Awards...

PARAGON RECOGNIZED AS TOP CMO

Paragon Bioservices has been selected as the Best Contract Manufacturing Organization by the World Vaccine Congress. The Vaccine Industry Excellence (ViE) Awards honor the industry's most outstanding achievements in vaccine development from all corners of the globe. The award was based on attention to and quality of relationships with clients, reaching of milestones and outcomes, and building and maintaining long-term partnerships.

PAREXEL NAMED TO FORBES BEST EMPLOYERS LIST

Forbes has named Parexel to its America's Best Employers list for 2016. The list features the top 500 U.S. employers with more than 5,000 employees as rated by 30,000 employees in an independent survey.

PPD RECOGNIZED BY VACCINE GROUP

Pharmaceutical Product Development (PPD) has been named the Best Contract Research Organization (CRO) at the 9th Vaccine Industry Excellence Awards at the World Vaccine Congress 2016. The ViE awards celebrate the achievements of leaders who continually set standards of excellence and advocacy.

QUINTILES RECEIVES AWARDS

Quintiles has been named the Best CRO in Asia at the 2016 BioPharma Asia Industry Awards, winning the honor for the fourth time in the event's six-year history. Quintiles has been also recognized by the Ethisphere Institute as a 2016 World's Most Ethical Company, which recognizes companies that shape future industry standards.

VEEVA RECEIVES REWARDS

Veeva Systems has received several industry awards for its innovation, product excellence, and customer success. The company was ranked one of the fastest growing software companies in Deloitte's 2015 Technology Fast 500 and appeared in Forbes as a best software company to work for. "It's an honor to be recognized for our innovation," says CEO Peter Gassner.

Industry at Large

ASTRAZENECA AND DIABETES HANDS FOUNDATION PARTNER TO HELP ADULTS WALK THEIR WAY TO BETTER HEALTH

The Everyday Steps program offers resources to help those with diabetes start and stick with a walking routine.

AstraZeneca and the Diabetes Hands Foundation have launched Everyday Steps, a new campaign designed to help the almost 28 million Americans with type 2 diabetes develop and maintain a walking routine — one step at a time. The Everyday Steps walking guide, at www.everydaystepsguide.com, features tips to help participants create a walking routine.

Drugs TO WATCH

There are seven emerging therapeutics that are poised to enter the market in 2016 and achieve blockbuster sales status by 2020, predicts Thomson Reuters. Ranked by highest sales forecasts for 2020, the potential blockbuster drugs are:

- $2.62 billion — Intercept Pharmaceuticals and Sumitomo Dainippon's obeticholic acid for chronic liver disease;
- $2.01 billion — Combination emtricitabine and tenofovir alafenamide for anti-HIV-1 infection from Gilead Sciences and Japan Tobacco
- $1.57 billion — Tenofovir alafenamide and emtricitabine and rilpivirine from Gilead Sciences and Janssen R&D for HIV-1 infection
- $1.54 billion — MK-5172A (grazoprevir and elbasvir) from Merck for HCV infections
- $1.48 billion — Venetoclax from Abbvie for chronic lymphocytic leukemia agent
- $1.41 billion — Nuplazid (pimavanserin) from Acadia for Parkinson's disease psychosis
- $1.27 billion — Uptravi (selexipag) from Nippon Shinyaku Co and Actelion for pulmonary arterial hypertension

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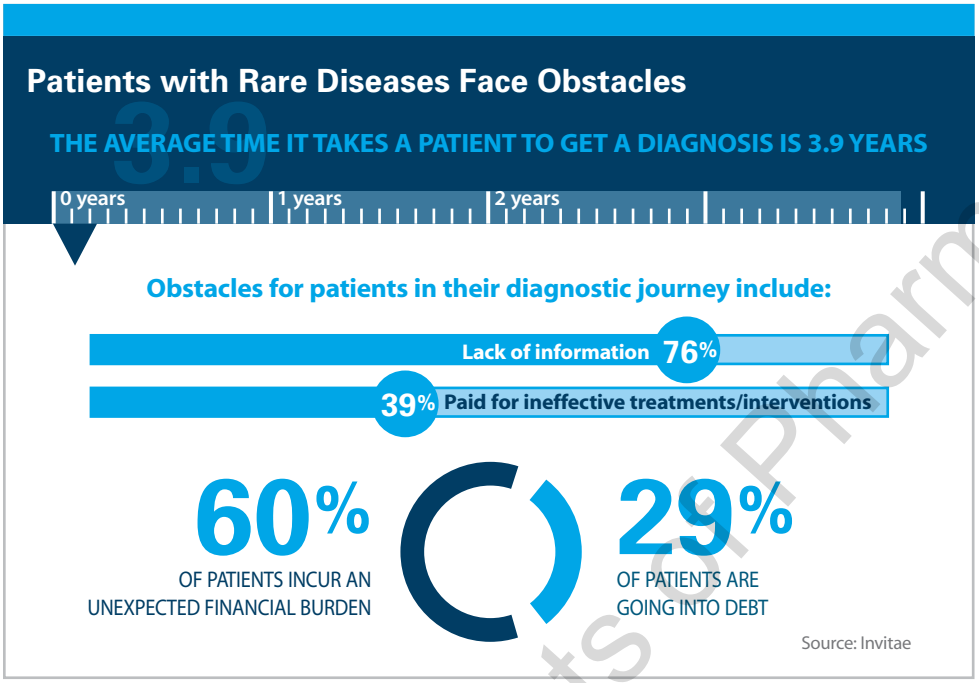
Millennials Delay HEALTHCARE BECAUSE OF COST

New consumer healthcare research released by Xerox shows millennials (Gen Y, ages 18 to 34) are the most cost conscious generation when it comes to healthcare, with the majority of respondents listing cost as a top consideration when selecting a healthcare provider and 50% even delaying treatment due to cost.

For Gen Xers (ages 35 to 49), 59% list cost as a top consideration in selecting a provider, whereas only 42% of boomers (ages 50 to 68) and 39% of the Greatest Generation (age 69+) do. On delaying treatment, 45% of Gen Xers have, but only 39% of boomers, and 15% of the Greatest Generation have.



Then and Now...

Over the last 15 years, how pharmaceutical companies sell their products has changed significantly. New regulations, consolidation, restricted access to physicians, and new technologies have all changed the way medicines are sold. When PharmaVOICE first began publishing, a pharma company might have had five or six reps calling on the same physician with the same product and providing lunches, free tickets to sports and other events, and other extras.

The 2010 Sunshine Act, changed all of that, requiring manufacturers of drugs and medical devices to collect and track all financial relationships with physicians and to report these data to the Centers for Medicare and Medicaid Services.

At the same time, doctors began to restrict access to sales reps. Now, according to a 2015 report from ZS Associates, about 53% of physicians in the United States place moderate-to-severe restrictions on visits from sales representatives, compared with 23% of physicians in 2008.

Physicians now want representatives to make more use of clinical studies in their conversations, and 77% want more high-quality representatives, according to a survey by Publicis Touchpoint Solutions.

Drug companies also have been downsizing their sales teams, giving rise to an increase in the use of digital sales tools. Reps are now using iPads, apps, and email, and they are able to provide updates and answers in real time.

Milestones

GSK Science in the Summer Expands for 30th Anniversary

GlaxoSmithKline is celebrating the 30th Anniversary of GSK Science in the Summer by expanding the free science program to 20 sites nationwide. Sponsored by GSK, the program for elementary students was launched in Philadelphia 30 years ago to engage kids in science at an early age.

In 2016, GSK Science in the Summer will bring free science lessons to more than 8,000 elementary students at 20 national locations, from Texas to Minnesota, and Arizona to Maine. The national program is administered by the American Association for the Advancement of Science (AAAS) and hosted by leading museums and science centers across the country.

THE AVERAGE COST TO DEVELOP AND GAIN MARKETING APPROVAL FOR A NEW DRUG IS NOW $2.56 BILLION.

Source: Tufts Center for the Study of Drug Development

Correction...

In the April issue, we included the wrong title for Mark Stevens. His correct title is Chief Commercial Officer, Publicis Touchpoint Solutions. We apologize for the error.

SPEAKout

Provided by: Medpace

Energizing Sites for Long Term Research

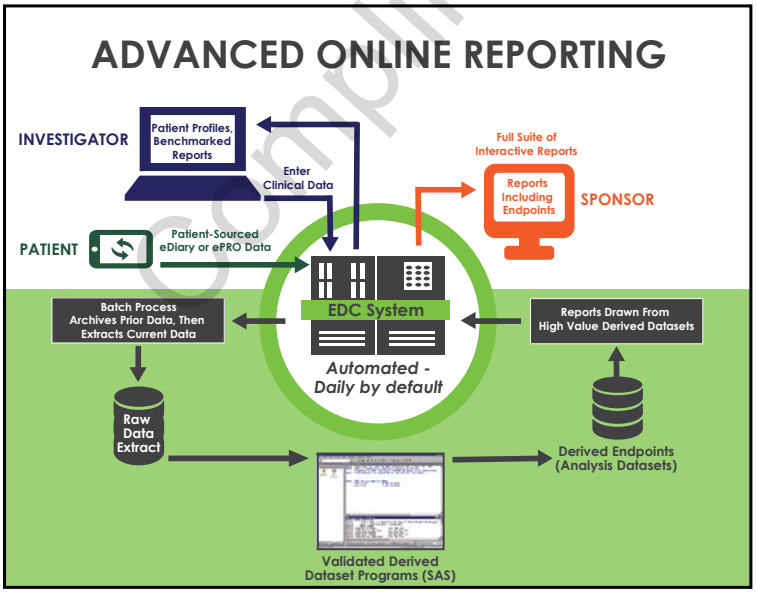
How advanced reporting can drive heightened engagement

Keeping clinical sites interested and engaged in research activities can be challenging for sponsors and CROs. Study coordinators and investigators are busy; patient care, administrative duties, and multiple trials compete for their time and attention. While we endeavor to maintain interest with newsletters, internet portals, in-person meetings, and providing well-configured data collection systems, these efforts may still fail to energize the sites over the long term.

Let's Focus on Common Ground: ADVANCING RESEARCH AND PROMOTING PATIENT HEALTH

This is incontrovertible – and easier said than done. Nevertheless, our industry has a real opportunity to dramatically increase site engagement by combining and harmonizing data in a visual and meaningful way. Using sophisticated interactive reporting and business intelligence tools we can combine, and offer meaningful insight into these sources of data:

- Patient-sourced diary and ePRO data
- Clinical data from EDC
- Complex derived endpoints



Sites are inundated with data. This initiative is not about building dashboards or overwrought displays of enrollment or raw clinical data. To deliver real value – which in turn will drive site engagement – we need to incorporate clinically meaningful endpoints that will enable site personnel to deliver better patient care. Potential endpoints might include opioid equivalents of rescue medication, scores such as the Charlson Comorbidity Index, aggregate pain scores, and length of hospital stay.

Imagine a report that benchmarks a patient's home-reported pain scores to the aggregate scores of other patients from that site, or to the entire study patient population. Or a patient profile that displays days of work missed adjacent to clinical outcomes, or analgesic rescue medication taken. As a health care provider, the investigator may reference this self-reported and aggregate data in patient conversations, and may devote more bedside time to care discussions, rather than data-gathering.

Developing The Derived Endpoints

Though EDC and Business Intelligence systems can perform the arithmetic to derive variables when the raw data is readily available, it's much more reliable and valid to develop and validate these variables outside of the data collection system. Traditionally, we create these variables after the database is locked, as part of the statistical analysis. Our goal is have these sophisticated derived endpoints earlier, reflecting the live data, without diverging from the methods and rigor that we use in post-lock statistical analysis. To achieve this, our data derivation process must incorporate more automated data quality checks, and a means to routinely transact with the EDC system.

Now we have, in one place, clinically meaningful research data that the site can use to better understand its contributions to the research, and its patient's progress.

Supporting Risk-based Monitoring

These reports also provide reassuring visibility into the study's progress for Sponsors, and are particularly helpful tools for routine data reviews as a part of risk-based monitoring. The trends they reveal can guide administration of the study, and prepare the research team for a rapid delivery of these items when the database is final.

A Win-Win for Patients, Sites and Sponsors

Harmonizing disparate data into meaningful reports and visual displays can provide Investigators and site personnel with meaningful, actionable information at their fingertips. This information is particularly helpful in observational research, where there is no blind to break, and the means to rewarding sites are limited by anti-kickback statutes. Investigators participate in observational research to advance the science and patient care. Helping them achieve this is the best way to keep them engaged.

Written by Lee Walke.

Lee Walke *is Vice President of E-Clinical at Medpace, a global full-service Clinical Research Organization specializing in drug and device development, research management and oversight, and analysis of programs supporting non-clinical, clinical, and outcomes research.*

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