

Awards...



CHIESI USA NAMED A BEST PLACE TO WORK

Chiesi USA was named among Triangle Business Journal's 2018 Best Places to Work. The 50 Triangle companies were chosen based on an employee survey process conducted by Quantum Workplace.

MEDIDATA NAMED TOP GLOBAL PERFORMER

Medidata has been selected for Fortune 100's fastest-growing companies list. The company was named a top global performer for the second year in a row. The Fortune list recognizes top three-year performers in revenues, profits, and stock returns. The ranking provides a snapshot of the trends driving the global economy, including the continued dominance of the technology sector.



NEWS

JEFF BERKOWITZ TAKES HELM OF REAL ENDPOINTS



Jeff Berkowitz

Real Endpoints, which provides development and implementation of proprietary tools, has named Jeff Berkowitz as CEO and member of the board of directors.

Most recently, Mr. Berkowitz served as an executive VP at UnitedHealth Group, CEO of its Optum International business, and as a strategic leader of OptumRx, its PBM. Mr. Berkowitz is a PharmaVOICE Red Jacket — 2014.

DONNA WRAY JOINS INVIBE LABS



Donna Wray

inVibe Labs has appointed Donna Wray executive VP of sales and marketing. She has spent most of her career in various thought leader and

entrepreneurial roles, and most recently was VP of multichannel marketing at TG&S Advisors. She is on the Health Literacy Initiative committee for Intellus. Ms. Wray is a PharmaVOICE 100 — 2017.

BMS Participates in V Foundation FOR CANCER RESEARCH BIKE RIDE



More than 100 Bristol-Myers Squibb employees will ride across the country with the goal of raising \$1 million for cancer research.

For the fifth year in a row, Bristol-Myers Squibb has launched the Coast 2 Coast 4 Cancer, a nearly month-long cross-country bike ride to raise money for cancer research. During the month of September,

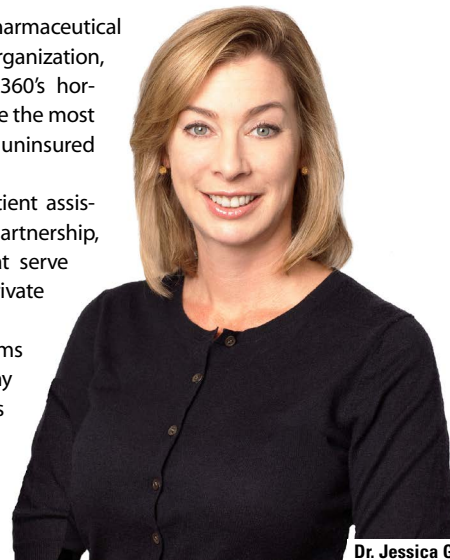
company employees ride nearly 3,000 miles from Cannon Beach, Ore., to Long Branch, N.J., with the goal of raising \$1 million for the V Foundation for Cancer Research.

Medicines360 and Direct Relief Partner TO EXPAND ACCESS FOR U.S. WOMEN

Medicines360, a mission-driven women's health pharmaceutical nonprofit, and Direct Relief, a humanitarian aid organization, announced a partnership to provide Medicines360's hormonal IUD, Liletta, free of charge to clinics that serve the most vulnerable women in the United States, such as uninsured women.

Medicines360 established an institutional patient assistance program (IPAP), known as the IUD Access Partnership, with Direct Relief to provide IUDs to clinics that serve women who cannot obtain the product through private insurance, Medicaid or other public funding.

"Unfortunately, access to the most effective forms of contraception, like IUDs, is an issue for many clinics where low-income women seek care," says Jessica Grossman, M.D., CEO of Medicines360. "This partnership delivers on our mission to expand access for the women who need it most, allowing them to avoid unplanned pregnancy if they choose."



Dr. Jessica Grossman

Avoid Enrollment Pitfalls by Engaging with Best-Fit Sites

Perhaps the single most important consideration in selecting a site is whether it can make its enrollment. Many don't; in fact, 20-25 percent of all clinical studies close because they fail to meet enrollment targets.¹

For decades, sponsors have found their "best fit" sites and returned to them for future studies. But in the era of precision medicine, that may not always be the best course of action. It is becoming increasingly necessary to turn to untapped resources to find potential enrollees.

According to Tufts research, sponsors and CROs report that 28 percent of their sites are new relationships with no prior history or familiarity. Those relationships can be tricky. The overall site initiation cycle time is nearly 10 weeks longer for new sites compared to repeat or familiar ones.² Moreover, sites with insufficient experience are more likely to violate protocols or have low-quality data, which leads to more on-site visits and more request for clarification—even additional training.³

In this environment, how do sponsors determine the best-fit sites for their studies? Much of what constitutes "best fit" is specific to the study and the patient population, but here are five characteristics that apply more broadly:

- **Strong Record of Success:** Past performance does predict future results. But how much do you really know about past performance of the site or the investigator? Without the right partner, it becomes difficult to assess past performance. With the right partner, however, you have access to verified data- as opposed to self-reported data- to help you make an informed decision.
- **Active Community Presence:** No matter how diligently they scour their records and recruit their own patients, no site is going to fully enroll a study from its own patient population. A site that's active in the community and has built community relationships is more likely to be successful at enrollment.
- **Takes an Integrated Approach:** Best-fit sites embrace clinical research as another offering of care to the patient. It's fully integrated into their practice, and they promote clinical research in a proactive manner with strategies that may include: showing a list of available clinical trials on a monitor in the waiting room, talking to patients who may be eligible to participate in trials, and engaging their colleagues in the practice to help spread the word.
- **Dedicated Clinical Research Team:** Given that 68 percent of sites fail to meet their projected enrollment targets,⁴ you'll want to ensure the right people are in place to execute against these timelines. Work with your coordinator during the pre-selection visit to determine if they manage too many protocols with too few staff, have a difficult time returning questionnaires in a timely fashion, or have trouble managing responses to ad campaigns. If any of these pop up as red flags, it may be time to bring in a dedicated resource to assist the site team.
- **A Best-fit Site is Open to Innovation:** Adopting technologies such as e-consent and a clinical trial management system is an indication of enrollment success. In our experience, the more open to technology a site is, the better their enrollment.

By working with sites that meet the aforementioned criteria, and by availing yourself of the data and other resources available, you can dramatically improve the likelihood that your next clinical trial will succeed. ●

References: 1. WCG Knowledge Base; Data on file. 2. March/April 2018 Tufts CSDD Impact Report. 3. March/April 2018 Tufts CSDD Impact Report. 4. WCG Knowledge Base; Data on file.

Clinical Operations Leaders TAKING ACTION TO UNIFY

Over the past year, there has been significant industrywide momentum toward streamlining clinical systems and processes, according to a survey of clinical operations professionals from Veeva Systems. Nearly all (99%) clinical leaders surveyed cite the need to unify their clinical environment. Most (87%) report their organizations are taking action with initiatives planned or underway to unify their clinical operations for improved trial performance.

"As organizations continue down the path toward a unified operating model, trial processes will be transformed for greater visibility and improved trial execution across the clinical lifecycle," says Jennifer Goldsmith, senior VP of Veeva Vault.



Jennifer Goldsmith

Biggest Challenges with Clinical Applications*



*Total respondents, N=331

90%

of healthcare CSOs think
new technologies will
upend their industry
over the next five years.

Rising Protocol Complexity IS HINDERING PERFORMANCE

Rising protocol complexity is hindering clinical trial performance and efficiency, and helping to drive up the cost of developing new drugs, according to a recently completed analysis by the Tufts Center for the Study of Drug Development.

"This trend will continue — and likely accelerate — as pharmaceutical and biotechnology companies target more difficult-to-treat and rare diseases, enroll more stratified patient populations, and collect higher volume and more diverse data," says Ken Getz, associate professor and director of sponsored research at Tufts CSDD.

Other findings include:

- ▶ Phase I and II clinical trials are the most complex, based on numbers of distinct and total procedures, whereas Phase III trials have seen the highest increase in complexity during the past 10 years.
- ▶ The total number of endpoints rose 86%, between 2001-2005 and 2011-2015, and procedures supporting these endpoints contributed a much higher proportion of data informing secondary supplementary, tertiary, and exploratory endpoints.

GSK Consumer Healthcare Partners TO ADDRESS CLEFT LIP AND PALATE

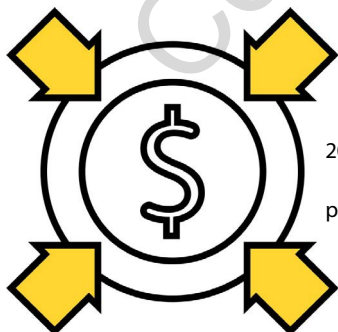


A before and after photo of Jaya, who is the recipient of the first GSK-funded cleft surgery.

GSK Consumer Healthcare has announced a new five-year partnership with Smile Train, an international children's charity with a sustainable approach to a single problem: cleft lip and palate. Smile Train empowers local medical professionals, by providing training and education, to provide

100%-free cleft surgery and comprehensive cleft care to children all over the world. Every year, one in 700 children is born with a cleft lip or palate globally. Clefts are the leading birth defect in many developing countries, and it is estimated more than 200,000 children are born with a cleft every year.

Drug Price Forecast Projects LOWER INFLATION IN 2019



Vizient's 2018 Drug Price Forecast estimates health systems can expect a 4.92% increase in the price of pharmaceuticals in 2019. This estimate represents an anticipated slower rate of growth as compared with previous Vizient forecasts, such as the 7.61% value projected for 2018.

Although the rate of price increases is projected to slow, the specialty pharmacy market is expected to continue its rapid pace of growth, which accounts for the majority of overall price inflation. According to a recent industry analysis, specialty pharmaceuticals now account for more than 46% of the total spend on drugs in the United States, in spite of being used for very small and targeted patient populations.

PODCASTS

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Provided by: PharmaSeek
- » **Clinical Trials in Children with Impaired Mental Capacity**
Provided by: PRA Health Sciences

Pharma Companies with the Highest Reputation

1. Sanofi
2. Genentech
3. Celgene
4. AbbVie
5. Biogen
6. Bayer
7. Gilead
8. Allergan
9. Novo Nordisk
10. McKesson



Source: Reputation Institute's 2018 US Pharma RepTrak



**Boxes don't
scare us.**

Healthcare marketing is a world filled with boxes—restrictions and regulations that lurk around every corner and challenge creativity. Luckily, we're not afraid of boxes. We think outside of them, inside of them, on top of them, under them, you get the point. So if you're ready to work with people who will push you outside your comfort zone and help you explore fearless, creative thinking, contact erin.byrne@ghgroup.com. **We're ready.**



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