsonJack**

**Dr. Susanne Michel MD, MSc**
Head of Global Market Access,
Pricing and Reimbursement
**TNS Healthcare**

FEATURING

## New Research on Public Reactions to the Proposed Obama Reforms

The pharmaceutical and biotechnology industry is confronting significant short-term and long-term challenges. Financial pressures from current generic competition, upcoming patent expirations, and pending healthcare legislation and reforms in both the US and EU, are forcing the industry to "rethink" everything from R&D to Marketing. Future revenue growth in the US and EU is unclear, so pharma and biotech companies are looking to Emerging Market opportunities in Brazil, Russia, India, and China (i.e., BRIC) to drive future business. The EU is wrestling with the cost effectiveness of treatments and working through key changes in important regulatory processes. In addition, US healthcare reforms and pending legislation are pointing to universal coverage or the emergence of a "national plan."

**What does this all mean for patients, physicians, payers, and pharmaceutical / biotech manufacturers especially as payer actions and priorities converge across borders?**

**KEY TAKE-AWAYS:**

- Guidance on Creating Effective Access Strategies for the High-Growth Emerging Markets
- Critical Developments Influencing US Market Access for High Cost Drugs: The Strategic Implications for Pharma and Biotech
- Insights Into New Trends for Financing Healthcare (Including Specific Country Examples Showing Key Changes in Health Systems and Regulatory Processes)
- The Growing Focus on Cost Effectiveness in the EU: The Impact on Future Branding and Pricing Strategy
- Understand How to Identify and Impact Decision Makers at Every Level – National, Regional, and Individual Insurer
- How and Why EU Healthcare Initiatives Can Better Inform the Debate on US Healthcare Reform

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