What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

New Trade Organization Launched With Goal Of

Creating A Voice For Research Sites

TRENDING NOW: Industry veterans seek to give sites an active community.

The Society for Clinical Research Sites (SCRS) was launched in October 2012. SCRS was founded in response to the growing need for a trade organization to represent the voice of clinical research sites within the clinical research enterprise. The society's mission is to unify and amplify the voice of the global clinical research site community.

Christine Pierre, founder of the Site Solutions Summit, was motivated, along with other research professionals, to provide sites with resources, mentorship, and new ideas through a membership organization dedicated to providing sites both a voice and community.

"Sites have a major role to play in the clinical trials process, and for too long, they have been the silent partner in the research enterprise, but they will no longer be passive participants," Ms. Pierre says. "Now is the time for sites to become active partners in the dialogues and solutions through the voice of SCRS."

SCRS's mission is to:

- Establish a trade organization whose member companies foster collegiality and appropriate sharing of information and insights.
- Advocate by vocalizing and disseminating the clinical research sites' positions on critical issues and educating other stakeholders regarding those positions.
- Connect by promoting opportunities for the investigative site community to connect and learn from fellow sites and other critical stakeholders.
- Educate and mentor sites to ensure success and the continuation of a legacy of excellence.

Recognizing the value of all industry stakeholders, any company involved in clinical research may participate as a member of SCRS. Membership in SCRS is open to individual clinical research sites, site networks, and companies that sponsor or support the work conducted at sites. Accordingly, membership dues are set at a sliding scale with a range of benefits.

For more information, visit myscrs.org.

SCRS' INAUGURAL LEADERSHIP COUNCIL

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Apostle Clinical Trials

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FRANK WILLIS
Executive VP
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Catalent Pharma Launches Catalent Applied Drug Delivery Institute

The Catalent Applied Drug Delivery Institute aspires to promote innovation, knowledge-sharing, and collaboration between industry leaders, academic experts, customers, and regulators to enhance understanding of available, emerging, and future drug delivery technologies and improve patient care.

"The mission of the Catalent Applied Drug Delivery Institute is to bring better treatments to market by advancing the development and adoption of applied drug delivery technologies," says Kurt Nielsen, Ph.D., senior VP, research and development. "By harnessing the knowledge of some of the world's leading experts in drug development, delivery and formulation, the institute will cultivate leadership and excellence in drug development through education, training, and innovation."

As part of its mission, the Catalent Applied Drug Delivery Institute will serve as a link between

industry and academia by providing guidance, counsel, and resources on major issues pertaining to drug development, delivery, and formulation. The institute will develop programs that facilitate mutually beneficial collaborations, increase communication, and shed light on regulatory issues affecting drug developers and researchers. It also will pursue a multi-tiered approach of seed funding, strategic counsel, and educational programs to advance the adoption of emerging technologies.

There will be a series of institute-led initiatives designed to enhance understanding of drug delivery and inspire the next generation of science leaders.

ICON Launches New Functional Service Provision (FSP) Strategy


Barry Balfe

ICON, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical device industries, has launched a new functional resourcing strategy delivered by a dedicated division, DOCS, which has developed the FSP Delivery Platform. This combines DOCS' global resourcing engine with the processes, quality oversight, systems, and training and governance structures to drive productivity through flexible FSP models. The DOCS FSP Delivery Platform also leverages ICON's therapeutic, geographic, and functional expertise to ensure greater efficiencies across customer programs.

"Functional resourcing and FSP continue to grow in popularity as sponsors look for innovative outsourcing strategies that enable them to gain efficiencies and accelerate the development of their pipelines," says Colin Stanley, president, DOCS.

The DOCS FSP business is being led by Barry Balfe, VP global program management.

ACP Digital Advertising Network Launched

The American College of Physicians has created the **ACP DIGITAL ADVERTISING NETWORK**.

"As digital offerings continue to evolve and create new methods for physicians to engage with our content, we feel it is important for our organization to maintain control of how those offerings are being positioned and sold," says Kevin Bolum, director of advertising sales for ACP. "The recent launch of our Annals of Internal Medicine iPad application presented an opportunity for us to reevaluate the positioning of all of our digital assets and invest our efforts on our internal digital infrastructure and capabilities."

ACP's websites receive visits from more than 500,000 unique users each month. Along with Annals of Internal Medicine, ACP Hospitalist, and ACP Internist allow ACP to provide insightful content that is relevant to all types of healthcare professionals, medical students, and hospital staff.

Watson Announces New Name — Actavis — for Global Operations


Paul Bisaro

Watson Pharmaceuticals has a new name: **ACTAVIS**. The change becomes effective in 2013, during which the company will begin a multi-year rebranding campaign for its facilities, operations, and commercial presence, and will transition to trading under a new symbol on the New York Stock Exchange.

"When we announced the proposed acquisition of Actavis in April 2012, we immediately instituted an extensive and accelerated review of our global brand position and naming equities," says Paul Bisaro, president and CEO of Watson. "A pioneer at the dawn of the U.S. generic industry in 1984, the Watson corporate name was never registered globally. As we initiated our global expansion strategy in 2009, it became clear that we could not establish a single, unified market presence under the Watson brand.

"With our expansion into more than 60 commercial markets around the world, we recognized the many benefits of uniting our company under one name to all stakeholders – customers, consumers, payers, institutions, and shareholders and potential shareholders," Mr. Bisaro continues. "We initiated an extensive review of the name equities within our portfolio, as well as assessing the potential of more than 2,000 potential new names. As this process progressed, it became clear that one of the many assets within the Actavis acquisition was a single name, trademarked and protected around the world. It evokes powerful words: action, vision and strength, time-honored attributes of both Watson and Actavis. Adopting the Actavis name on a global basis for our generics, brands, and biosimilars businesses was a logical and cost-effective solution."

In October, Watson finalized the acquisition of the Actavis Group for EUR 4.25 billion. The combination created the world's third-largest generic pharmaceutical company, with anticipated pro forma combined 2012 revenue in excess of $8 billion.

BioClinica Expands Imaging Support for Osteoarthritis Trials

BioClinica has launched new and expanded imaging services critical for clinical trials in the area of **OSTEOARTHRITIS (OA)**, a disease affecting more than 21 million people in the United States.

Colin Miller, Ph.D., senior VP, medical affairs, says BioClinica has amassed a thorough understanding of the FDA requirements and the challenges for these clinical trials. A new proprietary BioClinica positioning device was specifically developed to provide highly reproducible radiographs of subjects' knees and address the requirements of demanding DMOAD imaging endpoints.

Development of novel DMOADs requires acquiring highly reproducible plain film radiographs capable of showing joint space narrowing changes of less than 0.2 mm per year. BioClinica's experience in these studies led to the development of the new system. The use of this device ensures that patients are positioned correctly and consistently at each visit so that even minimal changes will be accurately measured. The proprietary BioClinica positioner supersedes other positioning devices, which have shown significant manufacturing variances and hence positioning variability.

WorldCare Clinical Introduces New Independent Review Services

WorldCare Clinical LLC, a CRO focused on maximizing the precision and accuracy of independent assessments in clinical trials, has launched new Endpoint Assessment Committee (EAC) services for blinded independent central review (BICR) of clinical trial data. WCC's EAC services include expert assessments by physicians drawn from multiple therapeutic areas for comprehensive efficacy and safety reviews.

WCC's strategic relationship with Massachusetts General Hospital (MGH) allows it to pull world-class, subspecialty-trained physicians from across departments for reads.

From radiology and dermatology to oncology, cardiology and neurology, WCC provides blinded independent assessments by subspecialty-trained, board-certified experts, who are trained by WCC under a uniform system to maximize the precision and accuracy of data interpretation.

"WorldCare Clinical is excited to unveil its Endpoint Assessment Committee offering to pharmaceutical and biotechnology companies conducting trials that depend on subjective endpoint assessments," says Richard Walovitch, Ph.D., president of WorldCare Clinical. "Across multiple therapeutic areas, the FDA is increasingly requiring EAC review of critical data for registration trials. We believe our EAC offering will enable sponsors to maximize their chances of regulatory success, by providing a more accurate and less variable interpretation of critical trial data.

Theorem Clinical Research Expands Service Area Worldwide

Theorem Clinical Research has launched **THEOREM STRATEGIC SOURCING SOLUTIONS** to provide staffing and outsourcing services to the pharmaceutical and biotech industries in more than 30 countries, with a special focus in Asia-Pacific and Latin America, but with the ability to deploy staff to any country where presence is required.

"It is fundamentally important to us that we are able to offer a full range of staffing solutions to meet the needs of clinical research professionals worldwide," says Theorem CEO John Potthoff. "That includes being able to provide qualified staff, help reduce overhead costs and increase productivity."

Theorem outsourcing managers are clinical research professionals who have experience in clinical trial administration, bioanalysis, data management, medical writing, drug safety, and other research areas. PV

AROUND THE GLOBE

Max Neeman International has expanded its Asia-Pacific footprint with new presence and capabilities in neighboring countries of Bangladesh, Sri Lanka, and Malaysia. These Asia-Pacific countries are ideal locations for clinical trials due to access to many treatment-naive patients across a variety of disease areas, local medical expertise and infrastructure, standard of care that is comparable to developed countries, and regulatory ease. Sponsors will have increased access to an additional 200,000 patient population while in close proximity to the Max Neeman organization.

Quintiles has begun its first global study involving Indonesia, made possible by an exclusive alliance with Prodia Clinical Laboratory to provide high quality in-country testing of samples from Indonesian patients in clinical trials. With a population of more than 240 million, Indonesia has been difficult to include in global trials because of requirements that all local samples be tested in-country before samples or data can be exported. Two things changed that: Prodia's exclusive alliance with Quintiles to test trial samples; and its recent accreditation by the College of American Pathologists, the world's foremost organization dedicated to laboratory quality improvement.

Indonesia's large, ethnically diverse population faces a wide range of infectious and non-communicable diseases, making it a promising location to conduct clinical trials needed to bring new, better medicines to patients in need. Quintiles first opened an office in Indonesia (Jakarta) in 2006.

Simulations Plus Inc., a provider of simulation and modeling software for pharma discovery and development, has accepted an invitation and signed a formal agreement to participate in the European Union Oral Bioavailability Tools (OrBiTo) project. Simulations Plus is the only non-European company invited to participate.

The OrBiTo project was established as part of the Innovative Medicines Initiative Joint Undertaking (IMI-JU). The purpose of this collaboration is to advance various tools, including computer software, used to predict oral absorption of drugs by sharing data and technologies across the member companies.

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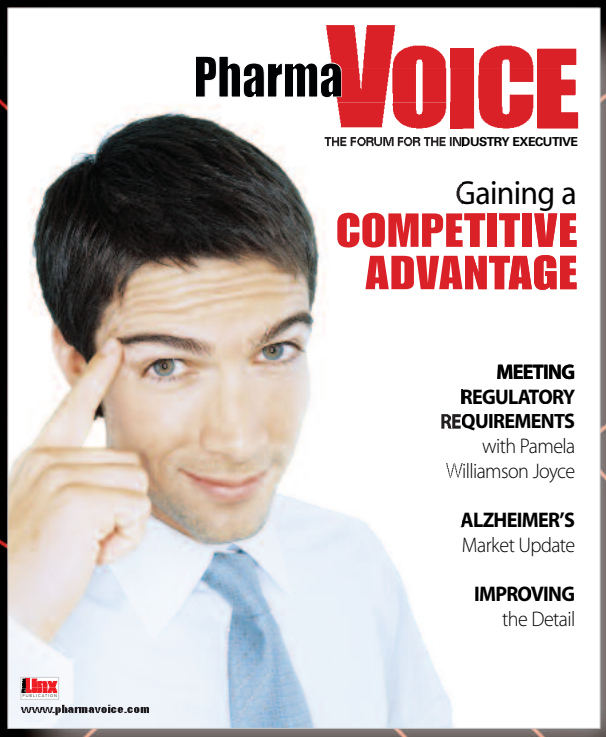

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