A Note from the Editor

PharmaVOICE is pleased to 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 attending and exhibiting at the DIA 43rd Annual Meeting in Atlanta, June 18-22, 2007.

For your convenience, we have divided the briefs into sections, including Trends, E-Solutions, What's New, and Who's Who.

We would also like to extend special thanks to Alberto Grignolo, Ph.D., DIA 43rd Annual Meeting Program Chairperson, for providing an insider's view to what it takes to produce a successful DIA Annual Meeting that addresses the needs of attendees, exhibitors, and thought leaders.

In keeping with our theme for this year's conference — **PharmaVOICE** is so Hot It's Cool — we are pleased to announce an exciting new enhancement to our WebCast Network offering, which allows us to conduct in-person interviews with thought leaders from the clinical arena at our booth. If you are interested in participating in an in-person Podcast episode, please contact us to learn more about this exciting program, which can help you extend your conference buzz for months!

In the meantime, we look forward to seeing you in Atlanta. Please stop by the **PharmaVOICE** Booth 1000 to learn about more hot trends and cool services and products in the clinical-services arena.

Regards,
Taren Grom
Editor

DOING IT RIGHT

Seven Success Factors for the DIA Annual Meeting

Alberto Grignolo, Ph.D.
2007 43rd DIA Annual Meeting Program Chairperson

Alberto Grignolo, Ph.D., Chairperson of the DIA 43rd Annual Meeting Program. Dr. Grignolo also serves as Corporate VP and General Manager, Drug Development Consulting Practice, Parexel Consulting, Parexel International.

Representing more than 20,000 members worldwide who are involved in the 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.

Nowadays, busy professionals have to choose very carefully how to spend their time away from work; as a result, the DIA Annual Meeting must provide compelling reasons to pull people away from the office and join the premier event of the year.

I have been associated with DIA in various roles since 1984, and I have consistently found the annual meeting to be a magnet for the people I wanted to be with and for the content I needed to do my job. So, when DIA asked me to Chair the 2007 Annual Meeting I accepted the responsibility with a mix of honor and awe, knowing that I would have to live up to a long legacy of success. Fortunately for me and wisely for DIA, this responsibility has been shared with numerous competent and capable individuals.

Producing a successful DIA Annual Meeting requires seven essential ingredients.

1. Timeliness and Innovation

The planning started in 2006, just as the 42nd Annual Meeting came to a close. The program committee came together and committed itself to building a program with content that was both timely and innovative. Timely means that the larger issues of our field of work must find the proper emphasis in the annual meeting; innovative means that the topics cannot be recycled from past years but must be fresh, relevant, and a bit mind-stretching if possible. We kept these criteria very much in mind as we reviewed submitted abstracts and made important decisions that affected the overall profile of the annual meeting.

2. Expertise

The drivers of our program are the experts who serve as track chairs, session chairs, and speakers. This has been true for every DIA annual meeting I can remember, but today we see that the range and diversity of expertise required to deliver strong content has expanded significantly. There are now 27 separate tracks to cover all of the important content areas of interest to DIA members, and 51 experts co-chair those tracks. The track chairs and cochairs have worked diligently to sift through 986 abstracts submitted and to select those that truly met our criteria for timeliness and innovation. The result, we believe, is a solid program built by experts for experts.

3. Range and Diversity

The span of interests of DIA Members is vast and diverse. The content of the annual meeting therefore covers an enormous range of topics in almost 400 sessions that include more than 1,000 speakers. By using our tracks effectively, we are able to provide solid coverage for all the topics of interest to the membership. We did this in two ways.

First, we used a bottom-up approach. The abstracts we received in response to the request for abstracts in May 2006 were ranked for suitability by the appropriate track experts. Second, we used a top-down approach. The track chairs and cochairs identified important areas that were not covered by submitted or acceptable abstracts and created new sessions to ensure coverage of timely topics.

In addition, we have scheduled 35 tutorials for in-depth coverage of numerous topics of interest to our members. The result is a program guided both by a vision of its overall content and by member-driven session topics reflecting the interests of our constituency. Overall, we believe that we have achieved a sound balance.

4. Globality

DIA has long been known for being a global forum where professionals from industry, government, and academia from around the world meet to learn, network, and grow in a neutral and supportive environment. The annual meeting has always been aligned with this philosophy, and this year we continued a tradition of featuring many topics that transcend national borders and leverage the flat world where we now live.

The pace of change is so intense today that people have come to regard the annual meeting as the place to learn about important new trends, verify their assumptions, learn how to do new things, and compare notes with colleagues from companies, agencies, and universities.

More than ever before, we all need to look beyond our immediate borders to get things done, but sometimes we do not know or understand the challenges that await us. Our program attempts to remove some of the uncertainty and to bring together people who can help one another. The most important example this year is our "Global Clinical Trials" theme, which comprises 24 sessions; we have put a significant emphasis on this theme in response to member interest and to the challenges of designing, monitoring, and reporting clinical studies that are now conducted more and more on a global scale.

Major issues to be covered in several sessions include global patient recruitment and retention strategies, opportunities, and challenges of running clinical trials in India and China, data collection and management, and strategic considerations for global clinical trials.

5. Hot Topics

Every year our members want to know the latest on the important issues affecting their work. For this reason, the program committee has identified several hot topics that command significant interest and impact, and has scheduled single or multiple sessions to cover them, including:

- GLOBAL CLINICAL TRIALS — There are 24 sessions targeting global studies.
- DRUG SAFETY REFORM: ACTIONS AND IMPLICATIONS — A multitrack plenary session that will highlight the very latest legislative and regulatory developments in drug safety in the wake of the IOM Report and pending actions in the U.S. Congress and at the FDA.
- PERSONALIZED MEDICINE — An exciting and emerging field that promises to increase the efficiency of drug development, improve patient safety, and deliver better medicines for unmet medical needs faster and more cheaply. What is the "state of play" today and what can we expect in the near future? Three sessions are scheduled to bring participants up to date on this topic.
- CRITICAL PATH — The FDA has issued a call to action to improve the way medical products are discovered, developed, and delivered to professionals and to patients. What progress has been made so far, and what does the future look like? Thirteen sessions will address this question.
- ADAPTIVE TRIALS/ADAPTIVE METHODS — Much interest has been generated by this topic, which is viewed as a way to accelerate drug development without "breaking the rules." There are also significant misunderstandings as to the meaning of "adaptive," and we have therefore scheduled eight sessions on this topic in an effort to promote clarity and progress.
- CDER TOWN MEETING — As this has become an annual meeting tradition, we have scheduled a CDER Town Meeting to foster dialogue between this key FDA Center and its constituents.

6. Keynote Speaker

The opening plenary session sets the tone of the annual meeting before the several thousand participants disperse to attend sessions and to network. This year we will be honored by the presence of Dr. Julie Gerberding, the Director of the Atlanta-based Centers for Disease Control and Prevention (CDC). One of the CDC's Health Protection Goals is "People around the world will live safer, healthier, and longer lives through health promotion, health protection, and health diplomacy" and resonates poignantly with DIA's own global vision: "DIA is the universally respected forum for quality information exchange leading to better medicines that enhance health and well-being." Dr. Gerberding is sure to inspire us and reinvigorate us in the pursuit of our collective mission to benefit patients everywhere.

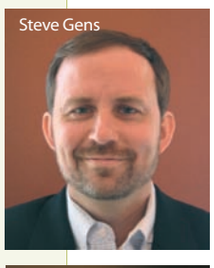
7. Logistics

Location, location, location — the DIA Annual Meeting is very much about expertise and content, but it is the DIA Logistics Machine that makes it a tangible reality. For 43 years the DIA staff has delivered excellence, dedication, quality, and attention to every detail — even as the annual meeting has grown in size from a few dozen to more than 8,000 participants. It is now a major event that requires convention centers to be booked 10 years in advance, minute planning to make sure that every participant receives the maximum benefit, and a commitment to a certain DIA style that has become distinctive and respected around the world.

The program committee has been blessed by the support of the DIA Annual Meeting team and their colleagues, without whom our work would not see the light of day.

For more information about the DIA Annual Meeting, visit diahome.org.

HOT TREND Enterprise Document Management/eCTD



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Steve Scribner, President, International Life Science Solutions Inc. For more information, e-mail stevescribner@nc.rr.com.

A comprehensive independent survey of 37 biopharmaceutical companies (32 in the top 50 by revenue) was conducted in early 2007. It examined the current state environments and indicated key trends for the next three years. The results showed that traditional approaches to enterprise document management (EDM) are quickly fading, companies are challenged with articulating quantifiable business benefits, and outsourcing is gaining acceptance. Additionally, most companies (59%) are not eCTD ready and are rushing to have this capability in place for 2008. At the same time, a new EDM paradigm is emerging with the marriage of traditional EDM and next-generation collaboration tools and a convergence of the document and data sides of information management. This emerging paradigm will streamline the management of content leading to lower overall total cost of ownership and changing vendor market share.

eCTD READINESS

Companies are still underestimating by 6 to 12 months the effort required to deploy an end-to-end eCTD solution. Many companies fail to gauge the level of process and procedure work. Others view an eCTD deployment as a late-stage tool for getting a dossier out the door. Until the eCTD, submissions were managed as one-time events rather than a fluid life-cycle process orientation. Interestingly, 45% of large companies cited budgetary constraints as the top deployment challenge. Many companies budgeted for the eCTD simply as a software product and then found that an opportunity existed to revise their approach to the entire publishing process. Several software vendors have responded aggressively to this need and their solutions are now showing signs of maturity for the combined paper and electronic market.

PROGRAM INVESTMENTS

The study explored investments for EDM program expansion, collaboration, outsourcing, and product vendors. As expected there were significant investments in integrated labeling solutions, eCTD deployment, collaboration tools, and EDM enterprise expansion. What was not expected was registration and submission tracking as a top priority for 2007/2008; 23% of respondents have a tracking capability today (primarily homegrown) and this should increase to 84% by 2009.

An examination of seven outsourcing categories found that on average 60% are outsourcing part of their operations and many are "in analysis." This is predominately driven by economic pressures or lack of skilled resources.

Finally, commercial manufacturing/supply chain document management will be deployed 60% of the participant companies in 2007 and 2008. This suggests either the eCTD's life-cycle management and/or consolidation of the document management platform to the enterprise level are driving this investment.

PROGRAM SUCCESS FACTORS

The survey design had eight data points to determine program effectiveness. The successful programs had these common characteristics: policy harmonization and nomenclature standards, program strategy formulation driven by the business units and supported by IT, formal business metrics tracking, and fewer product vendors (reducing integration complexity).

PRODUCT VENDOR STATUS

Market share for publishing, EDM, and collaboration vendors is shifting while registration tracking and labeling vendors are still battling for initial market leadership. The maturity of collaboration tools and the realization of enterprise harmonization are quickly changing the document management operating paradigm. Most survey participants discussed a collaboration/EDM tool combination strategy and are challenged by content location, specifically what content goes where and more importantly, when? Publishing and registration tracking vendors are also going through extensive change driven by the eCTD, platform simplification, and the integration of regulatory information. One participant stated, "The sucess or failure of implementing an EDM program lies in the ability to articulate business value at the VP/board level and be able to gain sustained support."

HOT TRENDS

- **82%** are not satisfied with their EDM systems for casual or mobile users
- **61%** will adopt an enterprise EDM model by 2009
- **61%** have outsourced a portion of their labeling operation (7 have outsourced completely)
- **55%** cited improved collaboration with health authorities
- **54%** are using off the shelf EDM tools and this will increase to 75% by 2009
- **54%** have adopted a business/IT combined support structure
- **21%** have completely outsourced their labeling operation

HOT TOPICS FOR FURTHER DISCUSSION

We took one last look at the data and have asked ourselves: "So what? What does this all mean going forward?" We concluded with these questions:

- Will the original vision and benefits of the eCTD be fully realized or will regional nuances degrade the anticipated value because of increased complexity?
- Will the new generation of collaboration tools be applicable for business processes supported by traditional EDM tools?
- Can EDM vendors substantially improve the user experience layer?

Note: For more information or detailed survey results, please contact Steve Gens or Steve Scribner.

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www.inventivclinical.com

Visit us at booth #1045 at the DIA Annual Meeting in Atlanta, Georgia, June 17–20.

Accelerate Results.

E-SOLUTIONS

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

ACS Offers Solution for Study Sponsors

We specifically set out to design a study management solution for middle-tier CROs and sponsors that typically can't engage the big vendors, says Bruce Schatzman, President and CEO of ACS.

Advanced Clinical Software Inc.'s (ACS) new clinical-trial management solution, StudyManager SE (Sponsor Edition) offers middle-tier research sponsors and CROs an affordable, robust trial-management platform. By providing clinical-data collection, study management, and real-time interaction among study administrators, study monitors, and site users in one package, StudyManager SE can improve overall performance by expediting operations and reducing costs.

In creating StudyManager SE, ACS has substantially lowered the price point, enabling many more organizations that conduct clinical research to achieve greater success. The product release also signals ACS's strategic move into the sponsor side of research after having established itself as player among research providers, such as health systems, academic medical centers, and research sites.

"We recognized that the middle-tier CRO and sponsor sector was an underserved group, and we wanted to create a solution that would bridge the gap both functionally and financially," says Bruce Schatzman, president and CEO of ACS.

For more information, visit studymanager.com, or stop by Booth No. 1700.

Aptuit Launches Next Clinicopia Solution

Aptuit's Clinicopia 4.1 marks the second milestone in a multiphase rollout of the Clinicopia Suite of products across all of its facilities worldwide.

The 4.1 release provides Clinicopia customers with a software solution to support clinical-supply management. Clinicopia 4.1 is the first off-the-shelf release that is ready for deployment without customization or a simplified qualification by customers.

"The final phase will be implementation of Clinicopia 4.2 in the spring of 2008," says Gerry Hepburn, president, clinical operations, Aptuit. "That release will put all of our operations on a common, Web-based inventory management system providing seamless operation across our packaging network."

For more information, visit aptuit.com, or stop by Booth No. 243.

Dendrite's PharmaLenz Addresses Clinical Performance Issues

The PharmaLenz solution from Dendrite Clinical provides operational modeling and decision support to proactively address performance issues at the site and country level.

PharmaLenz uses high-end predictive analytics, modeling, simulation, forecasting, and visualization tools to convert existing clinical trial management system data, electronic data capture data, and industry site performance data into actionable information for users.

For more information, visit dendrite.com, or stop by Booth No. 1645.

DSG Releases EDC with Multilanguage Capabilities

Global trials — which are fast becoming the industry norm — allow sponsors to greatly expand their population pool, recruit subjects more rapidly, and recruit more diverse populations, says Tony Varano, CEO of DSG.

DSG's new eCaseLink software has multilanguage capabilities for electronic data capture (EDC) in the life-sciences industry. The software now includes Japanese, Chinese, and Western European language capabilities.

The new multilanguage capabilities of eCaseLink allow sponsors to run their clinical-trial operations on a single, global platform without needing to install different versions of the software for different languages. All data managers and clinicians can work together collaboratively using a single, centrally managed global database regardless of geographic location or language.

Data screens can be translated into any language, and sponsors will no longer need to recreate separate clinical-research forms in multiple languages when conducting a global trial.

"The new multilanguage EDC capability can save our clients both time and money when conducting global trials because users can work in their native language without requiring translations of clinical data," says Tony Varano, CEO of DSG.

The first version of the new eCaseLink software — eCaseLink J — is in Japanese; sponsors can run all of their clinical-trial operations and present all data, application screens and study definitions in Japanese.

eCaseLink J incorporates double byte characters and data entry features necessary for Japanese, as well as the Chinese and Korean languages. eCaseLink J supports double byte characters in the user interface, data entry screens, and clinical data. It can handle queries, coding, data locking, and other functions using double byte characters.

eCaseLink J also includes an auto and interactive encoding module using MedDRA/J. All data screens allow real-time data entry and edits and use PDF technology so information appears the same in paper as on screen. The Japanese Ministry of Health, Labor and Welfare requires paper submissions of clinical-trial data.

In other company news, DSG and Acronet Corp., a leading Japanese CRO, have agreed to partner to offer EDC and data management services to the life-sciences industry in Japan.

For more information, visit dsg-us.com, or stop by Booth No. 1421.

Insightful Launches New Data Analysis System

Insightful has released S-PLUS 8 Enterprise Developer, the latest software platform for statistical data analysis and predictive analytics. S-PLUS 8 provides a comprehensive development environment and enables the rapid deployment and delivery of applications based on predictive analytic modeling to a much broader set of users across the enterprise.

With this release, IT developers, statisticians, and developers can use enhanced programming efficiencies, versatility, comprehensive graphics production, and advanced statistical methods to anticipate and plan for change across their organizations.

Additionally, S-PLUS 8 provides users with the visualization and reporting tools necessary to communicate results to technical and nontechnical audiences, delivering the knowledge to act on critical decision points.

For more information, visit insightful.com, or stop by Booth No. 2051.

Invivodata Introduces EDC Integration With Medidata Rave

We decided to base our ePRO-EDC integration on CDISC ODM standards to reduce the product specifications required and make the system quick and straightforward to implement, says Doug Engfer, President and CEO of invivodata.

Invivodata ePRO-EDC is now integrated with Medidata Solution's Rave to provide a standardized, configurable integration link that leverages Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) standards. The solution can be configured to meet the needs of each trial protocol and is fully validated and 21 CFR Part 11-compliant.

The joint solution enables PRO data recorded on invivodata's DiaryPRO handheld electronic patient diary and case report form (CRF) data captured on Medidata Rave electronic clinical data management platform to be viewed within a single system.

"We thought it was in everyone's best interest to create a standard, reusable process for ePRO-EDC integrations that could reduce costs and time required to implement," says Doug Engfer, president and CEO of invivodata. "It was also a logical extension of invivodata's strong partnership with Medidata."

The ePRO-EDC integration link provides sponsors with a comprehensive, integrated view of clinical-trial progress, allowing them to review data and resolve potential issues more easily. Patient assessments, visit tracking information, and other protocol-specific information are all available within Medidata Rave, giving sponsors greater visibility into site and subject performance.

The solution also grants study sites rapid access to trial data so that investigator personnel can actively monitor subjects' behavior and take proactive measures if necessary to improve their compliance with the protocol.

For more information, visit invivodata.com, or stop by Booth No. 1321.

For more information, visit mdsol.com, or stop by Booth No. 1327.

Nextrials Partners with Raining Data to Offer Patient Recruitment Tool

Nextrials has unveiled a comprehensive, standards-based electronic data interface for clinical-trial patient recruitment and randomization.

It's been estimated that 80% of all clinical trials experience recruitment delays, says Anthony Costello, Cofounder and VP of Product Development and Data Services of Nextrials.

In partnership with Raining Data, Nextrials has developed the PRT module for its e-clinical trial management and electronic data capture platform, Prism, to enable sponsors to tap disparate sources such as a hospitals, electronic health records (EHR), or patient records in other clinical trials to match subjects to study protocol criteria.

Because of Prism's tight integration with Raining Data's TigerLogic CTDS, the PRT module eliminates the significant cost and inefficiencies associated with patient enrollment at study initiation. It is built on a native XML platform that accepts clinical data in any format and transforms it into CDISC ODM format. Once data reside in ODM format, the information can then be pushed to patient randomization systems and other data warehousing solutions.

"By replacing the more traditional patient recruiting tools, such as radio ads and direct-mail pieces with Prism's PRT, sponsors can more quickly and efficiently identify and screen appropriate subjects — and then stream them directly into a randomization system," says Anthony Costello, cofounder and VP of product development and data services of Nextrials.

The Prism PRT module features a user-friendly dashboard that delivers a desktop-like experience for tracking patient recruitment activity. Perhaps more importantly, the PRT module eliminates the need for an interactive voice response system (IVRS) for phone enrollment and duplicate data entry at multiple sites.

For more information, visit nextrials.com, or stop by Booth No. 2202.

Octagon Releases Global eCTD Guidance Interpretation

Octagon Research Solutions' newly released Global eCTD Guidance Interpretation, which was developed by the company's regulatory affairs, regulatory operations, and process experts, includes detailed documentation of standards and practices that support the efficient development of compliant eCTD deliverables. Computer-based training also is included in the package.

"We understand how important it is to have a common organizational understanding of industry guidances," says Nancy Smerkanich, VP, regulatory affairs. "The Global eCTD Guidance Interpretation will save companies significant time and resources because they won't have to reinvent the wheel. We have ▶

The global eCTD Guidance Interpretation represents hundreds of hours of research and analysis of electronic submission guidances and specifications by experienced industry professionals, says Nancy Smerkanich, VP, Regulatory Affairs, Octagon Research Solutions.

work for them, and we present it in a clear and concise manner. We are also offering additional assistance to companies that choose to customize our interpretation to align with existing organizational standards."

The solution includes detailed documentation, training, and optional consulting services that can support customization and deployment of the interpretation across the United States, Canada, and Europe. It is available on a subscription basis and scheduled updates will reflect relevant changes in the regulatory landscape.

In other news, Octagon has released Data JumpStart, a new offering designed to assist companies in the efficient deployment of new industry data standards across their organization and outsourcing partners.

CDISC SDTM-compatible Data JumpStart is a collection of documents, libraries, and templates that facilitate institutionalization of data management standards and provide everything a company needs to deploy data standards across an organization and to outsourcing partners.

"We recognized that, frequently, many organizations experience a lack of resources and knowledge with regard to data management, particularly the emerging data standards," says Dan Crawford, director, clinical data strategies. "The goal of Data JumpStart is to assist organizations to push standardization upstream as far as possible. Once standardized, the next logical step is integration and analysis of safety and efficacy data across studies, which enables companies to make go/no-go decisions earlier in the drug-development process."

For more information, visit octagonresearch.com, or stop by Booth No. 1309.

Omnicare Launches E-Learning Tool

Omnicare Clinical Research has launched an online e-learning management system, OmnieView University (OVU). Through OVU, all Omnicare's clinical project team members — internal and external — can now receive targeted and timely project-specific training via electronic learning modules. Users access the tool through the company's Webportal.

"For almost every challenge facing the clinical trials industry today, training is a critical part of the solution," says Simon Taylor, senior director of global training and development for Omnicare Clinical Research. "Sites, contractors, CRO employees, sponsors, and even patients are faced with a rapidly changing landscape that demands new ways to ensure quick, yet thorough, comprehension of these issues. We can develop and implement a customized OVU e-learning plan for projects."

For more information, visit omnicarecr.com, or stop by Booth No.1701.

OmniComm Integrates Cancer Data Repository

OmniComm Systems has completed the first commercial integration of an EDC solution with the National Cancer Institute's Center for Bioinformatics (NCICB) cancer Data Standards Repository (caDSR).

This integration allows customers conducting cancer research to take full advantage of prepopulated global libraries of NCI-developed metadata for their clinical trials.

"This new functionality is just the first step in our adoption of the NCI's cancer Biomedical Informatics Grid (caBIG) initiative," says Randy Smith, chief technology officer of OmniComm Systems. "Our ability to seamlessly interact with the NCI's caDSR provides users of our TrialMaster suite of products the ability to quickly and efficiently design and deploy new protocols using a library of standardized common data elements and forms."

Mr. Smith says this functionality also allows the company to participate to a greater degree with the caBIG community as a whole by providing a means of sharing newly created objects developed in the TrialMaster environment, and then publishing these back to the community using the NCI's standard curation toolset.

One of the problems confronting the biomedical data management community today is the multitude of ways in which similar or identical concepts are described. This inconsistency in data descriptors (metadata) makes it very difficult to combine and manage data in order to be able to answer basic questions. The primary goal of the caDSR is to define a comprehensive set of standardized metadata descriptors for cancer research terminology used in information collection and analysis.

Various NCI offices and partner organizations have developed the content of the caDSR by registration of data elements based on data standards, data collection forms, databases, clinical applications, data exchange formats, UML models, and vocabularies.

For more information, visit omnicomm.com, or stop by Booth No. 442.

The Patient Recruiting Agency Launches Platform for Managing Patient Recruitment

For the investigator conducting clinical research, RADIUS365 is a secured, encrypted Web portal containing all response and referral contacts in one convenient location, says Lance Nickens, President, The Patient Recruiting Agency.

The Patient Recruiting Agency has launched RADIUS365, a complete real-time online platform for tracking and managing responses, referrals, and retention activities.

RADIUS365 combines telecommunication and new media services with server-hosted organizational and calendaring tools to enhance productivity and accountability.

The secure, encrypted Web investigator portal incorporates a number of easy-to-use and practical tools for tracking and managing contacts. It also includes an automated clinical visit window and retention activity calculator, calendar, and notification system.

The tool has the ability to simultaneously increase the investigators' effectiveness, while facilitating electronic reporting of their activities without the cost, time, and intrusion of manually collecting the data for site activity reports. The benefits that flow from this convergence include: supportive and more productive investigators, greater accountability of all vendors, more effective recruiting, less waste, and a higher rate of on-time study completions.

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

PharmaNet Releases Clinical-Trial Software

PharmaNet Development Group has released PharmaSoft 2007, which provides new data capture, monitoring, cleaning, and management enhancements to its clinical-trial data management software.

PharmaSoft 2007 is based on a new platform architecture that improves system performance, supports multiple application environments, and is completely independent of server operating systems.

The software enhancements include improved scalability, a new edit-check validation tool, new copy/paste protocol configuration elements that allow for the rapid set-up of new studies, advanced search functionality to facilitate customized data mining and ad hoc queries, and improved visibility of the clinical report form audit trail.

For more information, visit pharmanet.com, or stop by Booth No. 1037.

Phase Forward Enhances Clinical Trials Signal Detection System

With CTSD 2.5, we're making it even easier for safety reviewers to flag potential risks earlier in the clinical trial, says Chan Russell, President of Phase Forward's Lincoln Technologies safety division.

Phase Forward has introduced version 2.5 of the company's Clinical Trials Signal Detection (CTSD) system. A comprehensive tool for detecting, evaluating, and tracking potential safety signals, CTSD 2.5 provides an enhanced user interface with clear summary displays, a wide selection of data visualization tools, and the ability to easily access trial data without programming.

The new version also offers a user interface designed to facilitate the safety review workflow with interactive displays that include patient level drill downs, Lab Trend graphs, an Exposure Summary graph, and Kaplan Meier plots. Additionally, CTSD 2.5 offers Hy's Law alerts and the full set of standardized MedDRA queries.

The system also is integrated with Phase Forward's WebSDM (Web Submission Data Manager) platform, offering seamless support for the CDISC SDTM data

standard when submitting files to regulatory agencies and further provides the basis for a powerful clinical analysis data repository.

"The simplified user interface and new cross-functional collaboration capability streamline the review process and ultimately help to provide our customers with the ability to improve drug safety monitoring and reduce development costs," says Chan Russell, president of Phase Forward's Lincoln Technologies.

For more information, visit phaseforward.com, or stop by Booth No. 437.

PHT Launches Wireless Solution

PHT has launched SimpleSend Wireless Pak, which is a mobile wireless solution for global data transmission from an otherwise analogue e-diary, such as a Palm E2 or TX, which generally requires a landline to transmit data.

Together with PHT's other transmission options, the SimpleSend family of analogue and wireless modems provides sponsors with the greatest amount of device flexibility in global research and subject convenience.

The solution complements the company's upcoming StudyPad tablet, which is a mobile ePRO solution to be used at sites to collect e-source data from multiple subjects on one device, as well as the company's LogPad System.

PHT features the Palm TX as an optimal device for StudyPad studies. The larger screen better enables multilanguage translations and easy-to-read text for certain items. It can also be used horizontally to display specific scales.

For more information, visit phtcorp.com, or stop by Booth No. 1114.

Spotfire Tool Identifies Safety Issues Earlier

Spotfire has introduced Spotfire Clinical Trials Analysis, which is built on its DXP enterprise analytics platform. The tool enables companies to fail early by spotting potential health risks sooner in the product testing cycle through a more flexible, interactive environment for analyzing key aspects of drug safety and efficacy.

Spotfire Clinical Trials Analysis allows users to quickly and interactively ask and answer questions about the data. With a few clicks of the mouse, the visual analysis environment reveals hidden patterns, trends, and biases, providing a better understanding of data and accelerating analysis throughout every phase of product development.

"Competitive advantage in this industry depends upon the ability to quickly make strategic decisions about drug candidates," says Christian Marcazzo, senior director of Life Sciences Analytics at Spotfire. "Spotfire Clinical Trials Analysis empowers pharmaceutical companies to make these decisions earlier based upon fast analysis of complex and varied data sources with a highly flexible, easy-to-use solution."

Spotfire Clinical Trials Analysis provides the ability to: visually interact with and analyze data from various sources to identify patterns and trends, outliers, and exceptions in context; access visual representations of adverse event data, lab safety, demographic, and concomitant medications in one analysis environment; conduct ad-hoc querying of data without IT involvement; integrate and analyze diverse information streams in clinical and molecular data; find correlations between gene or protein expression and safety profiles; and adapt to new technologies and methodologies.

For more information, visit spotfire.com, or stop by Booth No. 1051.

Veritas Offers Clinical Data Disclosure Solution

Veritas Medicine's clinical data disclosure solution makes it easy for sponsors to comply with existing requirements and any new legislation that is passed into law.

The modular clinical data disclosure solution includes several features, including Veritas Medicine Clinical Trials Registry (VCTR), which is a secure Web application used internally by sponsors to enter, review, and approve clinical-trial listings and study results data for submission to clinical-

In addition to other features, the solution allows for patient response to happen in real time 24/7 via online clinical-trial screening, says Rick Ward, VP of Sales and Marketing, at Veritas Medicine.

trials.gov, clinicalstudyresults.org, and a sponsor registry Website. The Sponsor Registry Website Development & Management feature enables public searches for clinical-trial listings and/or study results postings by disease or drug. Another feature, Clinical Trial Listing & Results Posting Submission, includes scheduled updates, emergency posts, and site de-activations.

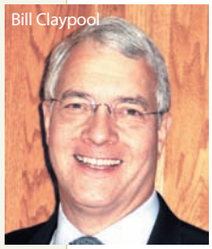
Additionally, patient response can happen in real time 24/7 via online clinical-trial screening.

"The industry trend toward more globally managed clinical trials will require sponsors to integrate more sophisticated feasibility assessment tools, streamline their site selection methods, and incorporate more comprehensive patient recruitment strategies," says Rick Ward, VP of sales and marketing.

In other company news, Veritas Medicine's Enrollment Intelligence tool offers users access to targeted patient populations, study sites, and real-time performance data with a commitment to aggressive program management to generate unmatched enrollment impacts.

For more information, visit veritasmedicine.com, or stop by Booth No. 746.

HOT TREND Blending Technology with Clinical Expertise


Bill Claypool

Contributed by: Bill Claypool, M.D., CEO of Phoenix Data Systems

Data, Data, Data

The sole product of the drug-development enterprise is the creation of information. Given this pre-eminent role of data, it is remarkable that every serious drug-development enterprise does not use the most advanced methods for data collection, cataloging, distribution, and analysis for every clinical trial. This is especially baffling as these technologies are robust, cost-effective, and are really the only way to deal efficiently with the growing quantity of data needed to support a drug marketing application.

Despite earlier reluctance, it is evident that the adoption of these technologies is now accelerating.

A recent study, conducted by Phoenix Data Systems and PharmaVOICE, found that 83% of clinical-trial sponsors reported using EDC as part of their research efforts. That same study also found that half of all clinical-trials professionals find EDC more attractive as an outsourced service.

Pharmaceutical companies of all sizes seek EDC vendors that can tackle the whole spectrum of the data-collection process with both clinical experience and technological expertise. These findings and respective rationales support the bottom line: demand for trials that are cost and time efficient and also ensure better subject safety through real-time data reporting.

Does Size Matter?

EDC use for small to midsized companies has commonly been perceived as a potentially risky proposition. Resource-challenged clinical groups of fewer than 100 employees often do not have the internal support, funds, or infrastructure to support a large investment in EDC technology. Issues surrounding hardware installation, IT support, system validation, ongoing training, and high recurring costs have, at one time or another, been claimed as reasons why EDC is not for them. The cost and time associated with training is often more than a typical small to midsize drug developer can absorb, especially since the software requires customization for each trial. These companies simply don't run enough trials to rack up the necessary experience to become fluent in the process. Adding sophisticated tools and integration requirements can worsen the chances for success instead of improving the results. Larger organizations often reach the same conclusion when they look honestly at their core competencies.

Outsourcing Alternatives

Drug developers of all sizes may turn to their CRO as a resource for both EDC and data management. Many CROs looking to expand their product list and increase revenue are eager to offer data management as a line item. But, in many instances their attempts at combining e-clinical with outsourced data management do not meet sponsor expectations. If the CRO has not fully embraced electronic processes, it may not be capable of using the chosen technology to its maximum effect.

For many CROs, their EDC experiences are often spread across a variety of technologies and vendors. With the combination of staff turnover or competing availabilities, their learning curve on these technologies may start closer to the bottom than sponsors would like to believe.

The Full Arsenal

The solution is not just to outsource EDC, but to couple EDC with electronic data management as an integrated offering, supported by experienced staff. It's not just the EDC technology that needs outside expertise — it's the clinical data management experience, too. This is especially valuable when trying to extract the most from these powerful data capture, data visualization, and data analysis technologies.

Combining EDC with electronic data management yields faster start-up time with more comprehensive edit checks, better compliance to the data management specifications, real-time access to high quality data, and the ability to change the study as a result of emerging information (i.e., adaptive trials).

With all of the pressures on pharmaceutical companies from regulators, investors, patients, and the public at large, the more efficient, transparent, and integrated the clinical data management process is, the faster the data can be put into use.

Source: Phoenix Data Systems, King of Prussia, Pa. For more information, contact phoenixdatasystems.net, or visit Booth No. 1651.

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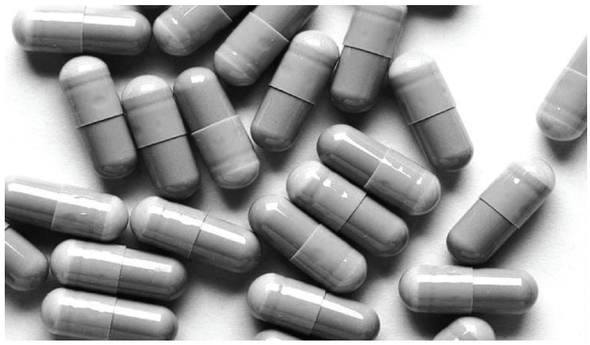

Averion International is a globally preeminent clinical research organization with a focus in oncology, dermatology, nephrology and medical devices. Averion International offers a comprehensive understanding of what it takes to efficiently manage clinical trials; from Phase I-IV through to post-marketing studies, safety surveillance and patient registries.

Our expertise assures quality, service and results. Our experience means your success.

www.averionintl.com

WHAT'S NEW

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

Averion Opens Four European Offices

Averion International has strengthened its European operations by opening four European-based offices.

"Expanding geographically is key to our growth strategy as it supports our ability to provide services to international clients and to capitalize on the rapid growth that characterizes the CRO industry," says Philip Lavin, Ph.D., CEO, Averion.

The new Averion offices include: Averion Europe GmbH, located near Frankfurt, Germany, which provides financial, administrative, and operational support for Averion's European operations; Averion Ltd., located in the United Kingdom, which oversees operations for Averion's clinical trials in northwestern Europe and coordinates activities with Averion's UK-based clients; Averion Clinical Research GmbH, located in Austria, which handles responsibilities for Averion's Central and Eastern European operations; and Averion Sp. z.o.o., located in Poland, which provides operational support and coordinates studies in Poland and the Baltic States.

For more information, visit averioninc.com, or visit Booth No. 2037.

Chiltern Introduces Specialist Division to Boost Enrollment

Chiltern International has expanded the services it offers clients through its Resourcing Solutions division with the introduction of a specialist group dedicated to providing experienced study site coordinators directly to investigators and hospital sites.

"Chiltern's Resourcing Solutions division offers flexible solutions tailored to the site's specific recruitment needs," says Cathy Gooch, associate director, Resourcing Solutions. "Sites may choose to use these staff on an hourly paid or permanent basis, according to their needs at that time."

Linda Christmas, global head, Resourcing Solutions for Chiltern says, "It had become very apparent that investigator sites needed greater flexibility to manage personnel fluctuations and meet their recruitment goals, most specifically during the enrollment phase of clinical studies. Our new resourcing solution does provide the sites with an answer."

For more information, visit chiltern.com, or stop by Booth No. 208.

i3 Acquires European Health Economics

i3 has acquired European Health Economics (EHE), a European health economics research firm. EHE joins the i3 Innovus business unit that provides health economics expertise, rich data, and sophisticated econometric research to the biopharmaceutical industry.

With the addition of EHE, we have expanded our team of methodological leaders in healthcare economics in the European market, says Dr. William Crown, Ph.D., President of i3 Innovus.

This acquisition contributes to i3's continuing strategic global expansion and brings EHE's leading health economic experts and methodologies to strengthen i3 Innovus' position in the market as a global health economics and outcomes research organization.

With offices in Sweden and the United Kingdom, EHE is known for its high-quality health economics and modeling and now has complete access to i3 Innovus' rich database and smart software applications. EHE further strengthens i3 Innovus' ability to deliver timely, meaningful information to support every aspect of product decision-making.

"i3's strategy is to bring together the best minds in health economics and outcomes with access to the best informatics and richest databases available," says William Crown, Ph.D., president of i3 Innovus.

For more information, visit i3global.com, or stop by Booth No. 1721.

INC Research Acquires Advanced Biologics

We have a tremendous synergy with Advanced Biologics on our approach to clinical trials, from how we kick off a project, to how we develop a therapeutically focused team, to how we ensure the accuracy and speed of the database lock, says James T. Ogle, CEO of INC Research.

INC Research has acquired Advanced Biologics to strengthen its infectious disease practice. Advanced Biologics is a full-service contract research organization (CRO) specializing in full-service clinical development to the pharmaceutical and biotechnology industries worldwide.

"Advanced Biologics has built a world-class team of therapeutic experts that are focused on the needs of its clients," says James T. Ogle, CEO of INC Research. "There is a tremendous amount of synergy in our approaches to clinical trials, from how we kick off a project, to how we develop a therapeutically focused team, to how we ensure the accuracy and speed of the database lock. By joining forces, our clients will greatly benefit from our expanded infectious disease capabilities."

Advanced Biologics has full-service clinical development support for Phase I to Phase IV clinical programs and has coordinated numerous IND, NDA, sNDA, and ex-U.S. submissions. Beyond its highly respected infectious disease experience, the CRO has handled studies for drugs being developed for cancer, neurological diseases, urologic conditions, and women's health.

The Advanced Biologics' facility will continue to function as a full-service drug development hub of operations, now serving as the seventh of INC Research's North American locations.

In other company news, INC Research and GVK Biosciences (GVK BIO) have entered into a 50-50 equity stake joint-venture agreement to form INC GVK BIO Private Ltd.

The joint venture gives INC Research the capability to run full-service, Phase I to Phase IV clinical trials in India for its pharma and biotech customers, using clinical research resources at GVK that are fully dedicated to INC GVK Bio India projects.

For more information, visit incresearch.com, or stop by Booth No. 409.

inVentiv Health Consolidates Sampling and Regulatory Compliance Offerings

inVentiv Health has consolidated its sampling and compliance services into a technologically advanced and state-of-the art company named PRS Franklin.

PRS Franklin unifies the sampling services of Pharmaceutical Resource Solutions (PRS), The Franklin Group, and inVentiv Commercial Services into a single best-in-class operating company within inVentiv Health.

The Franklin Group, a healthcare consulting firm, continues its work in the design and management of patient services to include patient-assistance programs, Medicare-related assistance programs, reimbursement counseling, and other related specialty services.

With the move, PRS Franklin can further provide small, emerging through large pharmaceutical companies with customized best-in-class sampling and complementary services to meet their business needs. A full range of sampling and regulatory compliance services are available for prescription and controlled substance sample tracking, direct-to-physician sample programs, and PDMA, CSA and state law management, audit, and security programs.

Robert Melillo, JD, heads up PRS Franklin as VP and managing director. Mr. Melillo is an expert on PDMA and other regulatory matters impacting the pharmaceutical industry. Formerly he was general manager of PRS.

"Combining the company's sampling and regulatory compliance services into one group not only strengthens our offerings in these areas, but allows us to create more comprehensive programs for clients and to assist our customers in a more focused way," Mr. Melillo says.

For more information, visit inventivhealth.com, or stop by Booth No. 1045. ▶

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Lifetree Clinical Research Unveils New Services

Lifetree Clinical Research has integrated its Pain Clinic in a seamless, multibed, state-of-the-art facility in Salt Lake City.

The synergy between Lifetree Clinical Research and Pain Clinic offers the ability to both operate efficient Phase I to Phase III clinical trials and effectively treat patients suffering from chronic pain with forward-thinking pain treatments, combined with progressive drug research opportunities.

In addition to an integrated, on-site pain clinic, Lifetree offers sponsors real-time quality assurance, which is crucial in the early drug-development process.

"Lifetree's goal is to promote the growing need for better pain-management solutions," says Alice Jackson, CEO and cofounder of Lifetree Clinical Research. "Working in the early-development stage of drug-development clinical trials with large pharmaceutical and biotechnology companies is the first step to achieving this goal."

For more information, visit lifetreeresearch.com, or stop by Booth No. 2208.

The acquisition of a proven electronic data capture technology completes a critical aspect of our vision, says Jim Walker, Chairman and CEO of Octagon.

Octagon Acquires EDC Company

Octagon Research Solutions has acquired Ninaza, an electronic data capture technology company based in San Mateo, Calif.

Ninaza's EDC technology has been used by numerous pharmaceutical and contract research organizations in Phase I-IV clinical trials and is being integrated into Octagon's product suite to provide full collection-to-submission electronic capabilities.

The newly branded ViewPoint FUSE technology solution allows for process efficiency throughout the clinical data life cycle by automating the collection of electronic clinical data in concert with process facilitation and visibility.

"We are working hard to provide transparent, cross-functional technologies and processes that facilitate the efficient management of electronic clinical data across the enterprise," says Jim Walker, chairman and CEO.

In the coming months, Octagon will unveil a suite of packages originating from the ViewPoint platform that will provide clients with clinical data management (CDM) and clinical trial management (CTM) capabilities.

CTM, CDM, EDC, and eSUB functionalities provide for quality, cost, and time improvements in the clinical research and development process.

For more information, visit octagonresearch.com, or stop by Booth No. 1309.

We want to offer our clients a single source of support, so they can access additional clinical development and regulatory resources without adding the associated fixed costs to their R&D overhead, says Miganush Stepanians, Ph.D., President and CEO of Prometrika.

Prometrika Expands Clinical Trial Management Services

Prometrika has updated its management offerings to provide clients with a fully integrated set of services necessary to plan and execute a clinical trial, including preliminary study assessment and planning, primary document development, investigator/study site selection and management, regulatory document management, monitoring plan development and implementation, and overall study direction.

"The addition of these services offers our clients a single source of support, so they can access additional clinical development and regulatory resources without adding the associated fixed costs to their R&D overhead," says Miganush Stepanians, Ph.D., president and CEO.

To establish and direct these enhanced service offerings, Prometrika has appointed Gretchen S. Richards, MS, to the role of director, clinical operations. In this role, Ms. Richards is responsible for all aspects of clinical operations. Ms. Richards joins Prometrika from Nucryst Pharmaceuticals.

For more information, visit prometrika.com, or stop by Booth No. 2003.

Thomson CenterWatch Tracks Emerging Research Markets

Thomson CenterWatch has released a new book, The Emerging Markets of Clinical Research, a comprehensive resource that provides original CenterWatch data on topics to include: regulatory and business landscape, market intelligence, patient recruitment opportunities, investigator training and patient recruitment, CRO and pharmaceutical company strategies and experience, CRO opportunities, and size and growth of the emerging clinical research markets.

The new book features hundreds of interviews with clinical research professionals, and market research articles and charts analyzing emerging markets in clinical research, including Russia, China, India, Central and Eastern Europe, South Africa and Africa, Asia/Pacific, and Latin America.

"Many countries in Asia, Latin America, and Eastern Europe as well as South Africa, have now either adopted ICH-GCP as a guideline, or formally made ICH-GCP law," says Sara Gambrill, author of The Emerging Markets of Clinical Research and senior editor at Thomson CenterWatch. "This adoption has revolutionized the international research and development strategy of pharmaceutical and biotechnology companies and contract research organizations of all sizes. Rare is the Phase III clinical trial initiated today that includes no plan for conduct in countries outside the United States, Canada, and Western Europe."

For more information, visit centerwatch.com, or stop by Booth No. 520.

The integration of Unleashed Informatics with Thomson Scientific data enables us to deliver greater value for research scientists working in biology-driven drug discovery, says Jon Brett Harris, Executive VP of Pharmaceutical and Chemical Markets at Thomson Scientific.

Thomson Scientifc Acquires Unleashed Informatics

Thomson Corp.'s Scientific business unit has acquired privately held Unleashed Informatics Ltd., a life-sciences data management company.

Unleashed Informatics' management team and employees become part of Thomson Scientific.

Unleashed Informatics is regarded for its subscription-based stable of public and proprietary biological databases, including BIND (Biomolecular Interaction Network Database) containing 200,000 biomolecular interactions; SMID (Small Molecule Interaction Database) containing more than 230,000 experimentally observed small molecule interactions; and BOND (Biomolecular Object Network Database) data warehouse that combines access to BIND and SMID data with publicly accessible databases, plus similarity search algorithms.

"The volume and variety of biological data being generated in laboratories worldwide represents a profound scientific challenge," says Jon Brett Harris, executive VP of pharmaceutical and chemical markets at Thomson Scientific. "The integration of Unleashed Informatics with Thomson Scientific data, particularly the 8.5 million genetic sequences in our GENESEQ database, enables us to deliver greater value for research scientists working in biology-driven drug discovery."

In other company news, Thomson Scientific has added coverage of emerging and growing pharmaceutical markets in Asia and the Pacific rim to the IDRAC Database. The new ASEAN module in the IDRAC database provides comprehensive regulatory information related to the Association of Southeast Asian Nations (ASEAN), including details of planned harmonization schemes for its pharmaceutical industry. This is essential information for pharmaceutical companies seeking to develop drugs in this region.

IDRAC is recognized by regulatory professionals the world over as the leading authority in global regulatory intelligence. Updated weekly, it brings together all the information needed to monitor regulatory requirements in 48 countries and regions.

ASEAN member countries are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

For more information, visit scientific.thomson.com, or stop by Booth No. 521.

The best ideas are usually simple ideas.

—David Ogilvy

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HOT TREND Clinical Research Staffing Models


Jeff Souza

Contributed by: Jeff Souza, VP, the Americas, i3

Change continues to permeate our industry in the manner in which drug-development staffing services are provided to pharmaceutical sponsors. Three leading staffing models are described in this article.

Master Service Provider (MSP)/ Vendor Management System (VMS)

The MSP or VMS operates on behalf of a client to manage a prescreened roster of specialized staffing vendors. The core ingredients involve control and standardization of the vendor relationships, direct legal agreements with vendors, and the creation of a hyper-competitive environment for cost savings and containment.

Some of the risks with these models center around missed opportunities whereby certain specialty vendors may choose not to work within such a system. Because the MSP/VMS charges the vendor a fee percentage for every hour a vendor's employee works, those vendors may choose to focus their recruiting efforts within a base of higher profit-margin clients with whom they have direct relationships, particularly those end-user managers with whom they work directly who may give very specific and direct feedback around the sourcing and hiring process.

The Functional Service Provider Staffing Model

In this model, the pharmaceutical company outsources a complete function, such as data services, biostatistics, regulatory, or medical writing. The questions are: is it a passing fashion or a species of delivery that will endure throughout time; does it result in savings and increased levels of quality; or get drugs to market faster? In essence, pharma companies have contributed heavily to the development of functional staffing models in their quest to reduce the cost of bringing products to market. As sponsors focus on savings, quality, and time to market, boundaries are being redefined and paradigm shifts appear to be more a goal than a threat. The intent of this model is to deliver temporary, temporary-to-hire, and direct-hire staffing services to pharmaceutical and biotech companies, CROs, and medical-device companies in a cost-effective, quality-driven, and expeditious manner. Inherent in the planning and execution of a functional staffing model are relatively high volumes of hours worked by vendor employees. This volume sets the stage for discounts and subsequent savings to the client sponsor.

Partnership pricing should account for the following: resource category (dedicated, nondedicated, insourced/contractor); staff type; location; treatment of management/oversight costs; shared overhead/pass-through; and utilization targets.

The Buffer Pool Model

Long- and short-term staffing, conversion-to-full-time, and direct-hire placements are all ingredients of a partnership that can avail itself of low-risk attributes, including flexibility, to address peak and trough periods, study/project start ups, ramp ups and scaling down. The pool will also include rotation of trained vendor employees who can, when possible, rotate in and out of partnership projects or studies.

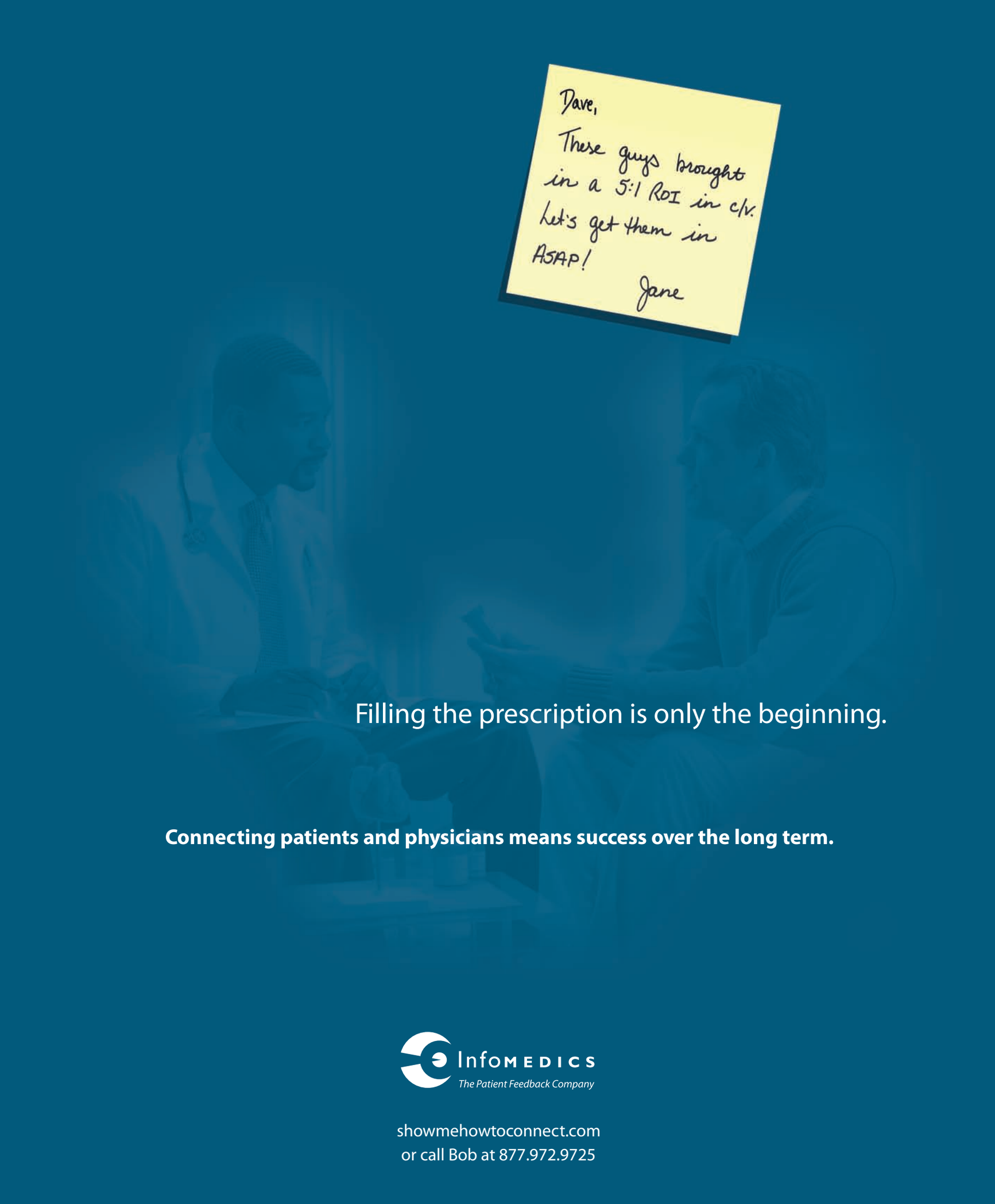
An example here could be a vendor employee who is trained, dedicated, and working for a client for six months and is no longer needed for that particular study. The vendor, who has multiple clients in the marketplace, moves that employee to any of the opportunities that may exist at any given time. The employee may work for that client for some time and, on ending of that assignment, may be called back to the previous client with virtually no lag for onboarding (background checks, etc.). Advantages are the return of a trained/on-boarded employee and cutting costs moderately while cutting start times dramatically.

A strong staffing vendor with flexibility and depth may execute more than one model at a time to meet the client's needs, customizing and providing flexibility to meet the fast changing needs of the client. While these three are the most common staffing models we see, several others not mentioned here provide still other ways to obtain quality personnel.

HOT TIPS TO CONSIDER WHEN CHOOSING A STAFFING VENDOR

- QUALITY. This is best accomplished through management by objectives or key performance indicators set by a vendor with feedback from its clients. Those metrics reflect a combination of the needs of both the vendor and client in quality measurements.
- EXPERTISE. Vendors should provide staff along prescribed lines of therapeutic, indication, and phase experience.
- PRINCIPLES OF STAFF RETENTION. A high-quality benefits package coupled with career development helps the vendor retain staff, and that saves money and angst in the long run.
- CUSTOMIZATION. Vendors should be willing to fit their functional staffing model into the client's structure and process environment as closely as possible.
- FLEXIBILITY. Change happens, and the staffing model should be able to accommodate client, vendor, and industry alterations.
- TRANSPARENT PROCESSES AND MEASUREMENTS. Vendors that have line of sight with this model have the benefit of making changes expeditiously, avoiding cost overruns and delays. Confident relationships within the leadership teams of both the client and vendor will have the same effect on management and line employees.
- OPEN COMMUNICATIONS. Achieving a mutually open and honest partnership is one of the key elements to a successful outcome. Transparency of a company's processes and people on both sides and a recognition and respect for industry knowledge on both sides of the table are vital. This plays heavily during planning and execution stages. Titles should be left at the door.

Source: i3, Basking Ridge, N.J. For more information, visit i3global.com, or stop by Booth No. 1721.



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WHO'S WHO

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

Jim Adamek

Octagon Appoints VP, Commercial Software

Octagon Research Solutions, Wayne, Pa., has appointed Jim Adamek as VP of commercial software. Mr. Adamek provides strategy and leadership by building the software organization, streamlining development, software support, and commercial software sales. He oversees the entire ViewPoint Implementation Services (VIS) department at Octagon.

Before joining Octagon, Mr. Adamek was executive VP at FullTilt Solutions.

For more information, visit octagonresearch.com, or stop by Booth No. 1309.

Dr. Joe Avellone
Carolyn Finkle
Dr. Matthias Grossmann
Dr. Lawrence Grylack
Patrick Guinn
Dr. Sally Hargus
Dr. David Morse
Dr. James Wong

Parexel Expands Consulting Capabilities, Adds Early Drug Development Experts

Parexel International has appointed Joe Avellone, M.D., to the position of VP of operations for Clinical Research Services, Americas. Dr. Avellone leads operational aspects of Phase II to Phase IV clinical development programs for clients, including project management, clinical operations, and management of the Americas Medical Affairs group. In addition to North America, his responsibilities span the company's operations in Latin America.

Before joining Parexel, Dr. Avellone was the former CEO of Veritas Medicine. With more than 20 years of experience in healthcare management, Dr. Avellone's expertise includes establishment of strategic direction; developing and growing products, services, and technologies; managing operations of major business lines; directing senior management teams; and managing major care networks and contractual relationships.

Dr. Avellone is a Fellow of the American College of Surgeons, having received his M.D. from the Harvard Medical School, and completed his general surgery residency at Brigham and Women's Hospital. He also received a master's degree in public administration from the John F. Kennedy School of Government at Harvard University and a bachelor's degree from Dartmouth College.

Parexel also has appointed Carolyn Finkle to lead the Washington, D.C.-area office of Parexel Consulting, a business unit of Parexel. As VP, Ms. Finkle is responsible for managing the product development and regulatory consulting team in North America. Previously, she was VP of regulatory affairs at Celsion. Ms. Finkle holds a master of science in chemistry from the University of Toronto and a bachelor's degree in chemistry from the University of Ottawa.

Matthias Grossmann M.D., Ph.D., joins Parexel's International Clinical Pharmacology Network as VP, clinical pharmacology consulting services. Dr. Grossman provides consultation to clients sponsoring early-phase clinical trials. He holds an M.D. from Humboldt University and a Ph.D. in clinical pharmacology from Technische University.

Lawrence Grylack, M.D., has been appointed a principal consultant at Parexel Consulting. Before joining Parexel, Dr. Grylack served as medical officer in the Division of Pediatric Drug Development in the Office of Counterterrorism and Pediatric Drug Development, and the Division of Pulmonary and Allergy Drug Products at the FDA Center for Drug Evaluation and Research (CDER).

Dr. Grylack holds an M.D. from Tufts University School of Medicine and a bachelor's degree from Brandeis University.

Patrick Guinn has been named a manager at Parexel Consulting. Previously, he served as consumer safety officer/regulatory health project manager at CDER. He holds a bachelor's degree in biology from Virginia Tech.

Sally Hargus, Ph.D., joins the company as a senior consultant at Parexel Consulting. Previously, Dr. Hargus held senior positions in toxicology at 3M Pharmaceuticals and CBER. She holds a Ph.D. and master's degree in pharmacology from the University of Rochester School of Medicine and a bachelor's degree in biology from Augustana College.

David Morse, Ph.D., has been named as a principal consultant at Parexel Consulting. Previously, Dr. Morse worked as a supervisory pharmacologist for CDER. He was awarded his doctorate from the Uniformed Services University of the Health Sciences.

James Wong, Ph.D., has been appointed VP, clinical pharmacology consulting services, at Parexel's International Clinical Pharmacology Network. Dr. Wong joined Parexel from The Medicines Company, where he was director of clinical pharmacology. He holds a B. Pharm. from the School of Pharmacy at the University of London, an M.Sc. from King's Chelsea College of Pharmacy at the University of London, and a Ph.D. from the College of Pharmacy at the University of Texas.

For more information, visit parexel.com, or stop by Booth No. 724.

Terrance J. Bieker
Colin Shannon

PRA Appoints CEO and President/COO

PRA International has appointed Terrance J. Bieker, 61, CEO; he had been serving as interim CEO since December 2006. Before joining PRA in December 2006, Mr. Bieker served as director, president, and CEO of BioSource International (now part of Invitrogen) from November 2003 to November 2005. Mr. Bieker is a graduate of the University of Minnesota.

In addition, Colin Shannon, 47, has been named president and chief operating officer. Mr. Shannon's most recent position was executive VP, global clinical operations, with PPD.

Mr. Shannon holds a master's degree in business administration from London's City University.

For more information, visit prainternational.com, or stop by Booth No. 1401.

Dana C. Cambra
Dr. Dan Weiner

Pharsight Strengthens Management Team

Pharsight has strengthened its management team with the addition of Dana C. Cambra as VP, research and development, and the promotion of Dan Weiner, Ph.D., to chief technology officer.

Before joining Pharsight, Mr. Cambra was VP of engineering at Stentor. He holds bachelor's degrees in engineering and mathematics from the Massachusetts Institute of Technology and a master's degree in engineering from the University of California.

Dr. Weiner was previously senior VP at Pharsight. He graduated from the University of Kentucky with a doctoral degree in mathematical statistics and has an M.S. in statistics and a B.S. in mathematics.

For more information, visit pharsight.com, or stop by Booth No. 1755.

Dr. Hugh Levaux

Medidata Solutions Appoints VP, Product Strategy

Medidata Solutions has named Hugh Levaux, Ph.D., as VP, product strategy. He is responsible for the overall definition and management of Medidata's product offerings, and he joins Medidata from Ninaza.

Dr. Levaux holds a Ph.D. in policy analysis from the Rand Graduate School. He has masters' degrees in international economics and international relations from SAIS at Johns Hopkins University and international politics from Université Libre de Bruxelles in Belgium.

For more information, visit mdsol.com, or stop by Booth No. 1327.

Dr. Ed Richards
Patricia A. Steigerwald

Kendle Appoints VPs

Kendle has appointed Ed Richards, Ph.D., as VP,

global clinical development — Europe and Africa. Dr. Richards provides strategic oversight and direction for Kendle's Phase II to Phase III operations in Western Europe and Africa and will continue to expand upon the company's existing capabilities across these areas.

He brings 30 years of management, marketing, and therapeutic experience to Kendle, including working on a variety of clinical studies for a number of new compounds focusing on oncology, transplantation, and anti-infectives.

Dr. Richards earned both his bachelor of science in chemistry and his doctorate in physical chemistry from Imperial College, University of London. He will be based in Kendle's European headquarters in Crowthorne, Berkshire, England.

Kendle has also promoted Patricia A. Steigerwald, MS, RN, to VP, global late phase. In this role, she provides executive leadership responsibility to drive continued growth in Kendle's late-phase brand globally, with a focus on the design and conduct of Phase IIIB/IV clinical trials, health economics, and outcomes research and product/disease registries.

Ms. Steigerwald most recently was senior director, late phase, for Kendle and brings more than 20 years of CRO and clinical experience to this new position.

Ms. Steigerwald earned a master of science in health science/allied health and a bachelor of science in nursing from Slippery Rock University. She is a member of the Sigma Theta Tau Nursing Honor Society and the Oncology Nursing Society and has served as an adjunct faculty member for Cape Fear Community College School of Nursing and the University of North Carolina, Wilmington School of Nursing.

For more information, visit kendle.com, or stop by Booth No. 1737.

William J. Sharbaugh

PPD Names Chief Operating Officer

PPD has named William J. Sharbaugh as its new chief operating officer. Mr. Sharbaugh comes to PPD from Bristol-Myers Squibb, where he most recently served as VP, global development operations.

Mr. Sharbaugh holds a master's degree in the management of technology from the University of Pennsylvania Wharton Business School and School of Engineering, a master's in regulatory affairs and quality assurance from Temple University School of Pharmacy, and a master's in international relations from Boston University School of Arts and Sciences. He also graduated from the U.S. Military Academy at West Point with a bachelor's degree in engineering and subsequently held various leadership positions in a Patriot missile battalion.

For more information, visit ppdi.com, or stop by Booth No. 739.

Kathryn Starzyk

Outcome Appoints Associate Director, Scientific Affairs

Outcome Sciences has appointed Kathryn Starzyk as associate director of scientific affairs. In this new role, she is providing scientific guidance on pharmacovigilance and safety.

Ms. Starzyk joins Outcome from Genzyme, where she was manager of medical affairs, pharmacovigilance.

For more information, visit outcome.com, or stop by Booth No. 1414.

Steve Swanson

ICRS names VP and COO

Imperial Clinical Research Services has named Steve Swanson as VP and chief operating officer. In addition to operational oversight, Mr. Swanson works closely with Matthew Bissell, Imperial's president and CEO. Together, they are refining the company's strategic direction.

Mr. Swanson comes to Imperial from an assignment as a group president for a private holding company, where he was responsible for three operating divisions with 12 locations in the United States, Mexico, and China.

For more information, visit imperialcrs.com, or stop by Booth No. 409.

Stephanie Wells

Senior Appointment at Charles River

Charles River has appointed Stephanie Wells as corporate senior VP, marketing, and chief marketing officer. Ms. Wells is responsible for establishing and implementing global marketing strategies and branding initiatives.

Before joining Charles River, Ms. Wells was VP, worldwide marketing, clinical labs for Ortho-Clinical Diagnostics. She holds the equivalent of a bachelor's degree in medical laboratory sciences and clinical chemistry from Paddington College.

For more information, visit criver.com, or stop by Booth No. 942.

Diana Wood

Chiltern Appoints Global Head, Business Development

Chiltern International has promoted Diana Wood to global head, business development. Ms. Wood was previously VP, business development, North America. She is based at the company's Carlsbad, Calif., office and is responsible for formulating, implementing, and executing Chiltern's global sales and marketing strategy.

For more information, visit chiltern.com, or stop by Booth No. 208.

PharmaVOICE Webcast Network – Podcasts and WebLinx Interactive WebSeminars

The following is a list of archived Podcasts and WebLinx Interactive WebSeminars related to the clinical research and services arenas that PharmaVOICE and industry thought leaders have conducted during the year. To access any of PharmaVOICE's archived Podcasts, please visit pharmavoice.com/podcasts, to access archived WebLinx programs, please visit pharmavoice.com/weblinx.

A New Paradigm in Drug Development: How Cross-Functional Teams Can Improve the Drug-Development Process

Thought Leader: William Jacobson, Ph.D., Director, Project Management, Women's Health & Pharma Business Units — Wyeth Pharma

Learn about the advantages of employing cross-functional teams in the drug-development process, Wyeth's "Learn and Confirm" model for drug development, and the importance of a broad-based training program that gives everyone the tools to be a better drug developer.
For more information, visit wyeth.com

Agile Clinical Trials and the Use of Real-Time Data

Thought Leader: John Hudak, MBA, President and Founder — Criterium Inc.

How does real-time data improve the agility of clinical trials? How can the process be improved through technology? What are the benefits of using real-time data? Are there any obstacles to be overcome? What is the impact of real-time data on sites, sponsors, and CROs? Learn the answers to these and other questions in this informative Podcast episode.
For more information, visit criteriumusa.com, or stop by Booth No. 836.

The Challenges of Pharmacogenomics

Thought Leader: Brian Spear, Ph.D., Director of Genomic and Proteomic Technologies, Global Pharmaceutical Research and Development — Abbott

Pharmacogenomics is a serious science that has the potential to revolutionize the life-sciences industry. Dr. Spear discusses the myths, misconceptions, trends, and challenges associated with pharmacogenomics and personalized medicine. In addition, he talks about the future of this groundbreaking science.
For more information, visit abbott.com.

eClinical Integration

Thought Leader: Steven Kent, CEO — ClinPhone

New technologies will play a key role in accelerating and transforming the drug-development process. In this Podcast episode, Steven Kent, CEO of ClinPhone, discusses the challenges and solutions involved with integrating different electronic systems, the barriers to adoption, the impact of regulatory standards, and the technology trends that will have the greatest impact on clinical research.
For more information, visit clinphone.com, or stop by Booth No. 1001.

EDC and After

Thought Leaders: Dr. Stephen Rhys Thomas, Senior Partner, and John F. Murray, Senior Partner — Procela Partners

Based on Procela Partners' comprehensive research into the EDC landscape, Dr. Thomas and Mr. Murray provide an independent, insiders' review of the latest trends in the EDC market, including a discussion related to convergent strategies for streamlining the adoption cycle for new technologies as well as the challenges vendors and sponsors face in implementing enterprisewide systems. They also provide a provocative preview of the e-clinical landscape after EDC.
For more information, visit procela.com.

Electronic Submissions and eCTD Challenges

Thought Leader: John Lawrie, VP, Process Solutions — Octagon Research Solutions Inc.

Submitting new drug applications electronically to regulators has many advantages for sponsors, and the life-sciences industry is progressively adopting this practice as its standard. This Podcast discusses best practices for navigating the complex waters of e-submissions and developing eCTD capabilities.
For more information, visit octagonresearch.com, or stop by Booth No. 1309.

Evolving from R&D to Commercialization

Thought Leader: Richard W. Pascoe, VP and Chief Commercial Officer — Ariad Pharmaceuticals Inc.

Transforming a company from an R&D organization into a commercialization entity can be a daunting undertaking. You'll learn about the building blocks of a commercial platform, strategic planning, inevitable obstacles, and best practices that can be used on the journey.
For more information, visit ariad.com.

Innovative Technologies in Clinical Research

Thought Leader: Anthony J. Costello, Founder and VP, Product Development and Data — Nextrials Inc.

Discover the latest technologies in clinical research, including a discussion on the ROI of technology implementations and industry adoption rates. Also covered in this Podcast are expert views on electronic data collection, electronic health records, industry standards, and regulatory guidances.
For more information, visit nextrials.com, or stop by Booth No. 2202.

Integrated Data Management and EDC Solutions

Thought Leader: Glen de Vries, Cofounder and Chief Technology Officer — Medidata Solutions Worldwide

Clinical trials can benefit greatly from standardization, integrated data management, and the right electronic data capture solution. This episode covers a variety of issues that can help you achieve better ROI from the data management tools being used in clinical trials.
For more information, visit mdsol.com, or stop by Booth No. 1327.


YOU'VE PROVOKED THE MARKET LEADER.
THEY HAVE A PLAN OF ATTACK.
WHAT'S YOURS?
WE LIVE HERE.
LIVE_BREATHE_LAUNCH
TORRE LAZUR McCANN
The intensity of a launch ignites everything we do—
every opportunity, every project, every brand.
When will you need launch intensity?
torrelazur.com

PharmaVOICE Webcast Network – Podcasts and WebLinx Interactive WebSeminars

Patient Safety and IRB Accreditation

Thought Leader: Lynn A. Meyer, CIP, CIM, President — IntegReview Ethical Review Board

Does an accredited Institutional Review Board (IRB) improve patient safety? This Podcast covers the pros and cons of accreditation and some of the issues involved in patient safety and trial efficiency during clinical trials on humans.

For more information, visit integreview.com, or stop by Booth No. 847.

Clinical Performance Management

Thought Leader: Bill Stevens, Senior Director, Life Sciences — Cognos

Organizations are looking for new efficiencies in their clinical-development processes, which has led to an industrywide push for clinical performance management solutions that can streamline and shorten the clinical development process, mitigate risk, and better support profit objectives. This WebSeminar discusses how to better understand performance to make timelier, better informed decisions to take clinical trials to the next level of performance.

For more information, visit cognos.com.

Practice Makes Perfect: eClinical Process Change and Standardization

Thought Leaders: Nikki Bonnell, Director of Technology Implementation, and Robert Sammis, Chief Operating Officer, etrials

In an examination of why e-clinical adoption in the industry is not faster, this WebSeminar covers: e-clinical cost-benefit analysis, standardization, integration, and process change.

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

DIA Exhibiting Companies at a Glance

Advanced Clinical Software (ACS), Seattle, develops mission-critical clinical-trial software for the biopharmaceutical and clinical research industries. For more information,visit studymanager.com.

Aptuit Inc., Greenwich, Conn, streamlines and supports the drug-development process for biotechnology and pharmaceutical innovators. For more information, visit aptuit.com.

Averion International Corp., Southborough, Mass., is a global clinical research organization. For more information, visit averioninc.com.

Charles River Laboratories, Wilmington, Mass., provides research models and laboratory animal support services, preclinical services, and clinical services to the biomedical market. For more information, visit criver.com.

Chiltern International Inc., Carlsbad, Calif., is a global contract research organization. For more information, visit chiltern.com.

ClinPhone Inc., East Windsor, N.J., is a clinical technology organization. For more information, visit clinphone.com.

Criterium Inc., Saratoga Springs, N.Y., is a global contract research organization. For more information, visit criteriuminc.com.

Dendrite Clinical Optimization, a division of Dendrite International, Bedminster, N.J., accelerates clinical trials and builds loyal investigators in the process. For more information, visit dendrite.com.

DSG Inc., Malvern, Pa., has been supporting clinical-trial data collection with innovative technology solutions. For more information, visit dsg-us.com.

etrials Worldwide, Morrisville, N.C., is an e-clinical software and services company. For more information, visit etrials.com.

i3 Research, Basking Ridge, N.J., an Ingenix company, is a full-service, therapeutically focused, global CRO. For more information, visit iresearch.com.

Imperial Clinical Research Services Inc., Grand Rapids, Mich., produces case report forms for the pharmaceutical and medical-device industries. For more information, visit imperialcrs.com.

INC Research, Raleigh, N.C., is a therapeutically focused contract research organization. For more information, visit incresearch.com.

Insightful Corp., Seattle, provides scalable data and text analysis solutions. For more information, visit insightful.com.

IntegReview Ethical Review Board, Austin, Texas, merges ethics and technology to accelerate the IRB process while respecting and protecting human research participants. For more information, visit integreview.com.

inVentiv Clinical, Houston, is a business segment of best-of-class providers in clinical staffing, clinical operations, biostatistics, and data management solutions. For more information, visit 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.

Kendle, Cincinnati, is a global clinical research organization. For more information, visit kendle.com.

Lifetree Clinical Research, Salt Lake City, is a specialized research organization offering multitherapeutic clinical trials management and site expertise for Phase I-III clinical trials. For more information, visit lifetreeresearch.com.

Medidata Solutions, New York, helps pharmaceutical, biotechnology, medical-device, and research organizations maximize the value of their clinical-research investments. Fore more information, visit mdsol.com.

Nextrials Inc., San Ramon, Calif., develops Web-based software solutions for the clinical-research industry. For more information, visit nextrials.com.

Octagon Research Solutions Inc., Wayne, Pa., develops process-centric solutions to aid in the electronic transformation of clinical R&D. For more information, visit octagonresearch.com.

Omnicare Clinical Research, King Of Prussia, Pa., is a global CRO. For more information, visit ominicarecr.com.

OmniComm Systems Inc., Ft. Lauderdale, Fla., provides pharmaceutical, biotech, and medical-device companies with Web-based applications that integrate the significant elements of the clinical-trial process. For more information, visit omnicomm.com.

Outcome, Cambridge, Mass., provides strategies and solutions designed to meet the needs of the postapproval market. For more information, visit outcome.com.

Parexel International Corp., Waltham, Mass., delivers a full range of clinically related services and solutions. For more information, visit parexel.com.

PharmaNet Development Group, Princeton, N.J., is a global drug development company. For more information, visit pharmanet.com.

Pharsight Corp., Mountain View, Calif., facilitates strategic decision making in drug development. For more information, visit pharsight.com.

Phase Forward, Waltham, Mass., provides integrated data collection and data management solutions for clinical trials and drug safety. For more information, visit phaseforward.com.

PHT Corp., Charlestown, Mass., provides electronic patient reported outcome (ePRO) solutions used in clinical trials around the world. For more information, visit phtcorp.com.

PPD Inc., Wilmington, N.C., is a global contract research organization. For more information, visit ppdi.com.

PRA International, Reston, Va., is a clinical development organization. For more information, visit praintl.com.

Prometrika Inc., Cambridge, Mass., is a clinical research organization. For more information, visit prometrika.com.

Spotfire, Somerville, Mass., provides enterprise analytics software. For more information, visit spotfire.com.

The Patient Recruiting Agency, Austin, Texas, develops, engineers, and places customized data-driven advertising solutions specifically targeted for patient-recruiting efforts. For more information, visit tprausa.com.

Thomson CenterWatch, Boston, is a publishing and information services company and a business of The Thomson Corp. For more information, visit centerwatch.com.

Veritas Medicine Inc. Cambridge, Mass., is a free confidential resource providing access to clinical trials and information on treatment options. For more information, visit veritasmedicine.com.