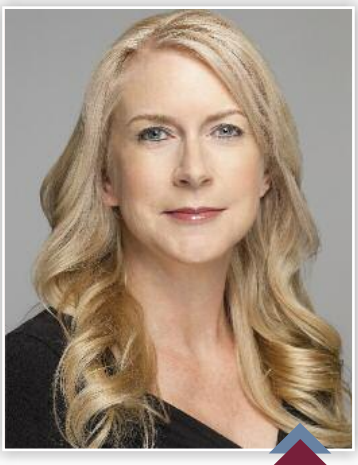
2013 DIA Preview

This year's theme: Advancing Therapeutic Innovation and Regulatory Science.

The Drug Information Association's 49th Annual Meeting will be held June 23 to 27 at the Boston Convention & Exhibition Center. There will be more than 250 sessions covering 22 tracks on hot topics from key thoughts leaders from the life-sciences industry.

Physician, scientist, inventor and innovator Dr. Daniel Kraft will headline the opening session. Dr. Kraft has more than 20 years of experience in clinical practice, biomedical research, and healthcare innovation. He chairs the Medicine track for Singularity University and is executive director for FutureMed, a program that explores convergent, exponentially developing technologies and their potential in biomedicine and healthcare.

Dr. Kraft recently founded IntelliMedicine, focused on enabling connected, data driven, and integrated personalized medicine. He is also the inventor of the MarrowMiner, an FDA-approved device for the minimally invasive harvest of bone marrow, and founded RegenMed Systems, a company developing technologies to enable adult stem cell-based regenerative therapies.



DR. SANDRA MILLIGAN
Genentech and DIA Program Chair

Regulatory science has to move just as fast as technology. That's why it's important to focus on regulatory science at these meetings.

SUSAN CANTRELL ▪ *DIA*

The global regulatory town hall gives participants an open forum to pose questions to regulators and gain additional insight.

Susan Cantrell, director, North America at DIA, says the theme of the meeting — Advancing Therapeutic Innovation and Regulatory Science — follows the relaunch of the Drug Information Journal as Therapeutic Innovation and Regulatory Science, a move that took place in January of this year.

"As we were thinking about the meeting and the name of the journal, we concluded this is what the annual meeting is all about," she says.

There is a higher awareness that regulatory science cannot be the gap that is hindering the progress happening in science and technology, says DIA Program Chair Sandra Milligan, M.D., who is VP, global regulatory therapeutic area head at Genentech.

"These dialogues around regulatory science are very important," she says. "Regulatory agencies seem willing and thirsty for discussions around novel pathways and endpoints. These forums help everyone start thinking in a different way."

Dr. Milligan says this year for the first time, regulators from China and Taiwan will participate on the same panel. In addition, regulators from the United States, Japan, Europe, and Korea will each hold their own town halls.

New this year is a focus on Alzheimer's disease, and Dr. Milligan hopes future annual meetings will continue to focus on different therapeutic areas.

"In Alzheimer's research, there is a culmination of not just the science but the durability of the science and regulatory pathways," she says. "There is also a surge of patient advocacy and patient groups that are coming together to address the struggles everybody is facing to get to the next phase. The annual meeting is a nice forum for Alzheimer's and is very timely."

Executives from Eisai and Merck and researchers from Massachusetts Alzheimer's Disease Research Center will discuss the challenges encountered in early- and late-clinical development, lessons learned from past trials, and recommendations in trial design.

Ms. Cantrell says another exciting session at the meeting is focused on a report released in January by the President's Council of Advisors on Science and Technology (PCAST). Included in the panel will be Bernard Munos, founder of InnoThink Center for Research in Biomedical Innovation, and Dalvir Gill, CEO of TransCelerate Biopharma. This session will examine how companies across the pharmaceutical sector are transforming their R&D business models to meet current and future market demands.

This special DIA section highlights news, as well as new and innovative products by companies exhibiting at the annual meeting. Also included are key personnel news at some of the industry's leading companies.

Please stop by the **PharmaVOICE DIA Booth No. 1426** to say hello.

DIA-HBA Skill Building Workshop

A Custom-Fit Leadership Approach for Women in the Regulatory, Medical, Legal, and Compliance Functions


Ilyssa Levins

This joint workshop developed by DIA and the Healthcare Businesswomen's Asscociation (HBA) — June 23,1-6 p.m. — is part of a new leadership skill-building initiative for women in regulatory, legal, compliance, and medical roles within product development companies. The curriculum is designed to improve leadership agility and performance, as well as to help women identify and articulate why they are uniquely valuable to their companies within the pharmaceutical, biotech, and device industries.

"Attendees will walk away with actionable and practical tips on how to recognize, package, and communicate their value and master the skills for long-term leadership effectiveness and impact," says Ilyssa Levins, DIA-HBA co-chair, and president of the Center for Communication Compliance (CCC).

Executives in these functions — regulatory, legal, compliance, and medical — spur innovation, in addition to increasing compliance and commercial effectiveness. Ultimately, they help drive better business results and enhance their organizations' reputations through their ability to maintain product access and protect the bottom line. However, many of these executives may not be adept at recognizing, packaging, and communicating their value within the larger context of the business, and are missing key career leadership opportunities. The workshop's goal is to change this dynamic by providing new leadership tools and insights that are immediately applicable.

The event will begin with an overview of industry trends and define key criteria for business success in today's highly regulated environment. Attendees will then be given a business acumen tool designed to support strategic thinking and to help frame their functional roles within a business context. Industry leaders will provide advice on three critical areas: how to move from technical to strategic thinking, how to command executive presence, and how to work with or become a mentor/mentee.

To register for the workshop, visit diahome.org/DIA2013; search preconference tutorials and select tutorial No. 41.

New Tools

BBK Expands Mobile Strategy for Patient Recruitment

BBK Worldwide has released a suite of advertising tools for mobile applications that are designed to increase campaign effectiveness and return on investment. Developed to complement BBK's existing suite of mobile products and services, this new group of in-app advertising tools creates recruitment opportunities in video, radio, and banner mobile ad networks.

"Mobile advertising has many potential benefits for clinical trial sponsors," says Lucas Garmon, media strategist, at BBK. "Not only does it open doors to untapped audiences of smartphone and tablet users, but it's very effective when combined with desktop advertising."

Matthew Stumm, principal, creative and media strategy at BBK, says companies lacking a mobile-friendly website drive about 61% of their mobile traffic to competitors.

For more information, visit bbkworldwide.com.

DIA Booth No. 307

BioClinica Releases Integrated Medical Image Management Solution


Mark Weinstein

BioClinica has released the newest version of **WEBSEND**, the company's medical image submission technology for clinical trials.

WebSend is an electronic data transfer solution. Investigator sites can use WebSend to securely transmit medical images for clinical trials over the Internet. The newest version of the solution includes:

- Protected Health Information (both metadata and pixel data) that is removed before image submission.
- Protocol deviations that are fully documented before images leave the investigator site.
- Both DICOM and non-DICOM image data that are supported through one system.
- Browser-based DICOM viewer that is for both Web-submitted and couriered images.

"Electronic image submission is the best way to ensure data quality and reduce the cost of imaging-based clinical trials," says Mark Weinstein, CEO of BioClinica. "When an image is uploaded via WebSend, it automatically becomes part of BioClinica's integrated image management and independent review system. There are no manual steps, data entries, or transfers required.

In other news, Bioclinica has made available Express EDCplus, and EDC technology transfer program. The tool helps organizations exert greater control over the development and implementation timelines of the technology they use to support their clinical trials.

For more information, visit bioclinica.com.

DIA Booth No. 1210

Formedix Partners with OmniComm for EDC System


Mark Wheeldon

Formedix has partnered with **OmniComm Systems** to deliver **TRANSFORM FOR TRIALMASTER**. Formedix Transform for TrialMaster can reduce clinical study set-up time by allowing instantaneous visualization of TrialMaster eCRFs as they are designed. Furthermore, study builds are automated and drag-and-drop reuse is enhanced by leveraging portable, vendor-neutral CDISC designs.

In addition to Transform for TrialMaster, the Formedix portfolio also includes Transform tools for many of the other leading EDC providers.

"Often our customers ask us to build integrations for particular EDC systems and that's how these partnerships often come about," says Formedix CEO Mark Wheeldon.

For more information, visit formedix.com.

DIA Booth No. 1846

NextDocs and Microsoft Offer Clinical Trials Solution


Matt Walz

NextDocs has launched **TRIAL EXCHANGE,** a solution combined with Windows 8 that addresses the need for efficiently managing clinical trials. The solution provides an easy-to-use interface for investigators and site staff to access and contribute essential documents for clinical trials. The documents and workflows can then be managed within the NextDocs eTMF solution. NextDocs Trial Exchange can be accessed through the

Web browser or through a native Windows 8 app.

"We live in an ever more global, mobile, and connected world that can pose business challenges, but also opportunities," says Matt Walz, chief technology officer at NextDocs. "It makes clinical trial document management solutions easy to use without sacrificing compliance, security, or mobility."

In other news, NextDocs has released NextDocs 6, the latest version of its regulated content management and compliance suite. The latest version includes expanded capabilities to meet the demands of the highly global, mobile and collaborative life-sciences operating environment.

For more information, visit nextdocs.com.

DIA Booth No. 1722

Perceptive Updates CTMS


Nick Richards

Perceptive Informatics, a subsidiary of **Parexel International**, has released an enhanced version of **IMPACT** clinical trial management system (CTMS). The enhanced version is a customizable system that allows managers the flexibility to define which information is most important to their clinical trial. Highlights include:

- Configurability by Clinical Trial Type — Customers can define their own clinical trial types, enabling them to select the critical screens and fields that each requires.
- Assistance for Field Monitors — The MySites Module now enables contract research associates to record and manage contacts for the sites they monitor.
- Improved Data Mining Capabilities — The Investigator Module's advanced search feature enables users to select physician names based on their location, specialty, therapeutic interests, responses to qualification questionnaires and investigator performance metrics.

"Many top global pharmaceutical companies and CROs rely on a CTMS solution to plan, administer, and track every aspect of their clinical trials," says Nick Richards, VP, product management, Perceptive Informatics. "As clients face further globalization of clinical trials and require site management and monitoring of increasingly complex studies, they need technology that keeps pace."

For more information, visit parexel.com.

DIA Booth No. 215

PharmaVigilant Releases Updated Solution


James DeSanti

PharmaVigilant has released **I-VAULT 2.7**, an ETMF system. The solution has been expanded to include the new I-Batch uploader, imbedded Redactor tool, and the Report Generator. I-Batch enables high volumes of documents and images to be uploaded into the correct location with a click of a button.

The Redactor tool ensures privacy while maintaining an audit trail, and the Report Generator enables the sponsors to export their customized data automatically with a corresponding indexed table of contents in PDF format.

"We have incorporated configuration tools and workflow enhancements that enable the product to be sponsor-process agnostic," says James DeSanti, president and CEO, PharmaVigilant.

For more information, visit pharmavigilant.com.

DIA Booth No. 443

PPD Offers Expanded Access to Clinical Data

Pharmaceutical Product Development (PPD) has introduced **PPD INVISION**, a data solution that consolidates and standardizes data from multiple sources, giving pharmaceutical clients real-time access to their clinical trial data.

The solution has an end-to-end clinical data management capability that provides increased visibility to study data, creating time and cost-efficiencies.

The complete data package includes a clinical data repository, improved standards around EDC and statistical outputs, a combination of in-house and onsite monitors, the PPD cross-functional data liaison and interactive dashboards for data visualization.

The dashboards provide interactive visualizations of operational and patient data, giving clients and PPD teams the ability to identify trends and drill down into the data for detailed information.

"This real-time access and its transparent reporting capabilities provide pharmaceutical clients with the ability to address issues quickly and efficiently, while potentially making faster strategic and tactical decisions about their studies," says Niklas Morton, VP of global biostatistics, programming and medical writing.

For more information, visit ppdi.com

DIA Booth No. 1823

Veeva Systems Introduces Complete, Cloud-Based Customer Master Solution for Life-Sciences Companies

Veeva Systems unveiled **VEEVA NETWORK**, a complete, cloud-based customer master solution. Veeva Network, the newest addition to Veeva's commercial suite for life sciences, combines healthcare professional (HCP), healthcare organization (HCO), and affiliations data with software and data stewardship services in one solution that's seamlessly integrated with Veeva CRM.

It replaces the disparate customer data and master data management solutions that cost life-sciences companies millions of dollars a year.

"Without the right information, it is impossible for life-sciences organizations to orchestrate the customer experience and comply with mounting regulations," says Dan Goldsmith, general manager, Veeva Network. "The industry has struggled to assemble accurate customer profiles and the undertaking is a massive, endless effort. With Veeva Network, life-sciences companies will finally have reliable customer information to enable multichannel sales and marketing and maintain compliance."

Veeva Network delivers complete, up-to-date HCP, HCO, and affiliations data through integration with Veeva CRM, so the information is always available where sales and marketing users need it most.

Veeva Network will also provide pre-built integrations to standard sources of external data and an open API to bring together all relevant customer information in one solution.

For more information, visit veevasystems.com.

DIA Booth No. 1557

What's New

Aptiv Solutions Establishes Adaptive Clinical Center of Excellence

Aptiv Solutions has established the **ADAPTIVE CENTER OF EXCELLENCE (ACOE)**. The


Pat Donnelly

ACOE is a further development of the growing relationship that Aptiv Solutions has as a strategic provider of adaptive clinical trial services for three of the 10 largest global pharmaceutical companies.

These three companies also have agreed to join a consortium organized by Aptiv Solutions to develop and implement novel methodologies for adaptive dose finding trials.

The ACOE will focus on defining, developing, and implementing a new execution paradigm for adaptive clinical trials. It is led jointly by Michael McKelvey, Ph.D., chief operating officer, and Reinhard Eisebitt, executive VP of the Aptiv Solutions Innovation Center and managing director of Addplan, the Aptiv Solutions statistical software subsidiary.

The ACOE is comprised of a group of 15 senior level individuals from various departments of Aptiv Solutions.

They take a multidisciplinary approach to addressing the requirements for integrated design and execution of adaptive trials.

The ACOE has three initial goals:

- Develop breakthrough methodologies for efficiently and effectively executing adaptive clinical trials using our unique internal design and execution resources.
- Embody these methodologies in AptivAdvantage, the company's proprietary technology platform for adaptive trial execution.
- Create joint collaborative partnerships with selected clients to develop novel methodologies for adaptive trial design and execution.

"The main challenge we see is to synchronize the design and the execution of adaptive trials, which will bring significant productivity benefits to the product development process," says Patrick Donnelly, chairman and CEO at Aptiv Solutions. "We believe that the ACOE will provide innovative ways to achieve this and we look forward to working with our valued clients on some very exciting joint projects."

For more information, visit aptivsolutions.com.

DIA Booth No. 1419

inVentiv Health Forms Alliance With Bell Medical

inVentiv Health has formed a strategic alliance with **Bell Medical Solutions**, one of Japan's top clinical research organizations with more than 700 clinical research associates serving the growing Japanese market.


Paul Meister

Together, inVentiv and Bell are offering comprehensive global drug development services to Japanese and international clients conducting clinical studies in Japan.

"This alliance provides Bell Medical Solutions with inVentiv's significant international reach and the ability to participate in larger, global studies," says inVentiv Health CEO Paul Meister. "For inVentiv, the alliance bolsters our already significant position in Japan to better support our pharmaceutical clients that are capitalizing on exciting opportunities for growth."

For more information, visit inventivhealth.com.

DIA Booth No. 1205

PHT Launches Investigator Engagement Tool


Sheila Rocchio

PHT has launched the **MYSTUDYHOME** online community that connects sponsor companies with sites to share up-to-date training and documentation, calendars, and study specific updates.

MyStudyHome gives pharmaceutical sponsors and contract research organizations a competitive edge in retaining high performing clinical trial investigation sites and improving site engagement and compliance.

MyStudyHome is part of the StudyWorks portal, which delivers real-time access to electronic clinical outcome assessment (eCOA) data collected via the LogPad, SitePad, or NetPRO Systems.

MyStudyHome gives investigator sites centralized, single sign-on access to their eClinical systems in addition to their news, training, and study-related content, all in one place.

"While pharmaceutical sponsors are rapidly building therapeutic portals for patients there has been less focus on creating communities for sites working on the study," says Sheila Rocchio, VP of marketing and product management, PHT.

For more information, visit phtcorp.com.

DIA Booth No. 1907

RPS and Japanese CRO form Joint Venture

ReSearch Pharmaceutical Services (RPS) and **Asklep**, one of Japan's largest CROs, have create a joint-venture company to deliver leading-edge R&D outsourcing solutions in Japan to the biopharmaceutical and medical device industries.

The exclusive RPS-Asklep collaboration will leverage RPS' proprietary structures and global footprint to deliver customized solutions across large, mid-size and small and virtual organizations. A breadth of options ranging from embedded, hybrid, and full-service solutions will be available to clients using best-in-class standard operating procedures, processes and systems.

Alan Morgan, RPS' chief operating officer, assumes the role of CEO of the joint venture in addition to his current responsibilities.

For more information, visit rpsweb.com.

DIA Booth No. 151

Talent Pool

Advanced Clinical Taps Julie Ross

Julie Ross as joined the leadership team of **Advanced Clinical** as executive VP of CRO operations.

She is a tenured executive leader who has been instrumental in the development and the success of multiple clinical operations divisions. Previously with inVentiv Health Clinical, Ms. Ross served as senior VP, global strategic services. Before her role at inVentiv, Ms. Ross led Essential Group, a full-service CRO and patient recruitment company, which she helped build and position for its acquisition by inVentiv Health.

A graduate of the University of Wisconsin, La Crosse with a bachelor's degree in Nuclear Medicine Technology, Ms. Ross has been in the clinical research industry for more than 25 years.

She has authored many clinical research articles and is a well-known industry speaker.

For more information, visit advancedclinical.com.

DIA Booth No. 1322

Catalent Announces Two Senior Appointments to Drive Growth in China

Catalent Pharma Solutions has made two

senior appointments to support its recently established joint ventures in China for its Softgel Technologies and Clinical Supply Solutions (CSS) businesses. Dr. Weiyan "Jackson" Zhu has joined as Catalent's country general manager for China, while Yufeng (Paul) Cao becomes the new site operations director, for Catalent (Shanghai) Clinical Trial Supplies Co. facility, which is currently under construction. Dr. Zhu and Mr. Cao will both be based in Shanghai.

Dr. Zhu plays a pivotal role in Catalent's China growth strategy, focusing on business development and government agency interaction. He joins Catalent following a long tenure at Boehringer Ingelheim, where he had the distinction of being the company's first, mainland China hire in its 120-year history. Most recently, he served as VP and head of Boehringer Ingelheim consumer health care division in China.

Mr. Cao has overall day-to-day responsibility for Catalent and ShangPharm's China joint-venture business and is charged with establishing the new Shanghai clinical trial operation. He leads Catalent's local China CSS team to complete the site construction and launch operations by late summer 2013.

Before joining Catalent, Mr. Cao was most recently the general manager for Fisher Clinical Service (Beijing, China).

Mr. Cao has a bachelor of science degree in industrial electrical automation from Beijing University of Science and Technology and also holds an MBA from Vlerick Leuven Gent Management School.

For more information, visit catalent.com.

DIA Booth No. 1423

Greenphire Appoints UK-based Global Product Manager to Facilitate European Growth


Rory O'Hare

Greenphire has hired Rory O'Hare as global product manager, its first U.K-based appointment. This strategic appointment enables Greenphire to leverage its existing core expertise in both the UK and European markets. In this new role, Mr. O'Hare is responsible for global requirements across all products, including product positioning and sales support.

He will liaise between the European business and U.S. headquarters to elevate Greenphire's global footprint in the clinical trials industry.

He is an IT professional with 20 years of experience in a variety of industries with a particular focus on healthcare for the last eight years. He has completed several assignments for the Irish Health Service Executive (HSE) and ICON plc.

He has a BSc in computing science and a masters in business administration.

For more information, visit greenphire.com.

DIA Booth No. 840

PPD Appoints Senior VP

Pharmaceutical Product Development (PPD) has appointed Jay Dixon as senior VP, global quality and compliance.

Mr. Dixon is a seasoned executive with more than 27 years of research and development experience in the pharmaceutical and biotechnology industries. Most recently, he was chief operating officer at PRACS Institute, with responsibility for providing strategic direction and leadership to the company's service lines.

Mr. Dixon is a member of the Drug Information Association and the Society of Quality Assurance. He holds a bachelor's degree in biology from Campbell University.

For more information, visit ppdi.com.

DIA Booth No. 1823

Premier Research Augments Staff in Pediatrics and Rare Disease Clinical Trials Divisions

Premier Research has added four clinicians to key leadership roles in its fast-growing pediatric and rare disease clinical trial research disciplines. The CRO named Dr. Susan Tansey, medical director, pediatrics. Her medical specialty areas include vaccines, cardiovascular, and oncology, although her initial training was in neonatology and pediatric medicine. She has considerable experience in pediatric clinical research and trial design.

She joins Premier Research from TMC Pharma Services, where she was director of medical services.

Dr. Tansey received her bachelor's degree from the University of St. Andrews and her MBChB degree in medicine from The University of Manchester.

Dr. Ilze Balode — also a neonatologist and pediatrician — has been named senior project manager at Premier Research Europe and is based in Latvia. Her global experience within the CRO and pharmaceutical industries is highlighted by her expertise in infectious diseases, pediatric dermatology, central nervous system, oncology, endocrinology, genitourinary, and respiratory conditions.

Dr. Balode came to Premier Research from ICON Clinical Research, where she was a project manager. Dr. Balode received her bachelor's degree from Turiba, Riga, and her M.D. from the Academy of Medicine of Latvia, Riga.

Dr. Alison Sampson has been named project director at Premier Research Europe and is based in the United Kingdom. Previously she was project director for oncology at INC Research, UK. She earned both her bachelor's degree in chemical sciences and a Ph.D. degree from Leeds University.

Mary Kay Seeland has been named director, clinical planning and study start-up. Based in the United States, Ms. Seeland previously had managed clinical operations at PRA.

She earned her bachelor's degree in communications and information management from Rutgers University having studied nursing at Middlesex County College.

For more information visit, premierresearch.com.

DIA Booth No. 1610

Theorem Augments Senior Leadership Ranks


Sara Davis


Connie Wierman

Theorem Clinical Research has appoined Sara Davis as VP of global business development. Ms. Davis has more than 15 years of sales and management experience and a proven track record of building industry-leading business development teams. She is responsible for driving strategic business development growth plans for Theorem in all regions of the world.

Ms. Davis began her career as an account executive with PRA. She is a graduate of the University of Wisconsin Oshkosh.

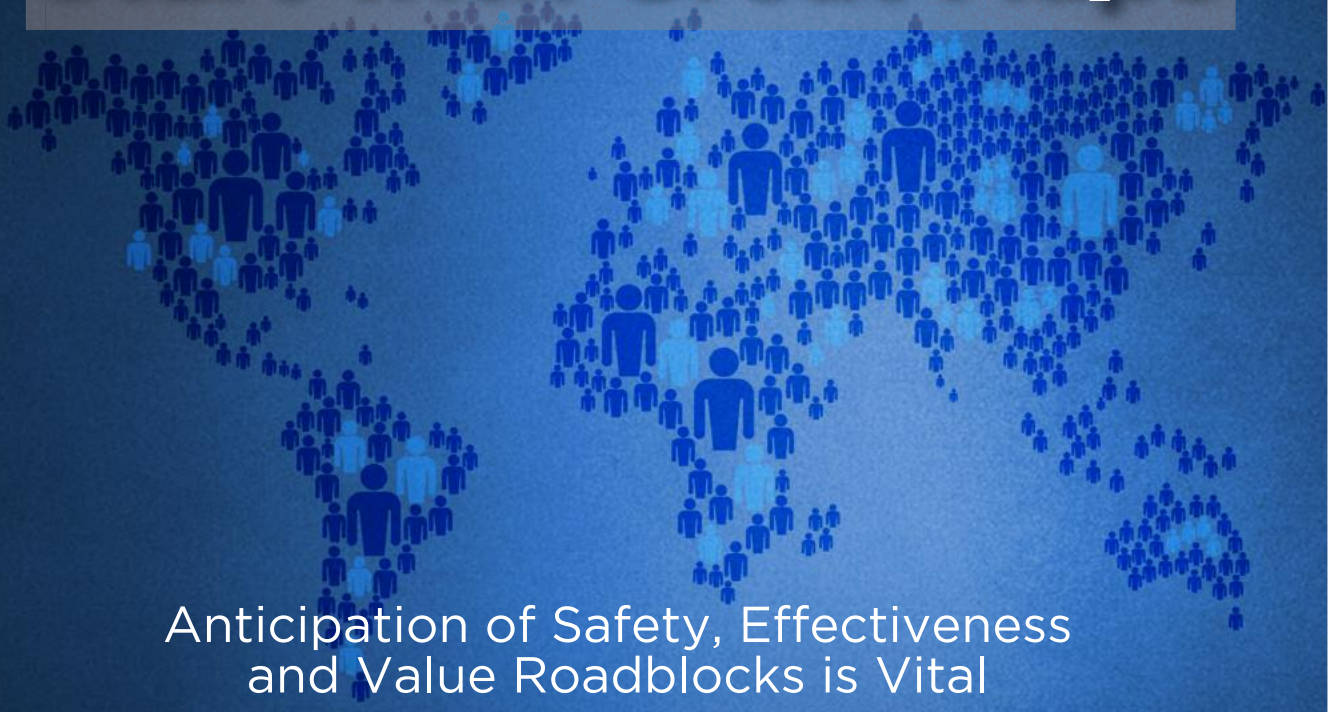
Connie Wierman has been named VP of biopharmaceutical development. Ms. Wierman leads the company's oncology therapeutic focus for the biopharmaceutical business unit. She had been VP of clinical development in oncology for INC Research.

She received both her bachelor's degree in medical microbiology and her MBA in marketing from the University of Wisconsin.

For more information, visit theoremclinical.com.

DIA Booth No. 1643 PV

Successful Journeys Start with Great Maps



Anticipation of Safety, Effectiveness and Value Roadblocks is Vital

UBC experts are working in unison to bridge development and delivery in a way that is new to the industry. Find out how our global product safety, brand loyalty and patient access strategies can steer your product on the path to success.

LIVE WEBINAR
Wednesday
July 17
9:00 a.m.
EDT

Strategies for Implementing Risk Minimization in Europe
Janine Collins, M.D., Senior Director, European Risk Management

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