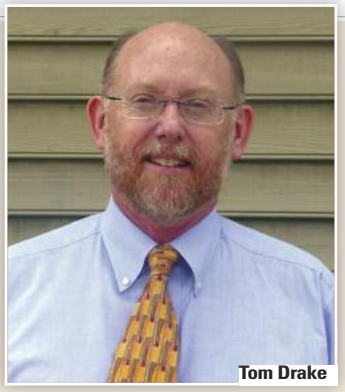
What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

Global Outcomes Group Launches

to Support Outcomes Research

TRENDING NOW: New full-service medical communications agency focuses on supporting growing health economics and outcomes research in biopharma industry.


Tom Drake

The Global Outcomes Group has been formed to support the content and communication needs for the growing health economics and outcomes research (HEOR) sector in the biopharmaceutical and medical device industries. Assembling one of the largest groups of experienced international HEOR talent in writers, editors, and educators, the Global Outcomes Group fills a void with comprehensive support for HEOR management.

Global Outcomes Group's Founder Tom Drake, a 25-year industry veteran, says: "The HEOR sector in bio/pharma has grown rapidly in the past decade and will become an even more important segment as healthcare decision makers require demonstrated outcomes and value along with clinical safety and efficacy data. The Global Outcomes Group is a unique, globally focused HEOR ecosystem designed to deliver content and communications services using its large team of experienced HEOR writers and editors to meet the growing needs of industry HEOR professionals."

For more information, visit globaloutcomesgroup.com.

SPBT Changes Names

Society of Pharmaceutical & Biotech Trainers is now the Life Science Trainers Network (LTEN). The new name underscores the growing diversity of its membership, acknowledges external influences, and speaks to a new paradigm of training excellence. The new name also reinforces the transformation of SPBT into a social organization that harnesses the collective intelligence of its members.

"Our new name and branding represent a deeper commitment to creating a community focused on improving learning through all segments of life sciences, and that will be forward-thinking and solutions-oriented," says John Sjovall, LTEN president, and executive director, sales training and development, Daiichi Sankyo.

The name LTEN reflects the complete range of life-sciences companies inclusive of pharmaceutical and biotech as well as medical device and diagnostic.

Of the 1,400 LTEN members, 16% are from medical device and diagnostic companies, and the numbers continue to steadily grow.

For more information, visit L-TEN.org

Biomedical Discovery Project Innovation Launched

The National Patient Advocate Foundation (NPAF), a national nonprofit organization providing the patient's voice in improving access to quality cancer care, has released a blueprint to accelerate the delivery of promising new treatments to patients and launched a new grassroots movement called Project Innovation to drive action.

"Cancer kills 1,600 Americans every day and this number will only increase in the years ahead unless we commit as a nation to hasten the pace of medical discovery," says Nancy Davenport-Ennis, NPA's founder and chairman. "It is time to put cancer innovation on the national agenda and press for solutions that will save lives instead of continuing a one-sided conversation on the cost of treatment."

NPAF will spearhead Project Innovation, a social activation effort to involve patients, their family members, and local citizens in speaking out about the importance of accelerating cancer innovation.

Using the online hub — projectinnovation.org — digital advertising and multiple information channels, Project Innovation will tap the energy and ideas of cancer patients, advocates, healthcare professionals, biomedical researchers, medical innovators, payers, and policymakers on ways to move cancer discovery forward.

For more information, visit projectinnovation.org

Global

Covance has acquired Medaxial, a London-based value communication consultancy. The company specializes in offering clients an integrated approach to market access strategy, health economic modeling, and data dissemination services, and focuses on defining and communicating the value of a biopharmaceutical product or medical device to healthcare payers and the stakeholders who influence them.

For more information, visit covance.com.

CSL Ltd., parent company of CSL Behring, has opened the CSL Behring Biotechnology Manufacturing Facility in Melbourne, Australia. The new facility, located adjacent to the site's manufacturing plant for plasma products, is the centerpiece of CSL's $250 million expansion at its Broadmeadows site and will play an increasingly important role in the company's global operations, particularly in the late-stage development of new types of hemophilia products.

For more information, visit csl.com.au.

Global Investigator Databank Expands

Novartis, Janssen, Merck (known as MSD outside the United States and Canada), Lilly, and Pfizer have joined together with DrugDev in hosting a repository of specific investigator information as part of the Investigator Databank.


David Detoro

In addition, investigators can now access the Investigator Databank through the launch of investigatordatabank.org. Through this website, investigators can securely log in, view and add to their information kept on file by the participating pharmaceutical companies or DrugDev.

The Investigator Databank was established to improve the efficiency of industry-sponsored clinical trials and serves as a one-stop repository where key information about investigators and clinical trial sites, such as infrastructure and good clinical practice (GCP) training records and site profile forms, are housed. Hosted by a third party, DrugDev, the Investigator Databank benefits both investigators and members of industry by increasing awareness of clinical trial opportunities for investigators, and by reducing the administrative burden of identifying clinical trial sites for the pharmaceutical industry.

"The global community of clinical trial investigators is a common and highly valued resource upon which the pharmaceutical industry relies," says David Detoro, associate VP, clinical operations, at Merck. "By supporting our investigators, and helping to optimize how they partner with our industry, we can continue to develop new therapies for the patients who need them."

For more information, investigatordatabank.org.

Quintiles and APTA Implement Physical Therapy Registry

Quintiles and the American Physical Therapy Association (APTA) have launched a new strategic collaboration to develop and implement the Physical Therapy Outcomes Registry. Recruitment of users for a pilot version of the registry will begin in the third quarter of 2014, with a full launch in early 2015.


Cynthia Verst

The Physical Therapy Outcomes Registry will use a hub-and-spoke model to collect data, wherein data is collected from multiple sources and deposited into a centralized repository. The "spokes" include electronic health record systems, billing and documentation systems used by health systems, APTA chapters across the country, private practices, other facility-based practices, and individual physical therapists.

"Patient registries are an increasingly vital component of real-world, comprehensive evidence development for identifying the causes of disease and, in this case, injuries, and designing effective treatments," says Cynthia Verst, president of real-world and late phase research at Quintiles. "Our goal is to build a new registry that will provide clinicians and practices with benchmark data to improve healthcare delivery and achieve better patient outcomes."

For more information, visit quintiles.com.

FDA Launches openFDA to Provide Easy Access to Public Data

The U.S. Food and Drug Administration has launched openFDA, a new initiative designed to make it easier for Web developers, researchers, and the public to access large, important public health datasets collected by the agency.


Walter Harris

In alignment with the recent Presidential Executive Order on Open Data and the Department of Health and Human Services Health Data Initiative, openFDA makes the FDA's publicly available data accessible in a structured, computer readable format that will make it possible for technology specialists and researchers to quickly search, query, or pull massive amounts of public information instantaneously and directly from FDA datasets on an as-needed basis.

"The openFDA initiative leverages new technologies and methods to unlock the tremendous public data and resources available from the FDA in a user-friendly way," says Walter Harris, the FDA's chief operating officer and acting chief information officer. "OpenFDA is a valuable resource that will help those in the private and public sectors use FDA public data to spur innovation, advance academic research, educate the public, and protect public health."

For more information, visit fda.gov.

Lilly Announces Increased Access to Clinical Trials Data


Tim Garnett

Lilly has announced that it will begin sharing its clinical trial data with scientific researchers through clinicalstudydatarequest.com. This website, which houses data from several clinical trial sponsors, was created in support of ongoing efforts by the Pharmaceutical Re-

search and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) to increase access to and transparency of clinical trial results with researchers around the world.

The new portal differs from previous Lilly data-sharing sites in that access will only be granted after approval of a research proposal by an independent scientific review panel. Lilly will not be involved in the decisions made by the independent scientific review panel. The multi-sponsor portal will include Lilly-sponsored interventional clinical studies from approved medicines and indications in the United States and European Union.

Now that this coordinated access is available, Lilly will replace the current website, lillyclinicalstudydata.com, with the new clinicalstudydatarequest.com.

"Scientific advancements to improve patient care require the collaboration and creative thinking of researchers around the world," says Tim Garnett, M.D., senior VP and chief medical officer, Lilly. "Since our early partnership with academic researchers brought about the first commercial insulin, we've continued to seek new ways to bring our internal expertise together with the high-quality research being done beyond our walls."

For more information, visit lilly.com.

Biotech Consortium Launches KPI Therapeutics


Charles Magness

Five biotech firms and private investors have announced the launch of KPI Therapeutics with the aim of speeding advancement of novel, promising drug candidates that can improve the quality of patients' lives. KPI is launching with an array of international research team partners, including MPI Research, Chimera Biotec, Life Chemicals, Medical Marketing Economics, and Kineta, all experienced in translational drug development.

The lead drug in KPI's investment portfolio, ShK-186, is a novel, immune-sparing therapeutic, which recently completed a Phase IB trial. Additional proof of concept trials in psoriatic arthritis (PsA) and psoriasis are planned in 2014.

"Despite recent advances in scientific knowledge and reports of promising new medicines from early stage discovery, we have not seen a concurrent surge in innovative therapies for patients reaching the market," says Charles Magness, president and CEO of Kineta. "KPI is designed to bring the capabilities of world-class drug development players and investors into a collaborative alignment where all patients, partners, and investors can benefit."

For more information, visit kpitherapeutics.com.

Fight the Fakes Increases Membership

Eleven new partners have joined Fight the Fakes, a campaign that aims to raise awareness about the dangers of fake medicines. The campaign gives a voice to those who have been personally impacted and shares the stories of those working to put a stop to counterfeit products.

The new partners, representing wholesalers, pharmacists, mobile app services, coalitions for consumer protection and generic pharmaceutical manufactures, bring the total number of member organizations to 25. These organizations add to a diverse group of standing partners, including healthcare professionals, disease-specific organizations, research-institutes, product-development partnerships, foundations, nonprofits and the private sector.

Though it is a challenge to measure the scope of these dangerous products, the World Health Organization (WHO) estimates that fake medicines can account for up to 30% of the drug supply chain in parts of Asia, Africa and Latin America.

For more information, visit fightthefakes.org.

Cell Therapeutics Changes Name

Cell Therapeutics, a biopharmaceutical company focused on acquiring, developing and bringing to market novel targeted therapies for blood-related cancers, has changed its corporate name to CTI BioPharma Corp.

"The rebranding from Cell Therapeutics to CTI BioPharma comes at a defining moment in our company's history and better reflects who we are today and our aspirations for becoming a leader in developing therapies for patients with blood-related cancers," says James Bianco, M.D., president and CEO of CTI BioPharma.

"From the beginning, CTI has looked at potential therapies from the patient's perspective to address both the clinical need and the impact treatment can have on a patient's life. This inspires everything we do and is evident in the drug candidates we are currently pursuing and those we'll look to acquire."

For more information, visit ctibiopharma.com.

Lumara Health Launches With Focus on Women's Health

K-V Pharmaceutical has a new corporate name, Lumara Health Inc., which reflects the fundamental changes the company has made since emerging from Chapter 11 bankruptcy protection last year to align with its core mission of helping women achieve healthier lives.

"With new ownership, a new board of directors


Greg Divis

with a strong and diverse background in healthcare, new members of our leadership team who bring deep expertise that complement our current capabilities, and the recapitalization of our finances, we are in a stronger position today to deliver on our core mission," says Greg Divis, CEO of Lumara Health. "We're excited about the direction the company is headed and our ability to contribute to advancements in women's healthcare."

For more information, visit LumaraHealth.com.

WIRB-Copernicus Group Launches WCG Oncology

The WIRB-Copernicus Group (WCG), a provider of regulatory and ethical review services for clinical research, has formed a new cancer-focused institutional review board, WCG Oncology.

WCG Oncology is constituted by three dedicated IRB panels, which focus wholly on the ethical oversight of oncology research, and a cadre of expert oncological specialists to assist in the review of complex and scientifically challenging research.

"Oncology is one of the fastest-evolving medical fields," says WCG Chief Clinical Research Officer Lindsay McNair, M.D. "We are seeing significant advances in gene therapy, targeted treatments, and companion diagnostics.

"In the past four years, WCG has reviewed more than 4,000 oncology protocols, which have substantially increased in complexity."

For more information, visit cgclinical.com.

Vector Oncology Announces New Company Name

Vector Oncology Solutions, formerly ACORN Research, is announcing their company name change. The change comes as part of a strategic shift focusing on the growth of Vector Oncology's pharmaceutical services (CRO) and HEOR/HOPE data analytics businesses.

The company had previously announced the divestiture of its ACORN community oncology research network (SMO) unit to support the research mission of the West Clinic.

Vector Oncology is also announcing the appointment of Michael Choukas as CEO, and Sean Hart as executive VP and managing director, pharmaceutical services.

For more information, visit VectorOncology.com. PV

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Mark Wiley
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Top 5 Reasons to Attend

- Through **case studies**, gain a better understanding of how pharmaceutical companies use social media platforms and digital tools to **connect** with online **patient communities**
- **Discuss** the evolution of the ePatient and it's role in generating tailored content applicable in healthcare
- **Explore** the use of third party contributors and **multichannel engagements** to strengthen stakeholder relationships with online patient communities
- Learn about how multiple stakeholders **interact with ePatients** and the impact on **health outcomes** and patient engagement
- **Examine** the challenges that industry and ePatients face when trying to understand the **regulatory** landscape of **social media**

Topics Covered:

- The **impact** of digital engagements on **healthcare providers** and patients
- Vehicles used by pharma and healthcare providers to **engage with ePatients**
- Content **marketing** to reach ePatients
- Connecting with ePatients for **Medical Device**
- **Social Media** Regulatory /FDA **Guidance** on Social Media

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