Awards...

JBK AMONG BEST PLACES TO WORK IN NJ

JBK Associates International has been named one of the 2016 Best Places to Work in New Jersey by NJBIZ. The executive talent solutions firm is among 100 employers named to the list, which recognizes and honors the state's top employers who show a dedication to their employees' professional growth and quality of life. CEO Julie Kampf says the company is committed to developing talent in their own firm as well as for clients.

QUINTILES NAMED A WORLD'S MOST ETHICAL COMPANY

Quintiles has been named one of the Ethisphere Institute's World's Most Ethical Companies. The designation recognizes companies that align principle with action, work tirelessly to make trust a part of their corporate DNA, and in doing so, shape future industry standards by introducing tomorrow's best practices today.

Quintiles was also awarded the HR.com 2016 Leadership Excellence Award for Innovation in Deployment of Leadership Programs. Quintiles' Lisa van Capelle, acting chief HR officer, Melissa Carlson, director leadership development, and Brenda Wagner, VP global talent, accept the award.

Industry at Large

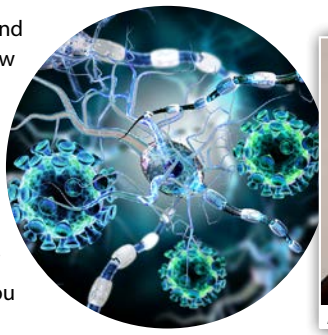
PFIZER CONSUMER PARTNERS WITH GALVANIZE ON HEALTH AND WELLNESS PROGRAM

Pfizer Consumer Healthcare and Galvanize have formed a joint health and wellness innovation program that will enable up to 10 start-up companies specializing in the development of potential solutions for improved sleep, stress management, energy, aging, and nutrition to access Galvanize's network of technical talent and investors.

The first cohort of companies was jointly selected by Galvanize and Pfizer Consumer Healthcare for a six-month program beginning in March 2016.

Actress Madeleine Stowe and Sanofi Genzyme LAUNCH MS WEBISODE SERIES

Sanofi Genzyme is collaborating with television and film actress Madeleine Stowe to launch a new online webisode series, Take Action on MS, to educate and empower people living with relapsing multiple sclerosis. In this series, Ms. Stowe has teamed up with a registered nurse, a certified life coach, a medical exercise specialist, and patients to address lifestyle topics. The webisodes cover topics including managing the feeling of being overwhelmed, asking for help when you need it, and building intimacy with a partner.



Actress Madeleine Stowe

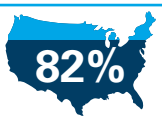
The Recall Scorecard — Fourth-Quarter 2015

374
FDA TOTAL RECALLS
DOWN 10 FROM 3RD QUARTER 2015

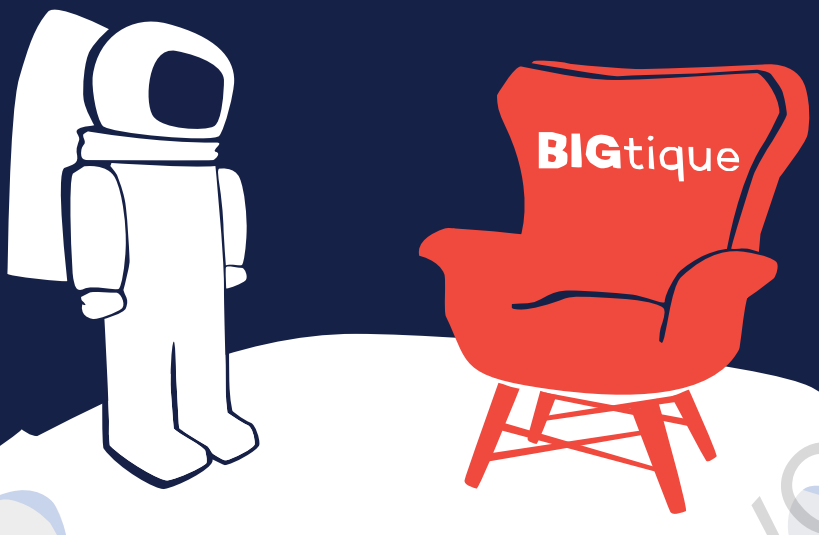
50
FDA PHARMA RECALLS
DOWN 25% FROM 3RD QUARTER 2015

32%
OF FDA RECALLS WERE INTERNATIONAL

216
FDA MED DEVICE RECALLS
DOWN 18% FROM 3RD QUARTER 2015



OF FDA RECALLS WERE NATIONWIDE



Relax.
You've landed in the right place.

JUICE
PHARMA WORLDWIDE

Your quest for a creative agency with big-time launch expertise and a boutique touch is over. We'll love your brand to the moon and back, the BIGtique way.

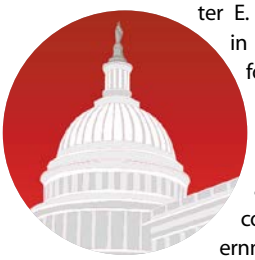
connect@juicepharma.com
juicepharma.com

322 8th Avenue, 10th Floor
New York, NY 10001

300 Broadway Street, Suite 31
San Francisco, CA 94133

STEM Event to be Held IN WASHINGTON, D.C.

The X-STEM: Extreme STEM Symposium — presented by MedImmune, the global biologics research and development arm of AstraZeneca — kicks-off the 4th USA Science & Engineering Festival Expo. Being held on April 14th at the Walter E. Washington Convention Center in D.C., X-STEM is a TED-style event for kids featuring talks by 40 of the nation's most noted science, technology, engineering and mathematics (STEM) professionals representing top universities, corporations, nonprofits, and governmental agencies.



PHARMAVOICE.COM

EBOOK

» **Women Leaders Transforming the Future**
Provided by: Healthcare Businesswomen's Association (HBA)

PODCAST

» **Utilizing Behavioral Insights for Healthcare Marketing**
Provided by: Guidemark Health

WEBINAR

» **Evolution or Revolution? How Life Sciences Organizations are Transforming to Meet the Evolving US Healthcare Market Needs**
Sponsored by: Prolifiq Software

WHITE PAPERS

» **Implementing a Clinical Data Repository and Analytics Platform in 90 Days**
Provided by: eClinical Solutions

» **Improving Marketing Performance with Behavioral Insights**
Provided by: Guidemark Health

PharmaVOICE@INDUSTRY EVENTS

WINNERS OF THE 2016 MICROSOFT HEALTH INNOVATION AWARDS

The winners of the 2016 Microsoft Health Innovation Awards were announced at the Healthcare Information and Management Systems Society Annual Conference & Exhibition. Each year, Microsoft acknowledges innovative health organizations and their technology solution partners that are using Microsoft technology to improve healthcare for patients and communities while meeting rigorous compliance and security standards.

Building the Intelligent Cloud

Primary Health Medical Group and Proskriptive — Proskriptive blended electronic medical records with claims data to provide a single unified patient view, enriched by risk models sourced from leading healthcare organizations, allowing Primary Health to more easily identify and manage cost/quality commitments. The platform securely de-identifies and aggregates electronic health record data so that clinical trial protocols can be automatically processed, rapidly identifying where and how many patients match the criteria requirements.

Creating More Personal Computing

Dartmouth-Hitchcock Medical Center and Tribridge — Tribridge Health360 is a consumer-centered, cloud solution built on Microsoft Dynamics CRM to enable Healthcare Providers to Personalize Care Experiences and achieve Population Health goals. Dartmouth-Hitchcock is using Health360 as a component of its ImagineCare offering.

Reinventing Productivity and Business Processes

Apollo Hospital Enterprises — Apollo Hospitals, a pioneer of private healthcare in India, developed an analytics solution consuming clinical big data to ensure analysis and communication of disease and infection surveillance information to both clinical and nonclinical teams using Microsoft's data and analytics services. The analytical tool brought the process of analysis and clinical decision support systems to near real time.

Open Innovation

Montecatone Rehabilitation Institute and Liquidweb — Braincontrol is a breakthrough technology that gives those with severe communication and mobile disabilities the ability to control objects with their minds. It works like a "mental joystick," allowing people suffering from pathologies such as ALS, MS, tetraplegia, and muscular dystrophies, to overcome severe physical and communicative disabilities.

Then and Now...

Much has changed in the last 15 years in the research and discovery of new medicines. For example, 15 year ago, an understanding of how the immune system can be triggered to address cancer was just beginning to emerge. In 2015, Merck and Bristol-Myers Squibb introduced Keytruda and Opdivo, two immunotherapies for non–small cell lung cancer and melanoma. Opdivo is also approved to treat renal cell carcinoma. These two products are a step forward in cancer treatment. Former President Jimmy Carter was treated with Keytruda and is now cancer free.

When PharmaVOICE first began publishing, the term "personalized medicine" was just beginning to be introduced into the industry's vocabulary. In 2015, 28% of novel new drugs approved by the FDA are personalized medicines. President Obama's Precision Medicine Initiative launched in 2015 aims to accelerate these efforts with funding for NIH research in this area.

Looking ahead, gene editing technologies could lead to additional breakthrough therapies.

One technology, CRISPR-Cas9, holds potential as "molecular scissors" that cut and edit, or correct, disease-associated DNA in a cell.

SPEAK out

Provided by: WIRB-Copernicus Group

Increasing Patient Engagement is Key to Reducing CLINICAL TRIAL DROPOUT RATE

When I started working in the biopharmaceutical industry, one thing quickly became clear to me: this is a world in which acronyms reign. It took me just a few weeks to become fluent in this new dialect. One of the first acronyms I learned was FPFV or "First Patient, First Visit." This is the date on which the first study subject makes his/her first visit to the clinical research site, consents to participate in the study, and possibly undergoes the first evaluation to determine their eligibility to participate in the clinical trial.

In hindsight, it is not surprising that FPFV was one of the first acronyms I learned, because it is heralded as one of the most important milestones in a study. The starting point from which biopharmaceutical companies and contract research organizations (CROs) measure the health of the study, FPFV is used to project enrollment timelines. It is also the date on which statisticians begin to review trial data.

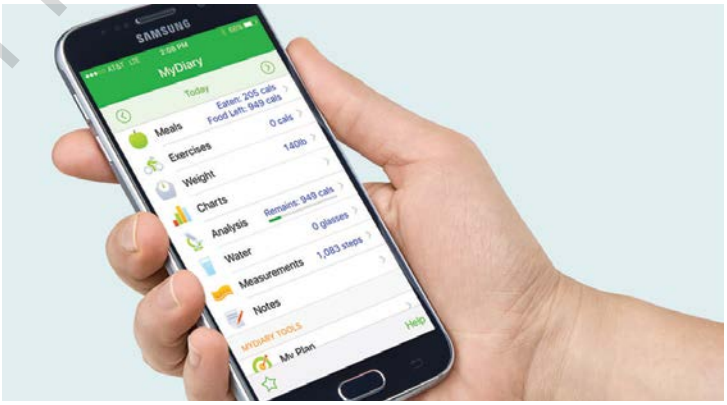
While FPFV is a milestone that draws much attention to the trial — and takes a tremendous amount of effort to reach — it cannot predict the timeline of the trial, nor can it ensure that the actual study operations adhere to that timeline. Focusing our effort —and our resources— on subject engagement and retention is a much more reliable means of ensuring the timeliness of the trial. Why? Because, on average, more than 30 percent[1] of clinical trial participants drop out before a meaningful determination of efficacy and safety can be made using their data. This failure to retain participants not only results in study delays, but requires that resources be devoted to the enrollment of additional subjects so that the trial can reach statistically-significant endpoints. As a result, biopharmaceutical companies and CROs are seeking new approaches that will allow them to hit their endpoints earlier than projected.

The more than 30-percent dropout rate can be thwarted by increasing study subject engagement and retention. Investigators can begin to improve subject engagement at the first visit by using an electronic patient consent. The electronic consent process increases a subject's understanding of the study in a number of measurable ways. Electronic consent platforms harness multimedia tools, such as video clips and animation, to explain the study more clearly. The video can explain quickly and clearly what subjects may experience during the study; it can describe the visits they will have, what drugs they will be given, and the potential risks of these interventions. As a result, study subjects will be better prepared to engage effectively with the study team.

Patient engagement tools and technologies have also become a virtual support system for study participants post-consent. These tools make trials less burdensome for subjects by simplifying complicated trials.

For example, just a few years ago, a subject in a diabetes trial would have to carry around a paper diary to record every morsel eaten and every minute of exercise. The subject would then have to mail or deliver his/her diary to the investigator's office every month. After submitting the diary, the study subject would be given another diary to begin the arduous and tiring process again. Now, we have alternative electronic options. Using a "virtual" food and activity diary, such as the one provided by ePharmaSolutions (pictured), study participants can track their activity and food intake more simply by downloading a study-specific app. The app is responsive to their search criteria and automatically populates the necessary reports with information about how many calories they've consumed and how many steps they've taken. Once they hit "save," they have submitted their information and can put their virtual diary away. The ease-of-use of this app significantly decreases the work required by the subjects, which in turn, significantly reduces the burden that the study places on their quality of life.

It has been shown that subject engagement technologies such as virtual diaries make subjects feel more connected to the ecosystem of their clinical trial. That connectedness results in a lower drop-out rate during the study, allowing biopharmaceutical companies and CROs to achieve another important milestone: LPLV, or "Last Patient, Last Visit." Companies that endeavor to bring new therapies to patients more quickly should change their focus from FPFV to LPLV. By focusing on subject engagement and retention— and by investing in the technologies that support them—we can reduce the time it takes to achieve LPLV, and really make an impact on the overall success of the trial.



Written by: Suzanne Caruso

Suzanne Caruso *is vice president of clinical solutions at WIRB-Copernicus Group, the world's largest provider of regulatory and ethical review services for human research and a leading provider of software solutions designed to accelerate clinical trials safely.*

[1]. National Academy of Sciences. The Prevention and Treatment of Missing Data in Clinical Trials. Washington, D.C.: National Academies Press; 2010. Available at: www.nap.org. Accessed March 1, 2013.