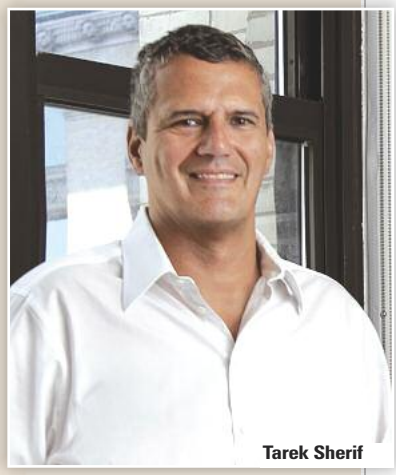
By Carolyn Gretton

Clinical Force Acquisition Strengthens

Medidata's CTMS Offerings

TRENDS: E-clinical solutions providers continue to bolster their clinical trial management solutions (CTMS) offerings as demand surges amid increased use of collaborative tools by sponsors and CROs for clinical study and regulatory document management.


Tarek Sherif

With the acquisition of U.K.-based **CLINICAL FORCE**, a provider of software-as-a-service-based CTMS offerings, **Medidata Solutions** can now offer a cost-efficient alternative for both large and midsized study sponsors and CROs.

While many software systems aiming to address the financial and operational management burden of clinical trials have typically required complex implementation projects with large up-front investments, lengthy timelines, and ongoing maintenance costs, Clinical Force's alternative CTMS solution eliminates these risks.

"Clinical Force brings a new, different, and better approach to CTMS with broad appeal to large clinical development organizations as well as the largely underserved midmarket sponsors and regional CROs," says Tarek Sherif, Medidata's chairman and CEO. "The company's offering strategically enhances our comprehensive SaaS platform, providing further opportunities for our customers to optimize key clinical, financial, and operational processes; accelerate time to value; and lower clinical development costs."

"By introducing a SaaS-based approach to CTMS, Clinical Force has changed the paradigm for how life-sciences companies adopt and scale state-of-the-art clinical trial management technology within their organization," adds Clinical Force CEO Christopher Broderick. "Joining forces with the leading SaaS clinical technology solutions provider will give our customers access to Medidata's global resources and best-in-class solutions."

In other moves, Medidata has unveiled the following additions to its portfolio of SaaS-based clinical development solutions:

- Medidata Standards Accelerator, a solution that provides end-to-end support for the CDISC study data tabulation model (SDTM), the FDA's recommended format for electronic submission of case report form data.
- Medidata Insights, a clinical business analytics solution that offers immediate access to hundreds of metrics across critical operational areas such as site enrollment, data quality, and eCRF design, alongside industry benchmarks based on data from thousands of current and historical clinical trials.
- Medidata Coder, an enterprise-grade, SaaS coding solution providing a single centralized coding environment that integrates with any source system and works seamlessly out of the box with the company's Medidata Rave EDC/CDM.

For more information, visit mdsol.com.

BioClinica CTMS Platform Focuses on Improved Collaboration


Peter Benton

BIOCLINICA ONPOINT CTMS, the new release of the CTMS platform **BioClinica** acquired from TranSenda in 2010, helps clinical-trial sponsor companies and CROs to efficiently access, share, and analyze operational trial data by leveraging standard collaboration and office automation tools.

BioClinica's data interchange technology eases the acquisition of operational data from multiple sources in real time. OnPoint's tight integration with Microsoft SharePoint enables users to interact with the system via Microsoft Office applications, speeding user adoption and compliance and decreasing cost of ownership for large implementations. BioClinica also offers hosting options for OnPoint for organizations that want to minimize infrastructure investment.

"The combination of features, value, and fast implementation — augmented by OnPoint's out-of-the-box integration with SharePoint — is changing market perceptions of CTMS' utility and cost-effectiveness," says Peter Benton, president of eClinical solutions for BioClinica.

For more information, visit bioclinica.com.

Perceptive Informatics Takes CTMS to the Cloud


Nicholas Richards

Perceptive Informatics, a subsidiary of **Parexel International**, has made its **CTMS** available as an on-demand, software-as-a-service application, enabling sponsors to plan, administer, and track clinical-trial activities in a cost-effective and efficient manner.

"SaaS-enabled technologies are experiencing tremendous acceptance because they can be rapidly implemented, and they eliminate up-front

capital investment and decrease associated maintenance," observes Nicholas Richards, VP, product management, at Perceptive.

The CTMS solution allows sponsors to save time in study start-up because of its rapid, flexible, scalable, and secure deployment approach supported by Perceptive's eClinical platform. A subscription option provides users with the benefits of an on-premise solution without the need for up-front investments or additional internal resources.

For more information, visit perceptive.com.

In other technology news…


Neil de Crescenzo

ORACLE HEALTH SCIENCES TRIAL CENTER is an application that delivers a unified view of actionable, real-time information across multiple trials, sites, and systems and provides direct access to relevant trial technologies. The solution enables health sciences organizations and CROs to maximize productivity of their study managers, coordinators, and monitors, while strengthening collaboration and relationships between sponsors, sites, and partners.

"Life-sciences organizations and their CRO partners are focused squarely on reducing costs, improving clinical trial efficiency, and accelerating insight; but the complexity of the networks, relationships, and systems required to execute trials has made those efforts more difficult than ever," says Neil de Crescenzo, VP and general manager, Oracle Health Sciences.

For more information, visit oracle.com.

Aptiv Solutions, a global biopharmaceutical and medical device development services company, is working with business analytics solutions provider SAS to develop solutions that drive clinical trial design and deployment of adaptive clinical trials. The two companies are collaborating to automate workflow and improve drug trial design through simulation and efficient execution.

"Aptiv Solutions has combined advanced simulation and software capabilities with the knowledge of adaptive clinical trial subject-matter experts and broad capabilities," says Aptiv Solutions Chairman and CEO Patrick Donnelly.


Patrick Donnelly


Jason Burke

"The difficulties facing companies developing products in life sciences continue to intensify, and those that rely on conventional techniques risk missing out on emerging opportunities and the successes that typically follow," notes Jason Burke, director of SAS Center for Health Analytics and Insights (CHAI). "Adaptive clinical trials can mean the difference between being a market leader and lagging behind."

In other news, Aptiv Solutions has made available the latest release of **ADDPLAN** (Adaptive Designs-Plans and Analysis). The ADDPLAN 6 software package incorporates multiple comparison procedures for multi-armed adaptive trials, including treatment selection designs, a flexible combination of clinical research phases, and population

enrichment designs. Additionally, ADDPLAN 6 satisfies all requirements identified in the FDA's recent Guidance on Adaptive Design for Clinical Trials for Drugs and Biologics.

For more information, visit aptivsolutions.com.

TransPerfect and **Sentrx** are collaborating on a **DRUG SAETY MODULE** incorporating TransPerfect's Trial Interactive portal technology to streamline end-to-end global drug safety capabilities in both clinical and postmarketing event management.

The solution enables direct safety information collection on a global basis from investigative site personnel via multiple communications channels into a secure data portal. The approach speeds safety data exchange between safety teams and reporters.


Michael O'Gorman

The portal is fully compatible with Sentrx's SaPh drug safety solution, which provides Argus Safety management in a hosted deployment.

"Web-based portal solutions have been identified as a critical imperative for achieving new gains in adverse event management efficiency," says Sentrx President and General Manager Michael O'Gorman."Our collaboration with Trial Interactive has produced a fully compliant safety portal platform to enhance workflow efficiency."

For more information, visit trialinteractive.com.

QUINTILES INFOSARIO is a business-to-business platform that enables customers to leverage **Quintiles'** data for improved collaboration and decision-making throughout the drug development process.


Tom Grundstrom


Paula Brown Stafford

The cloud-based SaaS combines IT provisioning, including configured systems, with core clinical business process delivery, providing users with direct, cost-effective access to state-of-the-art IT systems such as safety management and clinical trial management.

According to Tom Grundstrom, Quintiles Infosario global head, the platform's technology helps convert Quintiles' wealth of data into actionable insights for customers.

"Through the platform's intuitive user interface, key stakeholders will be able to make faster, better-informed decisions about the programs and therapies they are working on," Mr. Grundstrom adds.

"The release of Quintiles Infosario marks an important new day for both the biopharmaceutical industry and those patients who benefit from their breakthroughs," says Paula Brown Stafford, president of Quintiles Clinical Development.

For more information, visit quintiles.com.

BBK Worldwide, a provider of clinical trial patient recruitment services, has introduced **E-BINDER 2**, an Apple iPad 2 specifically customized for the research and development community and its regulatory guidelines to restrict data consumption to study-related activities.


Matthew Kibby

The e-Binder 2 deploys a proprietary virtual "tunnel" that permits only designated IP addresses to be accessible through a 3G network, with other sites available using a Wi-Fi connection. Direct connections between the e-Binder and the sponsor's Web-based portals, as well as content updates, are managed by BBK's sister company, TCN e-Systems.

"Fast, accurate, and green, the e-Binder significantly reduces operational costs through savings in printing, shipping, and storage," says Matthew Kibby, BBK's global operations leader.

For more information, visit bbkworldwide.com.

The **ADLIB CONTENT TRANSFORMATION PLATFORM** is designed to streamline document-intensive business processes to improve efficiency, mitigate compliance-related risks, and reduce costs.


Peter Duff

The platform is deployed as a shared service and can scale enterprise-wide, enabling centralized content-to-PDF transformation capabilities to multiple applications, departments, and lines of business.

"The Adlib Platform provides organizations with a competitive advantage by optimizing document-centric business processes with centralized content transformation capabilities," says Adlib CEO Peter Duff.

For more information, visit adlibsoftware.com.

Sparta Systems' on-demand **TRACKWISE TRAINING** solution is designed to provide a cost-effective, convenient way for companies to train large groups of users and intermittent users on the basics of TrackWise enterprise quality management (EQM) software. The TrackWise Training solution is part of Sparta Systems' comprehensive suite of training offerings, which also include live and e-learning instructor-led courses.


Mike Jovanis

"Organizations of all sizes use TrackWise software to manage their quality and compliance processes across the enterprise," says Mike Jovanis, VP of product management for Sparta Systems. "Our on-demand training offering addresses the challenge organizations face in getting all their users trained on the basics of the system so that they are getting the most out of their TrackWise implementations."

For more information, visit spartasystems.com.

PHT has announced the free publication of its **EPRO MODALITY TOOL**, which helps clinical trial managers to successfully determine the right electronic patient-reported outcomes (ePRO) modality for specific trial types and phases. By publishing the tool and lifting all previous restrictions for its use, PHT continues its drive to promote worldwide ePRO adoption.


Phil Lee

"The ePRO Modality Tool makes it fast, easy, and free for any pharmaceutical company to learn how and why ePRO is the best patient data collection method for ensuring a safe, economical, efficient clinical trial," says PHT President and CEO Phil Lee.

For more information, visit phtcorp.com. PV

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Robert Oscar

RxEOB has introduced **EMWELLICS**, a modular mobile platform that connects managed care plans, pharmacy benefit managers (PBMs), and payers one-to-one with their members.

emWellics empowers health plans and PBMs to reach millions of members with their own branded, HIPAA-compliant mobile application, and to customize their mobile offering with an array of applications.

The platform supports all mobile operating systems and easily integrates with client-maintained claim, benefits, and eligibility databases or enterprise data warehouses.

"emWellics allows individuals — including Medicare, Medicaid, and commercial members — to understand and manage their pharmaceutical benefits through their smartphones," says RxEOB CEO Robert Oscar. "Using a list of pre-loaded visit preparation questions — from medication use to diagnostic test questions — members will experience more productive appointments with their physicians and can easily communicate notes about their discussions to family members and caregivers through their smartphones."

For more information, visit rxeob.com.

Bristol-Myers Squibb (BMS) has created **STUDY CONNECT** to provide information and support to patients who may be considering participating in a clinical study, as well as their caregivers and loved ones.

The online resource includes answers to frequently asked questions, information for caregivers, patient stories, and a "find a study" tool that allows users to search for relevant BMS-sponsored studies, both adult and pediatric, in their region and across the country.

For more information, visit bms.com/study-connect.

eMedFusion, KnowledgePoint360's digital healthcare agency, has unveiled **E-PATH**, a five-phase methodology that provides clients with a clear road map for sustainable success in the digital healthcare environment.

e-Path provides clear insight into a client's online presence and understanding of the needs and requirements of all stakeholders and delivers a sustainable digital strategy to meet these requirements.

"As the pace of change within the pharmaceutical and healthcare industry accelerates, innovation and creativity are fundamental value drivers, and nowhere is that more evident than in the digital arena," notes David Moore, senior VP for eMedFusion. "With e-Path, eMedFusion's digital consultancy team is able to offer our clients a robust approach fueled by insights and best practices from a variety of different industries applied to the particular dynamics of the digital healthcare space."

For more information, visit emedfusion.com.

SEAMLESS SAFETY, a joint offering from **Aris Global** and **Synowledge**, provides life-sciences organizations with a subscription-based, hosted pharmacovigilance solution combined with expert case processing services for end-to-end safety. The scalable offering comes preconfigured

E-UPGRADES AND ENHANCEMENTS

Accelrys has issued a new version of its **DISCOVERY STUDIO** life-sciences modeling and simulation software that incorporates the first commercially available software for predicting protein-protein aggregation to advance biotherapeutics research. In addition, a major update to the software's 3D-molecular ActiveX control enables researchers to display dynamic molecular visualizations in Web pages, Microsoft Office applications, and Microsoft SharePoint collaboration software.

For more information, visit accelrys.com.

The Chubb Group of Insurance Companies has added Italy, Poland, South Africa, and Turkey to its **WORLDCERT** proprietary online system that instantly generates certificates of insurance, helping life-sciences companies avoid costly delays in human clinical trials overseas.

For more information, visit chubb.com.

ClearTrial's **CLEARTRIAL 4.2** release includes the ClearTrial Web Services application programming interface, which streamlines the integration of ClearTrial with any system that can use a Web service. The latest version of ClearTrial also delivers several enhanced features that provide greater flexibility and configurability in study planning, forecasting, outsourcing, and tracking.

For more information, visit cleartrial.com.

DecisionView has announced the participation of a number of pharma industry leaders, including GlaxoSmithKline and Roche, in creating a set of **INDUSTRY PATIENT ENROLLMENT BENCHMARKS** based on real-world clinical performance data. Each of the initial sponsors will contribute its historical enrollment data, which will be anonymized, aggregated, and made available to all participants via DecisionView's StudyOptimizer for use in benchmarking, planning, and forecasting clinical trial enrollment.

For more information, visit decisionview.com.

iWorx has introduced the **LABSCRIBE2 MONOPHASIC ACTION POTENTIAL (MAP) MODULE** for measuring and analyzing MAP signals in physiological animal research. The MAP software module identifies common parameters such as maximum, minimum, and plateau voltages and enables user-defined recovery points and records rates of change.

For more information, visit iworx.com.

Octagon Research Solutions has unveiled **CONTENT MANAGER AND DOCUMENT PUBLISHER** as the next applications built on Octagon's Quantum platform, joining the existing Submission Manager. The Quantum platform provides the life-sciences industry with a single, consolidated system to provide robust, highly scalable, and top-tier capabilities to companies of all sizes.

For more information, visit octagonresearch.com.

Simulations Plus has released **DDDPLUS VERSION 4.0** with a set of expanded and powerful capabilities for simulating in vitro dissolution experiments. Additions to DDDPlus 4.0 include expanded parameter sensitivity analysis, a new virtual trial capability, a new immediate-release capsule dosage form, and a variety of enhanced input and output functions.

For more information, visit simulations-plus.com.

ValueCentric's **VALUETRAK MOBILE 2.0** enables access to the ValueTrak platform for on-demand data management and performance analytics through all mobile devices. It also includes geolocation using GPS or Wi-Fi.

For more information, visit valuecentric.com.

based on industry best practices and ready to use for any of Aris Global's safety solutions.

"We've eliminated the burden of time, effort, budget, and staff to give companies a stress-free, plug-and-play solution for meeting global regulatory reporting obligations," says Vikram Anand, head of agOnDemand and global customer support for Aris Global.

"We entered into this collaborative offering so that companies could focus on their core competencies and allow us to handle their end-to-end safety requirements, including case processing," adds David Ingraham, director, sales and marketing at Synowledge.

In other moves, Aris Global has added agOnDemand Swift to its agOnDemand suite of SaaS-based safety and pharmacovigilance offerings. agOnDemand Swift comes pre-configured with features and functionality based on Aris Global's ARISg pharmacovigilance and safety system, with subscribers paying for what they need based on the number of cases processed.

For more information, visit arisglobal.com.

PDR Network's **RXEVENT** is an online network developed to collect and distribute adverse drug events in the United States in a less time-consuming, more efficient manner. The service is available to all U.S. prescribers via integration into electronic health record (EHR) platforms and other online services, as well as directly via the RxEvent.org website.


Dr. Edward Fotsch

PDR Network CEO Edward Fotsch, M.D., says RxEvent is part of the new eCare services PDR is rolling out with content integrated into EHRs to increase drug and device efficacy and efficiency.

"RxEvent was designed to improve the convenience of adverse event reporting for physicians, the cost-efficiency for manufacturers, and the quality of information ultimately reported to the FDA," Dr. Fotsch explains.

For more information, visit pdrnetwork.com.

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