DIA ANNUAL MEETING SHOWCASE

A review of new products, tools, and services being launched by exhibitors at the 42nd Annual Meeting in Philadelphia, June 18-22.

BBK Healthcare Releases TrialCentralNet 4.0

TrialCentralNet 4.0 gives our clients the flexibility to navigate the clinical-study process, communicate real-time study status to colleagues, and make confident, data-driven decisions, says Joan F. Bachenheimer, Founding Principal of BBK.

BBK Healthcare Inc., Newton, Mass., a patient-recruitment consulting firm serving the biopharmaceutical and medical-device industries has released TrialCentralNet 4.0, a cost-effective tool to accelerate patient enrollment for clinical-research studies.

The Web-based data-management application cuts time, money, and administrative effort from clinical study life cycles and budgets — from investigative site selection through patient retention — by providing study team members anywhere in the world up-to-the-minute information with the click of a mouse.

TrialCentralNet gives key members of a clinical-study team (sponsors, clinical site staff, clinical research associates, country study managers, and patient-recruitment specialists) 24/7 access to clinical-enrollment data in a secure, password-protected Web environment that's not only user friendly, but highly functional.

The application is compatible with all operating systems and can be customized to give users a personal view — according to group or individual needs — in any language. It also provides a common location for all study-related documents, reducing the need to search multiple file directories and applications.

A document tracking feature eliminates confusion and wasted time managing version control. TrialCentralNet also integrates seamlessly with other applications study team members typically use, such as clinical trial management systems, electronic data capture, and interactive voice response systems.

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

Covance Introduces IVRS Express Services

Covance Inc., Princeton, N.J., has released its Express Suite of interactive voice response services (IVRS) for small, noncomplex clinical trials. The Express Suite comprises preconfigured solutions to address the most common patient enrollment, randomization, and drug-supply management needs of biopharmaceutical firms sponsoring trials and studies in which automated methods have previously not been a viable or cost-effective option. The suite provides sponsors with a studywide view of patient and drug-supply activities, enabling them to monitor progress, anticipate problems, and take preventive actions before they occur.

The suite leverages the drug-development services company's IVR technology.

For more information, visit covance.com or stop by Booth No. 1709.

Data Communiqué Launches Application for Bridging EDC and Print Data

CRF-Bridge allows clinical-research professionals to gracefully transition from paper to EDC at their own pace, says David Curran, CEO of Data Communiqué International.

Data Communiqué International's CRF-Bridge is an application designed to combine electronic data capture (EDC) and print in a single workflow. CRF-Bridge eliminates the need for clinical-research professionals to decide between EDC or print, while providing a cost-effective single point of contact for managing all data-collection and trial-management needs.

Data Communiqué, Carlstadt, N.J., which provides technology-enabled publishing solutions that address challenges faced at the intersection of marketing and compliance, built the tool to support both paper and EDC, from document creation through data management. Additionally, CRF-Bridge integrates with existing IT infrastructures using a familiar Web-based ASP model. The tool tracks inventory and shipments, while facilitating print, storage, and distribution anywhere in the world. CRF-Bridge also supports PDA data entry as well as interactive voice recognition.

For more information, visit datacom-usa.com or stop by Booth No. 1136.

DataLabs Releases Software Specifically for the CRO Market

Our new tool offers CROs the unified functionality of paper data entry with the flexibility of electronic data capture, which is revolutionary for the industry, says Jim Langford, President of DataLabs Inc.

DataLabs Inc., Irvine, Calif., a developer of Web-based applications for clinical-study design, data capture, and data-management tools to help CROs and biopharmaceutical companies accelerate clinical trials, has unveiled Clinical CRO Edition. This clinical-data management system allows CROs to increase revenue, lower costs, and better manage the diverse needs of their customers. CROs benefit from this software by realizing time and operational savings while increasing efficiencies in managing clinical trials.

DataLabs Clinical CRO Edition's features include modules for study design, data capture, and data management as well as capabilities that help CROs offer more robust interactions with their biopharmaceutical customers. The browser-based solution also features clinical-trial status reporting functionality, event notifications, and out-of-the-box integrations with "best of breed" external applications.

For more information, visit datalabs.com or stop by Booth No. 1829.

Elsevier Agrees to Buy Gold Standard

Elsevier, a healthcare and scientific publisher based in Amsterdam, The Netherlands, has entered into a definitive agreement to acquire the entire share capital of Gold Standard Inc. Based in Tampa, Fla., Gold Standard develops online clinical drug information products, services, and solutions for the healthcare market.

Russ Thomas, CEO of Gold Standard, remains at the company's helm.

For more information, visit elsevier.com or stop by Booth No. 317.

For more information, visit goldstandard.com.

etrials Unveils New Clinical Trial Management System

As the newest addition to the etrials eClinical Suite, CTMS can be combined with EDC, e-diaries, and IVR or used as a stand-alone application, says John Cline, CEO, etrials Worldwide Inc.

etrials Worldwide Inc. has released its Clinical Trial Management System (CTMS), a complete set of logistical tools to help pharmaceutical, biotechnology, and contract research organizations improve the efficiency and effectiveness of clinical studies.

The new system, which was developed based on a technology that etrials, Morrisville, N.C., acquired from Quintiles Transnational Corp. in April 2005, provides users with access to data via standard and customizable reports to best manage sites and project team staff.

The tool offers custom integration for seamless sharing of data with various external sources, such as IVRS, patient diaries, central lab data, and safety database adverse-event reports.

The system also provides automated alerts, monitoring report templates, grant payment management, and flexibility in granting user data access, which can be limited to a single project or site.

The new Web-based application is built on the ASP.NET platform.

etrials, which is an e-clinical software and services company, also includes a maintenance module that allows users to configure the software for specific clients, projects, and sites.

For more information, visit etrials.com or stop by Booth No. 1627.

FDA Adopts Standardized Nomenclature For Electronic Drug Labeling

In an effort to advance the federal initiative to create electronic health records for Americans within the next decade, the FDA has adopted the Systematized Nomenclature of Medicine (SNOMED) as the standard computerized medical vocabulary system to be used to electronically code important terms in the highlights section of prescription drug labeling.

This initiative allows healthcare professionals nationwide to electronically access and share critical health and treatment information more easily and efficiently.

The SNOMED system, developed by the College of American Pathologists (CAP), provides coding for clinical terminology to make it computer readable across

Once we have implemented a national e-health record, health professionals will have quick, reliable, and secure access to patient information that can be cross-referenced with critical treatment information, says Dr. Andrew C. von Eschenbach, FDA Commissioner.

systems. The use of SNOMED in the highlights section of prescription-drug labeling will enhance the interoperability of electronic systems exchanging FDA-approved labeling information in the care of patients.

Specifically, the FDA is adopting the "Problem List" subset of SNOMED. The subset can electronically code certain terms in the highlights data elements of the new format for prescription-drug information.

This use of SNOMED for medical-product labeling is expected to improve the domestic exchange of product information in FDA-approved package inserts. The format will be required starting June 30, 2006, for newly approved products as well as those approved within the last five years.

For more information, visit fda.gov or stop by Booth No. 400.

inVentiv Health Expands Promotech and GSW Worldwide Divisions

Promotech and GSW Worldwide — two divisions of inVentiv Health Inc. — have expanded their operations to meet the needs of their healthcare client bases.

Promotech, part of inVentiv Commercial, has expanded its state-of-the-art literature warehouse and fulfillment center in Louisville, Colo., by 19,500 square feet. The expansion doubles the amount of warehouse and distribution space.

Promotech, which provides marketing support services to healthcare clients, also has grown its print services competency by adding services that support expedited PI printing, high-quantity form production, and expanded four-color print production.

Across all of our GSW Worldwide locations, we've experienced growth over the past six months, and this new office is a result of that expansion, says Phil Deschamps, President and CEO, GSW Worldwide.

In related news, GSW Worldwide, a Westerville, Ohio-based division of inVentiv Communications and one of the largest healthcare advertising agencies in the world, has opened a new office in Newtown, Pa.

Led by Mark Frank, executive VP/general manager, the office houses about 35 employees. According to GSW managers, the company is looking to add between 20 and 25 new jobs in Pennsylvania, including a variety of positions in account services, creative, and creative services/production.

For more information, visit inventivhealth.com or stop by Booth No. 1458.

Invivodata Expands Wireless Solutions and Consulting Services

Invivodata Inc., Pittsburgh, a behavioral science, information technology, and clinical expertise company has added the Enfora Wireless Portfolio to its established line of global ePRO solutions, giving clinical-trial sponsors additional options for reliably capturing critical patient-reported outcomes (PRO) data across global clinical trials.

Given the recent FDA draft guidance, sponsors must be certain that their PRO research strategies meet regulatory expectations, says Bob Young, President of PRO Consulting and Senior VP, Sales and Marketing, at Invivodata. Inc.

By giving wireless capabilities to handheld devices, the Enfora Wireless Portfolio enables trial sponsors to provide clinical-trial patients with a portable device that can upload PRO data regardless of the country in which it is being used or the type of phone connection the patient has at home. Its portability ensures that sponsors that require visibility into real-time patient data will have access to critical PRO information as close to the point of patient experience as possible.

In related news, invivodata's PRO Consulting division, the firm's scientific and regulatory consulting arm, has expanded its services to help clinical-trial sponsors optimize PRO-data collection and adhere to the draft guidance recently issued by the FDA on the use of PRO measures in clinical trials.

The four new services include: PRO Audit, providing strategic review of PRO measures in a trial, program, division, or company to ensure that practices are in line with FDA expectations; PRO Migration and Validation, offering expert counsel on the type and degree of revalidation required when assessments are migrated from paper to electronic methods; PRO File, delivering a structured review of a PRO instrument or set of instruments, thus resulting in comprehensive documentation about the psychometric properties and regulatory compliance of the implementation; and PRO Meetings, a collaborative process through which the scientific and regulatory experts of PRO Consulting prepare sponsors for and, if requested, accompany them to meetings with FDA reviewers.

For more information, visit invivodata.com or stop by Booth No. 801.

Medidata's Rave 5.5 Empowers Global Trial Management

New York-based Medidata Solutions Worldwide, which provides EDC, management, and reporting solutions to streamline clinical trials, has released Rave 5.5.

Rave 5.5 is the first EDC product that allows sponsors to run all of their clinical-trial operations — regardless of the study phase, geography, or language requirements — on one global platform. Unlike other products that require different software versions for each language, Rave 5.5 offers one unified solution that can be viewed in any language — thereby creating a fluid platform and central repository for all data managers and clinicians working in worldwide locations.

Sponsors are now able to capture, manage, and report on clinical data in the language of their choice and gain earliest visibility into critical data to drive better decision-making, increase ROI, and reduce overall risk, says Tarek Sherif, CEO, President, and Cofounder of Medidata Solutions Worldwide.

A complete clinical data-management solution, Rave 5.5's features include a local language translation workbench, application screens, and study definitions such as form names. Users can work in any language against a single, global, centrally-managed repository of clinical data. Web-based tools allow for the translation of data-entry screens into multiple languages; and pick-list data can be presented to users in their local language and automatically translated for reporting and analysis. Sponsors avoid the burden of recreating separate clinical research forms (CRFs) in multiple languages.

Additionally, Rave 5.5's double data entry (DDE) feature allows for paper and paper/EDC hybrid studies to be run on a common platform. Both heads-up and heads-down DDE processes can be run within the same enterprise-level installation, which sites use to directly enter data over the Web.

Rave 5.5 also includes a new Central Lab Data feature, which allows for the definition of central labs and their corresponding ranges and can be automatically varied according to any user-defined criteria, such as age, sex, and fasting status.

For more information, visit medidata.com or stop by Booth No. 229.

Microsoft Partners with Life-Sciences Leaders to Form BioIT Alliance

Life-sciences companies have unique technical challenges, such as the need for more comprehensive data-integration solutions, better technical collaboration, and stronger knowledge-management capabilities. With this in mind, Microsoft Corp., Redmond, Wash., has formed the BioIT Alliance, a cross-industry group working to improve biomedical information technology on the Microsoft platform.

By bringing together people from innovative life-sciences organizations that span the biomedical industry, the BioIT Alliance will play an important role in the development of solutions that transform today's data into knowledge and improve the quality of millions of lives, says Bill Gates, Chairman and Chief Software Architect of Microsoft Corp.

The alliance unites the pharmaceutical, biotechnology, hardware, and software industries to consider innovative ways to address biomedical IT challenges and use technology to reduce costs, streamline research, and market their products more effectively. It explores new ways to share complex biomedical data and collaborate among multidisciplinary teams to ultimately speed the pace of drug discovery and development and, make personalized medicine a reality.

Founding members of BioIT Alliance include: Accelrys Software Inc., Affymetrix Inc., Amylin Pharmaceuticals Inc., Applied Biosystems, and The Scripps Research Institute, among more than a dozen industry leaders. The organizations have already begun to collaborate on solutions that target common technology problems faced by life-sciences companies. The first of these solutions is the Collaborative Molecular Environment, which

provides a means for data capture, visualization, annotation, and archiving using Microsoft Office, Windows Presentation Foundation, and SharePoint Technologies.

Along with making data easier to manage, early efforts of the alliance are focused on making data easier to share. The BioIT Alliance is providing independent software vendors with industry knowledge that helps them commercialize informatics solutions more quickly and with less risk.

For more information, visit microsoft.com or stop by Booth No. 401.

Octagon Offers eCTD Training

Octagon Research Solutions Inc. has initiated an interactive training program on the practicalities and processes of electronic publishing and submission compilation.

The course — eCTD 101: Introduction to the Electronic Common Technical Document — is designed to facilitate awareness and understanding of the practical issues and challenges that arise in the implementation of the electronic common technical document (eCTD). The one-day program covers practical examples of life-cycle management and strategies for tracking continuous applications, using case studies, meta data gathering activities, and common submission scenarios to reinforce presentation topics.

We have developed these programs simply to promote both knowledge and a better understanding of the regulatory submission landscape, says Jim Walker, Chairman and CEO of Octagon Research Solutions Inc.

The training courses feature Octagon's VP of Regulatory Affairs Nancy Smerkanich as the primary instructor. Ms. Smerkanich has participated in more than 100 electronic submissions, has led multiple tutorials and training programs, and continues to provide leadership and actively participate in industry activities, such as the Drug Information Association SIACs.

The first program took place in May at the process-centric solutions provider's Wayne, Pa., headquarters. Additional training programs are scheduled throughout the United States and Canada:

Octagon's eCTD 2006 Training Schedule

July 19	Chicago	Embassy Suites, Lakefront
Aug. 16	San Francisco	Embassy Suites, Bay
Sept. 13	Boston	Hotel at MIT
Oct. 4	Toronto	Sutton Place Hotel
Nov. 8	Tampa, Fla.	Embassy Suites, Tampa

For more information, visit octagonresearch.com or stop by Booth No. 1809.

Parexel Expands Global Presence

Parexel International Corp., Waltham, Mass., has opened an office in Mexico City to provide clinical research and consulting services. The new office marks the biopharmaceutical outsourcing organization's fourth location in Latin America.

Parexel's Mexico City site enhances opportunities for clients to conduct clinical-research programs in Mexico, Central America, and throughout Latin America. Like the contract service company's three other South American locations in Argentina, Brazil, and Chile, the Mexico City office offers clients regulatory advice for drug development as well as a broad range of Phase II-IV study services, including project management, site management, data management, biostatistics, and medical services.

For more information, visit parexel.com or stop by Booth No. 1024.

Pharsight Releases DMX Web Server

Pharsight Corp., Mountain View, Calif., has launched version 1.5 of its Drug Model Explorer Web Server (DMX). The Web-based tool allows clinical drug-development teams to present and exchange complex information on modeled drug attributes and to efficiently compare probable outcomes based on different treatment strategies, patient populations, and competing products.

The new release supports increased compatibility with customer requirements for deployment of Web applications and allows future DMX releases to take advantage of Microsoft .NET technologies.

DMX continues to support Microsoft's leading database product, SQL Server, as well as Oracle. The solution also continues to process simulations created in SAS XPORT transport format, a data exchange mechanism accepted by the FDA, as well as S-PLUS, a leading analysis software product.

"Enhancement of the DMX architecture using .NET technologies responds to our customers' drug-development technology infrastructures and deployment requirements for enterprise Web applications," says Shawn M. O'Connor, president and CEO of Pharsight, which develops integrated products and services that help pharmaceutical and biotechnology companies achieve enduring improvements in the development of therapeutic products.

For more information, visit pharsight.com or stop by Booth No. 1658.

Phase Forward Offers Out-of-the-Box FDA-Mandated Standardization of Clinical-Trial Input

Phase Forward, Waltham, Mass., a provider of integrated data-management solutions for clinical trials and drug safety, has released Central Coding for InForm. The Web-based application, which is optimized to work with InForm Integrated Trial Management (ITM), Phase Forward's EDC product, automatically standardizes clinical-trial data input to provide cleaner data more quickly and efficiently.

Central Coding for InForm features the following:

Data coding involved in trials is one of the most critical aspects — and one of the most in need of efficiency improvement; in response we have designed Central Coding for InForm, says Bob Weiler, President and CEO, Phase Forward.

- Centrally optimized process control, offering centralized collection and management capability since clinical trials are often geographically distributed.
- Coding-centric workflow, including workflow automation capabilities that originate with the InForm system for verbatim terms and can initiate auto-code and auto-approval of coded terms.
- Out-of-the-box integration with InForm, which can save sponsors and CROs valuable time and money.
- Advanced dictionary administration, supporting unlimited coding dictionaries and versions.
- 21 CFR Part 11 compliance and adherence to good clinical practices (GCPs) for documentation, validation, and auditing.

For more information, visit phaseforward.com or stop by Booth No. 1427.

PHT's eSense PiKo Seeks to Improve Clinical Data Quality

PHT Corp., Charlestown, Mass., has unveiled eSense PiKo, developed in collaboration with PiKo manufacturer Ferraris Respiratory, Louisville, Colo., a developer and manufacturer of respiratory-care products and services. The eSense PiKo relies on a wireless personal area network to integrate objective measurement of respiratory function with e-diary entries by subjects in clinical trials reporting on their experiences (symptom impact and behavior). This new offering is one of several eSense devices that expands the possibilities and improves the quality of clinical-data collection across dozens of therapeutic areas, including respiratory and asthma trials.

By enabling PiKo to communicate directly and wirelessly with our LogPad System, PHT and Ferraris have created an important opportunity in clinical research: helping study sponsors improve the quality and reliability of the self-reported subject data they collect, says Phil Lee, President and CEO of PHT Corp.

The customized eSense PiKo monitors are equipped with special radio-sensor technology that wirelessly and automatically transmits all data from the PiKo directly to the subject's handheld e-diary. Subjects then enter additional self-reported information on the PHT eSense LogPad and submit the completed diary to a centrally hosted server. Study sponsors and site coordinators can then access the data in real-time using the PHT StudyWorks online portal.

PHT, which provides ePRO solutions for clinical trials worldwide, designed PiKo to be user friendly and unlike other wireless communication technologies; the protocol is designed for ultra-low power, wearable sensors that are capable of storing and sending data. This enables subjects to use the eSense PiKo without having to carry the LogPad with them throughout the day.

For more information, visit phtcorp.com or stop by Booth No. 524.

For more information, visit ferrarisrespiratory.com or stop by Booth No. 1561.

DIA ANNUAL MEETING SHOWCASE

A review of new products, tools, and services being launched by exhibitors at the 42nd Annual Meeting in Philadelphia, June 18-22.

Quintiles Launches Expanded Partnering Group Under NovaQuest Brand

Quintiles Transnational Corp., Research Triangle Park, N.C., has expanded its strategic partnering group under the NovaQuest brand and, to further NovaQuest's mission, has entered into an alliance with TPG-Axon Capital, a global investment firm. NovaQuest helps life-sciences companies realize greater value from their product portfolios through innovative strategic partnering solutions.

TPG-Axon, led by the former head of Goldman Sachs' Principal Strategies Department, Dinakar Singh, will be NovaQuest's first-line partner for significant codevelopment and copromotion investments.

Since 2000, when Quintiles started a formal strategic partnering function, more than $1.5 billion has been invested or committed to Quintiles' partnerships with companies of all sizes. Within NovaQuest are Quintiles' key investment partnering functions, including agreement structuring and due diligence (formerly known as PharmaBio Development) and alliance management.

Through its alliance with TPG-Axon, NovaQuest has access to capital to fund strategic partnerships of virtually any size.

NovaQuest offers partnering solutions in three major categories: codevelopment and copromotion investments in which NovaQuest invests with cash or Quintiles services, or a combination of both, in a customer's drug-development or commercialization programs.

For more information, visit quintiles.com or stop by Booth No. 601/701.

Radiant Research Sells 8 Sitesto Covance

Radiant Research Inc., Bellevue, Wash., a comprehensive clinical research company, has agreed to sell eight early-phase clinical-development sites to Covance Inc., Princeton, N.J., a drug-development services company. The estimated purchase price is $65 million.

These sites, which generate about $25 million in annual revenue, are expected to expand Covance's Phase I/IIa trial capacity. The eight facilities are located in: Austin, Texas; Boise, Idaho; Dallas; Daytona, Fla.; Gainesville, Fla.; Honolulu; Portland, Ore.; and San Diego.

For more information, visit radiantresearch.com or stop by Booth No. 1044.

For more information, visit covance.com or stop by Booth No. 1709.

Wolters Kluwer's Pharma Information Tool Speeds Business Development Analysis and Targeting

For pharmaceutical and biotechnology companies, finding the right partner at the right time can make the ultimate difference between the success or failure of an intellectual property asset. Traditionally, there has been no simple way for either the buyer or seller of health assets to bring together all of the information they need to make a partnering decision.

In response to this need, Wolters Kluwer Health, Conshohocken, Pa., a unit of Wolters Kluwer, has introduced Adis Business Development & Licensing Insight (BD&LI), a powerful search system that helps pharma companies zero in on potential partnering opportunities. Adis BD&LI provides an overview of drug-related intellectual property information and a new means for companies to present the science behind their assets.

Wolters Kluwer Health's new tool provides in-depth commercial, scientific, and intellectual property information for each opportunity — all in one database.

Adis BD&LI is sold as a subscription service, searchable by indication. The oncology subset was the first released, with other therapeutic areas to follow throughout the coming year.

For more information, visit wkhealth.com or stop by Booth No. 447.

Adis BD&LI is the new tool for pharma business development. We've made it searchable by therapeutic area right down to a specific molecule. It's going to unlock the door to a multitude of potential in-licensing and acquisition opportunities, says John Monahan, President and CEO of Wolters Kluwer Health Pharma Solutions.