A Rare Passion for Patients

Energetic. Unrelenting.

In healthcare, there is nothing more rewarding than working alongside a leader who is ambitious, kind, has no ego, and works with urgency because she knows there is a family waiting for the next breakthrough medicine. This description perfectly sums up L. Mary Smith, Ph.D., senior VP of clinical R&D at SpringWorks Therapeutics.

Mary has spent the majority of her career working in the rare disease space, a powerful motivation for working hard.

"I went into science, and ultimately, drug development because I felt I could help a greater number of patients," she says. "We can never work fast enough to bring therapies to patients in need."

Mary left her position at Bamboo Therapeutics, a subsidiary of Pfizer, in 2017 to be one of the first employees at SpringWorks Therapeutics, a rare disease and oncology start-up, because she saw a unique opportunity for underserved patient communities to identify and advance promising science that otherwise would be sitting on a shelf.

SpringWorks was launched with licensed medicines that had been de-prioritized at Pfizer. Mary was one of the driving forces behind getting these promising products back into clinical trials, so they can be evaluated and have a chance to become available for patients with rare diseases.

Mary's keen eye for transformative science is fueled by her desire to make an impact. By way of example, an investigational therapy called nirogacestat showed promising Phase II data in patients with desmoid tumors — a rare and devastating soft tissue tumor with no treatment options. In just over a year, Mary and her team were able to get nirogacestat ready to start a Phase III clinical trial, which required extensive work and tenacity to complete the manufacturing, regulatory, and other requirements for re-igniting clinical development. Importantly, the patient community and physicians who are eager for a treatment have expressed their excitement and appreciation that nirogacestat is back in development.

A true career highlight for Mary was collaborating with the National Cancer Institute and Children's Oncology Group to bring Unituxin to the market for a rare pediatric cancer called neuroblastoma.

While her accomplishments as a clinical executive are clear, her energy and enthusiasm for mentorship are what set her apart.

"It's important to me to give other people opportunities to grow and succeed," she says. Mary is passionate about developing the next generation of female leaders in biotech.

"The greatest accomplishment I felt was when a colleague who worked for me for a number of years told me that I gave her the confidence to take a job that she felt under-qualified for," she says. "She told me that I gave her the opportunity to learn, grow, fail, and flourish. I was so happy for her."

Mary's colleagues say she promotes a culture of inclusion and collaboration, which has resulted in the development of high-performing, talented teams that are able to deliver every day for patients in need.

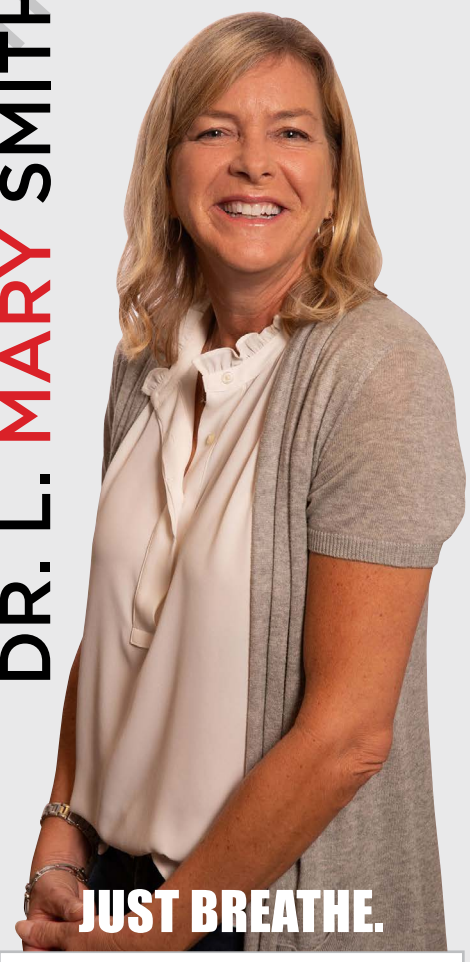
She is credited for offering sound guidance and creating an open, approachable, and supportive environment for her team.

Mary gives her colleagues opportunities for career development and flexibility so they can grow professionally, while maintaining balance by spending important time with their families and friends.

"I am supportive, open, and honest," she says. "I like to work with people to solve issues and problems. When challenges arise, we work as a team to find solutions. I encourage everyone to listen to each other and above all stay calm."

She leads by example, noting there is no job too big or too small for anyone. She measures success when those around her succeed and when the team moves programs forward.

"We succeed when everyone succeeds," Mary says. "There is no job, obstacle, or issue too big to face head on. I teach my team that we can persevere no matter what the day brings." PV



L. Mary Smith, Ph.D.

TITLE: Senior VP, Clinical R&D
COMPANY: SpringWorks Therapeutics
ASSOCIATIONS: American Society for Clinical Oncology.
TWITTER: @Lmsl66

FACILITATIVE. PASSIONATE.

DR. DAVID DANIEL

Bringing Certainty to Clinical Trial Data

With a unique perspective on clinical research development, David Daniel, M.D., chief medical officer and senior VP at Signant Health (formerly CRF Bracket), is driving the design of new, market-leading solutions that he hopes will become ubiquitous in CNS clinical trials.

A board-certified psychiatrist with a deep understanding of the clinical trial space, Dr. Daniel is passionate about connecting patients to facilitate the efficiency of new drug development and contribute to the confidence in the quality of clinical trial data.

Over the last decade, progress has been made in clinical studies, however, the pharmaceutical industry still struggles with designing studies that result in generating breakthrough medical therapies in the CNS space due to challenges with an increasing number of endpoints and procedures, variability in rater eligibility requirements and experience, recruitment and retention challenges, smaller budgets, and an additional training burden driven by incorporating numerous vendors and technology applications. Dr. Daniel is acutely aware of these challenges and colleagues say he has successfully helped to develop Signant's methodologies to improve data quality and the monitoring of clinical trials as well as the development of intelligent eCOA and predictive analytics that evaluate data quality as it is generated, allowing investigators to make changes as required.

A specialist in clinician-reported outcomes, Dr. Daniel's vision for delivering endpoint quality is the driving force behind the company's rater training and certification program. Dr. Daniel has helped to develop comprehensive training materials across several multimedia platforms, providing clients with a diverse offering of programs to meet their clinical trial needs.

At Signant, Dr. Daniel has been instrumental in the recruitment and supervision of the team of primary CNS experts, including recognized world authorities in schizophrenia, mood disorders, and dementia clinical trial methodologies.

Early in his career, he and colleagues significantly contributed to the National Institute of Mental Health's (NIMH) intramural program for the elucidation of the effects of dopamine agonists on cerebral blood flow and cognition in schizophrenia and understanding the patterns of structural brain loss in schizophrenia. At the Stanley Medical Research Institute (SMRI) he oversaw the clinical trial program that focused on proof-of-concept studies in mood and psychotic disorders and established an industry-style site performance monitoring program. Dr. Daniel's previous company, Global Learning, was a pioneer in the use of online rater training for establishing precision in global clinical trials. Global Learning was acquired by United BioSource Corporation (UBC), which spun out Bracket which later acquired CRF to become Signant.

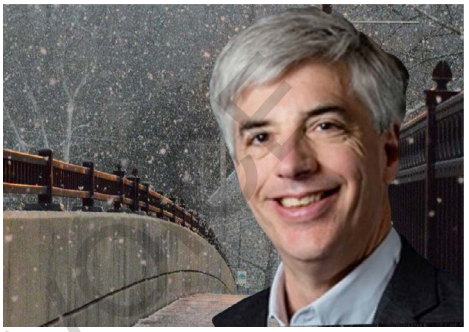
Dr. Daniel is committed to integrity, honesty, fairness, the success of the company and the individuals within it, and the development of safer and more effective medicines. "My job is to guide each medical scientist to fulfill his or her full potential to contribute to the company and the field," he says.

Dr. Daniel places great importance on his workforce and he has made it his focus to ensure that success is embedded into the team, and he is committed to helping the scientists in the company continue to grow in their careers. "There was a renaissance in psychiatry as a science in the 1980s and 1990s, and I had the opportunity to work with some of those who shaped the future as my mentors."

He believes in an equitable workplace, noting everyone who works to the best of their ability and contributes should have a "piece of the rock," financially and in terms of credit for the accomplishments of the company.

In everything he does, Dr. Daniel is committed to making progress to help patients and their families. In fact, he wrote the novel A Life Twice Given, which is an adventure and a family drama about transcendent love, life-changing decisions, and the restoration of the joy of life after disaster. The book was adapted for the stage in 2018 by Gail Louw through funding by UK Arts Council for production and is on tour in five venues in 2019.

Dr. Daniel is also an advocate for The David Gordon Louis Daniel Foundation, established in memory of his oldest son, which furthers the love of reading and learning in disadvantaged children. PV



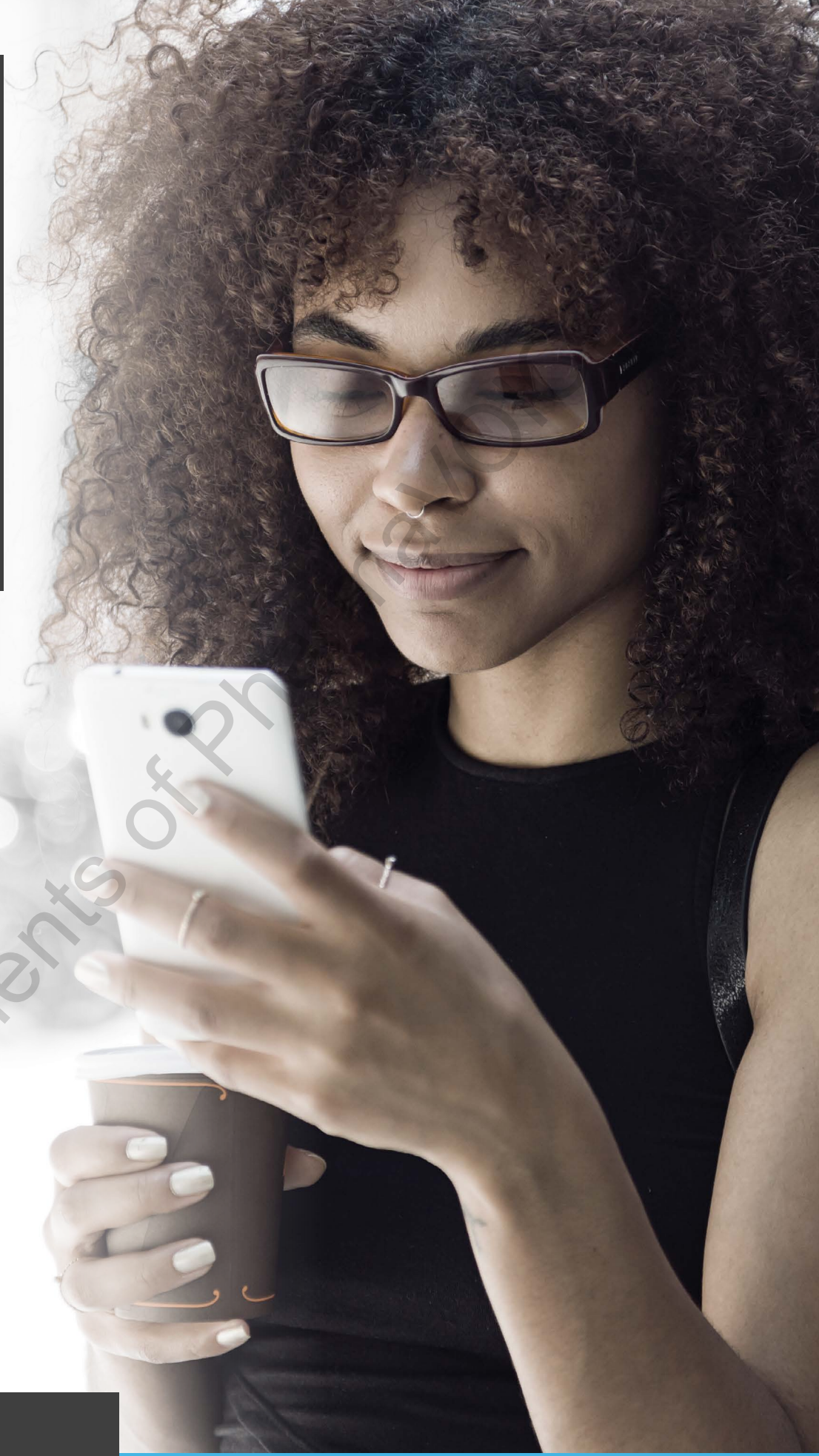
Make the most of everyone's strengths.

David Gordon Daniel, M.D.

TITLE: Chief Medical Officer and Senior VP
COMPANY: Signant Health
INDUSTRY AWARDS: International Society for Clinical Drug Development Scientific Leadership award, 2019; Executive Committee of CNS Summit; International Society for Clinical Trials Methodology Distinguished Poster Award; US Patent # 5457100: Method for Treatment of Paroxysmal Neuropsychiatric Disorders
COMMUNITY AWARDS: Marc Hollender Award in Psychiatry; American College of Neuropsychopharmacology Travel Award; International Schizophrenia Workshop Travel Award; National Alliance for the Mentally Ill Exemplary Psychiatrist Award; Co-Director, David Gordon Louis Daniel Foundation; Clinical Professorship, Psychiatry and Behavioral Sciences George Washington University, Washington, D.C.; Vanderbilt Basic Science Board of Visitors
ASSOCIATIONS: Society for Biological Psychiatry; Society for Neuroscience; American Psychiatric Association; Collegium International Neuropsychiatric; Schizophrenia International Research Society

IMAGINE IF...

CNS clinical trials were truly focused on the most troubling symptom of each patient and the treatment assignment was guided by effective biomarkers.



INTRODUCING THE INDUSTRY'S MOST COMPREHENSIVE PATIENT-CENTRIC TECHNOLOGY SUITE

[Patient Data]

[Patient Experience]

[Clinical Supplies]

[Endpoint Quality]

eCONSENT

"I get what this trial requires. I can do this."

eCOA

"Asthma flared up this morning. Feeling better now."

PATIENT ENGAGEMENT

"Site visit today - time to hail a ride."

CRF Health & Bracket are now

SIGNANT HEALTH

signanthealth.com

Bringing Transformational Medicines to Patients

Empowering. Working with Integrity.

IMAGINE IF...

there were no social determinants of health.

LORI PARISI

Lori Parisi is an inspiring, motivating, and tireless leader who puts patients first every time. As a senior global medical affairs leader, at Janssen Oncology, Lori is one of the best of the best at communicating scientific data and supporting Janssen's mission of bringing transformational oncology medicines to patients around the world.

Lori is the global medial affairs leader for Imbruvica, one of the leading hematologic malignancy therapies, which is approved in six distinct histologies and in more than 90 countries. She manages a large volume of rapidly evolving data through the ongoing clinical development of this first-in-class BTK inhibitor.

Lori thinks deeply about the science behind the molecule. She examines potential study designs with a critical mind, often coming up with novel perspectives and innovative ideas. As such, she is a much-valued partner to external thought leaders and her internal company partners on the compound development team and beyond. When engaging with medical experts in the hematology community, her command of the data enables her to gain critical insights into what the data means for patient care while advancing the scientific discourse on what more is needed to help patients.

Lori is a leader who has an abundance of energy and challenges teams across the globe to deliver the very best outcomes for patients with B-cell malignancies every day. She works tirelessly across time zones and personally engages key thought leaders to validate her hypotheses and thinking so she can lead her team with KOL-endorsed thinking.

When explaining data from new studies, she excels at translating facts into insights, emphasizing how Janssen, as a company, can effectively communicate the data to the medical community. Colleagues say each time they leave one of Lori's knowledge-transfer sessions, they have a deeper understanding of the data and how best to apply the information to the business. This is because Lori interacts with the team, understands her internal audiences, and translates the data through scientific storytelling in a way they can immediately take on board.

For Lori, success is less about achievement and more about fulfillment, which implies purpose, and purpose is important. "Working in healthcare requires a strong moral compass," she says. "We make decisions daily that have the potential to change lives. 'Right is right even if no one is doing it, and wrong is wrong even if everyone is doing it.'"

From a people development perspective, Lori welcomes members of her regional and local teams to join global working groups to raise their profile and experience stretched assignments. "The strength of a leader lies in his or her ability to inspire those around them to succeed and do things they never imagined were possible," Lori says. "I do my best to give others room to grow and take risks. Those are the best teaching moments."

Lori Parisi, MPH

TITLE: Senior Global Medical Affairs Leader
COMPANY: Janssen Oncology
COMPANY AWARDS: Multiple Johnson & Johnson Standards of Leadership awards; Nominee and participant in Smith College Leadership Consortium
COMMUNITY AWARDS: Gay Men's Health Crisis NY Teacher of the Year award for adult GED program
TWITTER: @ldparisi22

Lori says it's also important to be authentic. "It's hard to ask someone else to put their faith in you if you don't know who you truly are and what you stand for," she says. "Some days I'm no-nonsense. Some days, I'm witty and sarcastic. But every day, I'm me. Particularly for those who are early in their careers, it can be eye-opening to see that you don't have to fit into a pre-defined corporate mold to be happy and succeed."

Lori recommends the book Quiet Revolution: Unlocking the Power of Introverts. "I spent some of my early life masquerading as an extrovert, because extroverts were viewed as the successful leaders of the future," she says. "It was exhausting. This book taught me the true value I could bring to the workplace."

A career highlight, Lori says, occured while working in the field of infectious diseases at Janssen. She shaped U.S. public health investment by designing and implementing community-based grant programs in HIV and hepatitis C, which led to expanded critical health resources for highly marginalized populations, such as LGBTQ, transgender, and injection drug users. "The program, which spanned seven years, required an investment of millions of dollars in low-resource communities to increase access to compassionate care," she says. "We built a pipeline of new peer leaders and advocates who still continue the important, life-saving work to this day." PV

GISELA PAULSEN

Compassionate. Purposeful.

Removing Barriers

IMAGINE IF...

patient socioeconomic status was not a factor to have access to participating in clinical trials and all have access to any medicines.

In the last few years, Gisela Paulsen's career has taken her through roles in the commercial organization to finance to overseeing global clinical trial operations. Now as senior VP, global head, product development clinical operations, at Genentech/Roche, she is leveraging data and advanced analytics to optimize the selection of investigator trial sites and explore innovative tactics to drive recruitment and retention of diverse patient populations.

Gisela says she has a front-row seat to the future of clinical trial development. "There is so much potential, and what excites me most is how we can transform the clinical trial experience to bring medicines to patients faster," she says. "Whether it is by co-creating and simplifying clinical trial protocols together with investigators and patients, streamlining the trial process, decentralizing and removing barriers for patients to participate in clinical trials, or leveraging data and advanced analytics to accelerate development timelines, there are so many ways we are exploring to innovate the clinical trial landscape."

Before Gisela jumped into the clinical operations role, she provided finance support to Genentech/Roche's product development, late-stage portfolio committee and the Roche global product strategy function; she led a global team spanning five major sites. She also was VP of access solutions at Genentech, an organization that provides patients with access and reimbursement support. In each role, she focused on immediate impact, as well as long-term sustainable value derived from strategic changes, productivity gains, and improved employee engagement.

"I was able to push past my fear and make radical leaps from one role to the next," she says. "By building strong connections, fostering a culture of high-performance, and empowering my team, I was able to make a real impact in each of these very different roles and that has been my most rewarding career highlight to date."

She says Genentech's work environment allows for this type of connection. "Most do not have a permanent office or desk, which means that it's the people I work with who really create the environment," Gisela says. "I thrive off my colleagues' energy and cherish the relationships I have built over the years and the many yet to come."

Gisela says she is privileged to come to work every day and to know that what she does makes a difference in the lives of patients. "I get to do such meaningful work with incredibly talented people," she says. "I also am modeling for my daughter what it means to be a parent and a professional. I believe you can do it all, but you cannot do it all at the same time. You have to make career choices along the way that support your personal situation at that time. I hope that she sees my example and is inspired to prioritize what is most important to her at each moment in her life."

Those who work with Gisela say she is a role model who demonstrates clear business acumen and the ability to masterfully lead people and organizations through change. Gisela points out that a leader cannot just tell people what their vision is and expect them to follow it. "I like to bring people together and involve them in co-creating a shared vision of how we will achieve our goals together," she says. "As leaders, we can fool ourselves into thinking that our tenure or breadth of experience means we always have the answers, but I actually see it as my responsibility to create an environment of safety, trust, and creativity so that the best answers can come forward from the organization, and not leadership." PV

Gisela A. Paulsen

TITLE: Senior VP, Global Head, Product Development Clinical Operations
COMPANY: Genentech/Roche
INDUSTRY AWARDS: Healthcare Businesswomen's Association Leadership Excellence and Dedication Award, 2017; Healthcare Businesswomen's Association Council of Chapters' President of the Year, 2016; Professional Businesswomen of California Industry Leader Award, 2014; Genentech Healthcare Businesswomen's Association Rising Star, 2010
COMPANY AWARDS: Genentech Healthcare Businesswomen's Association HBA Rising Star, 2010; Genentech Commercial Excellence Award, 2006
ASSOCIATIONS: Healthcare Businesswomen's Association; Drug Information Association; International Pharmaceutical Federation; American Pharmaceutical Association; National Charity League; Women In Bio; Watermark; American Leadership Forum (ALF) - Silicon Valley
TWITTER: @GiselaPaulsen

If you want to go fast, go alone. If you want to go far, go together.

Leading Through Obstacles

Supportive. Tenacious.

David Fleishman is a stand-out talent in the clinical research arena who exemplifies the best of the new generation of industry thought leaders. He is making a significant impact for both his clients and their patients.

As principal, account and site services, at BBK Worldwide, David is the embodiment of a true, outside-the-box thinker who has a remarkable ability to accurately perceive and communicate about the patient experience with simple but penetrating insights. His talents have led to numerous enhancements of BBK's products and services, including revised strategic approaches, new technologies, and operational constructs and procedures, all of which are leading to better outcomes for both sponsors and patients.

"I want to make a difference by enhancing the awareness of, and participation in, clinical trials; improving patient access to care by removing barriers to clinical trial participation; and continuing to help pharmaceutical and biotech companies bring new drugs to market," David says.

David's well-considered approach in a highly demanding and complex industry demonstrates the simple truth that most great and lasting innovations emerge not so much from a single, brilliant moment of glory, but rather from adeptly and tenaciously handling every situation as it emerges and moving the game closer and closer to the goal line until the industry is permanently transformed.

What motivates him is solving the many recruitment and engagement challenges faced by pharmaceutical and biotech companies in their efforts to bring new treatments to market.

He says his biggest career highlight has been contributing to a recruitment and engagement strategy for a clinical study evaluating an investigational therapy for newborns with a rare, life-threatening genetic disease.

"We had to implement a global travel and reimbursement program that would eliminate the logistical and financial barriers to participation," David says. "Each family had unique challenges. Some needed a patient ambassador to assist with medical care and monitoring, translation, and transportation. Others needed special overnight accommodations."

For this study, he says a particular challenge arose late one Friday afternoon. "We received news of a potential study participant in rural eastern Turkey," he realls. "My team had to act quickly to arrange travel for the newborn and the parents, which included securing visas and passports, as well as an accompanying interpreter. The goal was to ensure that the family arrived in the United States at the study site within the 72-hour window before the newborn would become ineligible for the study. The team met the challenge. I was very proud to have overseen this effort. The experience to be able to help a family so desperately in need of a potential treatment option and willing to travel half way around the world to pursue it was a defining moment for me."

David is a natural team captain, equally at home calling the plays as he is rooting for and offering advice to his colleagues on the other side of the agency — not to mention on the other side of the client relationship.

Like any good manager, David inspires by assisting his team and giving credit when credit is due.

Colleagues say despite his no-nonsense demeanor he encourages his teams to not take themselves too seriously. He has a talent for pairing up his department into project teams that not only align in skills and experience, but also push each other to conquer professional challenges.

"I try to inspire my teams with a strong work ethic and a sense of determination," he says. "I never let a challenge defeat me. I am always looking for new ways to solve a problem. I try to encourage confidence in those with whom I work with to succeed. I also hope my passion for the industry and drive to help make a difference in the lives of others are an inspiration to those I work with."

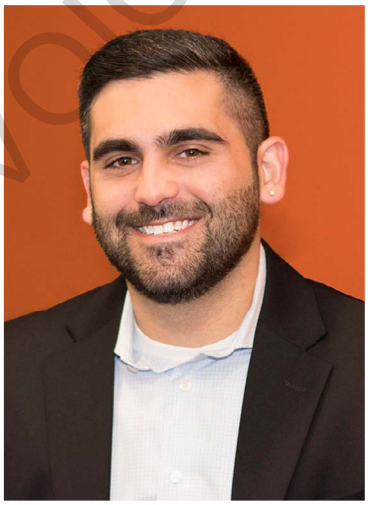
Colleagues say he also inspires by setting an example as a curious and constant learner. He always pushes himself to expand his skills and capabilities as a strategist, as a consultant, and as a patient advocate. David never lets his teams — or even his clients — settle when study participants stand to benefit.

"I like to lead as a mentor," he says. "To me, being a good leader is being a good mentor. I am fortunate to be in a position where I can support and nurture the development of others. I encourage my team members to be curious and independent thinkers. For me the greatest satisfaction is seeing those I work with succeed." PV

IMAGINE IF...

we could make the clinical research process more efficient and cost-effective.

DAVID FLEISHMAN



David B. Fleishman

TITLE: Principal, Account and Site Services
COMPANY: BBK Worldwide
ASSOCIATIONS: Community baseball coach

You miss 100% of the shots you don't take.