

Awards...



JOUNCE THERAPEUTICS FOUNDER RECEIVES NOBEL PRIZE

Dr. James P. Allison, the scientific founder of Jounce Therapeutics, a clinical-stage company focused on the discovery and development of novel cancer immunotherapies and predictive biomarkers, was awarded the 2018 Nobel Prize in Physiology or Medicine for the discovery of cancer therapy by inhibition of negative immune regulation. He played a fundamental role in ushering in the era of cancer immunotherapy, including his contributions to the understanding of the basic science of CTLA-4. There are CTLA-4 inhibitors on the market, including BMS' Yervoy.

Additionally, Japan doctor Tasuku Honjo won the 2018 Nobel Prize in Medicine for his work on the PD-1 protein that is expressed on T-cells. PD-1 inhibitors are now key lynchpins in the pipelines of several companies, particularly Merck and its leading drug Keytruda and Bristol-Myers Squibb's Opdivo.

MERCK NAMED TO TIME'S GENIUS COMPANIES LIST

Time magazine has named Merck to its list of genius companies that are driving progress. Time's global editors and correspondents nominate businesses that are inventing the future. Then the staff evaluates candidates on key factors, including originality, influence, success, and ambition.

Additionally, Project HOPE has honored Merck for its outstanding contributions in global health and humanitarian relief at the medical NGO's 60th anniversary Gala.

PHARMA COMPANIES RECOGNIZED BY WORKING MOTHER

Several pharmaceutical companies — including Abbott, Astellas Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, Johnson & Johnson, Lilly, Merck, Novo Nordisk, Roche, Sanofi, and Takeda — have been named to Working Mother magazine's 2018 100 Best Companies list.

The magazine honors organizations annually that lead in the areas of female career advancement. Companies are recognized for their forward-thinking initiatives that foster workplace flexibility, the advancement of women, maternity/paternity leave, child care support, and more.



Johnson & Johnson Announces 10-YEAR INITIATIVE TO HELP END TUBERCULOSIS



Dr. Anthony Fauci (left), National Institute of Allergy and Infectious Diseases (NIAID), and Dr. Paul Stoffels (right), Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson, speaking at the UN Tuberculosis (TB) Innovation Summit.

Johnson & Johnson has announced a comprehensive 10-year initiative in support of the United Nations' Sustainable Development Goal target of ending the TB pandemic by 2030. With the goal of saving an estimated 1.8 million lives and preventing

12 million new TB infections in the next decade, J&J will work with partners to improve detection of undiagnosed cases of TB, broaden access to its novel medicine for multidrug-resistant TB, and accelerate R&D to discover next-generation TB treatments.

In Memoriam: CHRISTINE PIERRE



Christine Pierre

Christine Pierre, an industry leader in the site arena, sadly passed away in October. Christine represented the site community globally through hundreds of speaking engagements and research articles published in her name. Her contribution to furthering the sustainability of clinical research sites is unmatched. Having grown from 12 attendees to almost 1,000, the Global Site Solutions Summit is now recognized as the leading conference representing clinical research sites and is just one component of the work she has contributed to advancing clinical research. Christine dedicated almost three decades of her life to advancing the work and voice of clinical research sites. With this passion and vision, she conceptualized the first Site Solutions Summit in 2006 and founded the Society for Clinical Research Sites in 2012.

For her many contributions, inspired leadership, and passion, Christine was recognized as a PharmaVOICE Red Jacket in 2016.

PharmaVOICE @INDUSTRY EVENTS



Actress, Jillian Rose Reed, with 2017 Champions of Hope Award Recipient, Taylor Kane

RARE Patient Advocacy Summit

Global Genes honored the 2018 award recipients at the 7th Annual RARE Patient Advocacy Summit. More than 200 individuals and organizations worldwide were nominated by their peers for a RARE Champion of Hope award for their notable efforts in rare disease advocacy, teen advocacy, science, medical care, and treatment and collaborations. The summit is the largest gathering of rare disease patients, advocates, and thought leaders worldwide. More than 100 experts in rare disease led 40 educational sessions.

Wings Over Wall Street

Wings Over Wall Street's (WOWS) annual benefit recognized Chef, Stephan Bogardus and Owner Claudia Fleming of the renowned North Fork Table & Inn. When Claudia's husband, Gerry Hayden, was diagnosed with ALS, Stephan became his mentor's hands at the restaurant.

WOWS raises critical funds to support the daily care and treatment of thousands of patients,

families, and caregivers, and funds researchers and doctors seeking to advance treatments and cures.

Wings Over Wall Street is one of the most successful Muscular Dystrophy Association benefits to fund research to find a cure for ALS.

A New New Era of Patient-Focused Innovation

NORD's annual meeting drew more than 800 individuals to Washington, D.C. The focus of this year's summit — A New Era of Patient-Focused Innovation — was examined from a variety of perspectives throughout the conference. This year, senior officials from the FDA and NIH and more than 85 speakers and roundtable discussion leaders discussed how patients are helping drive research and drug development, the impact of grassroots advocacy, what can be learned from advances in cancer therapies, patient perspectives on gene therapy, current topics from the FDA, and what's ahead for orphan drug development and more.

Merck Foundation Launches Song to Raise Awareness about MALE INFERTILITY

Merck Foundation, the philanthropic arm of Merck KGaA Germany, has launched a song, Life is Bigger, to break the stigma around infertility in Africa as part of Merck More Than a Mother community awareness campaign. The song was written and is performed by Tom Close, a doctor and singer from

Rwanda. Dr. Rasha Kelej, CEO of Merck Foundation and president of Merck More Than a Mother explains, "The song communicates an important message to the society that not only women but men too can be the cause of infertility. It also speaks about the stigma attached to infertility."

Awards...



SPECTRUM NAMED MEDIUM PR FIRM OF THE YEAR

Spectrum Science Communications, an independent health and science public relations agency, has been named PR News' 2018 Medium PR Firm of the Year. This win comes during a pivotal year for the firm, during which it introduced Galileo6 as its first product, welcomed six senior hires into newly formed roles, and completed its sale to President and CEO Jonathan Wilson ahead of schedule.



NEWS

GRANT THORNTON ACQUIRES TAYGANPOINT CONSULTING GROUP



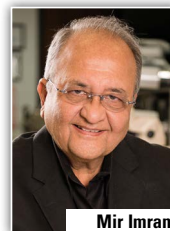
Joy Taylor

Grant Thornton has acquired TayganPoint Consulting Group, a life-sciences consulting. Taygen Co-founders Joy Taylor and John Cassimatis

are joining the leadership team of Grant Thornton's Business Consulting practice as the go-to-market leader and life-sciences industry leader, respectively.

Joy Taylor is a PharmaVOICE 100 — 2018.

RANI THERAPEUTICS' MIR IMRAN SELECTED FOR THE 2018 UPSTART 50 LIST



Mir Imran

Rani Therapeutics, a pioneer in oral biologics, has announced that Chairman and CEO Mir Imran was chosen for the 2018 Upstart 50 list. Selected by the

editors at the San Francisco Business Times and the Silicon Valley Business Journal, the Upstart 50 is an annual recognition of the most dynamic, disruptive and innovative people doing business today in the San Francisco Bay Area.

Mir Imran is a PharmaVOICE 100 — 2018.

CRO/Sponsor PARTNERSHIPS

There is a growing urgency for CRO expertise in early phase clinical research, i.e., first-in-human through proof of concept, finds a recent survey by Worldwide Clinical Trials. The percentage of respondents who were either likely or very likely to engage a CRO grew most sharply for early phase investigations, up 8% — from 55% in 2016 to 63% in 2017. Other findings:

- ▶ There is stable growth in the overall demand for CROs — 68% of respondents said they were much more likely to hire a CRO than they were five years ago, in comparison to 65% in 2016.
- ▶ Data quality tops the list of CRO evaluation criteria. In both 2016 and 2017, the most important factor in choosing a CRO was the ability to deliver high-quality data — with 92% in 2017.
- ▶ Sponsors are looking for CROs that provide innovative solutions; 36% of respondents ranked overall trial management as the area that can make the greatest impact for the sponsor/CRO relationship.
- ▶ Sponsors continue to push for clinical trial efficiencies. In fact, 74% still said costs are significant or very significant to new drug development.

Lifebox Launches Surgical Safety Campaign TO RAISE AWARENESS AMONG CLINICIANS



The international nonprofit organization Lifebox has been making surgery safer for millions of patients throughout the world. Founded in 2011 by four of the world's leading medical organizations with surgeon and writer Atul Gawande as its chairperson, Lifebox's mission is to improve surgical safety in low-resource countries.

Lifebox has teamed up with healthcare advertising agency precisioneffect to launch the "Deadliest Conditions" campaign. This new surgical safety initiative aims to raise awareness among U.S.

surgeons about the challenges that their peers in low-resource countries are up against, such as lack of electricity and basic surgical tools that can mean life or death for their patients. The campaign launched as surgeons gathered at the American College of Surgeons annual meeting in Boston in October, Dr. Atul Gawande spoke on the impact that a simple checklist — developed 10 years ago by the World Health Organization (WHO) — has had on surgical safety around the world, reducing complications and deaths by one-third.

PHARMAVOICE.COM

CASE STUDY

» **Adapting the Functional Services Model to Deliver Flexible Solutions**

Provided by: Covance

PODCASTS

» **Providing Effective Support for People Living with Cancer: Insights from Health Psychology**

Provided by: Atlantis Healthcare

» **Navigating the Complex Healthcare Landscape with a Strong 3PL Partner**

Provided by: RxCrossroads by McKesson

EBOOKS

» **Woman + Health: An Industry Movement**

Sponsored by: Cardinal Health

WEBINARS

» **OnDemand: Medical Storytelling — Combining High Science and High Emotion for High Impact**

Sponsored by: Avant Healthcare

» **OnDemand: Building a Secure, Automated Quality System to Accelerate Time to Market**

Sponsored by: DocuSign

» **OnDemand: Unlocking the Potential of Online Communities — Looking Beyond the Surface**

Sponsored by: Health Union

» **OnDemand: The Future of Work is Now. Are You Ready?**

Sponsored by: KellyOCG

» **OnDemand: Addressing Unmet Needs of Patients and Providers in Rare and Complex Disease**

Sponsored by: VMS BioMarketing

WHITE PAPERS

» **Supporting Adherence to Oral Anticancer Treatments: Key Components of Successful Adherence Interventions**

Provided by: Atlantis Healthcare

» **The Power of Insight**

Provided by: Blue Latitude Health

» **Cross-Border Enrollment of Rare Disease Patients**

Provided by: PRA Health Sciences

» **How Technology is Reshaping the Rare Disease Landscape**

Provided by: PRA Health Sciences

» **Precision Medicine: A Glossary of Terms**

Provided by: WIRB Copernicus Group

Looking to Simplify Your Safety Notifications Process? Consider a Cross-Trial SaaS Solution

Why new centralized SaaS solutions make more sense than ever before



Brian Fisher,
President,
Trial Management
at DrugDev

A traffic-light is out of service during rush hour in a busy city intersection. To prevent accidents, a police officer is there directing traffic. Suddenly, three more show up, each directing traffic for their own respective lanes. After some time, the police mix signals and an accident occurs. Confused motorists ask themselves “why didn’t they just use a single cop?” while others bemoan the loss of the traffic light.

To many, the inherent risk in the above scenario is obvious. However, this is the same risk still seen today with sponsors and CROs who use multiple systems or manual processes for safety notifications. Their method usually involves managing and combining many moving parts. While this has the potential to be a well-controlled process, it often leaves a large amount of room for error.

Recently, some larger sponsors have been pioneering the use of cross-trial systems that allow the dissemination, tracking, and documentation of safety notifications from a single-dash-board. In fact, DrugDev and a top-5 sponsor recently worked together to create the industry’s simplest centralized safety notifications solution. After piloting this system together, one thing’s clear – cross-trial systems simplify everything, providing the centralization needed to effectively and easily manage the safety process.

Why Choose Cross Trial?

It’s simple. A cross-trial system allows sponsors and CROs to control every aspect of the safety notification process from a single dashboard, removing the

need to independently manage and combine multiple moving parts. This includes:

- Disseminating safety notifications to all relevant site personnel who are affected by an adverse compound, regardless of trial differences, country differences, etc.
- Managing the receipt, acknowledgement, and tracking of safety notifications
- Keeping a comprehensive audit trail of each document, notification, acknowledgement, and more
- Identifying which site personnel are still outstanding for receipt and acknowledgement of safety notifications allowing study teams to follow up

The impact of these features allows sponsors to reduce costs, save time, and mitigate some of the liability around audits and safety errors.

Cost Reduction

For sponsors who manage their process electronically, a cross-trial system cuts down on costs by reducing the number of systems that must be managed, paid for, and serviced by consolidating all these processes. This has a large impact on “man hours,” especially during audits, when records must be found, pulled, and properly assembled.

For the many who still use paper, a cross-trial system has the potential to save millions of dollars by eliminating printing costs, shipping costs, labor payments, and more.

Time Savings

Cross-trial systems also help save time. Simply put, the ability to push out notifications to all required personnel from one dashboard no matter the trial, country, or role tremendously reduces the amount of time that safety notifications require. In the past, sponsors had to push out each notification separately based on the trial,

country, or other factors. Then, they would need to separately track receipt and confirmation of safety notifications. Often, this involved multiple study staff coordinating their work across multiple systems. With cross-trial solutions, these problems are removed.

Greater Audit Compliance and Increased Transparency

A cross-trial system also reduces the number of audit findings by providing an expert level of transparency and centralization. Centralized systems track each safety notification from the moment it is selected for dissemination, to the moment it is acknowledged by the site staff. This includes all updates to the documents, all channels that the document passed through, time-stamps, and more. This automatic tracking allows study teams easy and instant access to the electronic records in the event of an audit while eliminating the need to manually log and document each outreach and acknowledgement.

Reduced Liability

The automatic tracking and of acknowledgement of each notification also cuts down on potential legal liability. No longer are there lingering questions of whether an investigator or site staff read a safety notification, as this is automatically logged and timestamped as soon as the individual has completed acknowledgement.

Worth the Risk of Waiting?

With the new breed of cross-trial safety notification systems becoming more prevalent, sponsors and CROs must now ask themselves whether the inherent risks presented by their current processes are worth it. After all, there are very few who would argue for multiple police officers in one intersection. ●