2015 DIA PREVIEW

New tools, services, and products to improve drug development, as well as personnel appointments, from 2015 DIA exhibitors.

The DIA Annual Meeting brings together key thought leaders and innovators from industry, academia, government and regulatory agencies, health, patient, and philanthropic organizations from around the globe and across all disciplines involved in the discovery, development, and life-cycle management of medical products.

This year's meeting includes 76 forums, 117 sessions, 12 innovation theater presentations, 21 symposiums, 18 tutorials, and 14 workshops.

This year's keynote speaker, Daniel Burrus, president and CEO, of Burrus Research, is considered one of the world's leading futurists on global trends and innovation. The New York Times has referred to him as one of the top three business gurus in the highest demand as a speaker. He is a strategic advisor to executives from Fortune 500 companies, helping them to develop game-changing strategies based on his proven methodologies for capitalizing on technology innovations and their future impact.

New Tools

Accenture and Oracle Introduce an End-to-End Clinical Data Management Capability

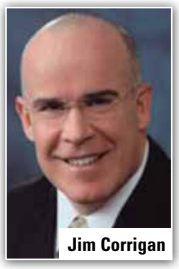
ACCENTURE has expanded the **Accenture Life Sciences Cloud for Research and Development (R&D)** powered by Oracle with the addition of enhanced clinical data management capabilities. This latest version of the Accenture Life Sciences Cloud for R&D offers the Oracle Health Sciences Data Management Workbench (DMW), which includes prebuilt integrations to the Oracle Health Sciences InForm, an EDC solution to create an end-to-end clinical data collection and management platform. This version automates the time-consuming and resource-intensive manual processes required to load, transform, and clean trial data. Trial sponsors and contract research organizations are now able to increase the speed and accuracy of data collection, integration, and analysis; achieve greater efficiency of clinical workflow and query management; and accelerate stakeholders' access to data across the trial lifecycle from source to submission.

"Being able to take advantage of new technologies for clinical data management in combination with Oracle InForm is a key factor to helping our clients bring life-improving medicines to patients faster," says Kevin Julian, managing director of Accelerated R&D Services, Accenture Life Sciences.

For more information, visit accenture.com.

DIA Booth No. BS 7

ERT Announces Availability of Insights Cloud


Jim Corrigan

ERT has launched **Insights Cloud**, a suite of data analytics, visualization, and workflow applications that leverage real-time clinical trials data to provide clinical trial sponsors and CROs with actionable insights and process optimization. Expert Central — ERT's research and integration platform — includes an eClinical data hub for integrating and harmonizing clinical trials data from any clinical system. The integration framework includes standard adapters to leading EDC solutions such as Medidata Rave and Oracle InForm, and facilitates the real-time exchange of clinical trials data.

"As the clinical research industry continues to struggle with the proliferation of data silos, ERT has been evaluating how best to help our customers overcome the challenges of data fragmentation," says Jim Corrigan, president and CEO of ERT.

For more information, visit ert.com.

DIA Booth No. 2025

ICON Launches Electronic Informed Consent


Frances Abeton

ICON has launched **Firecrest eConsent**, a next-generation electronic informed consent solution that incorporates key recommendations from the FDA's recent draft guidance on informed consent.

The eConsent solution is a component of ICON's new informatics hub designed to enhance the engagement of patient populations in the development process. One of the critical parts to this engagement is improving the informed consent process.

Addressing the FDA's recommendation for a more patient centric approach to presenting clinical trial information, ICON's Firecrest eConsent employs videos and visual aids to assist in the explanation of complex scientific concepts and medical terms found in trial protocols. The solution enables patients to access materials via portals or through other online channels provided by the sponsor, giving patients more time to independently review and prepare questions for the physician before subsequently consenting to participate in the trial.

"Electronic informed consent helps address one of the leading causes of regulatory findings — errors in the consent process — in current paper-based processes," says Frances Abeton, VP, Firecrest.

Conforming the FDA's requirement for validating that e-signatures are written by the actual patient, Firecrest eConsent uses a new proprietary method to capture, confirm, encrypt, and store biometrics for each patient's signature.

For more information, visit iconplc.com

DIA Booth No. 503

MedNet Solutions Releases iMedNet

MEDNET SOLUTIONS is releasing **iMedNet,** an eClinical technology platform that provides nontechnical clinical research personnel with a fast, intuitive, and cost-effective solution for building and managing their own clinical studies.

The 2015 Feature One version includes significant improvements to randomization and inventory management, ability to use synonym lists for autocoding, MedDRA, and WHO Drug, as well as risk-based monitoring using targeted source data verification.

For more information, visit mednetstudy.com.

DIA Booth No. 1838

PHT Launches New App of FDA Roadmap

Presented by **PHT**, the new **FDA Roadmap App** is the first mobile app designed to help sponsors navigate the Roadmap to Patient-Focused Outcome Measurement in Clinical Trials released by the FDA in conjunction with its Clinical Outcome Assessment Qualification Program. PHT's new mobile app optimizes the roadmap for Android phones and tablets.

The purpose of the roadmap is to help 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.

For more information, visit phtcorp.com.

DIA Booth No. 2000

Veeva Systems' CRM Engage

VEEVA SYSTEMS has introduced **Veeva CRM Engage**, a cloud-based application that enables life-sciences organizations to interact with healthcare professionals (HCPs) over the Web and through mobile devices. Engage adds the online channel to Veeva's Commercial Suite, which also supports face-to-face, phone, and email customer interactions, for unified multichannel communications. With Engage, life-sciences companies can extend the face-to-face visit by facilitating a two-way dialogue online with relevant, interactive content and personalized services like 'click-to-chat' and 'schedule a visit.'


Paul Shawah

"Veeva's customers can now easily add new channels as an integrated part of their promotional mix without any business disruption, helping create a differentiated customer experience, faster," says Paul Shawah, VP of commercial strategy for Veeva.

For more information, visit veeva.com.

DIA Booth No. 1203

Veeva Systems Introduces Global Key Opinion Leader Solution

VEEVA SYSTEMS has launched **KOL Data & Services**, a new solution empowering life-sciences companies to better understand and engage stakeholders worldwide. It delivers in-depth profiles of all relevant key opinion leaders (KOLs) and targeted engagement plans for more successful product launches. Veeva's KOL solution builds on the recently acquired Qforma CrowdLink KOL database, and segmentation and network visualization capabilities. The Qforma Crowdlink team, now part of Veeva, brings specialized expertise in KOL data, analysis, and engagement planning.

Veeva KOL Data and Services allows launch teams to accurately identify the right KOLs around the world and maximize coverage. It also delivers in-depth KOL profiles to personalize all interactions. Interactive relationship maps and hundreds of segmentation overlays, coupled with expert services, help to develop highly targeted engagement plans in each therapeutic area.

For more information, visit veeva.com.

DIA Booth No. 1203

What's New

ERT to Buy PHT

ERT, a global solution provider for high-quality patient safety and efficacy endpoint data collection, has signed an agreement to purchase **PHT Corp. (PHT)**, an eClinical innovator leading the adoption of patient-driven mobile apps for improved clinical research.

The transaction combines the flexible eCOA platform of PHT with the clinical trial technology and service offerings of ERT, creating one of the most innovative and comprehensive solutions for patient endpoint collection and data analytics for global clinical trials.

"This combination is about better serving our customers and delivering solutions to support the tremendous growth projected for the eCOA industry," says Jim Corrigan, president and CEO of ERT. "By joining forces we are creating a truly innovative eCOA offering with global reach across therapeutic areas."

For more information, visit ert.com.

DIA Booth No. 2025

ICON's New Book Advocates for Re-Engineering Clinical Trials

ICON, a global provider of drug and development solutions and services to the pharmaceutical, biotechnology, and medical device industries, has released the book **Re-Engineering Clinical Trials,** edited and co-authored by Brendan Buckley, ICON's chief medical officer, and Peter Schüler, ICON's senior VP of global medical and safety services.

Joined by co-authors at AstraZeneca, Bayer, Boehringer Ingelheim, IBM, McGill University, the Tufts Center for the Study of Drug Development, and 22 other institutes and companies, Mr. Buckley and Mr. Schüler set forth a comprehensive collection of reforms for a progressive model of drug development. The editors hope to propel faster change in some businesses restrained increasingly by companies, not regulators.

In this book, ICON and industry leaders have asked and answered some critical questions about the fundamentals of clinical development.

"For example, what causes good drugs to fail? Why do so many expenditures in clinical trials not benefit patients? Have other industries already invented what we need? The answers can spur reforms of fundamental processes that, when implemented together, represent a new business model for drug development," Mr. Buckley says.

For more information, visit iconplc.com.

DIA Booth No. 503

INC Research and DrugDev Create Cloud-Based Solutions

INC RESEARCH, a global Phase I to IV CRO, entered into a strategic collaboration with **DrugDev** to drive increased efficiencies in clinical trials through enhanced access to and


Ibraheem Mahmood

management of critical investigator and site data. Under the agreement, INC Research becomes the first CRO to complete integration with and implementation of DrugDev's SiteCloud platform, the same technology used by TransCelerate's Investigator Registry, which is expected to launch later this year, and the Investigator Databank, to facilitate more efficient feasibility, site selection, and study start-up processes.

"Real change will only come to the clinical research industry through meaningful collaboration and the widespread adoption of technology standards such as the DrugDev Golden Number, so naturally we could not be more excited to work with INC Research on this essential initiative," says Ibraheem (Ibs) Mahmood, president and CEO of DrugDev. "As a platform-agnostic leader, INC is committed to leveraging future-proof technologies that best meet customer requirements."

For more information, visit incresearch.com.

DIA Booth No. 2303

For more information, visit drugdev.com.

DIA Booth No. 820

INC Research Has Formed a New Site Advocacy Group (SAG)

INC RESEARCH has formed a new **Site Advocacy Group (SAG)** focused on streamlining and enhancing the payment process for clinical research sites.

Through this forum, INC Research will be at the forefront of working with sites to improve a key aspect of clinical trial management and facilitate ongoing dialogue on operational best practices for conducting successful research.

"Clinical research sites are essential participants in bringing new therapies to market and making them readily available to patients in need," says Clare Grace, VP, site and patient access. "To this end, we as an industry must take an active role in providing them with the support they need to be successful. By improving and streamlining the payment process and reducing administrative challenges in managing clinical trials, we are enabling sites to maintain their focus on conducting quality research and meeting enrollment goals. This forum will facilitate meaningful discussions to develop actionable plans that make a real difference for sites and ensure a continued high standard of patient care."

SAG was established in response to specific feedback from sites that noted financial challenges to their ongoing sustainability as a participant in the clinical research enterprise.

According to a 2014 Site Solutions Summit Survey conducted by the Society for Clinical Research Sites, 65% of sites have less than three months' operating cash on hand. The survey also concluded that pass-through items are increasing for sites, placing more pressure on cash flow. CROs can play a role in alleviating this pressure by improving infrastructure and refining processes to better support sites.

For more information, visit incresearch.com.

DIA Booth No. 2303

Parexel Acquires Quantum


Josef Von Rickenbach

PAREXEL, a global clinical research organization, has acquired all of the business assets of privately owned **Quantum Solutions India**, a provider of specialized pharmacovigilance services, based in Chandigarh, India.

QSI was established in 2004, and delivers a range of pharmacovigilance services including individual case safety report processing, brand physician activities, affiliate support, aggregate report writing, literature reviews, and signal detection.

"The acquisition of QSI strengthens our capabilities in the growing field of outsourced safety management solutions, or pharmacovigilance," says Josef von Rickenbach, chairman and CEO of Parexel. "It will help us to create greater scale in this service area, and thereby enable us to provide a more comprehensive, efficient, and economical solution to clients around the world. Combined with the existing post-approval and regulatory strengths of the company, this acquisition will support the expansion of our pharmacovigilance services onto a broader platform."

For more information, visit parexel.com.

DIA Booth No. 1535

Precision for Medicine Acquires Precision Health Economics

PRECISION FOR MEDICINE, a specialized services company supporting next-generation approaches to drug development and commercialization, has acquired **Precision Health Economics (PHE)**, which leverages the expertise of policy analysts, economists, clinicians, and academics to advance research on the most complex healthcare questions.

"Precision Health Economics is the leader in developing innovative approaches to the science of value. Their work impacts policy and influences payment systems across some of the most important and fastest growing sectors of medicine," says Ethan Leder, chairman, Precision for Medicine. "Adding PHE's differentiated capabilities fortifies our approach to helping life-sciences companies deliver more effective treatments to patients in the era of precision medicine by integrating research, analytics, science, and communications."


Ethan Leder

For more information, visit precisionformedicine.com.

DIA Booth No. 1351

Synchrogenix, Certara's Regulatory Writing Consultancy, and CISCRP Join Forces


Kelly Kendle

CERTARA, the global biosimulation technology-enabled drug development consultancy and the nonprofit Center for Information and Study of Clinical Research Participation **(CISCRP)**, have formed a partnership to provide lay language clinical trial results to clinical trial volunteers. Through this collaboration, Synchrogenix, Certara's regulatory writing consultancy, significantly increases global medical writing capabilities supporting an initiative that CISCRP pioneered four years ago.

"With increasing and impending regulation, sponsors are feeling the pressure to proactively address the demands of disclosure to the community," says Kelley Kendle, Synchrogenix president and CEO. "This new partnership combines Synchrogenix's technology-enabled operational expertise and clinical writing talents with CISCRP's unbiased governance and dedication to engaging patients and the public in the spirit originally intended of the clinical research process."

For more information, visit ciscrp.org.

DIA Booth No. 2440

For more information, visit certara.com.

DIA Booth No. 1105

PPD Laboratories Opens Central Lab in Shanghai, China

PHARMACEUTICAL PRODUCT DEVELOPMENT (PPD) has opened a **central laboratory in Shanghai, China**, to deliver global scientific

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and technical laboratory expertise to meet growing client demand for these services in China. The new facility, which has been established in association with Shanghai Clinical Research Center (SCRC), is equipped with cutting-edge analytical equipment to provide high-quality data across a wide range of technologies and applications for all phases of pharmaceutical development. The central lab service offering of PPD Laboratories includes safety and general lab testing, specialized testing, biomarker testing, and custom assay development and testing services.

For more information, visit ppdi.com.

DIA Booth No. 2227

SAS and Optum Building Cloud-Based Health Analytics Platform


Brian Kelly

OPTUM is the first collaborator to join **SAS** in offering an integrated solution that includes clinical and claims data with a user-friendly interface and a unified, scalable analytics toolset. Optum contributes healthcare expertise, analytics, and clinical data to the SAS data warehousing platform, which will provide the on-demand, advanced analytics necessary to provide valuable insights for life-sciences clients.

The new service features de-identified integrated claims and clinical data about everyday patients receiving healthcare, including prescriptions and labs — data from the real world, not just trials. The open data platform will soon incorporate data from multiple providers.

"With pay-for-performance reimbursement models rewarding quality over quantity, life-sciences companies must provide data-driven insights to help healthcare system participants make better decisions across the clinical and commercial continuum," says Brian Kelly, president of life sciences at Optum.

For more information, visit optum.com.

DIA Booth No. 1826

For more information, visit sas.com.

DIA Booth No. 2127

WIRB-Copernicus Group Supports Adoption of Accelerated Clinical Trial Agreement by WCG Global Research Network

WIRB-COPERNICUS GROUP (WCG), a provider of regulatory and ethical review services for human research and software solutions designed to **accelerate clinical trials safely**, is encouraging members of its global research network to accept the accelerated clinical trial agreement as their default agreement for industry-sponsored, multi-center clinical trials.


Donald Deieso

Development of the ACTA was initiated in 2012 by the National Center for Advancing Translational Sciences through its clinical and translational science awards (CTSA) program in collaboration with representatives from several pharmaceutical companies and took about two years to complete. NCATS is part of the National Institutes of Health.

"All of WCG's solutions help our clients to reduce the time, cost, and risks associated with bringing new therapies to market," says Donald Deieso, Ph.D., chairman and CEO.

For more information, visit wcgclinical.com.

DIA Booth No. 701

Talent Pool

Jim Nichols and Michael Tyrsted Join DitaExchange

DITAEXCHANGE, a provider of structured content authoring and management solutions, has named **Jim Nichols** as VP, U.S. operations, and **Michael Tyrsted**, as VP, engineering.

Mr. Nichols leads the DitaExchange life-sciences strategy and operations team, which helps life-sciences companies adopt new authoring processes.

Mr. Tyrsted is responsible for product development for all of DitaExchange's software solutions, leading development teams worldwide to build leading-edge solutions that meet and exceed expectations from customers and industry as a whole.

For more information, visit ditaexchange.com.

DIA Booth No. 2419

BioClinica Names Mukhtar Ahmed as eClinical President — Technology and Industry Leader to Head eClinical Business Unit

BIOCLINICA, a specialty clinical trials services and technology provider, has named **Mukhtar Ahmed**, president of its Global eClinical Business Unit. Mr. Ahmed most recently served as global VP at Oracle responsible for growing global consulting services and leading the life-sciences business toward transformative cloud platforms, big data solutions, and digital medicine.

For more information, visit bioclinica.com.

DIA Booth No. 1325

Dr. Richard Scheyer Joins Medpace as VP, Medical Affairs

MEDPACE, a global drug and medical device CRO, has named **Richard Scheyer, M.D.**, as VP, medical affairs. Dr. Scheyer brings broad experience in program strategy and study design across many therapeutic areas including neuroscience, oncology, cardiovascular, and metabolic, as well as rare disease indications.

For more information, visit medpace.com.

DIA Booth No. 1801

Dr. Scott Treiber to Head Biopharmaceutical at Theorem

THEOREM CLINICAL RESEARCH, a CRO, has selected **Scott Treiber, Ph.D.**, to spearhead biopharmaceutical development as executive VP and general manager.

Dr. Treiber, an industry veteran with experience at many of the top global CROs, oversees all aspects of Theorem's biopharmaceutical development, including early phase first-in-human and proof-of-concept studies and Phase II-IV studies across a wide range of therapeutic areas.

For more information, visit theoremclinical.com.

DIA Booth No. BS 1

Dr. Don Gabriel and Jeanne Ashton-Strain Join UBC

Don Gabriel, M.D., Ph.D., a renowned hematological oncologist, has joined **UNITED BIOSOURCE CORP. (UBC)** and directs the organization's consultative services to pharmaceutical sponsors developing oncology therapies. Dr. Gabriel has dedicated his medical career to treating oncology patients and developing innovative technology focused on improving clinical diagnostic procedures and therapeutic monitoring.

UBC also welcomes **Jeanne Ashton-Strain** as executive director of data management and biostatistics.

She is responsible for ensuring that data and information structures and workflow supporting the clinical development processes and corporate infrastructure are fully functional and operate effectively.

For more information, visit ubc.com.

DIA Booth No. 2401

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