

Awards...



ALTASCIENCES CLINICAL RESEARCH WINS BEST CRO SCRIP AWARD

Altasciences Clinical Research, an early-phase drug development CRO, has been named Best Contract Research Organization – Niche at the 12th Annual Scrip Awards.

“We continuously innovate to meet the evolving and increasingly complex needs of our clients,” says Chris Perkin, CEO, Altasciences and a PharmaVOICE 100 honoree 2015 and 2016.



BRAEBURN PHARMACEUTICALS AND CEO BEHSHAD SHELDON WIN STEVIE AWARDS

Probuphine, a six-month treatment for opioid dependence, was named a gold award winner at the 13th annual Stevie Awards for Women in Business in the category of “Best New Product or Service of the Year. Braeburn Pharmaceuticals’ President and CEO Behshad Sheldon was also selected as a bronze award winner in the category of Best Female Executive of the Year.

INTOUCH CEO HONORED

Intouch Solutions’ CEO, Faruk Capan (PharmaVOICE 100 - 2009, 2012 honoree), was recently honored as the American Marketing Association Distinguished Marketing Executive of the Year. The award is sponsored by the University of Central Missouri chapter of AMA and the Department of Economics, Finance and Marketing.



OGILVY COMMONHEALTH WORLDWIDE WINS GOLD AND SILVER AT THE 2016 RX CLUB SHOW AWARDS

Ogilvy CommonHealth Worldwide won Gold in the Drug Education-Doctors category, Silver in the Professional Print - Spread category, and 22 of the organization’s entries received Award of Excellence certificates at the 2016 Rx Club Show Awards. In addition, Ogilvy CommonHealth Worldwide won a Global Award and six Finalist Certificates at the 2016 Global Awards gala.

PIXARBIO NAMED BEST PLACES TO WORK

PixarBio has been named one of the “Best Places to Work by the Boston Business Journal. The company has been selected as a best place to work, extra small category on the annual regional list created by the journal..

LILLY TO EXPAND GLOBAL ACCESS TO HEALTHCARE



Known as Lilly 30x30, this new five-year program aims to invest \$90 million in the Lilly Global Health Partnership, which will improve access to treatment for diabetes, cancer, and tuberculosis in communities with limited resources.

Eli Lilly and Company has launched an ambitious plan to increase access to healthcare and to improve long-term health for millions of people worldwide. Through investments in people, medicines and health systems, Lilly aims to reach 30 million people

in resource-limited settings annually by 2030. Working with expert partners, the Lilly Global Health Partnership will help people living in communities with limited resources in Brazil, China, India, Kenya, Mexico, Russia, South Africa, and the United States.

PHARMACEUTICAL COMPANIES

LOSE \$637 BILLION
IN REVENUE
ANNUALLY DUE
TO MEDICATION
NONADHERENCE



Source: HealthPrize Technologies and Capgemini

Pennsylvania Bio CHANGES ITS NAME

Pennsylvania Bio has changed its name and brand to Life Sciences Pennsylvania. The association has expanded well beyond its founders’ original focus on biotechnology and today has a membership of more than 700 organizations representing the entire life sciences industry in Pennsylvania — biotechnology, pharmaceutical, medical device, diagnostic and healthcare IT companies; patient advocacy and investment organizations; research institutions; and myriad service providers that support the Pennsylvania life-sciences community.

Astellas Establishes PATIENT EXPERIENCE ORGANIZATION IN THE AMERICAS



Jim Robinson

Astellas has created a new department in the Americas that will formally build on efforts to ensure that the voice of the patient is incorporated across all facets of the company. Effective immediately, Doug Noland has been named executive director of Astellas’ Patient

Experience Organization and will report directly to Astellas Americas’ President Jim Robinson.

“Through the establishment of the Patient Experience Organization under Doug’s leadership, Astellas is committed to being a leader in this effort and advancing patient focus in everything we do,” says Mr. Robinson, also a PharmaVOICE 100 honoree — 2015, 2016.

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INC Research and CISCRP Announce WINNER OF INSPIRING HOPE IDEATHON

INC Research, together with the Center for Information and Study on Clinical Research Participation (CISCRP), announced Team C2: The Clinical Study Change Agent Collective was chosen as the winner of the 2016 "Inspiring Hope" Ideathon. The team's idea to create a corporate social responsibility program had longevity and momentum, and begins at the start of the patient journey.

Team C2, led by Angela Radcliffe, executive VP, FCBVIO and Patrick Tobin, executive VP FCB Health, presented their winning idea — a corporate social responsibility program enabling companies to improve wellness and health literacy for employees by connecting clinical trial awareness and participation with other social causes — in a competitive format at the Ideathon.

The team received a \$10,000 prize awarded by CISCRP.

Editor's Note: See the digital edition of the

January issue for a specialty publication covering the inaugural Ideathon.



The winning team's idea: improve wellness and health literacy for employees by connecting clinical trial awareness and participation with other social causes. (Note: Lisa Barket, publisher PharmaVOICE, far right)

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CONTRIBUTED ARTICLE

» **The Radical Implications of Indication-Specific Pricing**
Sponsored by: Promidian Consulting

EBOOK

» **Inspiring Hope Ideathon**
Sponsored by: INC Research and CISCRP

PODCAST

» **Enhanced 3PL: How the right third party logistics partner can optimize business for manufacturers**
Sponsored by: ICS, an AmerisourceBergen company

WEBINARS

» **Gene Therapy: Understanding Evolving Coverage and Reimbursement Challenges**
Sponsored by: Manatt Health
OnDemand Recording from Nov. 16, 2016

» **Early Asset Development and Commercialization: Partnering for Success**
Sponsored by: Cello Health
OnDemand Recording from Nov. 17, 2016

» **Engaging Gen X and Millennials Successfully in the New Patient Economy**
Sponsored by: RAPP
OnDemand Recording from Nov. 30, 2016

WHITE PAPERS

» **GSK's new "ethical" customer approach: Is it delivering?**
Provided by: Eyeforpharma

» **Maintenance of Mature and Generic Products: A Pragmatic Approach to Successfully Navigating the Safety and Regulatory Continuum**
Provided by: Sciformix Corp.

10 Best Countries For Oncology Clinical Research

1. China
2. Russia
3. South Korea
4. Ukraine
5. Poland
6. Romania
7. United States
8. United Kingdom
9. France
10. Germany



KMR Group's the Best Places For Clinical Research report ranks countries for specific disease areas using eight KPIs that assess performance, infrastructure, patient access, as well as cost. The results are presented for each individual metric in addition to an aggregate score, which combines all of them together to come up with a singular overall rank. KMR Group's Best Places series continues to highlight the strengths and weaknesses of almost 100 countries for over a dozen different therapy areas and diseases. This year's analyses confirm existing industry trends while highlighting some surprising new shifts.

Consumers Hold Drug Companies Responsible FOR HIGH OUT-OF-POCKET COSTS

North Star Opinion Research surveyed 1,000 registered voters nationwide and found that most voters blame drug companies not only for high drug prices, but also for out-of-pocket costs.

The findings undermine the drug industry's \$100 million PR campaign to blame higher costs on employers, unions, health plans, and the pharmacy benefit managers (PBMs) they use to negotiate discounts on prescription drugs.

Other findings include:

- By almost 3-to-1, voters blame high drug prices for increased cost-sharing.
- Only 1-in-5 voters buy the drugmakers' "rebates cause high prices" message.
- Three-quarters of voters say the cost of prescription drugs is too high.
- More than 4-of-5 voters with prescription drug coverage are satisfied with it.

Nagaraja Srivatsan joins EXL



Nagaraja Srivatsan

EXL, an operations management and analytics company, has appointed Nagaraja Srivatsan to executive VP and chief growth officer. In addition, he oversees sales and marketing, EXL consulting, and strategy. Before EXL, Srivatsan was senior VP and venture partner at Cognizant, where he spent 14 years holding various leadership roles. He was named a PharmaVOICE 100 honoree in 2010.

Novartis Big Winner at 2016 PRIX GALIEN USA



Novartis' long legacy of innovation was recognized by the Prix Galien USA with two awards: Cosentyx for 2016 Best Biotechnology Product and Gleevec for the inaugural Discovery of the Decade award. Considered "the pharmaceutical industry's Nobel Prize," the Prix Galien rewards excellence in scientific innovation that improves the state of human health. The Discovery of the Decade awards are a new form of recognition for exceptionally distinguished industry achievement, which was refined from the field of Prix Galien winners from the past 10 years.

Cosentyx is the first fully human interleukin-17A (IL-17A) antagonist, which has offered the 7.5 million patients in the United States suffering

from psoriasis a much-needed new treatment option to help them achieve relief and the goal of clear skin since its approval in 2015. In 2016, Cosentyx was further approved for new indications in the treatment of ankylosing spondylitis and psoriatic arthritis, becoming the first treatment advance in AS in almost two decades.

Gleevec gained international recognition as its creation marked the first time in the history of cancer treatment that scientists were able to identify a chromosomal abnormality and then develop a drug that would target that specific protein, helping to establish a new paradigm for drug development that has revolutionized the way researchers approach the disease.

Bracing for a New ADMINISTRATION

It is important to assess the implications of potential policies of the new government administration on the life-sciences industry in a Congress dominated by a Republican majority. One thing is certain, Arda Ural, Ph.D., EY, US, says this set of predictions is not a crisp black-and-white picture. Here is a speculative list of what life-sciences companies should brace for.

► Drug pricing

While a Republican administration and Congress would historically not legislate any capitation to, transparency of or negotiation around drug prices, statements were made from the Trump campaign about the affordability of drugs. Specifically, empowering Medicare to negotiate drug prices with manufacturers has been a hot issue all along in his campaign. However, these ideas were not codified in the Trump healthcare position.

Also, considering the failure of Proposition 61, The California Drug Price Relief Act — a state-specific ballot initiative that was seeking to regulate drug pricing in California — consensus is that drug pricing and regulation is not expected to be an immediate priority for the Trump administration.

► Affordable Care Act (ACA)

The Trump campaign has made repealing the ACA a clear and imminent target all along. The conventional wisdom states that in the absence of 60 votes in the U.S. Senate, the ACA cannot be totally repealed though there are sections that can immediately be clawed back. The ACA's implication for the life-sciences industry has been neutral to positive.

If the law would be repealed in its entirety without finding replacement coverage for this

population, the industry should expect a top-line erosion from the vanishing utilization of medications by these individuals who would no longer have insurance under the Trump proposal.

► Regulation

Less regulation has been a common theme life-sciences clients have been asking for and they are likely to get it in the next four years. The FDA has performed well in its ability to review and approve new medications and devices in a timely fashion within the confines of the U.S. Prescription Drug User Fee Act (PDUFA). Separately, on a different, recently passed U.S. regulation — the Physicians Payments Sunshine Act, which is aimed at creating transparency in life-sciences companies' payments to physicians — no changes are anticipated.

► Parallel Importation

This is a tricky one in that the last of Trump's seven policy statements calls for "removal of barriers to entry into free markets for drug providers that offer safe, reliable and cheaper products." It states that while "the pharmaceutical industry is in the private sector, drug companies provide a public service. Allowing consumers access to imported, safe and dependable drugs from overseas will bring more options to consumers."

Consensus is that it will disappear.

► Tax Outlook

Proposed lowering of the corporate tax rate for U.S.-based companies will help fuel net income and lead to bigger cash reserves, dividends, and/or stock buybacks, all helping the industry and its investors with better capitalization.

Astellas Oncology Announces Winning C3 Prize Ideas

Astellas Oncology has announced the inaugural C3 Prize, a global challenge designed to acknowledge non-medicine innovations to improve the cancer care experience for patients, caregivers, and their loved ones. The winning ideas were chosen after five finalists pitched their ideas live at Medicine X to a panel of judges, which included Robert Herjavec, entrepreneur and star of the television show Shark Tank.

More than 100 patients, caregivers, healthcare providers and technology entrepreneurs from around the world submitted ideas to the C3 Prize. The Grand Prize winner was awarded a \$50,000 grant, and two First Prize winners were each awarded \$25,000 grants.



The Grand Prize was awarded to Diane Jooris of Brussels, Belgium, co-founder of Oncomfort, a company that develops virtual reality modules designed to help manage anxiety in cancer patients before, during and after treatment.

Sandoz Invites Entrepreneurs TO ENTER SANDOZ HACK



Sandoz, the Novartis generic and biosimilar pharmaceutical division, has launched the Sandoz HACK — Healthcare Access Challenge — a global competition to generate innovative ideas and solutions to help tackle some of the world's most pressing healthcare access problems. The competition was open for entries until Nov. 30, 2016.

Six finalist entries will be published on OpenIDEO, a global community of leading organizations. Entrants' ideas will be refined and evolved in partnership with this online community before being presented to a panel of judges. Three winners will be chosen and awarded seed funding and mentorship to help bring their ideas to life.

Global Drug Market Will Reach Nearly \$1.5 TRILLION IN 2021

Total spending on medicines is forecast to reach \$1.5 trillion by 2021, up 33% from 2016 levels, even as annual growth moderates from the record pace set in 2014 and 2015, according to new research released by the QuintilesIMS Institute. While historically large numbers of high-quality new medicines will emerge from the R&D pipeline in the next five years, pricing and market access pressures, lower volume growth in pharmerging markets, and greater savings from patent expiries will contribute to the lower rate of growth.

The report, *Outlook for Global Medicines Through 2021: Balancing Cost and Value*, finds that medicine spending will grow at a 4% to 7% compound annual rate during the next five years, down from the nearly 9% growth level seen in 2014 and 2015. The total global spend for pharmaceuticals through 2021 will increase by \$367 billion on a constant-dollar basis.

"The outlook for medicine spending growth reflects a more sustainable level for health systems, following the unexpectedly high growth seen in recent years," says Murray Aitken, senior VP and executive director of the QuintilesIMS Institute. "At the same time, the astonishing level of scientific advances for disease treatments inevitably will place ongoing pressure on funding for medicines — requiring value-based assessments that balance patient needs and pricing levels with competing healthcare priorities." (Editor's Note: Mr. Aitken was

named a PharmaVOICE 100 honoree in 2005.)

Additional findings:

- ▶ Most global spending growth, particularly in developed markets, will be fueled by significant innovations in oncology, autoimmune, and diabetes treatments.
- ▶ The U.S. will continue as the world's largest pharmaceutical market, contributing 53% of forecasted growth over the next five years, while China will continue as the second largest market contributing 12% of the growth.
- ▶ New drug launches will reach historically high levels in the next five years. More than 2,000 drugs in the late-stage pipeline will yield an expected 45 new active substances (NAS) on average annually through 2021. The new medicines will address significant unmet needs across a wide range of disease areas, including cancer and autoimmune, metabolic, and nervous system disorders.
- ▶ The number of cancer treatments, their potential combinations in treatment regimens, and the variety of companies involved in development will bring complexity to the patient care landscape during the next five years.
- ▶ Dramatic improvements in survival and tolerability are expected and will be accompanied by substantially greater levels of clinical trial and real-world information in support of treatment decisions.

Wendy White Named CHAIR OF GLOBAL GENES



Wendy White

Global Genes, one of the world's leading nonprofit rare disease patient advocacy organizations, has named Wendy White, senior VP, rare diseases, Dohmen Life Science Services, and former president of the Healthcare Businesswomen's Association, as chairman of the board. Ms. White was also named a PharmaVOICE 100 honoree in 2012 and 2015. Natalie Douglas, CEO of Healthcare at Home, has been named vice chairman of the board. Also joining the Global Genes board of directors is Nauman Shah, VP, enterprise program office management, Johnson & Johnson.

2017

Year in Preview – Feedback

Precision medicine is already affecting how the pharmaceutical industry conducts R&D. Companies leverage genomics to better characterize the diseases that they are trying to treat. We used to think of many diseases, for example, cardiovascular disease, diabetes, or asthma as single diseases diagnosed primarily based on symptoms. Scientists now recognize these are actually groups of diseases. Within each group, there may be many sub-groups that differ in their molecular characteristics. These characteristics may be used to identify populations of people who may be more likely to respond favorably to treatment with certain compounds. Scientists also leverage genomics to better understand the drug target, associated pathways, and the relationship between the target and the disease.

Precision medicine is influencing the study populations that we use in clinical trials. This is particularly true in oncology. For example, basket trials are designed to stratify patients to a therapy based on the molecular/genetic characteristics of their tumor rather than the histology of their tumor, such as lung or skin cancer. By enrolling only the patients who are most likely to respond, developers can demonstrate the efficacy of their targeted therapies using fewer patients and over a shorter duration than traditional trials.

Doctors will be able to leverage molecular information about a patient to more accurately predict which medicines will be the most effective and safe for their patients to take. In some indications, we are already seeing evidence of patients living longer due to a more targeted treatment approach. For example, we have seen increased survival rates in several types of cancer, including HER2 positive breast cancers, lung cancers, and others.

Source: Anita Nelsen, Head of Genomic Medicine Services, Clinical Research Services, Parexel

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