2014 DIA Preview

New tools, services, and products to improve drug development — as well as personnel appointments — from DIA exhibitors.

This year marks the 50th Anniversary of the Annual Meeting of the Drug Information Association, the largest multidisciplinary event that brings together a global network of life-sciences professionals to foster innovation. The meeting is being held in San Diego and has as this year's theme Celebrate the Past — Invent the Future.

The keynote will be given by Jamie Heywood, founder and chairman of PatientsLikeMe, a Web-based community that allows patients to pool their experiences about disease and treatment. He is also the founder of ALS Therapy Development Institute, a nonprofit biotech company he founded after his brother was diagnosed with ALS. (Mr. Heywood was also a 2013 PharmaVOICE 100 honoree.)

Innovation will be a key topic at the meeting. DIA, in partnership with the Tufts Center for the Study of Drug Development, will convene healthcare experts for a forum called The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances and Precision Medicine.

This two-part session will review the roles of innovative, collaborative partnerships and strategic alliances in the discovery, development, and commercialization of new medical products and examine the ramifications of the industry's shift to targeted and precision medicines, as well as the impact smaller patient populations and smaller market opportunities are having on portfolio and R&D investment decisions.

One highlight of the meeting is a look at GetReal, a collaborative project recently launched by the European Union's Innovative Medicines Initiative (IMI). As Europe's largest public-private partnership, IMI seeks to create better and safer medicines for patients by supporting more effective discovery of information in the drug development process.

The GetReal project connects health technology assessment agencies, industry and regulatory bodies with academia, subject matter and patient group experts to enhance this discovery process by better understanding how real-world data and analytical techniques can inform and improve drug development.

"Our annual meeting is a global platform to facilitate innovation that will change the future of healthcare," says Barbara Kunz, DIA global chief executive. "The GetReal project exemplifies the collaboration needed to bring safer and better products to patients around the world."

Incorporating data from real-world clinical settings into drug development and associated decision-making represents a serious challenge for pharmaceutical companies, regulators, and health authorities; the GetReal project unites these key stakeholders to develop new approaches and greater consensus.

The DIA forum will focus specifically on the challenges in implementing alternative drug development strategies prior to medicine authorization, and explain how global drug development plans can better incorporate relative effectiveness objectives, real-world data, and analytical techniques prior to this authorization.

This year's meeting features more than 260 sessions across 21 tracks and more than 450 exhibiting companies. FDA Commissioner Margaret A. Hamburg and top global regulators from Europe and Japan will tackle the challenges facing international drug and medical device regulators and the impact on therapies and patients.

This special Drug Information Association section highlights news, as well as new and innovative products by companies exhibiting at the annual meeting.

Stop by DIA Booth No. 1037 to see what's new at PharmaVOICE.

> **"Our annual meeting is a global platform to facilitate innovation that will change the future of healthcare."**
>
> **BARBARA KUNZ** / DIA

New Tools

OmniComm Systems Releases New Version of Trial Management System

OMNICOMM SYSTEMS has released **TrialOne**

Version 4.3. TrialOne is a browser-based, mobile, clinic automation solution designed specifically for early-phase research that facilitates subject recruitment, source data capture, sample tracking, data management and reporting. TrialOne offers time-based data entry and automates many data collection activities via its ability to both print and scan barcodes, as well as to integrate directly with medical monitoring and laboratory equipment.

This version includes numerous productivity and functionality enhancements that drive efficiencies and reduces costs through faster volunteer recruitment, flexible screening questionnaires, direct data capture, work flow automation, and modern data processing.

For more information, visit omnicomm.com.

DIA Booth No. 2205

PHT Launches App for Clinical Trials


Sheila Rocchio

The new **FDA Roadmap App** from **PHT** helps sponsors navigate the Roadmap to Patient-Focused Outcome Measurement in Clinical Trials released by the FDA with its Clinical Outcome Assessment Qualification Program. The program and roadmap highlight the process by which sponsors should consider, choose, and/or develop clinical program patient-focused outcome measurement strategies. The Roadmap helps trial sponsors improve clinical research that collects patient data through understanding the disease or condition, conceptualizing the treatment benefit resulting in identification of the targeted context of use and concept of interest for future clinical trial measurement.

PHT VP of Marketing and Product Management Sheila Rocchio says, "Clinical trials are including more patient reported outcomes since the publication of the FDA Patient Reported Outcome Guidance. The new app helps clinical research professionals quickly and easily reference roadmap content."

For more information, visit phtcorp.com.

DIA Booth No. 1204

What's New

ECCRT Recognized by TransCelerate as an Accredited Training Facility


Dr. Gerald Van Roey

THE EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING (ECCRT), a SynteractHCR company, has been recognized by TransCelerate BioPharma as an official training facility that meets the standards established for investigator training by this association of biopharma companies. TransCelerate is a nonprofit organization focused on advancing innovation in R&D, identifying and solving common R&D challenges, and further improving patient safety, with the goal of delivering more high quality medicines to patients.

"Training is an important investment for companies, and one that will pay off in the long-run, in having both more engaged employees and better patient care," says Gerald Van Roey, M.Ph.Ed., managing director at ECCRT.

For more information, visit synteracthcr.com.

DIA Booth No. 1731

TrialNetworks is Acquired by DrugDev

DRUGDEV, a global network of active clinical trial doctors, has acquired **TRIALNETWORKS**, a clinical trial optimization system. The TrialNetworks platform is a unified, cloud-based suite of collaborative trial management apps and site-facing tools designed to improve processes, ensure transparency and streamline timelines for key aspects of clinical operations.

"DrugDev and TrialNetworks share a passion for optimizing the clinical trials process and driving efficiency through innovative and collaborative technology," comments Eric Silberstein, CEO of TrialNetworks. "We are pleased to join our team and solutions with DrugDev to provide an even more comprehensive platform for sponsors, CROs and sites."

For more information, visit trialnetworks.com.

DIA Booth No. 2510

UBC Named Preferred Partner by RainTree Oncology Services

UNITED BIOSOURCE CORPORATION (UBC) has been named the preferred oncology clincal research partner by RT Oncology Services (RainTree), a leading community oncology alliance.


Patrick Lindsay

UBC will have access to patient data from RainTree's alliance of oncologists throughout the United States. UBC also will partner with RainTree to administer prospective and retrospective observational studies that will provide information about the safety and efficacy of medication in daily clinical use.

"This partnership is at the core of UBC's distinction in supporting clinical development and optimizing the experience for the patient, physician, manufacturer, and payer," says UBC President Patrick Lindsay. "We now have an excellent opportunity for community oncologists to gain experience with new therapies in the same setting where about 80% of cancer patients are treated. When these same medications are approved and released more broadly, physicians will already have important experience with these new therapies."

For more information, visit ubc.com.

DIA Booth No. 923

Talent Pool

Covance Expands Biologics Capabilities

As part of the ongoing investment in biologics, **COVANCE** has appointed **Mike Holsapple, Ph.D.**, as executive director of global immunotoxicology. Dr. Holsapple is a Fellow in the Academy of Toxicological Sciences and past President of the Society of Toxicology bringing more than 30 years of experience in this important field. In conjunction with this appointment, Covance has launched molecule management teams of experienced scientific leaders who work closely with our clients to develop and implement tailored solutions for the development of their biologics which will leverage Covance's broad portfolio of services, including discovery, preclinical, early and late clinical, central laboratories and commercialization.

For more information, visit covance.com.

DIA Booth No. 2031

INC Names Chief Information Officer

INC RESEARCH has promoted **Jonathan Shough** to chief information officer. In this role, Mr. Shough leads INC Research's worldwide information technology strategy.

Mr. Shough previously served as INC Re-


Jonathan Shough

search's VP of IT operations, leading its worldwide infrastructure and telecommunications network systems. He brings more than 20 years of experience in the planning, design, implementation and administration of a broad range of worldwide IT and infrastructure systems, application platforms, and telecommunications network systems to his new role. His previous experience includes IT leadership roles with large CROs, including Quintiles.

For more information, visit incresearch.com.

DIA Booth No. 1313

Parexel Strengthens Leadership with Appointments


Dr. Roland Andersson


Dr. Thomas Senderovitz

PAREXEL has announced **Roland Andersson, Ph.D.,** and **Thomas Senderovitz, M.D.,** as senior VPs in the company's clinical research services strategic business unit. The executives will be centrally involved in developing and implementing Parexel's global corporate objectives.

Dr. Andersson has responsibility for the management of the Phase II-III client relationships, including strategic accounts and the company's biopharm unit that focuses on the needs of small and emerging companies. Before joining Parexel, Dr. Andersson served as managing director at Accenture, where he oversaw technology, consulting, and business services for leading pharmaceutical and biotech companies.

He received an MS in engineering and a Ph.D. in management from Linkoping Institute of Technology, Sweden.

Dr. Senderovitz has global management responsibility for the early phase and clinical logistics business units, as well as the global medical services function.

He joins the company from Grunenthal, where he served as executive VP of global compound development. He received his M.D. from the Faculty of Medicine at the University of Copenhagen.

For more information, visit parexel.com.

DIA Booth No. 1823

PHT Appoints Chief Operating Officer


Andrea Valente

PHT has promoted **Andrea Valente** from VP of service delivery to chief operating officer.

Before joining PHT, Ms. Valente was VP of global services, education and customer support at OpenPages, where she led bookings and delivery of all global services, education and support of governance, risk and compliance software products.

Before that, she was VP of North American Services at Phase Forward, where she was responsible for all U.S.-based service in support of eClinical trial management software products.

For more information, visit phtcorp.com.

DIA Booth No. 1204

PPD Adds Senior VP of Corporate Development


Bhooshi De Silva

PHARMACEUTICAL PRODUCT DEVELOPMENT (PPD) has named **Bhooshi De Silva** as senior VP of corporate development and strategy to its executive leadership team.

Mr. De Silva focuses on key strategic initiatives vital to supporting PPD's growth and client success, including corporate development, strategy and mergers and acquisitions.

With 15 years of experience in the biopharmaceutical industry, Mr. De Silva brings significant leadership expertise. He started his career at Pfizer, holding roles across the research and development and commercial organizations in portfolio management, strategy, and operations.

Most recently, he served as head of business development, corporate strategy and international teams at Optimer Pharmaceuticals.

For more information, visit ppdi.com

DIA Booth No. 1805

Quintiles Appoints Risk Management Head


Dr. Stella Blackburn

QUINTILES has appointed **Stella Blackburn, M.B. B.S.,** VP and global head of risk management for its real-world and late-phase research group.

In this role, Dr. Blackburn is responsible for leading the group's risk management efforts in the United States, EU, Australia, and Canada.

Dr. Blackburn also will develop multidisciplinary risk management services, review and assist with interpretation of pharmacovigilance legislation, and ensure compliance with regulations and best practices in the conduct of pharmacovigilance and risk management activities.

With more than two decades of experience in the pharmacovigilance and pharmacoepidemiology fields, Dr. Blackburn joins Quintiles from the European Medicines Agency (EMA) where she served for more than 16 years in various roles.

Most recently, she was the EMA Risk Management Development and Scientific Lead.

For more information, visit quintiles.com.

DIA Booth No. 905

SynteractHCR Appoints Global VP of Regulatory Affairs


Dr. Martine Dehlinger-Kremer

SYNTERACTHCR, a full-service, contract research organization, has appointed **Martine Dehlinger-Kremer, Ph.D.,** global VP of medical and regulatory affairs.

An expert in working with global regulatory organizations, Dr. Dehlinger-Kremer has more than 28 years of experience in the clinical research industry.

She will be based in Germany.

For 19 years, Dr. Dehlinger-Kremer served as a VP of international and global regulatory affairs and global medical affairs at various CROs with headquarters in the United States.

She also worked in fundamental research at the CNRS Institute of Physiology in Strasbourg, France, and the Max-Planck Institute for BioPhysics in Frankfurt, Germany.

Dr. Dehlinger-Kremer holds a doctorate in sciences from the University of J.W. Goethe in Frankfurt.

For more information, visit synteracthcr.com.

DIA Booth No. 1731 PV

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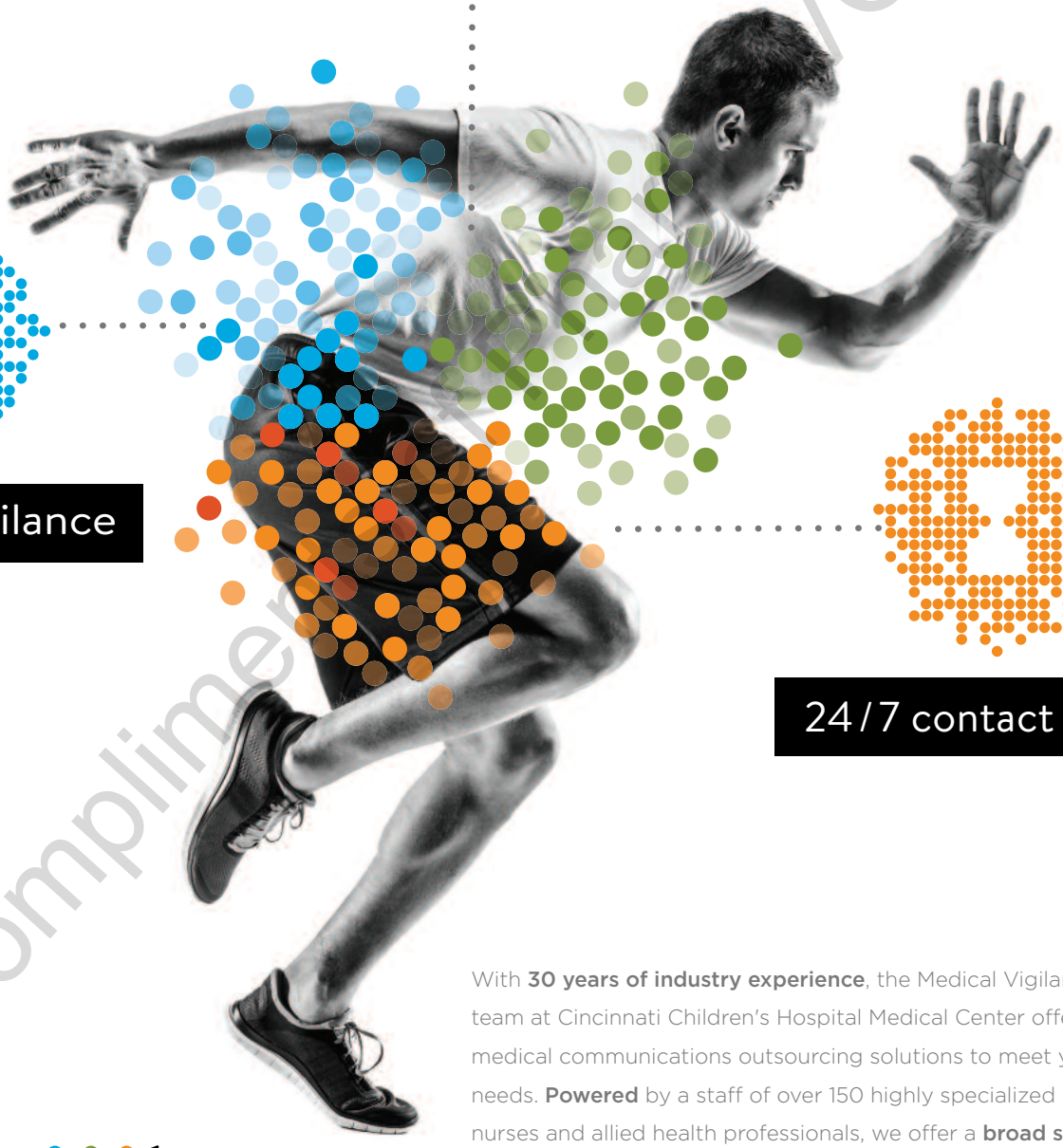

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