

Awards...



BMS EARNS ENERGY STAR PARTNER OF THE YEAR AWARD

For the third consecutive year, the U.S. Environmental Protection Agency (EPA) recognizes Bristol-Myers Squibb with an Energy Star Partner of the Year Award for outstanding efforts to improve the energy efficiency of facilities worldwide. BMS was recognized for achieving an annual energy intensity improvement of more than 3%, contributing to an 11.4% reduction in energy consumption since 2010, as well as implementing 36 major energy projects in 2016, bringing the total number of projects implemented since 2009 to 302.

ICON AWARDED BEST CRO AT WORLD VACCINE CONGRESS

ICON has been awarded Best Clinical Research Organization at the Vaccine Industry Excellence (ViE) Awards. The awards honor individuals and organizations that continually set standards of excellence and have made outstanding achievements in the vaccine industry over the past 12 months.

KLICK NAMED A GREAT PLACE TO WORK FOR SIXTH TIME

Klick has been recognized as one of 2017's Greatest Places to Work, marking the sixth time the company has been included on the Top 100 Best Workplaces list. Klick was also named a Best Workplace for Women and a Best Managed Company. Great Place to Work is a research and consulting firm whose mission is to build a better society by helping companies transform their workplaces.

MEDIDATA WINS AWARD FOR CLINICAL TRIAL PARTNERSHIP OF THE YEAR

Medidata and its technology collaboration with Tesaro has been recognized as the 2017 Clinical Partnership of the Year at the Clinical and Research Excellence (CARE) Awards.

TRACON AWARDED MOST INNOVATIVE TRIAL DESIGN

Tracon Pharmaceuticals has been recognized for its Phase III clinical trial of TRC105 in angiosarcoma as Most Innovative Clinical Trial Design at the 2017 Clinical and Research Excellence (CARE) Awards. The two companies worked together to update features to Medidata Balance, a randomization and trial supply management (RTSM) tool that is an integral part of the Medidata Clinical Cloud.

Allergan Encourages Those with Migraine TO SHARE EXPERIENCES THROUGH ART



Frames of Mind is an interactive campaign to promote awareness of the impact that migraine can have on patients' everyday lives. This submission was created by Colleen Brett from Philadelphia.

Allergan has unveiled Frames of Mind, an interactive campaign to promote awareness of the impact that migraine can have on patients' everyday lives. People living with migraine are encouraged to create art submissions that visually depict how the

various symptoms affect them both physically and emotionally. An estimated 36 million Americans are living with migraine, a chronic disorder with episodic attacks that is characterized by an extremely disabling collection of neurological symptoms.

Johnson & Johnson Innovation LAUNCHES QUICKFIRE CHALLENGE

Johnson & Johnson Innovation has launched the newest QuickFire Challenge: Advancing the Safe Use of Healthcare Products. The challenge seeks to identify entrepreneurs, academics, scientists, engineers, or startup companies that are advancing



Johnson & Johnson INNOVATION | JLABS

QUICKFIRE CHALLENGE

potentially game-changing, early-stage, innovative solutions to advance safety in healthcare products that help inform patients and consumers, simulate surgical procedures, and ensure proper storage and use of prescription, over-the-counter, and cosmetic products.

Prescription medication errors cause at least one death every day and injure about 1.3 million people each year. The challenge aims to improve safety in

healthcare through improving the provision of balanced and factual information — and development of solutions — to ensure safety across the spectrum of medical devices, pharmaceutical and consumer products.

The challenge will award up to a \$200,000 grant, entrance to a Johnson & Johnson Innovation – JLABS facility, and/or mentoring from Johnson & Johnson Innovation.

Bayer on Target to Provide 1 Million HANDS-ON SCIENCE EXPERIENCES



Tumi Ogunyankin joins her sister Kumi Ogunyankin to participate in a chromatography experiment at the Bayer U.S. "Take Your Child to Work Day" at the company's U.S. headquarters in Whippany, N.J., which featured hands-on science learning experiments for more than 200 students in grades 3-6. Photo credit: Patti Sapone for NJ Advance Media.

Bayer has surpassed the halfway mark of its five-year commitment aimed at inspiring the next generation of innovators.

The company launched the program in 2015, with the goal of providing 1 million hands-on science experiences to children in the United States by the year 2020. Bayer has provided 555,634 engaging science experiences to U.S. students.

The goal was timed to the 20th anniversary of Bayer's STEM initiative, Making Science Make Sense (MSMS), which advances science literacy across the United States through hands-on, inquiry-based learning, employee volunteerism, community partnerships, and public education, was instrumental in helping the company reach the halfway mark.

Site Payments and Patient Reimbursements IMPACT CLINICAL RESEARCH



Christine Pierre

Manual payment processes for clinical sites can take time away from patient care and shift focus away from research, according to a new survey by Greenphire and the Society for Clinical

Research Sites.

Key findings:

- ▶ 44% of sites employ personnel involved in accounting who also have other study-related duties

- ▶ 63% of sites prefer electronic payments
- ▶ 75% of sites reported that reimbursement timelines have an impact on their ability to pay stipends and reimbursements to patients
- ▶ 84% of sites prefer payment in 30 days or less

"Sites are looking to streamline the way payments are processed and received," says Christine Pierre, president of SCRS. "These survey findings demonstrate that sites, both in the United States and abroad, want to find new ways to cut down on administrative burdens and focus on research."

AbbVie Launches ENDOMETRIOSIS AWARENESS CAMPAIGN

AbbVie, a global biopharmaceutical company, has engaged actress, dancer, and Emmy Award-winning choreographer Julianne Hough to help raise awareness about endometriosis through a campaign called Get in the Know about ME in EndoMEtriosis. The campaign is dedicated to inspiring women to learn about and understand endometriosis.



Julianne Hough

INC Research and inVentiv Health to Merge



Alistair Macdonald



Michael Bell

Early in May, INC Research and inVentiv Health announced an agreement to merge in an all-stock transaction, creating a global biopharmaceutical solutions organization with combined net revenue of more than \$3.2 billion. The

combined company will be the second largest biopharmaceutical outsourcing provider, one of the top three CROs, and the largest contract commercial organization by net revenue.

Based upon the closing price common stock on Tuesday, May 9, 2017, the transaction values inVentiv at an enterprise value of about \$4.6 billion, and the combined company at an enterprise value of about \$7.4 billion.

Alistair Macdonald, CEO of INC Research, says: "Customers are increasingly seeking simultaneous approvals and product launches in multiple markets worldwide. Through this strategic combination we are bringing together two of the most innovative and respected players in the field to create a leading global biopharma solutions organization with a full suite of clinical and commercial solutions."

Michael Bell, CEO of inVentiv Health, says: "As biopharmaceutical companies of all sizes face increasingly complex challenges to bring products to market, they are seeking comprehensive outsourced solutions across the clinical and commercial spectrum. The new company is purpose-built to address market realities where clinical and commercial must work together, sharing expertise, data and insights, to improve client performance."

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PPD Heroes Advocate for Clinical Research TO IMPROVE PATIENT HEALTH

Pharmaceutical Product Development (PPD) has launched its 2017 educational campaign to raise awareness about the life-changing impact of clinical research, featuring a team of PPD Heroes who share their personal stories to inspire hope.

PPD Heroes are extraordinary people who have overcome illness with medical treatments developed through clinical research. They help raise awareness about the importance of increasing participation in clinical trials by both patients and physicians alike to advance the development of next-generation therapies.



Teresa Dunlap is one of the PPD Heroes for the battle she's waged against triple-negative breast cancer. Now five years following treatment, the PPD Executive Director of Project Management is well past the danger zone for a recurrence.

PhRMA Board of Directors Establishes NEW MEMBERSHIP CRITERIA



Stephen Ubl

The board of directors for the Pharmaceutical Research and Manufacturers of America (PhRMA) has approved new criteria for membership. The board has voted to eliminate the "associate" category of membership and to require companies to meet the following to be eligible to join the association:

- ▶ A three-year average global R&D to global sales ratio of 10% or greater; and
- ▶ A three-year average global R&D spending of at least \$200 million per year.

Because the associate category of membership has been eliminated those 15 companies are

no longer members, though they have the option of applying for full membership if they are eligible. In addition, seven existing full member companies are no longer eligible for membership because they do not meet the new criteria. These numbers are based on membership as of Jan. 1, 2017. Companies can reapply for membership as they meet the new criteria.

"We believe our association is best positioned to represent companies that are swinging for the fences and making the long-term investments needed to tackle the biggest challenges facing patients," says Stephen Ubl, president and CEO, PhRMA.

Healthcare Veteran Publishes Branding Book

Vince Parry, a 35-year healthcare industry veteran, has published a book to showcase the health and wellness branding industry from an insider's perspective.

Mr. Parry is president and chief branding officer of Parry Branding Group, a full-service brand identity firm for the health and wellness market.

Identity Crisis: Healthcare Branding's Hidden Problems and Proven Strategies to Solve Them began as part of a curriculum Mr. Parry teaches. It explores the ways in which illness comes to define people's identities — how it changes who they become in their



Vince Parry

own minds and how such an identity crisis drives brand choice for healthcare brands.

The book also look at how the consumer-goods branding model is inadequate in positioning and marketing healthcare brands, and it uses actual case examples taken from Parry's long and illustrious career.

The book is available as a paperback and ebook formats and is now available at online book retailers.

Editor's Note: Vince Parry was named a PharmaVOICE 100 honoree in 2010.

CASE STUDIES:

» **Implementing a Study Design Change Late in a Trial for Breast Cancer Indication**

Provided by: PAREXEL

EPUBLICATIONS:

» **HBAdvantage — Leadership in Action**

Provided by: Healthcare Businesswomen's Association

WHITE PAPERS:

» **Automated Site Grant Payment Solutions**

Provided by: Greenphire

» **Driving Greater Access to Healthcare Professionals and Increasing Brand Performance**

Provided by: TrialCard

PODCASTS:

» **Rescue Studies: Key Considerations for Getting Your Study Back on Track**

Sponsored by: PAREXEL

» **Virtual Engagement — A Must-have Component of Any Pharmaceutical Sales Strategy**

Sponsored by: TrialCard

U.S. Drug Spending GROWTH INCREASES IN 2016

Drug spending grew 4.8% in 2016 to \$323 billion, less than half the rate of the previous two years, after adjusting for off-invoice discounts and rebates, according to a QuintilesIMS Institute Study. The surge of innovative medicine introductions paused in 2016, with fewer than half as many new drugs launched than in 2014 and 2015. While the total use of medicines continued to climb — with total prescriptions dispensed reaching 6.1 billion, up 3.3% over 2015 levels — the spike in new patients being treated for hepatitis C ebbed, which contributed to the decline in spend.

"After a year of heated discussion about the cost and affordability of drugs, the reality is that after adjusting for population and economic growth, total spending on all medicines increased just 1.1% annually over the past decade," says Murray Aitken, senior VP and executive director of the QuintilesIMS Institute.

Electronic Data Capture Brings Speed, Efficiency to Early Phase Clinical Research



By Dr. George Atiee, Vice President and Medical Director at Worldwide Clinical Trials Early Phase Services Unit

At a time when technology is well and truly embedded within people's everyday lives, the adoption of modern technology within clinical research has been an obvious step forward for the industry. Fifteen years ago, Electronic Data Capture (EDC) in clinical research was still a relatively rare entity. However, fast forward to today's clinical trials and electronic data capture solutions have a proven track record of supporting studies of all sizes and complexities.

The potential gains from EDC are now well understood across the clinical trials industry, including reducing long-term study costs, minimizing errors, providing access to real-time data, improved data access for all stakeholders, and shortening trial duration. They also support a patient-centric approach to research.

That said, while the value of EDC in late stage clinical research is now well-established, adoption in early

phase clinical trials has been slow. Historically, early phase trials—particularly among smaller and mid-sized organizations—have preferred paper-based processes due to short study durations and low subject counts, the perceived initial setup cost of electronic data capture systems and the additional training needed for study teams, to name a few reasons. But it's important for researchers to understand that early phase research programs can also significantly benefit from EDC use.

Benefits to Electronic Data Capture Solutions in Early Phase Clinical Research

First, electronic data capture solutions allow for quicker patient recruitment and approval to participate in the study. They also facilitate faster and more accurate collection of data, meaning errors and potential issues can be detected much earlier, and the challenges that first-in-man studies represent can be addressed much quicker than with paper-based processes. By evaluating the safety and efficacy of information more quickly and efficiently via the supply of the data in real-time, EDC solutions ultimately support moving a new drug through the development process and to market sooner.

Recent improvements in technology also mean that setup and training times have been drastically reduced. What's more, by using an EDC system in Phase I of a clinical trial program, sponsors will already have a validated system in place when it comes to moving to the next phase of devel-

opment, saving valuable time and providing consistency.

Despite the recognized benefits, the reality is that adoption of EDC has remained relatively slow in early phase clinical trials. However, thanks to advances in technology, many of the barriers that prevented small and mid-size organizations from making the switch have been removed.

New Electronic Data Capture Solutions for Phase I Studies Expected to Accelerate Timelines and Improve Data Quality

Worldwide is transitioning to implementation of a total electronic data capture solution for its Phase I studies, which will significantly speed up how it collects data, as well as provide sponsors with the opportunity to review data in real-time, as a study progresses. Data is electronically delivered from the collection device (blood pressure machine/ECG) into the EDC system where it can be viewed by way of customizable reports. This 'paperless' approach will allow us to accelerate our study timelines and is expected to provide Worldwide and our study partners with higher quality data.

To learn more about Worldwide's early phase clinical research services, please contact Worldwide Clinical Trials at +1 (610) 964-2000 or visit www.worldwide.com.

