2016 DIA PREVIEW

A look at new tools, services, and products to improve drug development, as well as personnel appointments, from DIA 2016 exhibitors.

This year's annual meeting of the Drug Information Association is expected to draw more than 7,000 attendees for the largest global interdisciplinary gathering of life-sciences professionals. DIA 2016 is packed with more than 175 educational offerings over 22 tracks on today's hottest topics, and more than 450 companies will be exhibiting. This year's meeting will be held in Philadelphia, from June 26 to June 30.

The keynote address will be given by Larry Brilliant, M.D., acting chairman of the board of the Skoll Global Threats Fund, whose mission is to confront global threats like pandemics, climate change, water, nuclear proliferation, and the Middle East conflict.

He is board certified in preventive medicine and public health and co-founder of The Seva Foundation, an international NGO whose programs and grantees have given back sight to more than 3.5 million blind people in more than 20 countries.

New this year is the inclusion of DIAmond Sessions: Conversations on Today's Priorities. Top thought leaders will discuss global, interdisciplinary topics about the future of therapeutics. These sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts and to have a conversation on today's priorities. Sessions include discussions about regulatory convergence, changing cultures to advance patient engagement, next-generation collaborations, the future of big data, and outcomes-based healthcare.

Also new this year are Engage and Exchange Sessions: you spoke, we listened. These sessions in the exhibit hall allow attendees to engage with other attendees in a new, collaborative learning environment for peer-to-peer networking and education.

New Tools

Almac Group Launches U.S. Serialization Solution

ALMAC GROUP, the global contract development and manufacturing organization, has expanded its **serialization capabilities to include its U.S. commercial packaging facility in Audubon, PA**. Building upon Almac's in-house expertise and proprietary serialization/track and trace solution developed at its UK headquarters, this technology expansion addresses FDA regulations and meets the requirements of the Drug Quality and Security Act.

Almac has partnered with Optel Vision to provide a versatile line level solution (hardware and software) that integrated with Almac's in-house proprietary level 3, site level software. This new serialization solution is a high-spec stand-alone line that prints, verifies, and aggregates saleable packs through to the pallet with reporting functionality to ensure the client can meet the traceability requirements of the various markets.

Grainne Hughes, operations manager at Almac explains: "To expand the solution into our U.S. operations we decided that we needed an experienced partner that could integrate with our innovative product serialization site level software."

For more information, visit almacgroup.com.

DIA Booth No. 1035

Bioclinica and ArisGlobal Partner to Offer Pharmacovigilance Model

BIOCLINICA, a specialty clinical trials technology and services provider, has selected **ArisGlobal's Safety Cloud** as the preferred safety platform for its pharmacovigilance services.


Mukhtar Ahmed

Under this partnership, Bioclinica becomes the preferred partner for ArisGlobal in business process consulting and change management as sponsors implement or upgrade ARISg.

Together the partnership brings a flexible delivery model that fits any organization regardless of size or case volume.

ArisGlobal and Bioclinica's Safety and Regulatory Solutions division (formerly known as Synowledge) formulated this comprehensive partner strategy to deliver cost-effective and regulatory compliant services.

Bioclinica's Global Consulting group provides organizations with business and change management expertise when implementing or upgrading to new versions of ARISg, including ROI optimization, SOP creation, system validation and development of agile database conventions.

"The formation of this partnership addresses the full continuum of pharmacovigilance as a service," says Bioclinica President of eHealth Solutions Mukhtar Ahmed. "Together Bioclinica and ArisGlobal provide the most comprehensive solution, whether an organization wants to handle safety internally or outsource it to our team of safety experts."

For more information, visit bioclinica.com.

DIA Booth No. 725

For more information, visit arisglobal.com.

DIA Booth No. 1925

Bracket Announces New Patient Engagement Tools

BRACKET, a leading clinical trial specialty ser-


Dr. David Daniel

vices provider, announced platform updates to **Bracket eCOA** and **Bracket RTSM** to include native support for SMS messaging with patients and other stakeholders in clinical research programs. This update expands the medication compliance and adherence functionality across Bracket's eClinical portfolio and provides an effective solution for supporting patients participating in clinical trials.

In addition to direct-to-patient communication, the mobile text messaging platform can be leveraged to issue alerts to clinical trial sites, study sponsors, and CROs who are working with Bracket's RTSM and eCOA tools.

"Medication adherence is a critical variable in clinical trial success. Introducing a simple and effective communication tool like SMS could robustly improve compliance to medication regimens and a broad range of clinical trial procedures," says Dr. David Daniel, chief medical officer of Bracket.

For more information, visit bracketglobal.com.

DIA Booth No. 715

Exco InTouch Launches Data Capture and Mobile eCOA Solutions

EXCO INTOUCH has launched **Gather**, a product suite that addresses the key industry challenge of developing solutions that engage with all the major clinical trial stakeholder groups — expanding the reach of digital technology beyond patients to sponsors, study teams and site managers.

In the current environment, with such large volumes and range of data being collected during clinical trials, there is a critical need for a powerful system that can process and analyze data to generate meaningful insights and easy-to-understand reporting. An easy-to-use product suite is called for that fits easily into the everyday lives of sponsors, sites and study teams which removes silos and fully connects eCOA with, for example, workflow integration and reporting.

With Gather, sponsors are now able, for example, to have a macro-level view of the performance of a clinical trial, multiple trials, receive real-time data and use straightforward reporting tools.

Tim Davis, CEO and founder of Exco InTouch says: "DIA provides us with a highly beneficial platform to share our insights into how best to meet the current, pressing clinical trials challenges, whilst further strengthening our leadership position in the application of mobile in eCOA and patient engagement solutions."

For more information, visit excointouch.com.

DIA Booth No. 624

goBalto Delivers Study Startup Platform for Clinical Trials

GOBALTO, a provider of cloud-based clinical study startup solutions, has released **goBalto Select**, for optimizing site selection. With this release, goBalto offers a complete end-to-end platform for starting clinical trials, from site feasibility assessment and selection through to activation, with comprehensive metrics to track adherence to timelines and budget. Select provides a data-driven approach to weighing selection and performance variables to aid in the identification of sites and target populations ideally suited to studies.

For more information, visit gobalto.com.

DIA Booth No. 1204

Merge Releases Digital Offerings To Help Streamline Site Monitoring

THE ELINICAL DIVISION OF MERGE, an IBM company now offers powerful clinical site monitoring functionality inside its eClinicalOS data capture platform. A new optional module, **Monitor Management**, is a collaborative digital environment that helps site monitoring teams become more productive and efficient. The company also introduced **Monitoring Levels**, a targeted source data verification (SDV) tool that helps further reduce the monitoring burden. Through a partnership with Remarque Systems, eClinicalOS now also offers access to the risk-based monitoring (RBM) platform **Remarque RBM,** which is a knowledge engine that uses machine learning and statistical algorithms to predict, detect, analyze, and manage risk.

For more information, visit eclinicalos.com.

DIA Booth No. 607

Montrium Releases eTMF Navigator to Provide Business Intelligence in Trials


Paul Fenton

MONTRIUM, clinical trial technology specialists, and electronic content management software providers, has released the **eTMF Navigator,** an interactive intelligence dashboard integrated into eTMF Connect.

The eTMF Navigator leverages all of the information and documentation that surrounds your clinical trial and provides a visual, real-time, multi-dimensional view of TMF completeness. Clinical users now have the ability to manage their ongoing studies directly in the navigator by updating artifacts, sites or country information from a single location. As the study progresses, users can dynamically view the status of specific TMF artifacts and gain greater insight into clinical trial events and compliance. In addition, the introduction of the eTMF Navigator gives greater flexibility during audits and inspections with a dedicated inspector view. The eTMF Navigator tool is integrated with eTMF Connect, Montrium's electronic trial master File (eTMF) application, bolstering its already comprehensive set of features.

"Traditionally, clinical teams have found it increasingly difficult to leverage TMF information to drive better clinical decisions due to its inherent complexity," says Paul Fenton, president and CEO at Montrium. "The eTMF Navigator cuts through this complexity, allowing users to navigate across hundreds of thousands of TMF artifacts from a single centralized location, enabling them to identify and instantly modify all available, expected or missing artifacts in one interface."

For more information, visit montrium.com.

DIA Booth No. 2141

Parexel and EMC Form Alliance to Provide Cloud-Based Services


Dr. Paul Bidez

PAREXEL, a global biopharmaceutical services organization, and EMC have entered into an alliance to offer an end-to-end **regulatory information management (RIM)** and regulatory content management solution.

By combining Parexel Liquent InSight Regulatory Information Management platform and EMC Documentum for Life Sciences software solution suite, the companies now provide life-sciences companies with a complete solution for a product's entire regulatory lifespan. Life-science companies can use the solution for strategy and planning, authoring, publishing, submitting, viewing, archiving, and lifecycle management for a product. The offering is available through Parexel's Regulatory Cloud, a life-sciences content and regulatory information management solution structured within a dedicated, private cloud environment.

"A life-sciences company must navigate the complex, global and region-specific regulatory landscape to maintain registration and compliance for a product," says Paul Bidez, Ph.D., VP and global head of regulatory solutions at Parexel.

For more information, visit parexel.com.

DIA Booth No. 825

Newest Release of Veeva Vault Streamlines Global Business Processes


Jennifer Goldsmith

VEEVA SYSTEMS has introduced innovative features in its newest release of **Veeva Vault, version 14**. The Veeva Vault platform and suite of enterprise applications empower life-sciences companies to streamline their business processes across an increasingly broad ecosystem of internal and external stakeholders.

Today, many life-sciences companies use a multitude of disconnected, complex systems to manage critical content. This fragmented approach leads to process inefficiencies and increased regulatory risk.

Veeva counters this with Veeva Vault, a cloud-based content management platform and suite of applications that provide a single source of truth to reduce complexity and increase business agility. Veeva Vault not only manages regulated documents, but also tracks critical information for product development and commercialization processes. New capabilities include the ability to more accurately plan and track documents; provide better insight; and improve business processes.

"We continue to innovate at a rapid pace to deliver new levels of enterprise speed and compliance for our customers to improve their global business processes," says Jennifer Goldsmith, senior VP of Veeva Vault. "Veeva Vault is enabling life sciences companies to lower the cost, complexity, time, and compliance risk of developing and bringing new products to market."

For more information, visit veeva.com.

DIA Booth No. 1308

What's New

PharmaSeek Partners with PRCCI to Enhance Clinical Research in Puerto Rico

PHARMASEEK, an investigative site network, is expanding the reach of its network by partnering with the **Puerto Rico Consortium for Clinical Investigation (PRCCI)**. PRCCI is a newly established not-for-profit cooperative comprised of multiple clinical research sites throughout Puerto Rico. Through a collaborative network of investigators and the support of PharmaSeek, PRCCI will promote and enhance clinical research and drug development in Puerto Rico.

The setup of PRCCI's network will largely mirror that of PharmaSeek, which has grown to more than 250 research sites throughout the United States and Canada, and represents research in nearly all therapeutic areas. In addition to study identification, PharmaSeek provides assistance with site feasibility, contract and budget negotiation, and accounts receivable. At the forefront of these efforts will be PharmaSeek's Director of Network Operations, Jill Shilbauer, who will be stationed in Puerto Rico to provide on-site support

For more information, visit pharmaseek.com.

DIA Booth No. 1906

PPD Expands Medical Communications Operations into Asia-Pacific Region


Vivian Broach

PHARMACEUTICAL PRODUCT DEVELOPMENT has expanded its medical communications services into the Asia-Pacific region, enabling the contract research organization (CRO) to offer its portfolio of multi-lingual contact center services across the globe. By adding to its existing medical communications operations in North America, Latin America and Europe, PPD now is able to extend its services to biopharmaceutical clients in all regions of the world. PPD's Asia-Pacific medical communications operations are managed by teams in Tokyo and Singapore.

"Expanding our multi-channel medical communications operations into Asia-Pacific strengthens our ability to provide our clients a single source of global medical information services," says Vivian Broach, VP of operations and head of PPD's medical communications operation. "That ensures consistency of operations around the world while continuing to deliver high-quality health care services and expertise in an efficient, regulatory-compliant and customer-centric manner. There is strong demand for these services globally, and we have an experienced management team in place to oversee our operations and to create flexible and customized programs that meet our clients' needs at either a global or regional level."

For more information, visit ppdi.com.

DIA Booth No. 701

Veristat Expands Clinical Operations into Europe


Patrick Flanagan

VERISTAT, a full-service CRO, **has expanded its clinical research offerings into Europe** through the acquisition of UK-based CRO, Spero Oncology. Spero Oncology specializes in providing clinical operations support for oncology clinical trials primarily throughout Europe, but also in Australia and New Zealand. With this acquisition, Veristat now offers its clients full clinical operations support in Europe including feasibility studies, legal representation in the European Union, clinical monitoring, project management, protocol writing, and regulatory strategy.

"Veristat's expansion into Europe marks an important milestone in our history," says Patrick Flanagan, CEO of Veristat. "Adding the Spero Oncology team to Veristat will strengthen our ability to deliver value to our clients' multi-national trials throughout North America and Europe. We feel that this team is a great fit culturally and professionally and will enhance our ability to make a difference in the trials we perform on behalf of sponsors."

Veristat has appointed Spero's Founder and Managing Director Theresa Bruce, to the newly created position of VP of clinical operations at Veristat.

For more information, visit veristat.com

DIA Booth No. 1136

WIRB-Copernicus Group Acquires Clintrax


Dr. Donald Deieso

WIRB-COPERNICUS GROUP, a provider of solutions that measurably improve the quality and efficiency of clinical research, has announced that **Clintrax Global has joined its family of companies**. Founded by former biopharmaceutical and clinical research organization (CRO) attorneys, Clintrax Global provides outsourced services for negotiating clinical trial-related

contracts and budgets between biopharmaceutical companies, CROs and investigator sites around the world.

"WCG's solutions help biopharmaceutical companies reduce the time, cost and risks associated with bringing new therapies to market, while assuring the highest quality of human subject protection," says WCG Chairman and CEO Donald Deieso, Ph.D. "Our biopharmaceutical and institutional clients continue to cite — among the top impediments to clinical trial activation — the delays associated with negotiating study budgets and contracts. By adding Clintrax Global to the WCG family of companies, we can now offer them a more comprehensive and integrated suite of study start-up solutions."

Clintrax Global continues to operate as an independent company and its headquarters remain in Raleigh, N.C.

For more information, visit wcgclinical.com.

DIA Booth No. 1313

Talent Pool

ArisGlobal Expands with Appointments of Dr. Vivek Ahuja, George Phillips, and Stephen Schmidt


Dr. Vivek Ahuja


Stephen Schmidt

ARISGLOBAL, a provider of cloud-based software solutions for life sciences, **has appointed key leaders in the safety and pharmacovigilance team** to bring a wealth of insight to a growing business.

George Phillips joined ArisGlobal in the position of VP - safety. Mr. Phillips has more than 30 years' experience in pharmacovigilance. He worked for UCB, where he held the position of VP, digital safety surveillance. He is a registered pharmacist and received his Pharm.D., degree from Purdue University in West Lafayette, Indiana.

ArisGlobal has created the National Competent Authorities (NCA) to address the needs of health authorities. Dr. Vivek Ahuja leads this initiative as the VP - global pharmacovigilance. Dr. Ahuja was director, research and development at PATH India. Dr. Ahuja is a Bachelor of Medicine and Bachelor of Surgery (MBBS) from Government Medical College, Chandigarh, India and an MD from All India Institute of Medical Sciences, New Delhi.

Stephen Schmidt has joined as the product manager - safety. Before joining ArisGlobal, he was a senior safety systems analyst within the medical safety department at Alcon.

For more information, visit arisglobal.com.

DIA Booth No. 1925

BBK Names André Briola to Executive Management Team

BBK WORLDWIDE, a full-service marketing and technology firm serving the clinical research industry, **has expanded its senior management team with the addition of André Briola,** a long-standing strategic consultant to BBK's biopharma, medical device and pharmaceutical client base.

The appointment supports the company's continued growth and global expansion, fueled in part by increased demand for patient-centric solutions, including mobile apps, card-based study reimbursements and full-service travel support.

Mr. Briola brings more than 15 years of recruitment, regulatory and clinical research experience to his critical role at the helm of strategy and business development at BBK, where he has developed hundreds of programs to support successful study enrollment for clinical trials across a variety of therapeutic areas, from small, rare disease studies to large, multinational programs.

For more information, visit bbkworldwide.com.

DIA Booth No. 1610

Christian Hebenstreit Joins Medidata


Christian Hebenstreit

MEDIDATA, a leading global provider of cloud-based solutions for clinical research in life sciences, **has announced that Christian Hebenstreit has joined the company** as managing director of EMEA (Europe, the Middle East and Africa). Reporting to Medidata's chief operating officer Mike Capone and working from Medidata's EMEA headquarters in London, Mr. Hebenstreit heads up all operational functions in the region, playing an integral role in the development and execution of the company's overall growth strategy and success within the EMEA market.

Mr. Hebenstreit joins Medidata from Salesforce.com, where he was the regional VP for Central Europe.

For more information, visit mdsol.com.

DIA Booth No. 2125

PPD Strengthens Oncology with the Addition of Dr. Panteli Theocharous


Dr. Panteli Theocharous

PHARMACEUTICAL PRODUCT DEVELOPMENT has appointed Panteli Theocharous, Ph.D., VP of global product development in the hematology/oncology therapeutic area.

Dr. Theocharous most recently served as VP and head of clinical and medical affairs at Cell Therapeutics, Life Sciences in London. He earned a master's degree in applied clinical hematology from the University of Westminster; and higher degrees in medicine, specializing in hematological oncology, from the Royal Free and University College Medical School at the University of London.

In other news, PPD has announced that Hacene Mekerri has joined the company to serve as VP of its central laboratory organization. Mr. Mekerri has more than 15 years of management experience in the drug development industry, including with laboratory companies, CROs and pharmaceutical companies.

In his most recent post, he served as managing director for the Asia Pacific region of a large CRO.

For more information, visit ppdi.com.

DIA Booth No. 701

Pharm-Olam International Adds Tricia Bland to Management Team

PHARM-OLAM INTERNATIONAL, a multi-national, full-service clinical research solutions organization to the biopharmaceutical and medical device industries, **has appointed Tricia Bland to its management team** as the executive director, strategic projects.

Ms. Bland brings more than 20 years of demonstrated success in the clinical research industry, leading and implementing global development strategies and successfully managing global teams. She is based in Pharm-Olam's Research Triangle Park, North Carolina office.

Ms. Bland provides executive-level leadership to both staff and sponsors, strategic relationship management, and implementation of process improvement programs aimed at increasing efficiencies and improving data quality.

For more information, visit pharm-olam.com.

DIA Booth No. 811 PV