

What's New



NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

New Agency Brand ARCHITECTURE

► *Trending now:* Publicis Health Media launches new model across its three U.S. hubs.

PUBLICIS HEALTH MEDIA (PHM) has launched a new branding architecture, affecting its three key office locations in Philadelphia, New York, and Chicago. The strategic branding restructure was developed as a result of the company's rapid growth, its growing client needs, as well as the desire to showcase the uniqueness across all three major city hubs.

Each office is identified with a new signature brand name to highlight each individual location offering. The key PHM locations are named as follows:

- Publicis Synapse — Chicago
- Publicis Thrive — Philadelphia
- Publicis Pulse — New York

Operating under PHM's continued mission to develop breakthrough programs that ultimately help people make health decisions, each of these regional brands will collaborate together to leverage PHM's talent, scale, and Publicis Health Groupe (PHCG) partnerships.

To ensure alignment of these three new brands to the mission of PHM, a new leadership team has been named that is responsible for both driving the strategic growth across PHM and the integration of strategic capabilities across brands. Matt McNally is president.



Matt McNally

J. Knipper Expands



Jim Knipper

J. Knipper and Company has broken ground on a new high-volume distribution center in Charlestown, Ind. This new state-of-the-art distribution center will provide expanded distribution capabilities for many of the company's pharmaceutical, biotech, and medical device customers, including a high-volume direct-to-practitioner fulfillment business primarily for drug samples and medical devices. With warehouse and fulfillment capabilities to manage prescription, controlled substances, and cold chain products, the new facility will open in May 2016.

"Our East Coast facilities continue to provide the high quality and exceptional service that our customers have come to expect. The new Midwest expansion provides unique opportunities to exceed current expectations providing even greater specialization in DTP and broader flexibility in logistics," says Jim Knipper, owner and CEO of J. Knipper.

Parexel Expands Market Access and Clinical Evidence Services

Parexel International has expanded its evidence-based services for biopharmaceutical products, which focuses on clinical research and



Joshua Schultz

operations, market access consulting, medical communications, and pharmacovigilance to help companies identify, evaluate, generate, and communicate the evidence of product value needed to successfully position a drug for market access and to support the product throughout its lifecycle.

Parexel Access combines the expertise of Heron Commercialization, QSI's pharmacovigilance, Parexel Medical Communications, and Parexel peri/postapproval services to offer a range of fully integrated services to help clients position their products for market access and ongoing commercial success, including evidence identification and evaluation, evidence generation, and communication.

"No longer is demonstrating safety and efficacy enough to launch a product successfully," says Joshua Schultz, corporate VP and worldwide head of Parexel Access. "The pressures to control the cost of healthcare coupled with the development of payer oversight organizations mean drug developers must demonstrate clear value to add a product to the treatment landscape."

Flagship Ventures Launches Evelo Therapeutics

Flagship Ventures has launched Evelo Therapeu-

Around the Globe

PRA Health Sciences is relocating to a new office in Singapore to support its expanded operations in the region.

Since 2000, PRA has been strategically expanding its Asia Pacific capabilities. In the past two years the Singapore workforce has doubled in size. Since 2010, PRA has conducted 23 clinical trials in Singapore and three nonclinical consulting projects.

"We are excited about this new location," says Jonathan Newton, PRA regional senior director, clinical operations. "Singapore is an excellent center for clinical research and is the regional hub for PRA in Asia Pacific. This move is recognition of PRA's commitment to meeting the growing needs of our clients and providing high-quality services in the region."

Pharm-Olam International, a multi-national, full-service CRO has relocated its Polish location to a larger office to accommodate its growing staff.

With a population of almost 40 million people, Poland offers rapid recruitment in most therapeutic areas. When combining the extensive population with experienced investigational staff and the efficient transfer of study supplies as an EU member state, Poland is primed for extensive growth in the clinical trial arena.

tics, a new company focused on leveraging the power of the microbiome to develop novel therapies for cancer, with an initial capital commitment of \$35 million.

Evelo is pioneering oncobiotic therapeutics, a new modality in cancer therapy based on the cancer microbiome. Evelo is the first company to systematically identify, characterize, and understand the biology of cancer-associated bacteria (CAB) and bacterial immune activators (BIAs), providing new insights into cancer metabolism and immuno-oncology. The microbiome is the collection of



Dr. Noubar Afeyan

trillions of microbes that live in and on the human body. In recent years, scientists have found that the microbiome plays a crucial role in many areas of human biology and disease.

Evelo's oncobiologic platform would treat cancer through unprecedented therapeutic modalities. Evelo's novel approaches leverage tumor-microenvironment modifications that can be mediated by the microbiome to disrupt tumor metabolism and the interactions between the tumor and surrounding tissue.

Evelo is also exploring novel oncobiologic approaches that can leverage the ability of bacteria to uniquely and powerfully activate the immune system to fight cancer.

"Evelo's proprietary technologies and platforms lay the foundation for the first company to approach treating cancer through an understanding of the microbiome," says Dr. Noubar Afeyan, senior managing partner and CEO of Flagship Ventures, and co-founder of Evelo.

Strategies for Biosimilars Approval: A Map to 351(k) Success

Companies that would like to know how Sandoz received the FDA's first biosimilar approval, can learn how it navigated the agency's approval process in a new management report from FDAnews. The report provides candid "what to do — and how to do it" advice, including:

- ▶ The evolution of the FDA's thinking on the clinical requirements for showing biosimilarity, right up to and including the 2015 guidance
- ▶ How participating in the FDA's Biological Product Development Program (BPDP) can benefit you and your company
- ▶ The supporting clinical data you MUST include in your filings to gain approval quickly
- ▶ The correct way to apply the FDA's latest recommendations for demonstrating that a proposed product is "highly similar" to a reference
- ▶ How to effectively use key evaluations and modeling and simulation tools
- ▶ Anticipating legal and regulatory hurdles such as patent and litigation issues, interchangeability and state substitution laws

Also included is a detailed review of four critical topics from the recent FDA guidance:

- ▶ How to establish a step-wise approach to product development — the way the FDA prefers
- ▶ The agency's totality of evidence methodology for assessing 351(k) applications
- ▶ Using foreign reference products and the need for bridge studies
- ▶ How analytics should be designed for pharmacokinetics and pharmacodynamics

Physicians Interactive Evolves Services to Include Patients, Life Sciences



Brian Robinson

Physicians Interactive changed its name to Aptus Health to better reflect its mission of advancing health engagement and its role as a global digital health engagement partner for life-sciences companies, payers, employers, and health systems. The change comes as the company extends into new markets and expands its offerings to address a growing need for integrated digital health engagement strategies aimed at both healthcare professionals and consumers.

"Today, our capabilities include solutions for engaging both healthcare professionals and consumers, intelligent geo-targeting segmentation strategies, and more — serving biopharma, employers, and integrated delivery systems," says Brian Robinson, chief marketing and strategy officer at Aptus Health. "For our biopharma customers, we're focused on supporting their shift from a traditional field-based model to an integrated, digital multi-channel model."

ClearPath Development Launches Second Vaccine Company Under Strategic Partnership With Astellas

ClearPath Development Company launched its second vaccine company, Nosocomial Vaccine Corp., with the support of its partner, Astellas Pharma. The partnership between ClearPath and Astellas was established to support the goal of building a global vaccine franchise and launched its first company, RSV Corp. (RSVC), in December 2013. NVC has initiated research collaborations with two partners to develop a nosocomial vaccine: Affinivax Inc. and the Center for Vaccine Development at the University of Maryland School of Medicine. The research collaboration will use Affinivax's proprietary vaccine platform, Multiple Antigen Presentation System (MAPS), to develop vaccines that prevent bacterial nosocomial infections, also referred to as healthcare associated infections (HAIs).

"Together with our collaborators at Affinivax and the University of Maryland School of Medicine, we are accelerating research and development of a vaccine for important pathogens causing nosocomial infections, one of the most common HAIs," says Donna Ambrosino, M.D., CEO, NVC.

Foundation Medicine Launches Precision Medicine Exchange Consortium

Foundation Medicine has launched a precision

medicine partner program, Precision Medicine Exchange Consortium (PMEC), to facilitate data exchange, advance research, and support education and applications of precision medicine in oncology and molecular pathology. PMEC brings together oncology thought leaders from academic medical centers, regional hospital systems, and community oncology networks who share a vision for utilizing precision medicine as a means for improving clinical outcomes in oncology treatment.

Founding members of PMEC include The Cleveland Clinic's Taussig Cancer Institute, Hackensack University Medical Center, The Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Sidney Kimmel Cancer Center at Thomas Jefferson University, UC Davis Health Comprehensive Cancer Center, the University of North Carolina Lineberger Comprehensive Cancer Center, and Vanderbilt-Ingram Cancer Center, and The Wake Forest Baptist Comprehensive Cancer Center.

BioClinica Launches New eClinical CRO Partner Alliance Program

BioClinica has rolled out a new eClinical CRO partner alliance program to accelerate the adoption of industry-leading eHealth solutions by CROs. The decision to redesign the CRO partner channel comes in response to growing demand for an eClinical technology platform that enables CROs and sponsors to conduct studies in an efficient and accelerated manner.

Partners may leverage certification and services in the BioClinica platform or individual solutions to achieve unique financial benefits in areas, including randomization, trial supply management, and forecasting with predictive analytics; intelligent risk-based monitoring; clinical trial management, operations, and payments; and electronic data capture, comprehensive data management, and clinical operations support.

Moderna Launches Caperna to Develop Personalized Cancer Vaccines

Moderna Therapeutics, a pioneer in the development of messenger RNA (mRNA) therapeutics, launched Caperna, its fourth venture, to focus exclusively on the advancement of personalized cancer vaccines.

Caperna is applying Moderna's mRNA vaccine technology to cancer vaccines, building on advances in cancer immunotherapy, including the availability of checkpoint inhibitors and the ability to rapidly determine individual patient mutations. Caperna's develop strategy includes personalized cancer vaccines that encode a patient's specific neoepitopes, using Moderna's unique infrastructure to manufacture within weeks small batches of vaccines tailored to each patient. 