Annual DIA Preview Showcase Feature

PharmaVOICE is pleased to once again publish this Special Feature showcasing the new products, services, tools, and executive appointments and promotions at clinical-services companies that will be exhibiting at the DIA 46th Annual Meeting, June 13-17, 2010, in Washington, D.C. For your convenience, we've divided the briefs into sections, including E-Solutions, What's New, and People.

We look forward to seeing you in Washington, D.C. Please stop by the PharmaVOICE booth — No. 400 — to learn about what's happening in the clinical-services arena.

Please be sure to visit pharmavoice.com for more bonus content and more company news.

Regards,

Taren Grom, Editor

FACILITATING INNOVATION FOR BETTER HEALTH OUTCOMES

The 46th DIA Annual Meeting is charting a new course that will reflect DIA's new vision as a global forum for a knowledge exchange that fosters innovation to raise the level of health and well-being worldwide. This year's meeting aims to facilitate innovation for better health outcomes.

We have a shared responsibility to be facilitators of innovation as we continue to work together to provide everyone with better access to better medicines, says Dr. Gaby Danan, Global Pharmacovigilance and Epidemiology, Sanofi-Aventis, and Chairperson of the DIA 46th Annual Meeting.

More than 25 special topics are available in this year's annual meeting program, including oncology, biosimilars, pediatrics, and social media, as well as special sessions on comparative effectiveness research and multiregional clinical trials. The 46th DIA Annual Meeting Program Committee has created three megatracks designed to strengthen the presentations and their relevance to the challenges faced by today's professionals and to promote broader discussion of the topics. These megatracks are: Advertising, Marketing, Medical Communications; Clinical Research; and Information Technology.

The meeting will feature 37 live Webinars and 330-plus sessions, including audio synched PowerPoint presentations, and more than 400 exhibiting companies.

Keynote speakers this year include Margaret A. Hamburg, M.D., Commissioner of Food and Drugs at the Food and Drug Administration, and Jeff Goldsmith, Ph.D., Associate Professor, University of Virginia, and President, Health Futures.

PharmaVOICE Webcast Network – Podcasts, Webseminars, and White Papers

The following is a list of current and archived podcasts, white papers, and WebLinx Interactive Webseminars related to the clinical research and services arena that PharmaVOICE and industry thought leaders have conducted throughout the year. To access any of PharmaVOICE's archived episodes, please visit pharmavoice.com.

PODCASTS

U.S. and Global Information Security Standards in Patient Recruitment
Thought Leader: Roger Smith, Senior VP, Operations, Acurian
For more information, visit acurian.com, or stop by Booth No. 1145.

Social Networking for Patient Recruitment for Clinical Trials
Thought Leader: Scott Connor, VP of Marketing, Acurian
For more information, visit acurian.com, or stop by Booth No. 1145.

Performance-Based Pricing in Patient Recruitment
Thought Leader: Richard Malcolm Ph.D., CEO, Acurian
For more information, visit acurian.com, or stop by Booth No. 1145.

Return On Investment in Patient Recruitment
Thought Leader: Richard Malcolm, Ph.D., CEO, Acurian
For more information, visit acurian.com, or stop by Booth No. 1145.

The Evolution of the E-Patient
Thought Leader: Bonnie Brescia, Founding Principal, BBK Worldwide
For more information, visit bbkworldwide.com, or stop by Booth No. 1317.

Connecting Through Electronic Health Records
Thought Leaders: Landen Bain, Liaison to Healthcare, CDISC, and Dave Iberson-Hurst, VP of Technical Strategy, CDISC
For more information, visit cdisc.org, or stop by Booth No. 821.

Partnership Model for Clinical Development is Driving the Industry's Clinical Transformation Agenda
Thought Leaders: Nagaraja Srivatsan, VP, Head of Life Sciences, North America; Ramana Reddy, Practice Leader, Life Sciences; and Krishnan Rajagopalan, Ph.D., Global Head of Life Sciences BPO, Cognizant
For more information, visit cognizant.com, or stop by Booth 2235.

Commercial Operations Outsourcing: A Leading-Edge Response to the Financial Storm
Thought Leaders: Jassi Chadha, Head of Analytics Practice, Patrick Brundage, Practice Leader, Life Sciences Analytics, and Nagaraja Srivatsan, VP and Head of Life Sciences, North America, Cognizant
For more information, visit cognizant.com, or stop by Booth 2235.

Science is Greater than the Economy
Thought Leader: Lawrence Reiter, Ph.D., Director of Global Affairs, Criterium Inc.
For more information, visit criteriumusa.com, or stop by Booth No. 216.

Clinical Delivery Alliances in Drug Development
Thought Leader: Tim Dietlin, VP of Alliance Development, INC Research
For more information, visit incresearch.com, or stop by Booth No. 221.

FEATURED DIA EXHIBITING COMPANIES AT A GLANCE

Acurian is a full-service provider of clinical trial patient recruitment and retention solutions for the life-sciences industry. For more information, visit acurian.com, or stop by Booth No. 1145.

Almac Clinical Technologies is a division of the Almac Group that specializes in interactive technology and service solutions. For more information, visit almacgroup, or stop by Booth No. 1011.

Aris Global provides drug safety, drug safety monitoring, pharmacovigilance, regulatory compliance, medical information, and clinical trials management software. For more information, visit arisglobal.com, or stop by Booth No. 2027.

BioClinica Inc. is a global provider of integrated, technology-enhanced clinical trial management services. For more information, visit bioclinica.com, or stop by Booth No. 111.

Charles River Laboratories is a global provider of research models and preclinical, clinical, and support services. For more information visit criver.com, or stop by Booth No. 1217.

Covance is a drug development services company. For more information, visit covance.com, or stop by Booth No. 527.

ISI provides submissions solutions, process services, and consulting to life-sciences companies. For more information visit imagesolutions.com, or stop by Booth No. 326.

Medidata Solutions is a global provider of hosted clinical development solutions. For more information, visit mdsol.com, or stop by Booth No. 1517.

MMG is a full-service patient recruitment and retention group. For more information, visit wegetpatients.com, or stop by Booth No. 1931.

NextDocs is a provider of regulatory document and quality management software solutions. For more information, visit nextdocs.com, or stop by Booth No. 1439.

Nextrials provides clinical research software and services. For more information, visit nextrials.com, or stop by Booth No. 1320.

Oracle is an integrated business software and hardware systems company. For more information, visit oracle.com, or stop by Booth No. 2127.

Paragon Biomedical is a full-service clinical research organization (CRO) providing Phase I to IV clinical trial support. For more information, visit parabio.com, or stop by Booth No. 1121.

Perceptive Informatics is an e-clinical solutions provider and a subsidiary of Parexel. For more information, visit perceptive.com, or stop by Booth No. 921.

PharmaNet Development Group, a global drug development services company, provides a comprehensive range of services. For more information, visit pharmanet.com, or stop by Booth No. 445.

PPD Inc. is a global contract research organization. For more information, visit ppdi.com, or stop by Booth No. 1744.

Quanticate is a global biometrics clinical research organization (CRO). For more information, visit quanticate.com, or stop by Booth No. 1503.

Quintiles Transnational is an integrated biopharmaceutical services company offering clinical, commercial, consulting, and capital solutions worldwide. For more information, visit quintiles.com, or stop by Booth No. 1035.

Sparta Systems is a provider of enterprise quality and compliance management solutions. For more information, visit spartasystems.com, or stop by Booth No. 2200.

Charting a New Course by Catalyzing Transformation

Thought Leaders: Adrian McKemey, Ph.D., Managing Director, Quintiles Consulting, and Michael Arlotto, Ph.D., Senior VP, Quintiles Corporate Development.

For more information, visit quintiles.com, or stop by Booth No. 1035.

WEBINARS

Driving Site Performance: The Investigator Perspective

Speakers: Prof. Brendan M. Buckley, M.D., M.Sc., D.Phil., FRCPI, Founder and Director of Medical Affairs, and Nigel Hughes, B.Sc.,Pharm., Founder and Director, Firecrest Clinical

For more information, visit firecrestclinical.com, or stop by Booth No. 2205.

WHITE PAPERS

U.S. and Global Information Security Standards in Patient Recruitment

Sponsored by: Acurian

For more information, visit acurian.com, or stop by Booth No. 1145.

Leveraging On-Line Social Networks for Clinical Trial Recruitment

Sponsored by: Acurian

For more information, visit acurian.com, or stop by Booth No. 1145.

Predictive Modeling in Clinical Trial Enrollment

Sponsored by: Acurian

For more information, visit acurian.com, or stop by Booth No. 1145.

Leveraging Online Social Media for Clinical Trial Patient Recruitment

Sponsored by: BBK Worldwide

For more information, visit bbkworldwide.com, or stop by Booth No. 1317.

Partnership Model for Clinical Development is Driving the Industry's Clinical Transformation Agenda

Sponsored by: Cognizant

For more information, visit cognizant.com, or stop by Booth 2235.

In a Tight Economy: The Five Most Critical Clinical Research Factors

Sponsored by: Criterium Inc.

For more information, visit criteriuminc.com, or stop by Booth No. 216.

A New Approach to Outsourced Drug Development: How Sponsor-CRO Clinical Delivery Alliances Improve Performance

Sponsored by: INC Research

For more information, visit increasearch.com, or stop by Booth No. 221.

On the Rebalancing of Risk to Transform Cost and Productivity in Drug Development

Sponsored by: Quintiles

For more information, visit quintiles.com, or stop by Booth No. 1035.

E-SOLUTIONS

The following briefs include information about new e-based clinically related solutions. The companies in this section are presented in alphabetical order.

Acurian Offers Improved Patient Recruitment

There is a critical period of time between when we prescreen and refer good patient candidates and when they are finally seen by a doctor, says Roger Smith.

Acurian has introduced Bing, an online mapping software that is integrated with the company's recruitment manager platform to provide prequalified patient referrals with easy directions, driving distances, and maps to research site locations.

"Our goal is to improve the patient experience and keep them engaged in the process," says Roger Smith, VP of operations at Acurian. "Patients can view multiple sites in their area so they can choose the most convenient location for them, be it near home or work. It's visually enticing and easy to navigate so patients are more comfortable with the site selection."

Acurian also provides online, animated educational presentations that present a comprehensive understanding of what to expect during the trial process. Presentations typically include information on why clinical research is important, background on current treatments, and how a study may be different from available treatments.

The presentation lets the patient know what to expect from the doctor, testing procedures and paperwork requirements.

For more information, visit acurian.com, or stop by Booth No. 1145.

Almac Clinical Technologies Releases Reporting System

We have invested heavily in our reporting and IXRS technology this year to help clients manage their trials more effectively and productively, says Jim Murphy.

Almac Clinical Technologies has released a new reporting solution for its IXRS integrated phone and Web-response technology. The new reporting system, Almac Interactive Reporting, features dashboards and a suite of reports specifically designed to suit the needs of clinical and drug supply management professionals, including patient and site functions, such as screening, enrollment, randomization, and site activation.

Standard features include online sorting, filtering, pivoting, graphing, and other analytical tools. Downloading data into Excel and other formats is easy, but hardly necessary given the power of the solution.

"We have invested heavily in our reporting and IXRS technology this year to help clients manage their trials more effectively and productively," says Jim Murphy, Almac's president.

For more information, visit almacgroup, or stop by Booth No. 1011.

Aris Global Solution Integrates EDC and Safety

Drug-development costs can be significantly reduced by eliminating the overlap and redundant processes that exist across different departments, says Dr. Sylva Collins.

Aris Global has introduced Total Clinical 2.0, an integrated solution suite designed to help life-sciences organizations enter clinical safety data once and share seamlessly across their enterprise. Total Clinical is available on a hosted, managed platform and includes a full range of delivery and support services.

Total Clinical 2.0 integrates data from EDC and clinical safety to help companies improve consistency and accuracy by eliminating redundancies in data entry, coding, and SAE reconciliation.

"Our approach is to focus on smart integration across core systems and enable companies to enter data once and share seamlessly across departments," says Dr. Sylva Collins, Aris Global VP of e-clinical solutions.

For more information, visit arisglobal.com, or stop by Booth No. 2027.

BioClinica Launches Imaging Delivery System

We remain committed to driving the advancement of image management for clinical trials with a blend of new technologies and services, says David Pitler.

BioClinica has released BioClinica WebSend, a system that simplifies and accelerates image collection for clinical studies. WebSend transfers and tracks medical images in real-time, offering key benefits over the standard manual transport methods commonly used in imaging trials, including faster delivery of image data, enhanced data quality with fewer site queries, and reduced cost.

BioClinica WebSend is complemented by BioClinica WebView, a solution for managing the electronic sharing, blinding, tracking, archiving, and analysis of medical images for clinical trials worldwide. Originally developed more than 10 years ago by CardioNow, a business acquired by BioClinica from Agfa HealthCare in August 2009, BioClinica WebSend and WebView have evolved into a best-in-class solution for delivering true electronic clinical trial image management.

"BioClinica WebSend and BioClinica WebView are further examples of how BioClinica continues to develop innovative solutions to help our customers better manage their clinical studies and achieve the best possible results," says David Pitler, president of BioClinica's Bioimaging Services Division.

For more information, visit bioclinica.com, or stop by Booth No. 111.

Medidata Solutions Offers Clinical Trial Budgeting System

In the case of very complex protocols, sponsors may help to ensure site success and satisfaction by adjusting payments to reflect the greater work effort required, says Lori Shields.

With the launch of Medidata Grants Manager 3.0, Medidata Solutions introduces new capabilities to its clinical trial budgeting system. The PICAS database now incorporates complexity metrics for clinical protocols. The complexity metric provides a measure of the actual work required of sites in conducting clinical trials, which enables sponsors to further tailor their budgets to the actual work required in performing trial activities.

The new Grants Manager also assists users in selecting the correct procedure for budgeting in a trial by showing the actual frequency of use of procedures in numerous indications. The system now supports budgets with data for more than 80 countries, incorporates the ability to budget for multi-arm studies, and is Internet-browser enabled.

Lori Shields, VP of Medidata's data operations, says Grants Manager 3.0 offers sponsors a new way of tailoring trial costs to site satisfaction.

For more information, visit mdsol.com, or stop by Booth No. 1517.

MMG Launches Recruitment System

Recruitment is a critical component of study feasibility, not a by-product of that process, says John Benbrook.

MMG has launched MMG Catalyst, an intelligence-driven end-to-end approach to recruitment. This use of intelligence derived from a strategic mix of independent data sources is significantly reshaping how the industry approaches the entire patient recruitment continuum, from protocol feasibility, through site identification, into the active recruitment phase.

"Applying healthcare claims and other data is not in itself new to the clinical trial space," says John Benbrook, CEO of MMG. "Clinical development teams have looked to prescription and procedure data. But these assessments have been largely based on singular data sets, or small numbers of multiple data sets analyzed separately, to answer much higher-level feasibility questions and to provide basic site identification guidance."

MMG Catalyst has the ability to accurately and quickly mesh together and cross reference data sets with multiple differing attributes and to tie medical care data with clinical trial intelligence and consumer data. With data aggregation experts, sponsors now have a tool for these purposes specifically for clinical trials. The system also performs rapid what-if scenario analyses to quantify the impact on time and cost of study design changes.

For more information, visit wegetpatients.com, or stop by Booth No. 1931.

NextDocs Announces Clinical Collaboration Portal

Customers have been in need of easy access to clinical information and effective exchange of information among clinical trial collaborators for some time, says Chet Shemanski.

NextDocs has launched Clinical Collaboration Portal, which is designed to help life-sciences companies facilitate collaboration during clinical trials with external participants such as clinical researchers, laboratories, and physicians in a secure and easily navigable environment.

The new portal is a major enhancement to NextDocs' current Clinical Documents Module, which focuses on internal collaboration. Release 3.7 focuses on enhanced information exchange between trial sponsors, CROs, clinical investigator sites, IRBs, and labs.

Security is a critical feature of the Clinical Collaboration Portal, which is built on the NextDocs Compliance Platform for SharePoint Server and introduces features to support secure extranet collaboration. The portal also has external view/investigator view interfaces, automated trial Web site provisioning, electronic trial master file (eTMF), and integration support for CTMS by TranSenda, Oracle, and Perceptive Informatics.

"With SharePoint and the Clinical Collaboration Portal from NextDocs, we now have the tools necessary to fulfill that need and ultimately improve operational efficiency," says Chet Shemanski, director of product management at NextDocs.

For more information, visit nextdocs.com, or stop by Booth No. 1439.

Nextrials' Prism Adds Support for Google Chrome

We place a high priority on adding features, functionality, and compatibility, such as integration with leading electronic health records platforms, to keep Prism user-friendly and easier to deploy, says James Rogers.

Nextrials has announced that its EDC and clinical trial data management platform, Prism, is now compatible with the Google Chrome browser. Already available for use with Apple's Safari, Microsoft Internet Explorer, and Mozilla Firefox, Prism's compatibility with Google Chrome means more choices for customers who may be upgrading corporate systems with newer hardware or mobile devices.

"Although many of our customers are still using legacy systems, there is an increasing number that are migrating to newer hardware and mobile platforms such as the iPad," says James Rogers, CEO and co-founder of Nextrials.

By receiving a constant flow of data, Prism enables sponsors and sites to fully use real-time integration of disparate information and data sources to better provide a continuum of care for patients enrolled in clinical trials.

For more information, visit nextrials.com, or stop by Booth No. 1320.

Oracle Announces Latest On-Demand System

The new release will help customers gain more actionable insights, increase sales productivity, and achieve cost-savings, says Charles Phillips.

Oracle CRM On Demand Release 17, introduces extensive forecasting and analytics capabilities to gain more actionable insight and increase productivity.

New forecasting capabilities include flexible fiscal calendars for more productive business operations, the ability to perform both revenue and product quantity forecasting, and real-time information comparisons against current and historical forecasts for proactive pipeline management.

Oracle CRM On Demand Release 17 maximizes pipeline management with automated time-based workflows to manage sales, marketing, service, and channels, while enabling accelerated time-to-value and accurate and timely updates.

"The new Oracle CRM On Demand Release 17 will help customers gain more actionable insight, increase sales productivity, and achieve cost-savings," says Oracle President Charles Phillips.

For more information, visit oracle.com, or stop by Booth No. 2127.

Perceptive Informatics Enhances Medical Imaging Reporting

The various stakeholder groups within imaging-based clinical programs have diverse informational needs, says Dr. Kenneth Faulkner.

Perceptive Informatics, a subsidiary of Parexel International, has expanded its medical imaging capabilities with an enhanced reporting solution.

One of the key features is a dashboard that presents high-level imaging performance metrics to convey vital study information at a glance. The dashboard allows study leaders to view snapshots of study progress for rapid analysis of data. User-friendly graphical displays provide visibility into key performance indicators and enable centralized access to imaging metrics for multiple trials and cross-study program monitoring. The imaging reporting solution includes a suite of online interactive reports. The reports deliver data on study progress with interactive functionality that allows users to drill down on various aspects of tracking performance.

"The solution has been designed to provide high-quality data to enable greater insights into trial progress and support faster execution," says Kenneth Faulkner, Ph.D., VP of medical imaging, Perceptive Informatics.

For more information, visit perceptive.com, or stop by Booth No. 921.

Sparta Systems Unveils Audit Execution Package

Companies now have a broad set of additional capabilities available as they continue global audit management programs and align multiple auditing functions, says Mike Jovanis.

Sparta Systems' TrackWise Audit Execution Package provides auditors with a solution that accelerates the efficiency and compliance of conducting audits in the field. The tool offers comprehensive functionality for ensuring compliance with diverse global regulations and industry standards. Audit information is presented in a cohesive, intuitive format that balances the look and feel of a continuous document-like format with the inclusion of dynamic navigation, structured data fields, and a modern rich text authoring capability.

"We are excited to deliver a solution that adds structure and security to a process that has historically included open, nonsecure cutting and pasting from word processing tools," says Mike Jovanis, VP of product management at Sparta Systems.

For more information, visit spartasystems.com, or stop by Booth No. 2200.

WHAT'S NEW

The following briefs include company news about new clinically related operations. The companies in this section are presented in alphabetical order.

Charles River and WuXi PharmaTech to Combine

We are now offer clients upstream and downstream support for their efforts to bring new drugs to market, says James Foster.

Charles River Laboratories International has agreed to acquire WuXi PharmaTech, a research and development outsourcing company in China and the United States, in a cash and stock transaction valued at about $1.6 billion.

The combined company, which will retain the name Charles River, will offer an expanded portfolio of products and outsourced services to multinational pharmaceutical, biotechnology, and medical-device companies and academic and government institutions that increasingly seek the flexibility to access high-quality, early-stage drug development expertise from chemistry to man from one global company.

"This transaction revolutionizes the contract research landscape by creating the only global contract research organization, or CRO, to offer fully integrated research and drug development services from molecule creation to first-in-human testing," says James Foster, chairman, president, and CEO of Charles River.

For more information visit criver.com, or stop by Booth No. 1217.

PPD Facility Awarded Licenses by Irish Medicines Board

From our lab in Athlone, we provide a full range of small- and large-molecule testing capabilities, says Dr. Magdalena Mejillan.

PPD's contract research facility in Athlone, Ireland, has been awarded manufacturer licenses by the Irish Medicines Board (IMB).

The licenses support investigational medicinal products and marketed products and provide laboratory certifications for quality control of medicinal products.

PPD opened its contract research facility in Athlone, Ireland, in March 2010, in response to growing client demand from clients in Europe, Middle East, and Africa for cGMP analytical testing services.

The facility includes an 18,000-square-foot cGMP analytical testing laboratory and clinical supplies business.

"From our lab in Athlone, we provide a full range of small- and large-molecule testing capabilities, including inhaled products, allowing us to meet the changing needs of our clients more efficiently and effectively," says Magdalena Mejillano, Ph.D., VP of laboratory services at PPD.

In other news, the company has opened a vaccine clinical research center in Taizhou, China. Through the center, PPD will provide clinical monitoring services to global and local biopharmaceutical companies seeking to develop vaccines in China.

For more information, visit ppdi.com, or stop by Booth No. 1744.

United BioSource Acquires Abt Bio-Pharma

The scientists and capabilities that we gain with ABS are an excellent fit with our strategy, says Ethan Leder of UBC.

United BioSource (UBC) has acquired Abt Bio-Pharma Solutions (ABS), a provider of health economics and outcomes research, registries, and observational studies.

The acquisition of ABS is part of UBC's ongoing strategy to build a best-in-class portfolio of scientific and medical affairs solutions to support biopharmaceutical and medical technology companies.

"Whether we are building scientific evidence to address product value and comparative effectiveness or leveraging our expertise and technology to manage the safety risks associated with a new medicine, UBC plays a pivotal role in the development and commercialization of our clients' products," says Ethan Leder, CEO of UBC.

For more information, visit unitedbiosource.com, or stop by Booth No. 1127.

WHO'S WHO

The following briefs include personnel news, new appointments, and promotions in the clinical arena.

Ken Ashman
Dr. Marc Kamin
Dr. Mike Nelson
Dr. Ron Weishaar

PharmaNet Expands Phase IV Team

PharmaNet Development Group has announced the appointment of three key additions to its Phase IV development team: Ken Ashman as executive director of European operations; Marc Kamin, M.D., VP, medical and scientific affairs, neuroscience; Mike Nelson, Pharm.D., as executive director of health economics and outcomes research; and Ron Weishaar, Ph.D., executive director of observational research.

Rejoining PharmaNet after five years, Mr. Ashman brings substantial operational expertise. He coordinates Phase IV activity for global, pan-European, and country-specific projects. He leverages the Phase IV team's technical capabilities in safety and risk management, interventional and observational studies, and economic analysis for pharmaceutical, biotech, and medical device clients in Europe.

Dr. Kamin serves in an advisory role to clients in the area of neuroscience and provides medical support to PharmaNet project teams conducting neuroscience clinical studies.

He is a neurologist, certified by the American Board of Psychiatry and Neurology.

Most recently, Dr. Kamin was at Johnson & Johnson, where he led the central trial coordination group for medical affairs in global clinical operations.

Dr. Nelson spearheads PharmaNet's global services to clients seeking to document the economic and humanistic (quality-of-life) value associated with their products.

Dr. Weishaar has global responsibility for the design and implementation of non-interventional studies and patient registries. Dr. Weishaar holds an MA in chemistry and a Ph.D. in pharmacology.

For more information, visit pharmanet.com, or stop by Booth No. 445.

Dr. Ray Dawkins

Paragon Biomedical Appoints Medical Director

Paragon Biomedical names Ray Dawkins, M.D., executive medical director.

He leads the company's global medical affairs team for continued growth across the CRO's Phase I to IV clinical research services.

Dr. Dawkins has almost 30 years of experience in healthcare and clinical research.

Before joining Paragon, he was senior medical director at a global biotherapeutic and biotechnology company.

Since 2005, Dr. Dawkins has conducted medical device research and development for delivery systems and the design of new intravascular catheters for cardiovascular indications (peripheral arterial disease and stroke).

For more information, visit parabio.com, or stop by Booth No. 1121.

Dr. Douglas Fast

Covance Appoints Bioanalytical Services Director

Covance has appointed Douglas M. Fast, Ph.D., as scientific director, bioanalytical Services. With more than 16 years of drug development industry experience, including bioanalytical assay development, validation and sample assays for nonclinical and clinical studies, Dr. Fast leads the North American staff scientist and principal investigator teams for Covance small molecule bioanalytical services.

Dr. Fast joins Covance from Pfizer Global Research and Development, where he served as director of regulated bioanalytical research in pharmacokinetics, dynamics, and metabolism.

Dr. Fast received a doctorate in analytical chemistry from Purdue University. He is a member of the American Society of Mass Spectrometry, the American Chemical Society, and the American Association of Pharmaceutical Scientists.

For more information, visit covance.com, or stop by Booth No. 527.

Frank Gallo

PPD Strengthens Global Risk Management Services

PPD has named Frank Gallo as executive director of risk management, strengthening its expertise in risk evaluation and mitigation strategies (REMS). Mr. Gallo leads the development, management, and implementation of REMS programs that align with client program goals and product commercialization.

Mr. Gallo brings more than 13 years of pharmaceutical, commercial, and risk management experience to PPD's risk management teams in epidemiology, late-stage surveillance studies, pregnancy registries, pharmacovigilance and medical communications.

He previously served as VP of Rienzi & Rienzi.

Mr. Gallo is on the Scientific Board for National Addictions Vigilance Intervention and Prevention Program.

For more information, visit ppdi.com, or stop by Booth No. 1744.

Blair Gibson
Tony van Bijleveld

Quintiles Appoints VPs

Quintiles has appointed Blair Gibson VP, brand solutions for global commercial solutions. Mr. Gibson spearheads Quintiles' strategic brand solutions offerings in the United States, leveraging the breadth and depth of the company's expertise to optimize the success of products throughout their life cycle.

Quintiles' brand solutions help customers identify, prove, and promote value to regulators, payers, providers, and patients through market access evaluation, clinical and data analysis, and tailored targeted messaging.

Mr. Gibson has 20 years of experience in the biopharma industry in a variety of commercial, strategic planning, and consulting roles. He has worked on three blockbuster launches, and he most recently was executive director for portfolio strategy and strategic planning at Merck.

Quintiles has also appointed Tony van Bijleveld as VP, business development and operations, for global commercial solutions in Central and Eastern Europe, and the Russian Federation. In this role, Mr. van Bijleveld leads efforts to expand Quintiles' commercial presence in these strategically important regions.

In the biopharma industry since 1982, Mr. van Bijleveld most recently was general manager and VP, Russian Federation, for Schering Plough, leading substantial growth for the commercial business in the market.

For more information, visit quintiles.com, or stop by Booth No. 1035.

Dr. Lisa Jenkins

ISI Appoints Regulatory Affairs Director

ISI has appointed Lisa Jenkins, Ph.D., to the position of director of regulatory strategy. Dr. Jenkins joins the company's professional services unit, a global team that includes former biopharmaceutical industry professionals experienced in guiding companies through each phase of development. She advises clients on all aspects of clinical development and global strategic regulatory affairs.

Before her position at ISI, Dr. Jenkins served as a principal statistician and senior manager of regulatory affairs at Wyeth.

Dr. Jenkins maintains a number of professional affiliations, including the Drug Information Association (DIA) and the Regulatory Affairs Professionals Society (RAPS), and she is an active member of DIA's Drug Information Journal Editorial Board.

For more information visit imagesolutions.com, or stop by Booth No. 326.

Harshad Sodha

Quanticate Names Head of Clinical Data Management Team

Quanticate has appointed Harshad Sodha to lead its clinical data management teams in Europe and the United States. Mr. Sodha is charged with expanding the company's data management team and streamlining best practice processes for Quanticate's strategic functional resourcing services.

Most recently, he served as VP of clinical data management operations for Omnicare Clinical Research.

For more information, visit quanticate.com, or stop by Booth No. 1503.

E-SOLUTIONS

The following briefs include information about new e-based clinically related solutions. The companies in this section are presented in alphabetical order.

CSC Releases Content Management Solution

CSC has released version 2.0 of FirstPoint document management and collaboration solution to help life-sciences organizations improve user productivity by automating and simplifying the document creation, review, and approval cycle.

FirstPoint leverages CSC's configurations based on a multitude of real-world implementations involving more than 100,000 users at pharmaceutical companies worldwide. FirstPoint 2.0 is compliant with the life-science industry's taxonomy standards, including: International Conference on Harmonization (ICH), Electronic Common Technical Document (eCTD), E3 Essential Clinical Documents, and the DIA EDM Reference Model.

The application uses the built-in functionality in SharePoint, adds those features necessary for highly regulated environments, and complies with the FDA's 21 CFR Part 11 requirements including audit trail, electronic signature, and enhanced security. The solution offers enhanced quality and manufacturing functionality such as change request and advanced forms capabilities, which combine data and documents into more meaningful business solutions. In addition, CSC provides streamlined system validation packages for rapid deployment.

"CSC is offering small to midsize life-sciences companies a rapid deployment version of FirstPoint with the enterprisewide functionality enjoyed by our large global pharmaceutical clients," says Nigel Whitehead, managing director of life sciences in CSC's Healthcare Group.

For more information, visit csc.com, or stop by Booth No. 2004.

ePharmaSolutions Updates Clinical Trial Portal

ePharmaSolutions has launched version 4.0 of its Clinical Trial Portal Solution with new functionality and additional workflow to support global enterprise.

The new version includes new functionality such as eMVR (electronic monitor visit report) to support the authoring, completion, and submission of online and offline monitor trip reports with electronic signature, an improved SFA (site feasibility application) with self-service access to more than 200,000 clinical investigators in 127 countries, and the PRM (patient recruitment manager) solution that integrates an IRB/EC material management application with an on-demand ordering/tracking feature for global studies. PRM also tracks the impact of recruitment tactics and provides a comparison of planned vs. actual enrollment metrics at the site, country, and study levels.

"We have also made significant progress integrating with some of the leading CTMS and IVRS vendors to implement single sign-on and ensure a two-way transfer of data can be completed with little, if any, data discrepancy errors between the systems," says Steven Beales, ePharmaSolutions' VP of information technology.

The Clinical Trial Portal (CTP) provides biopharmaceutical companies and CROs with a fully validated solution to help accelerate and improve study start-up and site management through a variety of site friendly components that include: site feasibility application (SFA), secure document exchange (SDE), safety letter distribution (SLD), electronic monitor visit reporting (eMVR), learning management system (LMS), and the patient recruitment manager (PRM).

For more information, visit epharmasolutions.com, or stop by Booth No. 1900.

Parexel Introduces Platform for Late-Phase Studies

Parexel International has introduced a new Web-based technology platform for late-phase clinical research to meet the expanding regulatory and commercialization needs of the biopharmaceutical industry.

The platform brings greater cost-effectiveness to conducting large-scale studies and facilitates highly efficient capture of global safety and health outcomes data in a real world setting.

The solution integrates the innovative strategies and proven processes of Parexel's PACE (Peri Approval Clinical Excellence) team with e-clinical solutions from Perceptive Informatics, Parexel's technology subsidiary.

This approach helps biopharmaceutical companies ensure higher data quality, accelerate better decision-making, and achieve faster determination of evidence-based health outcomes in late-phase clinical research.

"A variety of late-phase studies, including observational studies and patient registries, are being used as either primary or adjunct vehicles for pharmacovigilance and health evaluation activities to meet increasing regulatory and payer demands for long-term safety and health outcomes data," says Carol Collins, Ph.D., corporate VP and worldwide head of PACE.

The platform includes many features and benefits to bring greater efficiency to late-phase studies, such as: a streamlined user experience with single access; an intuitive interface with functionality for site self registration and management; automated cues for unique late-phase site requirements to enable improved compliance; and enhanced reporting capabilities including site-based features such as investigator payment status reports.

For more information, visit parexel.com, or stop by Booth No. 917.

WHAT'S NEW

The following briefs include company news about new clinically related operations. The companies in this section are presented in alphabetical order.

CenterWatch Acquired by Founder Ken Getz

Ken Getz, the founder of CenterWatch, along with private equity investors, has purchased the company from Jobson Medical Information. The acquisition was completed in April.

Mr. Getz founded CenterWatch in 1994 and established the company as a leading provider of operating and business information on the $40 billion global clinical trials industry. Getz sold the company to the Thomson Corp. in 1998. CenterWatch was subsequently sold to Jobson Medical Information in 2007.

"I am very excited to have CenterWatch back," Mr. Getz says. "The company is focusing on providing the best analytical, data-driven, and timely coverage possible and on offering unrivaled access and reach to key professional and patient communities that comprise the global clinical research enterprise."

In addition to being an investor in, and board member of several companies, Mr. Getz is the chairman of CISCRP, a nonprofit organization that he founded to educate and raise public awareness of the clinical research enterprise, and a senior research fellow at the Tufts Center for the Study of Drug Development where he studies R&D management and operating models, investigative site, outsourcing, and study volunteer trends, and policies.

For more information, visit centerwatch.com, or stop by Booth No. 1628.

CRF Health Awarded DIA's Greenest Exhibitor Award

CRF Health has won the Greenest Exhibitor Award at the Drug Information Association's 2010 EuroMeeting in Monaco. DIA Europe launched its greening project in 2009 in an effort to reduce the carbon footprint of its annual EuroMeeting. CRF Health also won DIA Europe's first award at the 2009 meeting in Berlin.

CRF Health's winning entry included both large and small measures.

The company offset its carbon emissions by funding renewable energy projects with Carbonfund.org. These projects promote energy efficiency and work for both reforestation and avoiding deforestation.

Visitors to CRF Health's paperless booth received dual-purpose "Seed the Future" cards. Redeeming the card means that a tree will be planted in a global reforestation project. Planting the card under a thin layer of soil brings wild flowers into the visitor's life. The company also gave gift cards to winners of a tablet-PC-based game that tested their awareness of environmental issues.

"Not only do our ePRO products capture data electronically, which eliminates the need for paper to document the data, but our employees continue to show their commitment to environmental responsibility," says CEO Rachael King.

For more information, visit crfhealth.com, or stop Booth No. 810.

Icon and TigerMed Sign Alliance Agreement in China

Icon and TigerMed Consulting, a leader in the provision of clinical drug development services in China, have signed an alliance agreement. Through this agreement, Icon and TigerMed are collaborating to offer pharmaceutical and biotechnology clients better access to Chinese patients, using the global reach and experience of the Icon's organization, complemented by TigerMed's in depth knowledge of the Chinese drug development landscape and geographic coverage in China. With headquarters in Shanghai, TigerMed currently operates from 21 offices in China and has more than 300 clinical development staff there.

"TigerMed's strength in China complements Icon's strong regional presence in Asia Pacific and makes them the ideal partner for Icon as we continue to drive the rapid and effective development of our client's global drug development portfolios," says Dr. John Hubbard, group president, global clinical research services at Icon.

For more information, visit iconplc.com, or stop by Booth No. 2011.

Health Decisions Forms Partnership in South Africa

Health Decisions has welcomed South Africa-based CRO ClinResearch to the Agile Clinical Network, a community of research partners formed to eliminate the information gaps and prolonged timelines inherent to complex global studies. As the latest Agile Network partner, ClinResearch joins a global infrastructure of free-standing yet integrated research modules, each of which is held to stringent standards of research quality and regulatory compliance, yet is individually empowered to affect operational efficiency and capitalize on region-specific cultural expertise.

According to Rick Farris, chief operations officer at Health Decisions, the company's alignment with ClinResearch enriches the Agile Network's geographic and cultural scope and present promising opportunities to cost-effectively engage diverse, unique patient populations.

For more information, visit healthdec.com, or stop by Booth No. 929.

Kendle Receives Certification in China

Kendle's affiliate in China, Beijing KendleWits Medical Consulting Company (KendleWits), has obtained ISO 9001:2008 certification from the International Organization for Standardization, validating the quality and consistency of its operations in this growing region.

Through KendleWits, Kendle is the first global CRO to achieve ISO 9001:2008 certification in China.

"As we continue to build our presence in emerging markets, we are keenly focused on quality," says Candace Kendle, Pharm.D., chairman and CEO. "This certification reinforces our ability to provide our customers with the highest-quality early- to late-stage clinical development services anywhere in the world."

ISO is a global organization that encourages companies and organizations to adopt standards and processes for developing, implementing, and improving effectiveness of quality management systems.

For more information, visit kendle.com, or stop by Booth No. 211.

PRA International Extends Operations Into New Zealand

PRA International has established a legal entity and hired staff in New Zealand, which will complement the firm's extensive network of Asia-Pacific operations and partnerships.

PRA can now monitor New Zealand study sites with in-country staff. This local presence, combined with PRA's continued expansion in the region, further enhances its position as a CRO gateway to the world's most rapidly expanding clinical research environment. New Zealand is a key research location for studies in skin cancer, multiple sclerosis, asthma and several other conditions.

PRA's New Zealand staff will work closely with employees in the PRA Sydney, Australia, office.

"We are very pleased with the expansion to New Zealand," says Edward Ian, PRA's senior director of operations for Asia-Pacific. "It continues our expansion in this critical region and is an ideal complement to our operations in Australia."

For more information, visit prainternational.com, or stop by Booth No. 901.

WHO'S WHO

The following briefs include personnel news, new appointments, and promotions in the clinical arena.

Gregg Jewett
Dr. Ingrid Klingmann

CRF Health Makes Appointments

Gregg Jewett has been appointed to the new position of senior director, strategic alliances and Partnerships for CRF Health. Mr. Jewett has more than 12 years of experience in the pharmaceutical and clinical research industries.

Before joining CRF Health, he was senior manager for global strategic sourcing with Merck (formerly Schering-Plough), where he led the Schering-Plough Research Institute clinical sourcing department.

Mr. Jewett is dedicated to developing strong, effective working relationships with CROs and other complementary clinical service providers.

In other news, Ingrid Klingmann, M.D., Ph.D., has joined CRF Health as consulting clinical advisor. Dr. Klingmann provides training to both internal staff and investigator sites. She also represents CRF Health in special interest groups and presents on ePRO trends at industry forums. Dr. Klingmann's experience includes work in pharmaceutical companies and global CROs.

Dr. Klingmann received her medical degree at the University of Heidelberg, Germany.

For more information, visit crfhealth.com, or stop Booth No. 810.

Barry Russell

Catalent Pharma Solutions Appoints Packaging Services President

Catalent Pharma Solutions has appointed Barry Russell as group president, commercial packaging. Mr. Russell is responsible for Catalent's Packaging Services segment, including leading more than 2,200 employees at nine pharmaceutical packaging and printing facilities in both North America and Europe. He most recently served as an operating VP for Ferro Corporation, where he had full responsibility for the global electronic materials systems business.

For more information, visit catalent.com, or stop by Booth No. 745.