



## Annual DIA Preview Showcase Feature

**PharmaVOICE** is pleased to once again publish this Special Feature showcasing the new products, services, tools, as well as analysis and trends from dozens of clinical-services companies that will be exhibiting at the DIA 44th Annual Conference in Boston, June 22-26, 2008. For your convenience, we have divided the briefs into sections, including Trends, E-Solutions, What's New, and People.

We would also like to extend special thanks to Jeffrey W. Sherman, M.D., FACP, DIA 44th Annual Meeting Program Chairperson, for providing an insider's view about what it takes to produce a successful DIA Annual meeting that meets the needs of attendees, exhibitors, and thought leaders.

We look forward to seeing you in Boston. Please stop by the **PharmaVOICE** Booth — No. 1200 — to learn about what's happening in the clinical-services arena.

Special thanks to Managing Editor, Denise Myshko, for compiling the information for this DIA Preview.

Regards,  
Taren Grom, Editor

## DRUG SAFETY ISSUES ARE TOP OF MIND

*Jeffrey W. Sherman, M.D., FACP, Chief Medical Officer and Senior VP, Research and Development, IDM Pharma Inc., is program chairman for the 44th Annual Meeting in Boston. He gives a sneak peek at the upcoming meeting.*

**R**epresenting more than 20,000 members worldwide involved in discovery, development, regulation, and marketing of bio/pharmaceutical and related products, the Drug Information Association (DIA) each year has the significant task of designing an annual meeting that is timely, topical, and transforming.

This year we received the largest ever number of abstracts for the annual meeting, indicative of the fact that attendees truly want to talk and hear about a wide range of topics.

We have a number of hot topics as identified by past annual meeting attendees. One is "The Impact of FDAAA on Drug Safety," which will be held on Tuesday, June 24, from 8:00 a.m. to 9:30 a.m. Safety is always going to be a hot topic, and with the FDA and EMEA both paying increased attention to the issue, it is especially so today. The Food and Drug Administration Amendments Act of 2007 (FDAAA) will have a global impact in this area.

In the plenary session, we expect to hear exactly what this impact might be. Speakers from U.S. and European regulatory agencies, the Reagan Udall Foundation, PhRMA, and other organizations will discuss their goals and experiences with implementation of the FDAAA and its impact on drug safety.

Attendees can submit questions to the panel by e-mail through Friday, June 20, to [fdaaaondrugsafety-panel@diahome.org](mailto:fdaaaondrugsafety-panel@diahome.org).

Other hot topics that will be addressed include: adaptive clinical design; the critical path initiative; patient recruitment; combination products; multinational clinical trials; biotechnology, especially gene therapy; orphan drugs; personalized medicine and its clinical and regulatory considerations; and pediatric trials.

The almost 40 tutorials offer the opportunity to

study an area in depth. The sessions are 90 minutes long but the tutorials can last as long as a day. They are for people at all stages in their careers, from beginners to experts, and they cover a huge variety of topics and provide basic grounding through advanced training.

### The Keynote Presentations

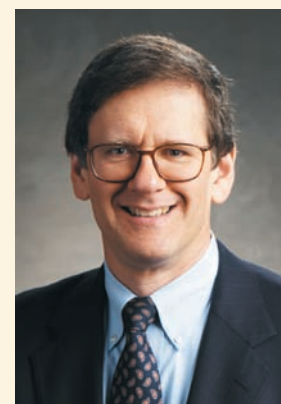
In drug development, there are four key groups that need to come together: regulators, industry (pharma, biotechs, and CROs), academia, and patients. Each group is integral to the drug-development process. Industry and regulators have always been well represented at the DIA Annual Meeting. In Boston, we are trying to bring all of these groups together.

The selection of the keynote presenters is a case in point. Dr. Dennis Ausiello is the Jackson professor of clinical medicine at Harvard Medical School and chief of medicine at Massachusetts General Hospital, one of the world's premier medical institutions. And Kathy Giusti is founder and CEO of the Multiple Myeloma Research Foundation (MMRF) and the Multiple Myeloma Research Consortium (MMRC) and is a graduate of Harvard Business School. And again, the links to Boston are very clear.

At DIA, we view the collaboration between all stakeholders in drug development as being very important. Indeed, Ms. Giusti is a great example of what can be done through such collaboration. Ms. Giusti was inspired by her personal situation — having been diagnosed with multiple myeloma — to draw on her pharmaceutical industry experience to foster links between research institutions and industry to speed the development of new treatments for myeloma.

### Making the Most of the Meeting

Scheduling your time around the more than 360 ses-



Jeffrey Sherman  
2008 44th DIA Annual Meeting  
Program Chairperson



sions offered at the annual meeting can be overwhelming. We've taken steps to help you maximize your time in Boston and advance your education about drug development and clinical research throughout the world.

The city of Boston has influenced much of this year's program. For example, Tutorial 36 on the "financing of pharmaceutical and biotech start-ups," on Sat., June 21, along with the venture capital roundtable: biotechnology and pharmaceutical/healthcare IT on Wed., June 25, will be of interest to many Boston-based companies.

Also, the FDA Center for Drug Evaluation and Review (CDER) will hold its Annual Town Hall, an interactive session where attendees can submit questions to senior CDER leaders, on Thurs., June 26.

**As always, global drug development is a key focus of this year's annual meeting. This year's event will include more than 100 sessions on issues affecting key regions of the world, including:**

- Western Europe – 27 sessions
- Japan – 23 sessions
- China – 18 sessions
- India – 12 sessions
- Latin America – 11 sessions
- Taiwan – 4 sessions
- Canada – 4 sessions
- Eastern Europe – 2 sessions
- Vietnam – 1 session

**In addition, speakers from the following regulatory agencies will present at the annual meeting:**

- ANMAT Ministry of Health (Argentina)
- ANMAT Ministry of Health (Brazil)
- Center for Drug Evaluation (Taiwan)
- EMEA (Europe)
- FDA MOPH (Thailand)
- Health Canada
- MHRA (UK)
- MHLW (Japan)
- Ministry of Health, Welfare and Sport (Netherlands)
- PMDA (Japan)
- SFDA (China)
- State Institute for Drug Control (Czech Republic)

- FDA (US)
- WHO (Switzerland)

A significant development to this year's annual meeting program is the formation of the Clinical Research and Information Technology "megatracks."

One of the things we have done this year is to try to minimize areas of overlap between tracks so that the program is more efficient. In creating megatracks, we have brought all relevant tracks together so that overlap is avoided. Megatracks also make it more efficient for attendees. For example, those in clinical research and IT can more easily identify the sessions that meet their requirements.

### Networking Events

Networking remains a hallmark of the DIA annual meeting, from the daily continental breakfasts and afternoon refreshment breaks

to the more formal networking receptions. This year we have expanded some of these opportunities to allow attendees to reap all of the benefits of a complete annual meeting experience.

- **Networking Reception at the Museum of Science** — June 22, 7:00 p.m. to 9:00 p.m.

This year, in addition to enjoying great food by Wolfgang Puck Catering and a host bar, DIA guests will have exclusive access to the Blue and Green Wings of the Boston Museum of Science.

- **Extended Luncheon Hours** — Tuesday, June 24, 11:30 a.m. to 2:00 p.m.

Back by popular demand, expanded luncheon hours on Tuesday will provide an additional networking opportunity and allow attendees to reap all of the benefits of a complete annual meeting experience.

For more information about the annual DIA meeting, visit [diahome.org](http://diahome.org).

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## E-SOLUTIONS

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

### Aris Introduces Planning Module for Regulatory Tracking

Aris Global has announced the availability of Register 5, an enhanced version of its Web-based tool for tracking all facets of global product registration and enabling compliance with regulatory requirements. The latest version of Register includes an integrated product planning component that automates the tracking of registrations against global and local project plans, helping life-sciences organizations meet the challenge of managing the numerous activities and resources associated with global regulatory submissions.

**The Register 5 planning module provides functionality that enables companies to:**

- Link project plans with registrations and updates.
- Automate definition and distribution of reporting of project plans.
- Create planning templates that are definable for each regulatory procedure type.
- Establish and re-use plan templates: define dependencies; assign owners, roles, resource types, and more; specify high-level and granular activities.
- Create and publish local plans for each country with the single click of a button.
- Intelligently update various activities within Register, based on defined business rules.
- Access productivity-related metrics.
- Run generic and productivity reports to track actual versus planned milestones and export project plans to other Microsoft applications.

"In the face of manual and error-prone processes that exhaust a company's planning and resource staff, management is discovering that it's nearly impossible to track the progress of regulatory submissions on a global and affiliate level," says Wim Cypers, VP, product management, Aris Global. "They are looking for proven mechanisms to better manage their limited resources to ensure they determine the correct priorities regarding registration submissions. With this newest release, Register improves visibility across the globe and enables faster, informed decision making at a lower cost."

**For more information, visit [arisglobal.com](http://arisglobal.com), or stop by Booth No. 834.**

### ClinPhone Updates Combined EDC-IVR Solution

ClinPhone has released the latest version of its electronic data capture (EDC) software, DataLabs by ClinPhone v4.2. Continuing to build on its hybrid technology incorporating EDC and paper data management in a single platform, DataLabs v4.2 now offers advancements in managing work flow at the item level, case report form (CRF) routing and messaging, event notifications, and improvements in its user-friendly interface and design.

In addition, DataLabs now enables sponsors and



The new features and enhancements are in direct response to customer and market requirements, says David Stein, VP of Product Management at ClinPhone.

CROs to take advantage of the industry's only EDC solution fully integrated with interactive voice and Web response (IVR/IWR) system, ClinPhone Randomization and Trial Supply Management.

DataLabs v4.2 incorporates a notification system, which allows study designers to schedule custom messages and alerts for important study events. The upgraded software also has an integrated internal messaging system, which enables secure

communication among study personnel.

Data verification and item-level work flow-management capabilities have improved significantly, which streamlines source data verification activity and saves time. Advanced capabilities include the ability to define whether status flags need to be collected at either the item or CRF level.

David Stein, VP of product management at ClinPhone comments, "The new features and enhancements are in direct response to customer and market requirements."

In other company news, ClinPhone and invivodata have formed a global partnership to provide electronic patient reported outcomes (ePRO) solutions.

As part of this collaboration, ClinPhone joins invivodata's PROPartner Program, which enables invivodata customers to leverage the strengths of its roster of affiliate technology and service companies whose offerings have been identified as best-in-class in their respective market areas.

**For more information, visit [clinphone.com](http://clinphone.com), or stop by Booth No. 217.**

**For more information, visit [invivodata.com](http://invivodata.com), or stop by Booth No. 600.**

### CRF Offers E-diary for Tablet PCs

CRF now provides TrialMax suite of ePRO software solutions for tablet PCs running the Microsoft Windows Vista operating system.

Tablet PC-based e-diaries provide investigators with the ability to obtain better data, by designing comprehensive patient questionnaires that take advantage of the tablet's larger display area and the stylus or touch screen flexibility for more natural information entry and navigation ease.

CRF's full TrialMax platform capabilities are intended for TrialMax Tablet PCs: the e-diary designer tool, TrialStudio, can be used to design Tablet PC-based solutions. TrialManager, CRF's Web-based trial reporting tool, provides constant real-time and controlled access to study data.

"We have seen how the portability and conve-

nience of our PDA and smartphone e-diaries increase compliance and provide sponsors and investigators with reliable, contemporaneous, high-quality data," says Pamela McNamara, CEO of CRF. "For particular patient populations, the added capabilities that a tablet PC provides can make a real difference in the compliance rate and therefore the success of the trial. For example, patients with tremors or visual impairment benefit from larger screen objects with which to interact."

**For more information, visit [crfhealth.com](http://crfhealth.com), or visit Booth No. 241.**

### DrugLogic Introduces Pharmacovigilance Solution

DrugLogic has unveiled SafeStart Hosting for its Qscan-ERM drug-safety management system, offering companies secure and fully configurable workflow management for individuals and departments that participate in drug safety surveillance across the entire enterprise.

Drug-safety workflow is an emerging need as drug companies set up standard operating procedures (SOPs) for pharmacovigilance, both the signaling of possible issues and the managing of these issues through resolution.

With Qscan-ERM in a hosted environment, customers have immediate access to a fully validated workflow system with roles management, workflow and task management, advanced statistical analysis, and reporting functions for AERS, WHO, and VAERS data in a full audit trail vendor-hosted environment.

"With several major installations over the past two years, we have seen the need to explore different workflow approaches," says Steve Wordham, DrugLogic's VP of client operations and chief technical officer. "Handling workflow and internal data transitions separately, without having to exercise SOPs on extensive internal report volumes, would greatly simplify implementations. Departments such as epidemiology, regulatory affairs, and drug safety can explore and even provide partial production capability without having to commit to an internal infrastructure upgrade."

**For more information, visit [druglogic.com](http://druglogic.com), or stop by Booth No. 141.**

### eCast Launches CT Select to Change Patient Selection for Clinical Trials

Developed by eCast, CT Select uses emerging data sources, including electronic medical records and practice management data, along with lab and medication data to select highly targeted candidates that match trial protocols.

The results equate to proven enrollment, saving



time and potentially millions of dollars during a product's life cycle.

These emerging data sources help populate the company's clinical data repository (CDR), which is a robust, content-rich source of HIPAA-compliant, de-identified patient data. It can be accessed for the rapid identification of specific research populations and their locations within the CT Select network of investigators. The CDR receives data from numerous sources resulting in a comprehensive collection of information that can be used to identify specific patient types as defined by the inclusion/exclusion criteria in a clinical protocol.

"We have access to HIPAA-secure CDR data," says Peter Bechtel, president and CEO of eCast. "We only use it for inclusion/exclusion criteria for our CRO and pharma customers. The data that come into the CDR come from the EMR. We supply the EMR as part of this system, so that we get the highest quality data possible."

When a clinical trial is placed with CT Select, the company's team identifies the most qualified research sites across multiple therapeutic areas from within its site network. With a site network representing hundreds of trained and credentialed research investigators throughout the United States and Europe, CT Select is able to rapidly target the most qualified research subjects for clinical trials directly from the patient population within each practice.

**For more information, visit [ecastcorp.com](http://ecastcorp.com), or stop by Booth No. 811.**

## eResearchTechnology and nSpire Health to Deliver Integrated Cardiac Safety Services

eResearchTechnology and nSpire Health have agreed to provide integrated cardiac safety and pulmonary core lab services to clinical researchers.

nSpire Health and eRT have a combined solution to meet the increased demand for cardio-pulmonary safety and efficacy services during clinical trials, in part caused by an increased interest in using inhaled therapeutics. The partnership offers integrated services from project planning and set up through study conduct, management, and data delivery for primary and secondary cardiac and respiratory clinical-trial endpoints.

nSpire Health is providing eSP Core Lab Data Management software, QA services, HDpft, KoKo, PiKo, and PiKoLogic (electronic diary) respiratory diagnostic measuring instruments. eRT is performing digital collection, measurement, interpretation, review, and distribution of cardiac safety data through its EXPeRT 2.0 workflow-enabled data management system.

"This alliance addresses a growing need in clinical research to offer comprehensive, best-in-class services in these two closely related areas of clinical study," says Michael McKelvey, president and CEO of eRT. "While many sponsors recognize and source each company for its respective area of expertise, customers increasingly seek consolidation and streamlining in all phases of a clinical trial."

**For more information, visit [ert.com](http://ert.com), or stop by Booth No. 800.**

**For more information, visit [nspirehealth.com](http://nspirehealth.com), or stop by Booth No. 1947.**

## Medidata Broadens Partner Program



We've expanded our program to enable our global network of business partners to choose the plan that best meets the needs of their customers and complement their unique capabilities, says Graham Bunn, VP of Global CRO Partnerships at Medidata.

Medidata Solutions is expanding its ASPIre to Win partner program for contract research organizations (CRO), consultancies, and other service providers. Medidata has broadened the program to offer various levels of training and support for a wide range of partner activity.

Medidata offers a flexible program to equip CROs and service providers with various Rave skills to help them optimize their services revenue around the technology. Medidata's ASPIre to Win Program is a nonexclusive enablement and accreditation program that supports selected CROs and other organizations, positioning them to create new services revenue around the implementation of Medidata Rave.

Medidata first announced the ASPIre to Win program in April 2005 to help CROs meet growing sponsor demand for Medidata Rave. Since then, ASPIre to Win has grown to include 11 partners, ranging from smaller clinical consultancies to large, global CROs.

"We value the contributions that CROs and other service organizations are making to the EDC growth trend and understand that each organization has a unique set of goals and requirements for EDC," says Graham Bunn, VP of global CRO partnerships at Medidata. "As a result, we've moved away from a one-size-fits-all approach and expanded our program to enable our global network of business partners to choose the plan that best meets the needs of their customers and complements their unique capabilities as well as grow their business with Medidata Rave."

**For more information, visit [mdsol.com](http://mdsol.com), or stop by Booth No. 1220.**

## OmniComm and Logos Partner for Phase I EDC

OmniComm Systems is partnering with Logos Technologies to create an integrated solution with Alphadas, an electronic data capture solution designed specifically for Phase I clinical trials. The combined technologies are available to customers using the TrialMaster, First in Functionality, EDC solution.

The collaboration allows customers that are conducting clinical research in Phase I to take advantage of a clinical study management and fully mobile electronic data capture system to capture data directly from the patient's bedside. For those clients running Phase I to Phase IV clinical studies, the combination



The interface between OmniComm and Logos Technologies offers a dynamic EDC solution for customers that are focused on Phase I clinical trials, says Stephen Johnson, Chief Operating Officer for OmniComm.

unifies the capture, reporting, exporting, and archival of clinical data into a common, cost-effective, Web-based user-interface. The final warehouse for data may reside in SQL, Oracle Clinical database tables, or in SAS.

"The interface between Logos Technologies and OmniComm offers a dynamic EDC solution for customers that are focused on Phase I clinical trials and delivers an excellent addition to our suite of targeted, integrated solutions," says Stephen Johnson, chief operating officer for OmniComm. "The integration

of OmniComm's TrialMaster and Logos Technologies' Alphadas extends the capabilities for data collected from Alphadas to be combined with clinical data imported from other outside sources. These combined data may then be exported, archived, and made available in various reports and reporting formats."

**For more information, visit [omnicomm.com](http://omnicomm.com), or stop by Booth No. 1014.**

**For more information, visit [logostechnologies.com](http://logostechnologies.com), or stop by Booth No. 1647.**

## Oracle Provides Closed-Loop Marketing Solution



Today's competitive environment is forcing life-sciences organizations to transform their commercial models and redefine sales and marketing processes to maximize the value of every interaction with customers, says Rajan Krishnan, VP, Product Strategy, Oracle Life Sciences.

Oracle is now offering Oracle's Siebel Personalized Content Delivery, a comprehensive closed-loop marketing (CLM) solution that helps life-sciences organizations plan, develop, and execute more effective customer communication strategies that deliver increased value for customers.

Siebel Personalized Content Delivery offers a powerful solution for closing the loop at multiple levels using a customer-centric approach that helps gather unique, actionable insight. The application makes it easier for sales representatives to deliver high-impact presentations that are tailored to individual customer

needs by leveraging multimedia visualization content provided by marketing teams.

Siebel Personalized Content Delivery leverages Siebel Life Sciences CRM capabilities such as workflow, business rules, and real-time decision technology while offering superior marketing measurement through cross-enterprise analytics.

Siebel Personalized Content Delivery combines CRM and closed-loop marketing capabilities into a single product. This reduces the need for duplicate infrastructure, costly integration, and ongoing maintenance of custom code. ▶



"Today's competitive environment is forcing life-sciences organizations to transform their commercial models and redefine sales and marketing processes to maximize the value of every interaction with customers," says Rajan Krishnan, VP, product strategy, Oracle Life Sciences. "Siebel Personalized Content Delivery offers companies a complete closed-loop marketing solution to dramatically improve the quality of customer interactions and help grow revenue and market share."

**For more information, visit [oracle.com](http://oracle.com), or stop by Booth No. 230.**

## Perceptive Informatics Improves Clinical Site Monitoring



We expect that clinical monitors will benefit from increased flexibility, productivity, and efficiency with the option to easily and securely capture site visit information from anywhere in the world at any time, says Todd Joron, Corporate VP and General Manager of Perceptive Informatics.

Perceptive Informatics now provides its clinical site management and monitoring software, Impact MySites, on a portable USB drive. Clinical monitors can now securely upload site visit information onto the USB drive, without carrying their laptop computers with them.

The MySites monitoring solution is a part of the Impact suite, Perceptive Informatics' clinical trial management system (CTMS).

The Impact MySites module supports online and off-line monitoring activities and the collection of associated data during site visits by clinical monitors in the field. As the entire MySites

module is housed on the USB drive, information collected by clinical monitors is securely stored and later synchronized with the Impact database.

Perceptive's software interfaces with interactive voice and Web-response systems, as well as electronic data capture (EDC) and data management applications, in addition to financial reporting.

"We expect that clinical monitors will benefit from increased flexibility, productivity, and efficiency with the option to easily and securely capture site visit information from anywhere in the world at any time, using the new portable functionality of the Impact MySites USB drive," says Todd Joron, corporate VP and general manager of Perceptive Informatics. "This capability represents an important step toward a truly mobile e-clinical environment."

**For more information, visit [perceptive.com](http://perceptive.com), or stop by Booth No. 903.**

## Phase Forward Delivers Enhanced InForm Solution

Phase Forward has introduced a new Japanese version of its electronic data capture (EDC) solution, InForm J Integrated Trial Management (ITM).

The new Japanese version offers comprehensive, real-time trial management reporting and analysis

capabilities embedded directly into the product, providing clinical organizations with the ability to help enhance the execution and management of clinical trials, as well as improve and accelerate clinical decision making.

Since 2003, Phase Forward's InForm J solution has been used by life-sciences companies of all sizes to help efficiently collect, manage, and clean clinical data and has been leveraged in more than 110 trials in Japan.

New product features include:

- **Comprehensive Reporting and Analysis Capabilities.** With its intuitive drag-and-drop interface, InForm J provides a robust and flexible set of out-of-the-box reporting and analysis tools. The InForm J solution also has powerful ad hoc reporting tools, enabling end-users to create and publish reports easily without the need for extensive report customization or IT assistance, unlike competitive offerings that require additional software, strong technical expertise, or custom report development from the EDC solution vendor.

- **Productivity Enhancements Across All Clinical Roles.** For monitors, remote access to detailed and up-to-the-minute site status allows for better visit planning to minimize travel and maximize effectiveness while on site. A monitor can run reports on data entry, query rates and response times, form completion, and signature status, as well as plan for an upcoming site visit.

With InForm J ITM, project managers are able to gain a real-time view of critical clinical events, such as adverse events or protocol violations, and can proactively monitor patient recruitment to identify slow enrollment or high dropout levels or track and trigger payment milestones.

"Our customers require innovative, sophisticated clinical data capture and management tools to support today's increasingly complex trials and the benefits afforded by improved clinical-trial productivity and efficiencies," says Steve Powell, senior VP, worldwide sales, at Phase Forward. "InForm J meets that requirement by offering real-time visibility into data and the ability to more effectively analyze the data, process reports, and ultimately take appropriate action."

**For more information, visit [phaseforward.com](http://phaseforward.com), or stop by Booth No.422.**

## PHT Launches SitePad Tablet

"PHT Corp. has launched its SitePad Tablet, which is designed to change the quality of site-based ePRO data capture worldwide. The large-screen mobile device uses the Samsung Q1 Ultra Mobile PC and resides at the investigative site. It is not sent home with the subjects participating in clinical studies.

The SitePad Tablet eliminates those inefficiencies by offering an easy-to-use device with a large 7-inch diagonal touch screen.

"The screen is about half the size of a piece of paper, so it is easy to see and large enough to accommodate complex questionnaires," says Phil Lee, president and CEO of PHT.

Subjects who are using the SitePad Tablet for the



The industry still overwhelmingly uses paper to collect patient reported outcomes, typically citing the cost of providing each subject with his or her own ePRO device as a reason for sticking with paper, says Phil Lee, President and CEO of PHT.

**No. 1309 and 1409.**

## PPD Enhances its Portfolio of EDC Services



Ease of use is critical when incorporating EDC technology into clinical trials, says Susan Atkinson, Senior VP, Biostatistics and Data Management, PPD.

first time can practice on a sample questionnaire, which includes multiple-choice questions and questions with visual analogue scales.

Data collected by the SitePad Tablet are transmitted to a hosted central server in real time using an integrated Ethernet port, without relying on wireless networks. The information on each patient then becomes available to the site through a Web portal.

**For more information, visit [phtcorp.com](http://phtcorp.com), or stop by Booth**

PPD has integrated Oracle's newest electronic data capture (EDC) solution into its suite of clinical trial management applications, providing clients and investigators easier, faster navigation to collect and report real-time data for large-scale, global clinical trials.

Oracle Remote Data Capture Onsite 4.5.3, the latest version of Oracle Remote Data Capture (RDC), is one of two full-service EDC technologies that PPD

offers clients. PPD GlobalView, the company's proprietary EDC technology, is available for global registries and postapproval studies.

An entirely Web-based system, RDC Onsite 4.5.3 requires no software download or installation. With a zero footprint, HTML data entry window, the application can be accessed globally with only an Internet connection and includes a 128-bit encryption to ensure data security.

This version features case report forms that are easy-to-navigate, search, and sort, as well as a robust system of edit checks to ensure data accuracy. Furthermore, PPD has integrated its interactive voice response system with the RDC platform. Investigators can now enroll and/or randomize patients while transmitting enrollment data into the Oracle Clinical RDC system, all during the same phone call.

"Ease of use is critical when incorporating EDC technology into clinical trials," says Susan Atkinson, senior VP, biostatistics and data management. "Designed for use by investigators and clinical research associates, Oracle Remote Data Capture Onsite 4.5.3 offers a simple interface with cleaner, faster data entry, enabling our clients to complete clinical trials faster and accelerate time to market of new therapies."

**For more information, visit [ppdi.com](http://ppdi.com), or stop by Booth No. 814 and No. 1447.**



## Take Solutions Expands Submissions Assurance Program

The life-sciences division of Take Solutions is expanding its Submission Consulting Services unit to include North America, Europe, Asia/Pacific, and Australia. The newly redesigned services unit is in response to market demand for its high-value submissions consulting services to provide direction and assistance in compiling error-free submissions.

Take Solutions' submissions assurance programs now offer two uniquely targeted submission assurance delivery models. One submissions assurance offering is available to Take Solutions' customers that license Take Solutions' PharmaReady eCTD software solution. A separate submissions assurance delivery model is available to customers that want to fully outsource this service without the requirement of licensing any software.

"The FDA mandate for regulated life-sciences organizations to submit INDs and NDAs electronically is requiring these fast-moving organizations to seek assistance from trusted partners," says Robert MacDougall, executive VP, sales and marketing. "Now adding to this, EMEA requirements for electronic submissions beginning in 2009 have created even greater demand for submission assurance services."

**For more information, visit [takesolutions.com](http://takesolutions.com), or stop by Booth No. 406.**

## Thomson Introduces Solutions for the Generics Market

The scientific business of Thomson Reuters has introduced two new products, Newport Horizon Premium and Newport Vision Premium, both of which are intended to give customers a competitive advantage in the global generics marketplace.

The Newport products are designed to enable professionals working in product selection, business development, competitive intelligence, and active pharmaceutical ingredient (API) sourcing to find the most appropriate product development opportunities more quickly, and to allow innovators to conduct deeper analysis on emerging generic competition.

Newport Horizon Premium focuses on helping generic, over-the-counter (OTC), and API companies build deals faster and accelerate time to market.

Newport Vision Premium assists branded pharmaceutical companies to evaluate the earliest signs of generic competition and identify backup or alternative sources of API supply.

"We recognize that there is a need for authoritative generics market information to give pharmaceutical companies a clear competitive advantage over their competitors," says Claude Basset, VP, Pharma-Chem specialty markets, at Thomson. "We developed Newport Horizon Premium and Newport Vision Premium to help customers improve productivity, accelerate

time to market, and gain that competitive edge in the generics marketplace."

Newport Horizon Premium and Newport Vision Premium combine sales, launch, patent, patent challenge, exclusivity, chemistry, prescribing, and regulatory information for more than 10,000 molecules, 18,000 companies, 67 markets, and 90 patent countries worldwide with early API development and manufacturing intelligence.

In other company news, Vertical\*i and Thomson, the scientific business of Thomson Reuters, have announced the availability of the Vertical\*i-Thomson Webservice, an interface between Vertical\*i's Application Suite and Thomson Pharma.

The Vertical\*i Thomson Webservice combines the drug pipeline information of Thomson Pharma and the business process optimization capabilities of the Vertical\*i Application Suite. The combination provides pharmaceutical companies with an end-to-end solution for streamlining their business development operations.

The Vertical\*i Thomson Webservice consists of technology components from each company, and provides a connection that allows Vertical\*i users to initiate a search for drugs in the Thomson Pharma pipeline of information from within the Vertical\*i application, and then directly import the data into a business development opportunity.

**For more information, visit [thomson.com](http://thomson.com), or stop by Booth No. 438.**

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- Covidien
- GlaxoSmithKline
- Medtronic, Inc
- Pfizer
- St. Jude Medical
- Zimmer

PLUS! CHOOSE FROM TWO PRE-CONFERENCE WORKSHOPS —  
TUESDAY, JULY 15, 2008

- A. **Align Compliance Practices with International Codes of Conduct**
- B. **Prepare for International Investigations and Respond to Inquiries**

### GOVERNMENT ENFORCEMENT PANEL:

#### "Enforcement Trends within the Jurisdiction of the FCPA"

*Moderator:* Michael B. Schwartz, Principal, KPMG Forensic, **KPMG LLP**

*Panelists:* Kathleen M. Hamann, Trial Attorney (FCPA), Fraud Section, Criminal Division, **U.S. Department of Justice**  
David Rauser, Special Agent, **Federal Bureau of Investigation**  
Cheryl J. Scarboro, Associate Director, Division of Enforcement, **U.S. Securities and Exchange Commission**

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## WHAT'S NEW

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

### Abt Associates Clinical Trials Changes Name



We are leveraging the increased flexibility that our new organization affords to invest in staff and resources to meet the expanding needs of our global client base without sacrificing any of the scientific rigor or timeliness that we are known for, says Steven Fosburg, Executive VP and Managing Director of Abt Bio-Pharma Solutions.

Abt Associates Clinical Trials has changed its name to Abt Bio-Pharma Solutions (ABS), a wholly owned subsidiary of Abt Associates Inc. The company continues to provide customized strategic research and communications solutions for the pharmaceutical, biotechnology, medical-device, and diagnostics industries using a team approach that blends decades of experience with wide-ranging technical and therapeutic area expertise.

ABS offers a wide range of integrated services across the product life cycle, including health economics and outcomes research, registries, and other real-world studies, clinical trials, biometrics, and marketing consulting and research.

"ABS helps sponsors achieve success for their products in a very competitive marketplace," says Steven Fosburg, executive VP and managing director of ABS. "We are leveraging the increased flexibility that our new organization affords to invest in staff and resources to meet the expanding needs of our global client base without sacrificing any of the scientific rigor or timeliness that we are known for."

**For more information, visit [abtbiopharma.com](http://abtbiopharma.com), or stop by Booth No. 1557.**

### Bio-Imaging Technologies Acquires Phoenix Data Systems

Bio-Imaging Technologies has acquired privately held Phoenix Data Systems, a global clinical data services provider of electronic data capture (EDC) services.

The acquisition is a cash and stock transaction valued at \$24 million, payable at closing, consisting of \$7 million of cash and 2,287,582 shares of Bio-Imaging stock, valued at \$17 million.

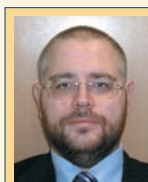
Together Bio-Imaging and Phoenix Data Systems can offer a broader set of clinical-trial services to their pharmaceutical and biotechnology customers.

Phoenix Data Systems is growing rapidly and generated \$12 million in revenue and an operating profit in 2007. The acquisition is expected to be accretive to Bio-Imaging's fully diluted earnings per share for fiscal 2008. Phoenix Data Systems will retain its name and continue to be managed by Dr. William Claypool, its current president.

**For more information, visit [bioimaging.com](http://bioimaging.com), or stop by Booth No. 1444.**

**For more information, visit [phoenixdatasystems.net](http://phoenixdatasystems.net), or stop by Booth No. 948.**

### Chiltern Opens a New Office in Russia



Dr. Alexey Kornilov has been appointed General Manager of Chiltern's Russian operations.

Chiltern has opened a new office in St. Petersburg, Russia, following the recent appointment of Alexey V. Kornilov, M.D., as general manager of its Russian operations.

This office is expected to grow rapidly under the leadership of Dr. Kornilov and is primarily focused on supporting the company's global clinical development brand.

Over the last few years, Chiltern has conducted many trials in Russia to fulfill sponsors' demands in the region and to take advantage of highly qualified investigator sites generating high-quality data.

"The opening of our St. Petersburg office is a logical next step in Chiltern's continued growth in Central and Eastern Europe," says Armand Czaplinski, M.D., MBA, Chiltern general manager, CEE. "Today, with an ever higher number of competing trials, the pharmaceutical industry increasingly recognizes the potential of CEE countries to meet enrollment goals. The availability of trained staff and the quality of the data produced have resulted in an increased number of FDA and EMEA approved clinical trials."

**For more information, visit [chiltern.com](http://chiltern.com), or stop by Booth No. 724.**

### Clinsys Launches New Division

Clinsys Clinical Research has launched Clinsys Alterna, a new division that uses its Global Project Solution (Clinsys GPS) to augment clinical resource services. The new division demonstrates Clinsys' commitment to aligning its service offerings with its sponsors' and the life-sciences industry's continuously evolving staffing needs.

Clinsys Alterna provides customized Phase I to Phase IV clinical trial alternative solutions to the conventional outsourcing model. The division is a core element of Clinsys GPS, an integrated project management solution that brings the sponsor and the Clinsys project teams together to collaborate and agree on all aspects of the clinical study to ensure the project's success.

"Clinsys Alterna provides a targeted and flexible clinical resourcing model that adapts to best serve a sponsor's trial management needs," says David

Williams, CEO of Clinsys. "We devoted the time and energy required to approach the evolution of resourcing in an innovative way that both maximizes efficiencies and decreases deliverable timelines."

Clinsys Alterna delivers a custom-designed, time-sensitive clinical solution that enables sponsors to engage its services in site management, clinical monitoring, project management, drug safety, regulatory, and medical writing on a contract basis.

In other news, Clinsys has introduced its therapeutically aligned program strategists (TPS), a concept for the evaluation and execution of clinical trials. The TPS teams are comprised of highly skilled and experienced professionals with defined therapeutic expertise who evaluate, create, and execute all sponsor projects, from clinical development plans and clinical-trial design through protocol finalization, leading to successful trial conduct.

Each TPS team consists of M.D.s, Ph.D.s, and a clinical operations program director with expertise in a specific therapeutic area. These strategists apply a research-oriented approach to clinical-trial strategy, design, and execution to either deliver a comprehensive clinical development plan or protocol, or review and critique client synopses and protocols. The TPS team also provides analysis of the competitive environment, the current standards of care, and market potential. TPS services extend to design and implementation of generic and bioavailability/bioequivalence (BA/BE) trials.

**For more information, visit [clinsys.com](http://clinsys.com), or stop by Booth No. 1041.**

### DSG Establishes Subsidiary in India

DSG has opened a wholly owned subsidiary, India Document Solutions Private Ltd., located in Noida, Uttar Pradesh, India, a suburb of New Delhi. The subsidiary employs software engineers focused on research and development and quality control for DSG's software. DSG has conducted business in India for the past three years with several partner companies in the life-sciences industry.

DSG has developed proven processes and procedures to ensure that workflows are seamless across offices in the United States and India.

The subsidiary employs 30 people and plans to add another 30 people by year-end. DSG continues to operate and staff its 24/7 help desk out of its U.S. offices.

"Our subsidiary in India enables us to better meet the needs of our global customers by providing innovative product solutions more cost effectively," says Tony Varano, president and CEO of DSG. "With around-the-clock product development, we are able to reduce the time required to bring new products to market. Having conducted business in India over the past three years,



we realized the tremendous amount of talent this region has to offer. The opening of our India office is a natural progression of our planned business expansion and international growth.”

DSG continues to investigate more global expansion opportunities and is currently developing plans to open an office in Japan later this year.

**For more information, visit [dsg-us.com](http://dsg-us.com), or stop by Booth No. 400.**

## Global Research Services Expands in China



With the world's increasing interest in China, vaccines, and drug development in general, we find our services in these emerging markets to be both extremely timely and relevant, says Jillian Lin, General Manager of Global Research Services.

Global Research Services (GRS) has launched a wholly owned subsidiary in China, Global Medical Consulting Services (Shanghai) Co. Ltd. (GMCS), and has expanded its capabilities to offer full-service clinical trial management.

The company has increased its services to offer full management to both Western and Asian pharmaceutical, biotech, and medical-device companies intending to conduct clinical trials in China. Services include protocol and case report form development, site selection, site monitoring, safety monitoring, project management, data management, and biostatistics.

“Our purpose is to offer both Western and Asian clients the ability to perform their clinical trials in China,” says Jillian Lin, general manager, GMCS. “We also intend to extend our clinical vaccine development services into the Asian market. With the world's increasing interest in China, vaccines, and drug development in general, we find our services in these emerging markets to be both extremely timely and relevant.”

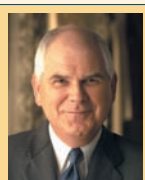
**For more information, visit [grs-cro.com](http://grs-cro.com), or stop by Booth No. 462.**

## i3 Offers Late-Phase Research Services

i3 Innovus has launched comprehensive and customized late-phase research services, offering customers increased efficiency and access to data and expertise in positioning their products for commercial success.

i3's late-phase service offering integrates and expands on the group's postlaunch real-world research competencies and includes: registry studies (product, disease and safety); postmarketing safety studies; Phase IV interventional trials; prospective, observational, and naturalistic studies; health economic outcomes research, including burden of illness, patient reported outcomes, and health economic piggyback trials; as well as expanded access programs.

“Efficient execution of late-phase research requires a multifaceted capability: demographic data



Efficient execution of late-phase research requires a multifaceted capability: demographic data mining, scientific study design and analysis, therapeutic expertise, epidemiology and pharmacovigilance, risk management, and global regulatory affairs expertise, as well as deep knowledge of real-world research, says Glenn Bilawsky, CEO of i3.

mining, scientific study design and analysis, therapeutic expertise, epidemiology and pharmacovigilance, risk management, and global regulatory affairs expertise, as well as deep knowledge of real-world research,” says Glenn Bilawsky, CEO of i3. “i3's late-phase research encompasses all of these areas with an intricate specialization that drives a competitive advantage for our customers. Our data assets can assess protocol design and feasibility, as well as optimize patient and physician recruitment.”

The late-phase research group is led by Cynthia Verst, Pharm.D., MS, as senior VP. Dr. Verst offers experience designing and conducting late-phase programs for maximum operational efficiency, cost-effectiveness, speed, and reliability.

In other company news, i3 has acquired the Russian clinical research organization (CRO) Lege Artis, strengthening its business in the global clinical trials market. The addition of Lege Artis and its capabilities in Belarus and Ukraine provide i3 Research customers with enhanced access to experienced investigators in Russia and the neighboring states of the former Soviet Union.

With headquarters in Moscow, Lege Artis is being integrated into i3 Research, which is led by i3 Research President Nigel Page. Its founder and CEO, Tatjana Zwereva, M.D., Ph.D., leads the new Russian company.

“Russia has become a strategic geographic area in the drug-development process, with well-educated and experienced medical doctors and a vast population of patients who are interested in participating in clinical trials,” Mr. Bilawsky says.

**For more information, visit [i3global.com](http://i3global.com), or stop by Booth No. 434.**

## inVentiv Clinical Expands to Latin American Region



Having established full off-shore operations in India, the expansion of our clinical operations into Latin America is an important next step to become a global clinical services provider, says Mike Hlinak, President and CEO of inVentiv Clinical.

inVentiv Clinical Solutions, a division of inVentiv Health, has established operations in Latin America, a growing region for drug development. The new location is based in Sao Paulo, Brazil; the company has plans to expand operations to other Latin American countries.

inVentiv Clinical's Latin American operation is led by Ana Paula Ruenis, Ph.D., recently appointed director of clinical operations, Latin America.

“Having already established

full off-shore operations in India, the expansion of our clinical operations into Latin America is an important next step in our goal to become a global clinical services provider,” says Mike Hlinak, president and CEO of inVentiv Clinical.

**For more information, visit [inventivhealth.com](http://inventivhealth.com), or stop by Booth No. 917.**

## Lifetree Clinical Offer Bioanalytical Services



By adding bioanalytical services, we're ensuring seamless sample transfer and rapid turnaround of critical data to our clients at a competitive rate, says Lifetree Clinical Research CEO Alice Jackson.

Lifetree Clinical Research has added bioanalytical services to its portfolio of services. Lifetree Bioanalytical is a full-service, good laboratory practice (GLP)-compliant bioanalytical facility that supports Lifetree Clinical Research and its clients during every phase of drug development.

“By adding bioanalytical services, we're ensuring seamless sample transfer and rapid turnaround of critical data to our clients at a competitive rate,” says Lifetree Clinical Research CEO Alice Jackson. “Lifetree

Clinical Research continues to broaden our scope of turn-key solutions for our clients' clinical development needs from protocol writing through final clinical study report with PK analysis and results integration.”

**For more information, visit [lifetreereseach.com](http://lifetreereseach.com), or stop by Booth No. 1547.**

## Parexel Expands Global Clinical Capabilities



Biopharmaceutical companies have been conducting more Phase I and proof-of-concept studies with increasing complexity, and Parexel has been well-positioned to meet their needs, says Dr. Herman Scholtz, Head of International Clinical Pharmacology, Parexel.

Parexel has completed the expansion of three clinical pharmacology research units located in Baltimore, Md.; London; and Berlin, Germany, to meet growing client demand for expertise-based studies in the early phases of clinical development.

“Continued expansion of local capabilities combined with an integrated global clinical pharmacology presence has been a cornerstone of Parexel's leadership in early clinical development,” says Herman Scholtz, M.D., head of international clinical pharmacology, Parexel. “As biopharmaceutical companies have been conducting more Phase I and proof-of-concept studies with increasing complexity, Parexel has been well-positioned to meet their needs.”

In Baltimore, Parexel's clinical pharmacology research unit has been expanding capabilities and capacity for client programs since 2001, when the unit opened. ▶





With its most recent expansion, the unit now has 90 beds, representing the largest such facility in the region.

The unit has deep specialization in many clinical areas such as vaccine and immunology, pulmonary, and oncology studies.

The Parexel clinical pharmacology research unit in London, established more than 15 years ago, has been expanded to a 64-bed capacity.

The unit has experience with all types of Phase I studies, including pharmacokinetic and pharmacodynamic studies, and has the ability to conduct PET studies, as well.

Parexel has two long-established clinical pharmacology research units in Berlin. With the recent expansion, the units now have 160 total beds. The two sites have dedicated medical teams that use identical equipment and systems to assure harmonized procedures and workflow.

**For more information, visit [parexel.com](http://parexel.com), or stop by Booth No. 803.**

### PharmaNet Subsidiary Enters Into Consortium

PharmaNet Development Group's Anapharm subsidiary has entered into a consortium with BCF Certification Inc., a member of the BCF LLP group, to provide turn-key services to life-sciences ventures.

The combined organizations are targeting the medical-device and nutraceutical industries to assist clients in commercializing their products in global markets.

Through this combined entity, BCF Certification assists Canadian and international companies in meeting regulatory, quality, and clinical requirements.

In turn, Anapharm complements the offering by providing clinical development consulting, clinical-trial, and laboratory services.

Through realizing synergies, the consortium presents a one-stop-shop for full-service trial processes, including due diligence, risk exposure management, and assessment. The consortium is continuing to work to add new partner companies and expand its service offerings to other life-sciences ventures.

**For more information, visit [pharmanet.com](http://pharmanet.com), or stop by Booth No. 1020.**

### PRA Opens New Office in India

To accommodate rapid growth and further enhance its ability to deliver clinical services, PRA International has moved its Mumbai, India, office to a larger, more centrally located facility.

The new Mumbai office expands upon the services PRA is able to offer its clients in India, the surrounding regions, and around the globe.

With an anticipated staff of up to 50 clinical team members by the end of 2008, PRA India can potentially increase its service capacity by 150% in comparison with September 2007.

**For more information, visit [prainternational.com](http://prainternational.com), or stop by Booth No. 830.**

### Premier Research and Octagon Research Agree to Partner

Premier Research Group and Octagon Research Solutions have agreed to a partnership to provide a broader solution set. This new partnership combines Octagon's expertise in electronic submissions with Premier Research's clinical expertise across a wide array of therapeutic areas. The partnership enables Premier Research to offer Octagon's electronic submission capabilities as part of its regulatory affairs services and for Octagon to offer Premier's regulatory development and scientific strategy.

James Ottinger, VP of global consulting and compliance for Premier Research says, "Our partnership with Octagon broadens our services by offering Octagon's proven expertise in the technical aspects of electronic submissions while we continue to focus on our core strengths of regulatory strategy and consulting."

**For more information, visit [premier-research.com](http://premier-research.com), or stop by Booth No. 1617.**

**For more information, visit [premier-research.com](http://premier-research.com), or stop by Booth No. 1617.**

### Quintiles Provides Central Services in Japan



Recent changes in legislation are allowing Japanese pharmaceutical companies to extend clinical trials normally conducted in Japan to other countries in Asia, but these companies have had difficulty finding central lab services that are harmonized throughout the region, says Tom Wollman, Senior VP of Quintiles Global Central Laboratories.

Quintiles Transnational has established an agreement with Medca Japan to provide central laboratory services, further extending the Quintiles global network of laboratories certified by the College of American Pathologists (CAP).

Quintiles is fielding its own staff at the CAP-certified Medca Japan laboratory in Saitama, a city in the greater Tokyo area. The lab supports clinical trials in Japan.

"Recent changes in legislation are allowing Japanese pharmaceutical companies to extend clinical trials normally conducted in Japan to other countries in Asia, but these companies have had difficulty finding central lab services that are harmonized

throughout the region," says Tom Wollman, senior VP, Quintiles Global Central Laboratories. "With CAP-certified labs in Beijing, Singapore, Mumbai, and now Japan, we can provide well-controlled processes and harmonized testing services throughout the Asia-Pacific region to customers in Japan as well as our multinational customers. This lab, along with all labs in our network, follows the same standard operating procedures, and data are available on our QNET database."

In other news, Quintiles has expanded its Quintiles Consulting business, which provides pharmaceutical, biotech, and medical-device companies with strategic guidance to maximize potential and minimize risk from early discovery through commercialization.

Quintiles Consulting is expanding its current services and building a global consulting organization to provide strategic, operational, and technical advice to pharmaceutical, biotechnology, and medical-device companies. The organization is focusing on market leading issues and addresses client needs in three practice areas: product development and commercialization, regulatory and quality, and market access.

Additionally, Quintiles has agreed to acquire Eidetics, a privately held decision-analytics and market research consulting firm located in Boston as part of its consulting business.

The acquisition of Eidetics strengthens Quintiles' core consulting offerings in the areas of product development, commercialization, and market access.

**For more information, visit [quintiles.com](http://quintiles.com), or stop by Booth No. 1406 and 1606.**

### Thomson Expands Web of Science



As the global distribution of Web of Science expands into virtually every region on Earth, the importance of regional scholarship to our emerging regional user community also grows, says Jim Testa, Senior Director, Editorial Development and Publisher Relations, at Thomson.

The scientific business of Thomson Reuters has added 162 regional social science journals to Web of Science. The newly identified collection contains journals that typically target a regional rather than international audience by approaching subjects from a local perspective or focusing on particular topics of regional interest.

For more than two years, Thomson has reviewed thousands of regional journals in all areas of science, social science, and arts and humanities. Although selection criteria for a regional journal are fundamentally the same as for an international journal, the importance of the regional journal is measured in terms of the specificity of its content rather than in its citation impact. The recently added regional social science journals include 49 titles from the Asia-Pacific region and 91 from the European Union.

"As the global distribution of Web of Science expands into virtually every region on Earth, the importance of regional scholarship to our emerging regional user community also grows," says Jim Testa, senior director, editorial development and publisher relations at Thomson. "We hope to be instrumental in expanding the audience for these journals and bringing attention to their scholarship."

Throughout 2008, Thomson is expected to expand the current collection of journals to include a more diverse coverage of regional literature. All journals added to the Web of Science go through a rigorous selection process. Regional journals, specifically, must be publishing on time, have English-language bibliographic information (title, abstract, keywords), and cited references must be in the Roman alphabet.

**For more information, visit [thomson.com](http://thomson.com), or stop by Booth No. 438.**



## United BioSource Acquires Publication Planning Company



Envision combines strategically driven scientific and technology solutions for life-sciences clients, says Ethan Leder, CEO of United BioSource.

United BioSource (UBC) has acquired Envision Pharma, a scientific communications and technology company based in Horsham, U.K.

With a focus on the pharmaceutical and biotechnology industry, Envision integrates scientific communication services and targeted software applications that contribute to marketplace awareness and comprehension of compounds at launch and beyond.

The acquisition of Envision Pharma expands UBC's global presence and capability in the development and delivery of scientific communication.

Envision Pharma has two market-leading applications. Datavision is a pharmaceutical industry application for developing and managing transparent, compliant publications programs.

Used by more than 30 companies with almost 400 products, Datavision provides a platform for strategic planning and workflow management, while ensuring compliance and precision in the publications process. Visiontracker, launched in 2007, offers management of

independent investigator trials, supporting the process from application through to study completion for both the investigator and sponsor.

"Envision combines strategically driven scientific and technology solutions for life-sciences clients," says Ethan Leder, CEO of UBC. "Given the increasing demand of regulators and public opinion for transparency in research, Envision's contribution to the production of objective, scientifically driven medical publications is a cornerstone of our company's evidence-based credo and highly valuable to the entire medical community."

**For more information, visit [unitedbiosource.com](http://unitedbiosource.com), or stop by Booth No. 1230.**

## Wolters Kluwer Health and Johns Hopkins Launch The Patient

The Johns Hopkins Bloomberg School of Public Health and Wolters Kluwer Health, a division of Wolters Kluwer, is publishing a new journal, "The Patient: Patient-Centered Outcomes Research," an international forum devoted to publishing research on patient-centered medicine.

The first academic journal in medicine to present solely the patient's perspective, The Patient addresses the growing concern that modern medicine has failed to adequately satisfy the needs of its most important stakeholder, the patient.



We expect "The Patient: Patient-Centered Outcomes Research" will quickly become the torchbearer for patient-centric medicine, says Bryce McMurray, Product Director, Adis Journals, Wolters Kluwer Health.

In an era of managed care and cost-containment, current trends in medicine are being driven primarily by the needs and wants of healthcare payers.

"We're pleased to add The Patient to our longstanding family of Adis journals," says Bryce McMurray, product director, Adis Journals, Wolters Kluwer Health. "We expect the journal will quickly become the torchbearer for patient-centric medicine and open a new window to all of the current, original research on the subject. In turn, we expect that it will spur further

study."

The inaugural issue includes contributions from world-renowned researchers investigating patient attitudes and preferences for healthcare, including topics such as health insurance; screening for disease; residential care; and the impact of ethnicity and gender on medication adherence.

Published four times per year, The Patient is available globally by subscription in both print and electronic form.

**For more information, visit [wkhealth.com](http://wkhealth.com), or stop by Booth No. 717.**

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## WHO'S WHO

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

### Dr. Malek Bajbouj Dr. Larry Ereshefsky Jacque Fisher Dr. Imogene Grimes

#### Parexel Makes VP Appointments

Parexel has appointed Malek Bajbouj, M.D., and Larry Ereshefsky, Pharm.D., F.C.C.P., B.C.C.P., as VPs of clinical pharmacology consulting services in the company's international clinical pharmacology business. These leading experts advise clients on early-phase clinical development in the central nervous system (CNS) therapeutic area, including psychiatry, neuropsychopharmacology, and neurophysiology clinical studies.

Dr. Ereshefsky is based at Parexel's Clinical Pharmacology Research Unit in Los Angeles, and Dr. Bajbouj is based at the unit in Berlin, Germany.

Dr. Bajbouj is board certified in psychiatry and clinical neurophysiology. He has expertise in CNS biomarkers and the development of new physiological procedures, including neurophysiological and neuroimaging measures used in cognitive function research. Dr. Bajbouj is a professor at the Charite University in Berlin, Germany.



Dr. Ereshefsky is board certified in psychiatric pharmacy and has more than 28 years of experience in the neuropsychopharmacology and psychiatry fields.

His expertise includes all phases of clinical research and psychopharmacological evaluations of medications for the treatment of a broad range of CNS and psychiatry disorders.

Dr. Ereshefsky has served on the U.S. Food and Drug Administration (FDA) and United States Pharmacopeia (USP) advisory boards. Before joining Parexel, Dr. Ereshefsky was chief scientific officer at California Clinical Trials. He currently serves on the executive committee of The International Society for CNS Clinical Trials and Methodology.

In addition, Parexel has appointed Jacque Fisher as a VP and general manager in the company's medical communications services business. In this position, Ms. Fisher leads a global team of experts who assist clients in translating complex scientific information into integrated communications. She also has responsibility for overall client management and advising biopharmaceutical companies on the effectiveness of their medical communications programs.

Ms. Fisher brings more than 20 years of experience in biopharmaceutical industry marketing to Parexel. Before joining the company, Ms. Fisher was president of Gardiner-Caldwell U.S., a former business unit of Thomson Healthcare.

Ms. Fisher holds a bachelor's degree from University College London.

Parexel has also appointed Imogene Grimes, Ph.D., to VP of data sciences strategic services. Dr. Grimes, a leading biostatistician with more than 25 years of experience, is contributing to the continued expansion of Parexel's data science services, including data management, biostatistics, and applications of information technology to the clinical development process.

Her responsibilities include advising clients on clinical study design, analysis methodology, and related regulatory guidelines. Dr. Grimes provides support for strategic data services, such as preparation of integrated data files suitable for registration packages and preparation of electronic submissions, compliant with regulatory expectations.

Before joining Parexel, Dr. Grimes served as VP, statistics, data management and informatics, at Regeneron Pharmaceuticals, where she provided statistical and data management expertise for all phases of drug-development research.

Dr. Grimes holds a Ph.D. in biostatistics from the University of North Carolina at Chapel Hill and master's and bachelor's degrees from the University of North Carolina at Greensboro.

**For more information, visit [parexel.com](http://parexel.com), or stop by Booth No. 803.**

### Dr. Alamelu Chandrasekaran Dr. Tom McCloskey

#### Icon Adds New Positions

Icon has appointed Alamelu Chandrasekaran, Ph.D., to the position of manager of molecular diagnostics at Icon Central Laboratories. The company also has appointed Dr. Tom McCloskey associate director, cellular immunology, research and development. These two newly created roles are expected to enhance the scientific consultation services that Icon Central Laboratories provides to its global customers.

Dr. Chandrasekaran obtained her master of science degree in biochemistry from University of Madras, India, and Ph.D. in immunology from MGR Medical University, Chennai, India.

She was a postdoctoral fellow at the department of pediatric immunology at North Shore-LIJ Research Institute in New York and then worked as a research associate and research scientist at North Shore-LIJ Research Core facility and Genomics Center, where she managed QPCR and microarray facilities.

Before joining Icon, Dr. McCloskey served as director of flow cytometry for the department of pediatrics at North Shore University Hospital, and most recently he was scientist-in-charge for the flow cytometry core facility.

He brings more than 20 years of experience to assay development using flow cytometry and has written more than 40 manuscripts related to flow cytometry.

He is a member of the New York/New Jersey Flow

Cytometry Society and the International Society for Analytical Cytology.

In 1998, Dr. McCloskey won the Presidential Award of Excellence, presented to the top young investigator in flow cytometry worldwide.

**For more information, visit [iconplc.com](http://iconplc.com), or stop by Booth No. 606.**

### Dr. Oren Cohen

#### Quintiles Makes Promotion

Quintiles Transnational has appointed Oren Cohen, M.D., as senior VP, clinical research strategies. Most recently, Dr. Cohen held the position of chief medical and scientific officer.

In this new role, Dr. Cohen is responsible for evaluating and implementing new clinical research strategies. He also continues to serve as managing director of Quintiles Public Health and Government Services.

Dr. Cohen is also a consulting professor of Medicine at Duke University School of Medicine. He earned a medical degree from Duke University and completed his residency at New York Hospital/Cornell University Medical Center and his fellowship in infectious diseases at the National Institutes of Health.

He is board certified in internal medicine and infectious diseases and has written more than 50 scientific articles and book chapters.

**For more information, visit [quintiles.com](http://quintiles.com), or stop by Booth No. 1406 and 1606.**

### Ben Daniel

#### MedPoint Names Business Development Director



MedPoint Communications has appointed Ben Daniel as director of business development. Mr. Daniel is responsible for growing business relationships with the company's major clients in the Northeast.

Before joining MedPoint, Mr. Daniel served in various business development roles in clinical research over the last six years. He has experience in both U.S. and global markets to provide best practices to clinical study teams to improve site performance in support of clinical trials.

Mr. Daniel holds a bachelor of business administration in marketing from Middle Tennessee State University. He is based in New York City.

**For more information, visit [medpt.com](http://medpt.com), for stop by Booth No. 1456.**

### Dr. Joan Drucker

#### Radiant Announces New Chief Medical Officer

Radiant Development has appointed Joan Drucker, M.D., chief medical officer. Dr. Drucker provides medical consultation, regulatory, and pharmacovigilance



expertise, as well as oversight for clinical studies managed by Radiant Development.

Dr. Drucker possesses clinical, management, and investigative experience in the area of infectious diseases, HIV, immunology, women's health, dermatology, and general internal medicine. With almost 30 years of experience, she has served as a medical director to several corporations.

Before joining Radiant Development, Dr. Drucker was a post-doctoral fellow in infectious diseases at Duke University and completed her residency in internal medicine at Faulkner Hospital, Tufts University.

She received her bachelor of arts from Harvard University and completed medical school at the University of Virginia School of Medicine.

**For more information, visit [radiantdevelopment.com](http://radiantdevelopment.com), or stop by Booth No. 214.**

**Dr. Chris Gregory  
Dr. Linda Patricia Miller  
Dr. Nermina Nakas  
Dr. John Oh  
Dr. Daniel Wood**

**Clinsys Realigns Management as Part of TPS Concept**

Clinsys Clinical Research has announced a number of additions and changes to its management team as part of its new Therapeutically-aligned Program Strategists (TPS) concept for the evaluation and execution of clinical trials.

Each Clinsys TPS team consists of M.D.s, Ph.D.s, and a clinical operations program director with expertise in a specific therapeutic area. These strategists apply a research-oriented approach to clinical-trial strategy, design, and execution to either deliver a comprehensive clinical development plan or protocol, or review and critique client synopses and protocols. The TPS team also provides analysis of the competitive environment, the current standards of care, and market potential.

Chris Gregory, Ph.D., has been named senior director, clinical development, responsible for supporting the TPS teams.

Dr. Gregory contributes more than 15 years of biotechnology/pharmaceutical and academic experience, with special emphasis on Alzheimer's disease, Parkinson's disease, and multiple sclerosis.

Dr. Gregory earned a B.S. in biology at Concord College and a Ph.D. in anatomy from Ohio State University.

To facilitate the development, growth, and success of the TPS teams, Clinsys has promoted Linda Patricia Miller, M.D., to VP, clinical development, and chief scientific officer.

Dr. Miller is in charge of selecting appropriate team members and providing strategic medical and scientific guidance throughout all phases of project planning and execution to ensure cohesive, consistent delivery of TPS services. Dr. Miller graduated from Rutgers Medical School with an M.D.

Nermina Nakas, M.D., MPH, also supports the TPS teams as director, clinical development.

Dr. Nakas applies more than 22 years of clinical, academic, and industry research experience in multiple therapeutic areas, with specific emphasis on respiratory disease, dermatology, and pediatrics.

Dr. Nakas received her medical degree from the Medical School University of Sarajevo in Bosnia.

John Oh, M.D., MBA, has joined Clinsys as director, clinical development. He is responsible for developing the TPS pain, stroke, traumatic brain injury, and spinal cord injury programs.

Dr. Oh most recently served as director, medical affairs, for an unspecified global CRO.

He received an M.D. from Temple University and an MBA from Duke University.

Daniel Wood, Ph.D., has joined Dr. Gregory and Dr. Nakas in clinical development as senior clinical research scientist.

Dr. Wood develops and prepares clinical trial synopses and protocols for designated therapeutic areas.

**For more information, visit [clinsys.com](http://clinsys.com), or stop by Booth No. 1041.**

**Stephen Johnson**

**OmniComm Appoints Chief Operating Officer**

OmniComm Systems has promoted Stephen Johnson to chief operating officer. Mr. Johnson most recently held the position of executive VP of business development and professional services. In this new role, he



is responsible for sales, marketing, professional services, and clinical services and support.

Mr. Johnson joined the company in September 2006 as senior VP of business development and has been promoted to roles of increasing responsibility over the last 18 months.

Before joining OmniComm, he was responsible for business development for the Oracle Clinical Applications' east coast division.

**For more information, visit [omnicomm.com](http://omnicomm.com), or stop by Booth No. 1014.**

**Michael Kaufmann**

**Cardinal Health Names Head of Pharmaceutical Segment**



Cardinal Health, a global provider of products and services that improve the safety and productivity of healthcare, today announced the appointment of company veteran Michael Kaufmann as group president of its healthcare supply chain services pharmaceutical segment.

In this role, Mr. Kaufmann, 45, is responsible for Cardinal Health's largest business, which provides ▶

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logistics services to pharmaceutical manufacturers, distributes about one-third of all medicine prescribed in the United States to hospitals, pharmacies, and other providers of care.

Mr. Kaufmann was most recently responsible for the turnaround of Cardinal Health's medical supply chain business and has spent the majority of his 17-year career with the company in senior operational, sales, and finance roles within the pharmaceutical business.

He replaces Scott A. Storrer. Mr. Kaufmann continues to report to George Barrett, 52, vice chairman of Cardinal Health and CEO of the company's Healthcare Supply Chain Services sector.

Mr. Kaufmann graduated from Ohio Northern University with a degree in accounting and management. **For more information, visit [cardinalhealth.com](http://cardinalhealth.com), or visit Booth No. 1430.**

## James Miskel Teresa Winslow

MDS Pharma Services Names  
Senior Executives

MDS Pharma Services has appointed James Miskel as VP of strategy and corporate development and Teresa Winslow as senior VP of global business development.



Mr. Miskel focuses on strategic partnerships, and Ms. Winslow is directing global business development efforts.

Mr. Miskel joins MDS from Wyeth Pharmaceuticals, where he was assistant VP for business planning and strategy. He spent much of his career with McKinsey. He holds an MBA from the Wharton School and an M.A. in international studies from the Lauder Institute, both of the University of Pennsylvania. He originally trained as an aeronautical engineer, earning M.S. and B.S. degrees from the Massachusetts Institute of Technology.



Ms. Winslow was previously president of Dendrite Americas and senior VP of Dendrite International. A pharmacist by training, she earned a B.S. in pharmacy from the University of the Sciences in Philadelphia.

**For more information, visit [mdsps.com](http://mdsps.com), or stop by Booth No. 838.**

## Dr. Lawrence Reiter

Criterion Appoints Director, Global Affairs



Criterion has appointed Lawrence Reiter, Ph.D., to the position of director, global affairs. Dr. Reiter was managing director of the company's South African office, which he opened for Criterion in 2003. At that time, it was Criterion's

first regional office that had been established outside the United States.

Among his many new duties in this newly created position, Dr. Reiter is responsible for coordinating the company's international clinical projects, and he is charged with codifying and standardizing Criterion's business processes outside the United States.

In other company news, the official registration process has been completed for the establishment of Criterion's ninth regional office, to be located in Toronto, Ontario. The official opening of this office will be in the fall of 2008.

**For more information, visit [criteriuminc.com](http://criteriuminc.com), or visit Booth No. 1201.**

## John Rogers

Octagon Research Makes New Hire



Octagon Research Solutions has appointed John Rogers director, process solutions, responsible for leading the company's process consulting team and supporting the development, execution, and delivery of consulting services across

global engagements.

Mr. Rogers came to Octagon from Stelex, where he served as director, regulatory services, and director, enterprise and strategic operations solutions.

**For more information, visit [octagonresearch.com](http://octagonresearch.com), or stop by Booth No. 630.**

## Laurie Streling

Clinical Resource Network Names  
Chief Financial Officer

Clinical Resource Network, a provider of in-home and alternate-site nursing services to facilitate the convenience, compliance, and retention of clinical study patients, has hired Laurie Streling as chief financial officer.

Ms. Streling is working collaboratively with the CEO and executive team to develop a vision and a long-term strategy for the organization while maintaining responsibility for all fiscal and financial management aspects of CRN's operations. She also is offering leadership and coordination in the administrative, human resources, legal, and risk management efforts of the company.

Ms. Streling joined CRN from Hewitt Associates, where she was CFO of global business services.

She received her B.A. in accounting from Eastern Michigan University and her CPA license from the State of Michigan.

**For more information, visit [clinicalresource.net](http://clinicalresource.net), or stop by Booth No. 2017.**

## Alison Taber

Copernicus Group Appoints Chief Operating Officer

Copernicus Group IRB (CGIRB) has appointed Alison Taber chief operating officer. Ms. Taber joins CGIRB from INC Research where she was executive director, global pharmacovigilance/drug safety and IVRS.

Reporting directly to CGIRB's Founder and CEO, Sharon Hill Price, Ms. Taber provides leadership and direction in scaling operations, growth, and the company's priority of protecting the rights and welfare of human subjects participating in clinical-research trials.

Ms. Taber has 15 years of experience in the clinical industry.

Ms. Taber, who received her degree in nursing from St. Albans City Hospital in Hertfordshire, United Kingdom, holds a Higher National Diploma (HDip) in Applied Biology, and a Diploma in Health and Disease.

**For more information, visit [cgirb.com](http://cgirb.com), or stop by Booth No. 854.**

## Dr. Mike Wilkerson

PPD Appoints Executive VP



PPD has appointed Mike Wilkerson, Ph.D., as executive VP of global clinical development. In this role, he will provide strategic leadership to the company's Phase II to Phase IV operations in North America; Latin America; Europe, Middle East and

Africa; and Asia Pacific.

Dr. Wilkinson most recently served as global head of internal medicine and VP of project management for another contract research organization.

He earned a doctorate in physiological optics from Indiana University, a master's degree from Penn State University, and a bachelor's from Ohio University.

**For more information, visit [ppdi.com](http://ppdi.com), or stop by Booth No. 814 and 1447.**

## Dr. Richard Williams

INC Research Appoints VP



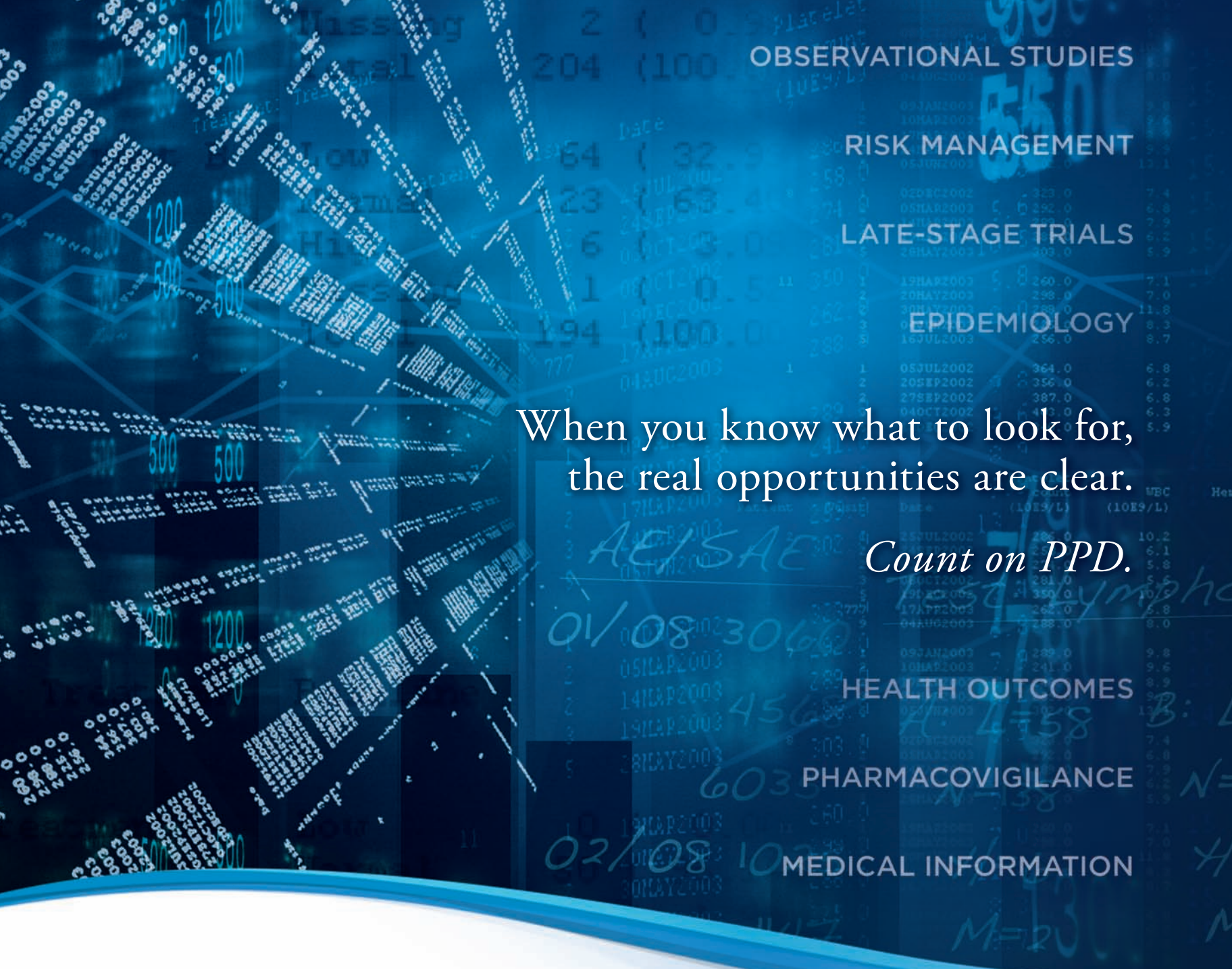
INC Research has appointed Richard Williams, Ph.D., as VP. In this position, Dr. Williams provides leadership for the strategic regulatory consulting group, as well as managing all global regulatory submissions. Before joining INC

Research, he held senior management positions in clinical research and regulatory affairs for large pharmaceutical companies, including Merck and Pfizer, as well as smaller successful start-up companies.

Dr. Williams earned his M.Sc. in pharmaceutical science from the University of Wales and a Ph.D. in pharmacology from the University of London, and he also earned his J.D. from La Salle University. While completing his doctorate in the United Kingdom, he conducted basic research at the Wellcome Research Laboratories where he was involved in drug discovery research.

After a faculty appointment at the University of Colorado Health Sciences Center in Denver, he became involved in product development in the biopharmaceutical industry.

**For more information, visit [incresearch.com](http://incresearch.com), or stop by Booth No. 1609.**



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## PharmaVOICE Webcast Network – Podcasts, Videocasts, and Weblinx Interactive Webseminars

The following is a list of archived Podcasts, Videocasts, and Weblinx Interactive Webseminars and Videocasts related to the clinical research and services arenas that PharmaVOICE and industry thought leaders have conducted throughout the year. To access any of PharmaVOICE's archived episodes, please visit [pharmavoice.com](http://pharmavoice.com).



### Late-Phase Research Success: Leveraging Secondary Data



**Thought Leader: Cyndi Verst, Pharm.D., M.S., Senior VP, Global Late Phase, i3 Innovus**

Dr. Verst covers the benefits of blending scientific and commercial objectives in late-phase research — saving time and money — the use of specialized data assets, the challenges of leveraging secondary data assets, and what is in store for late-phase research in the near future.

**For more information, visit [i3global.com](http://i3global.com), or stop by Booth No. 434.**



### The Brave New Real World: A Changing Paradigm for Documenting Product Value and Safety Postapproval



**Thought Leader: Jeff Trotter, Senior VP, Lifecycle Sciences Group, Icon Clinical Research**

Jeff Trotter speaks about the need for real-world value and safety in postmarketing research, the current landscape, designing new studies, and how the industry can leverage opportunities in the postapproval environment.

**For more information, visit [iconplc.com](http://iconplc.com), or stop by Booth No. 606.**



### ePRO's Impact on Clinical Trials



**Thought Leader: Jean Paty, Ph.D., Founder and Senior VP, Scientific, Quality and Regulatory Affairs, invivodata**

Dr. Paty talks about a defining moment in clinical trial data, how ePRO will revolutionize clinical trials, improving the adoption of ePRO, and the future of clinical data technology.

**For more information, visit [invivodata.com](http://invivodata.com), or stop by Booth No. 600.**



### Incorporating Electronic Health Records in the Trial Process

**Thought Leader: James Rogers, CEO, Nextrials**



Mr. Rogers discusses the benefits of incorporating electronic health records (EHR) into the clinical-trial process, what the challenges are, and how EHR can be used in other areas, such as patient

recruitment.

**For more information, visit [nextrials.com](http://nextrials.com), or stop by Booth No. 1817.**



### Phase IV Registries and Patient Outcomes



**Thought Leader: Nancy Dreyer, MPH, Ph.D., Chief of Scientific Affairs, Outcome**

Dr. Dreyer discusses her involvement in the development of the Registries for Evaluating Patient Outcomes handbook published by the Agency for Healthcare Research and Quality and what some of the significant findings were from the research and how these data can positively impact patient outcomes.

**For more information, visit [outcome.com](http://outcome.com), or stop by Booth No. 1314.**



### Training Seminar: Medical Education for Pharmaceutical Professionals: Information, May 6, 2008



**Thought Leader: Dr. Paul M. Krueger, Associate Dean for Academic Affairs, at the UMDNJ School of Osteopathic Medicine in New Jersey**

Dr. Krueger provides an overview of a day-long seminar focused on the diagnosis and treatment of medical disorders: Fundamentals of Clinical Practice. This is the first in a series of instructional forums called Medical Education for Pharmaceutical Professionals, also known as MEPP. The first seminar was held May 6, 2008, in New Jersey.

**For more information, visit [som.umdnj.edu/mepp](http://som.umdnj.edu/mepp), or stop by Booth No. 236.**



### Transform While You Perform: The Next Generation of Clinical Operations



**Thought Leaders: Nagaraja Srivatsan, Head of Life Sciences, North America, Cognizant, Kaushik**

**Bhaumik, Global Practice Leader, Consulting and BPO, Cognizant**

Mr. Srivatsan and Mr. Bhaumik discuss the strategies needed to transform the drug development process, the impact of such a shift on a sponsor's organizational structure, and how transformation differs from operational optimization.

They also outline best practices that companies should follow to begin the transformation process.

**For more information, visit [cognizant.com](http://cognizant.com), or visit Booth No. 1714.**



### The Clinical Data Liaison: The Key to Better, Faster Clinical Trials



**Thought Leader: John Hudak, President and Founder, Criterium**

Mr. Hudak talks about the need for a paradigm shift in work flow to improve the clinical-trial process and how the evolving role of a centralized clinical-trial liaison, or CTL, is integral to streamlining data management. Mr. Hudak also discusses how through real-time feedback, the CTL can reduce the number of field monitoring visits required, a major cost in managing clinical studies, and improve overall site efficiency.

**For more information, visit [criteriuminc.com](http://criteriuminc.com), or stop by Booth No. 1201.**



### Making Pharmacovigilance Work: Key Steps for Implementing a Proactive, Business-Critical Safety Model



**Thought Leaders: Uwe Maennl, M.D., Ph.D., VP and Worldwide Head of Pharmacovigilance, and Gadi Saarony, Corporate VP and Worldwide Head, of Parexel Consulting**



Dr. Maennl and Mr. Saarony discuss the paradigm shift in drug safety, which has led to new models based on pharmacovigilance. They also discuss how and why the quality of continuous re-assessment of the benefit/risk balance of medicines has become one of the most critical determinants of portfolio and business success.

**For more information, visit [parexel.com](http://parexel.com), or stop by Booth No. 803.**



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### Planning for Electronic Patient Recorded Outcomes: A Guide to Global Clinical Trials Success

**Thought Leaders:** Mark Wade, Global Practice Leader, Life Sciences, Lionbridge, and Hannah O'Gorman, Operations ePRO Specialist, ClinPhone



Mr. Wade and Ms. O'Gorman discuss the FDA's draft guidance for patient reported outcomes (PRO) and the EMEA's reflection paper on the use of health-related quality of life measures and how the advantages of using electronic tools for patient data collection are growing. As a result, the use of electronic patient

reported outcomes (ePROs) is becoming more widespread as a vital component of global clinical trials in the biopharmaceutical industry. To plan and launch a global clinical trial using ePRO, one of the critical components for success is to make sure language barriers do not become an obstacle. **For more information, visit [lionbridge.com](http://lionbridge.com), or visit Booth No. 1538.**

## FEATURED DIA EXHIBITING COMPANIES AT A GLANCE

**Abt Bio-Pharma Solutions Inc.**, Cambridge, Mass., is a wholly owned subsidiary of Abt Associates Inc. that specializes in demonstrating the value, safety, and efficacy of health technologies through prospective studies such as registries and clinical trials as well as through analyses of retrospective data. For more information, visit [abtbioharma.com](http://abtbioharma.com).

**Aris Global LLC**, Stamford, Conn., is a global provider of software solutions and consultancy services to assist life-sciences organizations. For more information, visit [arisglobal.com](http://arisglobal.com).

**Cardinal Health Inc.**, Dublin, Ohio, is a global manufacturer and distributor of medical and surgical supplies and technologies dedicated to making healthcare safer and more productive. For more information, visit [cardinalhealth.com](http://cardinalhealth.com).

**Chiltern International Inc.**, Carlsbad, Calif., is a global contract research organization with experience in conducting and staffing global Phase I to Phase V trials. For more information, visit [chiltern.com](http://chiltern.com).

**ClinPhone**, East Windsor, N.J., is a clinical technology organization providing innovative and proven solutions for global clinical trials. For more information, visit [clinphone.com](http://clinphone.com).

**Clinsys Clinical Research Inc.**, Bedminster, N.J., provides pharmaceutical, biotechnology, and medical-device companies a broad range of clinical research services in support of Phase I-IV drug development. For more information, visit [clinsys.com](http://clinsys.com).

**Copernicus Group IRB**, Research Triangle Park, N.C., is an independent institutional review board dedicated to protecting the rights and welfare of research study participants. For more information, visit [cgirb.com](http://cgirb.com).

**CRF Inc.**, Waltham, Mass., is a leading global provider of electronic patient reported outcomes (ePRO) and wireless data collection solutions for the life-sciences industry. For more information, visit [crfhealth.com](http://crfhealth.com).

**CRI Worldwide Inc.**, Clementon, N.J., is a leading provider of Phase I to Phase IV clinical development testing and research services for central nervous system (CNS), psychiatric, pain, and other drug compounds. For more information, visit [criww.com](http://criww.com).

**Criterion Inc.**, Saratoga Springs, N.Y., is a full-service, global CRO that offers a mix of high-quality clinical-

research services, real-time data acquisition, and personalized communication processes to manage a clinical trial from initial planning to approval, on time and on budget. For more information, visit [criterioninc.com](http://criterioninc.com).

**DrugLogic Inc.**, Reston, Va., specializes in developing analytical tools and enterprise process support systems for managing risks related to drug safety issues. For more information, visit [druglogic.com](http://druglogic.com).

**DSG Inc.**, Malvern, Pa., supports clinical-trial data collection with technology solutions, including EDC, electronic patient diaries, and digital on-demand CRF publishing management software. For more information, visit [dsg-us.com](http://dsg-us.com).

**eCast Corp.**, Raleigh, NC., a clinical research company, offers clinical integration and automation tools for physicians. For more information, visit [ecastcorp.com](http://ecastcorp.com).

**eResearchTechnology Inc.**, Philadelphia, is a provider of technology-based products and services that enable the pharmaceutical, biotechnological, medical-device, and contract resource companies to collect, interpret, and distribute cardiac safety and clinical data more efficiently. For more information, visit [ert.com](http://ert.com).

**Global Research Services LLC (GRS)**, Rockville, Md., is a full-service clinical-trials management organization with offices and/or presence on the ground across six continents. For more information, visit [grs-cro.com](http://grs-cro.com).

**i3 Innovov**, Basking Ridge, N.J., an Ingenix company, provides a scientific view of the marketplace and has expertise in health economics, outcomes, and late-phase research. For more information, visit [i3innovov.com](http://i3innovov.com).

**Icon Plc.**, North Wales, Pa., is a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit [iconplc.com](http://iconplc.com).

**INC Research Inc.**, Raleigh, N.C., is a therapeutically focused contract research organization. For more information, visit [incresearch.com](http://incresearch.com).

**inVentiv Clinical Solutions**, Houston, a division of inVentiv Health, provides clinical staffing, clinical operations, biostatistics, and data management solutions. For more information, visit [inventivclinical.com](http://inventivclinical.com).

**invivodata Inc.**, Pittsburgh, combines behavioral science, information technology, and clinical expertise to capture clinical-trial data of the highest integrity directly from patients. For more information, visit [invivodata.com](http://invivodata.com).

**Lifetree Clinical Research**, Salt Lake City, is a specialized research organization. For more information, visit [lifetreereseach.com](http://lifetreereseach.com).

**Logos Technologies**, London, is a provider of integrated clinical-trial solutions to the world's pharmaceutical, biotechnology, and clinical-research organizations. For more information, visit [logostechnologies.com](http://logostechnologies.com).

**MDS Pharma Services**, King of Prussia, Pa., offers a full spectrum of resources to meet the drug discovery and development needs of the pharmaceutical and biotechnology industries. For more information, visit [mdsps.com](http://mdsps.com).

**Medidata Solutions**, New York, delivers technology to safely accelerate the process of bringing life-saving treatments to market. For more information, visit [mdsol.com](http://mdsol.com).

**MedPoint Communications Inc.**, Evanston, Ill., provides communications and e-media services to the worldwide pharmaceutical and biotech industries. For more information, visit [medpt.com](http://medpt.com).

**nSpire Health Inc.**, Longmont, Colo., develops and manufactures respiratory-care products and provides related services. For more information, visit [nspirehealth.com](http://nspirehealth.com).

**Octagon Research Solutions Inc.**, Wayne, Pa., offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry. For more information, visit [octagonresearch.com](http://octagonresearch.com).

**OmniComm Systems Inc.**, Ft. Lauderdale, Fla., provides customer-driven Internet solutions to pharmaceutical, biotechnology, research, and medical-device organizations that conduct life-changing clinical-trial research. For more information, visit [omnicomm.com](http://omnicomm.com).

**Oracle Corp.**, Redwood Shores, Calif., is an enterprise software company. For more information, visit [oracle.com](http://oracle.com).

**Parexel International Corp.**, Waltham, Mass., provides a broad range of knowledge-based contract research, medical communications, and consulting services to the worldwide pharmaceutical, biotechnology, and medical-device industries. For more information, visit [parexel.com](http://parexel.com).

**Perceptive Informatics Inc.**, Waltham, Mass., is a division of Parexel International that offers medical ▶



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**Phase Forward Inc.**, Waltham, Mass., is a provider of integrated data management solutions for clinical trials and drug safety. For more information, visit [phaseforward.com](http://phaseforward.com).

**Phoenix Data Systems**, King of Prussia, Pa., is a global clinical data services provider of electronic data capture (EDC) services. For more information, visit [phoenixdatasystems.net](http://phoenixdatasystems.net).

**PPD Inc.**, Wilmington, N.C., is a leading global contract research organization providing discovery, development, and postapproval services, as well as compound partnering programs. For more information, visit [ppdi.com](http://ppdi.com).

**PRA International**, Raleigh, N.C., is a global clinical

development organization. For more information, visit [prainternational.com](http://prainternational.com).

**Premier Research Group Plc.**, Philadelphia, is a solutions-driven CRO that leverages its commitment to therapeutic focus and scientific expertise to deliver clinical-trial services of the highest quality for biopharmaceutical and medical-device companies. For more information, visit [premier-research.com](http://premier-research.com).

**Quintiles Transnational Corp.**, Research Triangle Park, N.C., provides a broad range of professional services in drug development, financial partnering, and commercialization for the pharmaceutical, biotechnology, and healthcare industries. For more information, visit [quintiles.com](http://quintiles.com).

**Radiant Development**, Chicago, is a full-service CRO and a division of Radiant Research Inc. For more information, visit [radiantdevelopment.com](http://radiantdevelopment.com).

**Take Solutions**, Princeton, N.J., is a leading international business technology company with products backed by a

strong domain expertise in life sciences and supply chain management. For more information, visit [takesolutions.com](http://takesolutions.com).

**Thomson Scientific**, Philadelphia, is a division of Thomson Reuters that provides information and knowledge to accelerate research, discovery, and innovation. For more information, visit [scientific.thomson.com](http://scientific.thomson.com).

**United BioSource (UBC)**, Bethesda, Md., is a global pharmaceutical services organization that combines deep scientific knowledge with broad execution expertise across the lifecycle continuum. For more information, visit [unitedbiosource.com](http://unitedbiosource.com).

**Wolters Kluwer Health**, Conshohocken, Pa., a division of Wolters Kluwer, is a leading provider of information and business intelligence for students, professionals, and institutions in medicine, nursing, allied health, pharmacy, and the pharmaceutical industry. For more information, visit [wkhealth.com](http://wkhealth.com).



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Meredith Hargus, MBA, Manager, Reimbursement Policy, GENZYME BIOSURGERY

### Forecasting in Challenging Markets

Anindya Banerjee, Manager, Planning & Analysis, Contracts and Pricing, TAP PHARMACEUTICALS

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Randi S. Tillman, DMD, Senior Director, Pricing & Reimbursement Strategy, ELAN PHARMACEUTICALS

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#### METRICS

Using Internal Metrics to Ensure Enhanced Recruitment and Study Success

Peter Dibiaso, Director of Clinical Operations, SHIRE PHARMACEUTICALS ACADEMICS

#### ACADEMICS

Ensuring Well Qualified and Experienced CRA's Through Required Academic Programs

Barbara Gladson, Director of Curriculum, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

Lisa Palladino, Manager, Patient Recruitment Specialist, MERCK U.S. TRIALS

#### US TRIALS

Public Perceptions of Clinical Trials and Specific Strategies

Gretchen Goller, Patient Recruitment & Compliance, SANOFI AVENTIS PATIENT PERSPECTIVE

FIRST 25 ATTENDEES RECEIVE A FREE TICKET TO THE ORIOLES VS ANGELS BASEBALL GAME, SUNDAY JULY 27TH

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