BUILDER. MENTOR.

KEVIN KUCHARSKI

Putting People First

While old school in the way he approaches study management, Kevin Kucharski is always looking for, and open to, new or better ways to conduct clinical trials.

An outstanding leader and mentor, Kevin Kucharski has an innate ability to guide individuals to their fullest potential, completely investing his time and energy into each project and each person.

His collaborative approach to working with others defines partnership. Mr. Kucharski says while Achillion Pharmaceuticals is focused on clinical development, his approach is that we should remember that we are in the "people business" first.

"Our people are the heart of who we are," he says.

Wherever he has worked, Mr. Kucharski has tried to put his staff members in positions where they can be successful.

"I want them to be in challenging situations where they can make independent decisions to move the business forward, while using me as a resource when confronted with a new or difficult scenario," he says.

His dedication, resourcefulness, industry knowledge, personable approach, and business methods are so admired by those he works with that as he has moved to new positions, several members of his team have clamored to join him.

Naturally team-centric, Mr. Kucharski maintains that teams win together and those he has worked with have bought into that concept and embraced his endeavors to explore new successes.

While he acknowledges being old school in the way he approaches study management, Mr. Kucharski is always looking for, and is open, to new or better ways to do things and enhance the company approach.

For example, he has expanded the home-based staffing concept in his current role as senior VP of clinical operations, allowing Achillion to recruit and retain high-quality and talented team members regardless of their location, which has resulted in a positive impact on results. He notes that companies that have embraced this concept are at the front end of recruiting and retaining top talent.

Mr. Kucharski has been instrumental in expanding site networks to Latin America, Eastern Europe, and other emerging markets to meet aggressive recruitment objectives. Again his focus on people comes to the fore, as he has sought out true local expertise to ensure the company is at the front of the curve using local know-how to expedite trials.

Before joining Achillion, he was VP of clinical operations at Pharmasset, and was instrumental in getting Sovaldi from IND to Phase III clinical trials in just under two years.

Mr. Kucharski and his team built the clinical infrastructure and network that led to a rapid and efficient program of highly innovative studies that completely changed the way physicians treat people with HCV.

"The work performed by my team was directly responsible for creating the tremendous value leading up to Gilead's acquisition of Pharmasset in early 2012," he says. "Hands down, this was the biggest thing I've been a part of in 27 years of clinical research."

His toughest assignment was as head of clinical operations at Altana Pharma US, where he was responsible for building the U.S. clinical operations staff to be able to manage the respiratory clinical programs in COPD and allergic rhinitis. Under his guidance, Altana grew the clinical operations team from 10 full time employees to 50 in just more than six months, and three years later filed and eventually had approval for its first NDA as a new organization with ciclesonide. In late 2007, Nycomed acquired Altana and disassembled most of the U.S. organization.

"The clinical operations team we put together were some of the finest professionals I have ever been around," he says. "I am fortunate that I've continued to work with a few of these folks over the last eight years, and I remain in contact with many others, however, breaking that team down was one of the most difficult things I've ever had to do." PV

GETTING TO KNOW...

Kevin Kucharski

TITLE: Senior VP, Clinical Operations
COMPANY: Achillion Pharmaceuticals
EDUCATION: B.S., Biology Research, University of Scranton
FAMILY: Wife, Marion; son, Kevin, 23; daughter, Alison, 21
HOBBIES: Golfing, landscaping, traveling, wine
BUCKET LIST: Golf at Pebble Beach with his son; travel to new destinations with family; finding the right beach house for retirement
ASSOCIATIONS: DIA, ACRP
SOCIAL MEDIA:
TWEET: @MrKuch1

DEDICATED. PASSIONATE.

DR. BRAD VINCE

Groundbreaking Clinical Research

Dr. Brad Vince, CEO and medical director of Vince & Associates Clinical Research, is a pioneer whose influence on the industry is being felt by his employees, clients, patients, and the industry. With relentless energy, sometimes fueled by Red Bull, Dr. Vince is transforming the clinical trial industry.

In 2010, Dr. Vince was convinced that the future of early development rested in special populations and decided to build a new clinic with the safety and comfort of special populations in mind. While a more common practice today, it was a new trend just five years ago when he invested in a multimillion-dollar 90-bed capacity unit. He and an impressive team of clinical researchers designed the research facility, which is still unmatched to this day with its boutique hotel-like design, bedside 20-inch touchscreen entertainment systems, movie theater, and other luxury amenities.

With some in-house stays lasting up to 30 days or more, it is vital to provide subjects with features to encourage recruitment and retention. Additionally, the state-of-the-art facility provided biopharmaceutical clients with enhanced safety monitoring features such as 24/7 video monitoring, a USP 797-compliant biosafety cabinet, full-time pharmacy staff, an extensive laboratory, and facial recognition security. This purpose-built unit was designed with complex clinical trials in mind as it allows sponsors to make earlier drug development decisions and advance their drugs to market more effectively than ever before.

Furthermore, Vince & Associates has been on the forefront of medical innovation by becoming a leader in complex clinical trials, such as the human abuse liability and early development cardiac safety assessment, a replacement to traditional TQT studies. Dr. Vince is driven to become a trailblazer for many medical breakthroughs.

In addition to cutting-edge research, Dr. Vince also invests time and energy into his employees. According to colleagues, he leads by example and is willing to do any task that a member of his staff has been asked to do. This leadership style shows his staff that every task is important to getting the job done and no one person is too important to pitch in to accomplish the goals of the company.

This leadership quality has fostered the teamwork that is present among all members in the various departments within the organization. He has created an environment of career focus within the company versus the feel of just being employed to do a job. He mentors staff by teaching them the importance of client relationships, ethical conduct within the industry, focus on quality, and always working to the highest standards when so many companies take shortcuts. He constantly takes the time to turn new or difficult situations into teaching moments for colleagues. He is always willing to provide guidance and he is compassionate about life circumstances that may have the potential to interfere with an employee's work performance.

Dr. Vince emphasizes the importance of building lasting relationships versus transactional interactions. He creates an environment that responds to the needs of a client versus reviewing the contract for what services were agreed upon. Dr. Vince touts customer service as important to the success on all fronts of clinical research, ranging from sponsors to vendors to CROs to study volunteers. Colleagues report that this focus directly translates to the organization's success over the past 15 years.

The company has more than quadrupled in size with 175 full-time employees and is expanding the research campus with a new four-story building. The new building will have an enhanced recruitment center to support the demand for qualified subjects, a controlled ventillation smoking room, additional research suites ideal for volunteers participating in overnight clinical trials, and a new state-of-the-art pharmacy to provide additional drug preparation methods and maintain an ISO Class 5 environment.

Dr. Vince says the expansion is one of his biggest achievements.

"My biggest career highlights to date have been winning a five-year contract with the FDA to conduct clinical trials and now our new four-story building being constructed on our research campus that is set to open later this year," he says.

Dr. Vince also supports his community and various charities. Over the past 15 years Vince & Associates and its employees have donated more than 10,000 hours of community service and donated/raised more than $100,000 for local and international charities. Recently, Dr. Vince spearheaded a campaign to raise funds for the local charities Make-A-Wish Foundation and Children's Mercy's hospital using a spectacular light show timed to holiday music. PV

DRIVEN TO INNOVATE BY

PATIENTS

GETTING TO KNOW...

Brad Vince, D.O.

TITLE: CEO and Medical Director
COMPANY: Vince & Associates Clinical Research
EDUCATION: D.O., Kansas City University; Residency, University of Kansas Medical Center
FAMILY: Wife, Patricia; three teenagers
HOBBIES: Work and work
AWARDS/HONORS: Six CRO Leadership Awards in 2015; NOVA Award, given to the fastest growing companies by the Overland Park Chamber Economic Development Council

Dr. Brad Vince's leadership, experience, and innovative approach to early phase study design are transforming the industry.

DR. DIXIE ESSELTINE

Imagining the Possibilities in Medicine

Few scientists have the chance to participate in the successful development and launch of a drug; even fewer see lightning striking twice with a second drug approval. Dixie Esseltine, M.D., was a key member of the Velcade development project in multiple myeloma and solid tumors at Millennium Pharmaceuticals. Today, the impending approval of ixazomib, the first oral proteasome inhibitor for multiple myeloma, represents a chance for her to continue to impact myeloma patients' lives.

Velcade has transformed the lives of thousands of patients with myeloma and was integral to the success of Millennium, which today is known as Takeda Oncology.

Dr. Esseltine currently serves as Takeda Oncology's VP of global clinical development for oncology, and is responsible for overseeing the company's company's protein homeostasis group. She manages cross-platform development opportunities and novel approaches to oncology drug development.

She has an uncanny ability to plan for very different scenarios and potential outcomes. She can imagine how a drug may be perceived five to 10 years after it first enters the clinic and whether the compound has the potential to become a game changer or only offer incremental impact.

Her decision to study medicine was motivated by the desire to treat and maybe cure patients. She spent 12 years working as a pediatric hematologist in Canada where she treated children with cancer and blood diseases. She also was responsible for the clinical hematology service in an academic tertiary care pediatric hospital and within this setting developed teaching programs and supervised medical students and pediatric and hematology residents. During her years as a physician, she developed a keen interest in clinical research and teaching —with a concentrated effort in sickle-cell disease and palliative care — while also participating as an investigator in NCI oncology cooperative group trials.

PASSIONATE. DEDICATED.

Dr. Dixie Esseltine is motivated by the people she works with and the conviction she is making a difference.

Looking to have a larger impact on patients' lives, Dr. Esseltine saw the beauty of joining the drug development industry, which provided a larger forum for her abilities. She joined the industry as an associate director with Johnson & Johnson, now Ortho McNeil, in Canada in 1990.

During an industry career spanning 25 years, Dr. Esseltine has impacted countless patients' lives.

She joined what was then Millennium Pharmaceuticals in 2001 as senior director, clinical research oncology, and went on to lead global medical affairs and then to her most recent engagement in global clinical development.

Dr. Esseltine is inspired to make a difference at work and in her life, and she is constantly eager to learn.

To maximize the value of the assets she oversees, Dr. Esseltine says she inspires her team to innovate by thinking beyond their experience and considering uncharted territory. Her colleagues would agree that it is her steadfast dedication to research when it comes to developing drugs that may possibly cure cancer someday that inspires them to strive for far-reaching goals. That, and the fact that she is very often the smartest person in the room. So it's probably not surprising to learn that Dr. Esseltine was part of a team that identified a new hemoglobin.

Dr. Esseltine says she wouldn't change a thing in her career as she learned from everything — good, bad, and neutral. However, she would tell her younger self not to worry so much.

When it comes to having the powers of a super hero, Dr. Esseltine already has what she would seek — strength of will. PV

DRIVEN TO INNOVATE BY

MAKING A DIFFERENCE

GETTING TO KNOW...

Dixie-Lee Winfred Esseltine, M.D.

TITLE: VP, Clinical Research, Oncology
COMPANY: Takeda Pharmaceuticals International Inc.
EDUCATION: CSPQ, Hematology; FRCPC Internal Medicine, ABIM; M.D., B.A., Zoology
FAMILY: Wife, mother, brother, sister
HOBBIES: Work, reading, visiting Maine, opera
BUCKET LIST: Lose weight, get more exercise
ASSOCIATIONS: American Board Internal Medicine
SOCIAL MEDIA:

Takeda ONCOLOGY

I Aspire to Cure Cancer.

Congratulations, Dr. Dixie-Lee Esseltine, On Being Named to the PharmaVOICE 100!

We would like to congratulate Dr. Dixie-Lee Esseltine on her recognition as one of the PharmaVOICE 100. Dixie is a longstanding and highly recognized expert in multiple myeloma therapy. She is a vital and compelling advocate for treatments that use precision and power and she continues to devote her life to our shared aspirations to cure cancer. With her wealth of knowledge, industry experience, and leadership, she remains an inspiration to both her colleagues and the cancer community. Her compassion for patients with cancer exemplifies our patient-centric approach and personifies Takeda's values of integrity, honesty and perseverance. Dixie is an integral part to Takeda Oncology's mission of aspiring to cure cancer.

A singular focus drives our aspirations to discover, develop and deliver breakthrough oncology therapies. By concentrating the power of leading scientific minds and the vast resources of a global pharmaceutical company, we are finding innovative ways to improve the treatment of cancer. We've built a portfolio of paradigm-changing therapies and a leading oncology pipeline. Though we've made great strides in our fight against cancer, we are determined to do more – to work harder and to reach higher. We continue to push our aspirations with the same passion, agility and entrepreneurial spirit that has sustained our patient-centric culture and has made us the leaders in oncology that we are today.

We know that our mission is not a quick or simple one, but we are up for the task: **we aspire to cure cancer**.

Visit us online at takedaoncology.com

In a fast-paced, high-pressure environment, Dr. Sandra Lottes pulls teams together to share knowledge of products, protocols, and programs to optimize communication and operational efficiencies.

DR. SANDRA LOTTES

Clinical Precision

VISIONARY. SOPHISTICATED.

DRIVEN TO INNOVATE BY

CHANGE

The status quo might be fine right now for some, but it might not work tomorrow and it doesn't work for Sandra Lottes, Pharm.D., who is an advocate for disrupting the accepted way of doing things.

As VP of global clinical development and operations at United BioSource Corp. (UBC), Dr. Lottes is going the extra mile to strengthen the company's clinical development expertise with patient-centric solutions. She is extremely knowledgeable in many aspects of clinical trials, everything from development to operations, data management, systems and infrastructure, and analytics.

Under her leadership, her team helps evaluate study protocols, target study populations, collect, clean, validate, and report data, often far earlier than projected timelines, allowing sponsors to submit findings to regulatory authorities or make a no-go decision in a timely and clear-cut manner. In the end, the high-quality data help expedite products to market so patients and physicians have more treatment options.

"By recognizing the changing needs of our customers, my team and I stay on the cutting edge and are able to bring new solutions to our clients," she says. "We realize we need to always bring something new to our pharma and biotech partners to provide the best support of their products and patients."

Since joining UBC in 2007, Dr. Lottes has expanded the company's early phase clinical development strategy with recent emphasis on UBC's oncology offering to one of its largest core therapeutic service areas. She was instrumental in the launch of the first-ever clinical trial record access program for clinical trial patients. And she has implemented novel approaches to clinical studies that drive efficiencies and increase patient access to life-changing therapies.

She understands the direction the company is headed and is dedicated to finding new ways to streamline the process and gain efficiencies. Dr. Lottes leads with a vision that is creative, insightful, and driven by a passion to do and be the best.

She can break down complex processes and pull out the important, high-level attributes, which help colleagues generate informative and persuasive materials for clients. And she always takes the time to make sure clients and colleagues understand every aspect of her team's services.

Known for her willingness to continually push for best results for the patient, the team, and the manufacturer, clients often remark on her practical solutions to address clinical development challenges. One of the top five pharma companies credits her personal contribution for the portfolio of oncology work under development in partnership with UBC.

According to Dr. Lottes, UBC's environment is built to encourage ideas from all staff members and ensures they have opportunities to expand their learning opportunities.

"We've learned team members often come back with new ideas and new applications for technology and processes," she says.

Managing within a global industry is a huge, but wonderful challenge, Dr. Lottes says. She believes the goal must be to manage global opportunities while ensuring patients are front and center and costs are controlled, which requires keeping the patient in mind when improving a process, developing a drug, or determining access and costs.

"Companies that are demonstrating a focus on the patient perspective are the most successful and will continue to be," she says.

Passionate about clinical pharmacology, she is ensuring her work is leading to new therapies and new opportunities to make people's lives better.

As a leader, Dr. Lottes values her employees and respects their individuality while holding them to the high standards she herself holds true. Colleagues say she is empathetic and listens openly to feedback on how to better her departments and teams. In addition, she supports and encourages professional development and she has implemented a training initiative for her team, which has increased employee engagement.

Dr. Lottes' career is replete with achievements. While at GSK, she helped develop the blockbuster carvedilol (Coreg), changing the paradigm of how heart failure is treated. At Salix Pharmaceuticals, she helped develop Visicol/OsmoPrep, a sodium phosphate tablet used in bowel preparation before colonoscopies, which improved patients' tolerance of bowel preparatory medication.

Dr. Lottes is very committed to causes that promote the development of young women, noting that it is easy for a single life event to knock women off the path of prosperity and self-sufficiency.

While raising her two daughters, she managed her own consulting company, which allowed her to drive her career and maintain a high-profile position, while having the flexibility to take care of her family.

She also commits to help the differently abled through Ability2Work, which is an employment opportunity organization that operates Baker's Treat. Health for all people matters to Dr. Lottes, who also supports Doctors without Borders. PV

GETTING TO KNOW...

Sandra Lottes, Pharm.D.

TITLE: VP, Global Clinical Development and Operations

COMPANY: United BioSource Corp. (UBC)

EDUCATION: Doctor of Pharmacy, Philadelphia College of Pharmacy; post-doctorate fellowship in Cardiovascular Pharmacology, Hahnemann University Medical School; B.S., Biological Sciences, University of Delaware

FAMILY: Two daughters: Stephanie and Samantha

HOBBIES: Reading, cross-country skiing, interior design

BUCKET LIST: Watch her daughters launch into the professional world and develop successfully; cross-country ski in Europe; spend more time in museums

ASSOCIATIONS: (Current and past) Healthcare Businesswomen's Association; Drug Information Association; American Society of Clinical Oncology; American College of Cardiology; American College of Gastroenterology

SOCIAL MEDIA:

CURIOUS. CREATIVE.

DR. WILLIE MUEHLHAUSEN

Hakuna Matata — No Problems

Dr. Willie Muehlhausen has always been at the forefront of innovative thinking and the implementation of new technologies.

GETTING TO KNOW...

Willie Muehlhausen, D.V.M.

TITLE: Head of Innovation
COMPANY: ICON plc.
EDUCATION: D.V.M., School of Veterinary Medicine, Free University, Berlin
FAMILY: Wife, Janette Muehlhausen; daughter Kate, son Oísin
HOBBIES: Underwater photography (sharks), piloting airplanes, gardening (vegetables and fruits), supporting the Irish Whale and Dolphin Group, reading, scuba diving
BUCKET LIST: Scuba dive with sharks off Cocos Island and whale sharks off Mexico; pilot a WW2 aircraft; attend a Super Bowl game; put paper diaries out of their misery
ASSOCIATIONS: DIA, ISPOR, ISOQOL, ePRO Consortium
SOCIAL MEDIA:
TWEET: @WMePRO

Head of Trouble — is how Willie Muehlhausen, D.V.M., describes his unofficial title at ICON and his attitude toward any sentiment that "it can't be done." In fact, he describes inertia as his biggest motivator, professionally and personally.

Dr. Muehlhausen, whose official title is head of innovation, and his team will always find a solution, even if it requires substantial changes at multiple levels. For some he says this spells "trouble" and he is not afraid to be the messenger.

A brilliant clinical technologist and thought leader, Dr. Muehlhausen has consistently directed and implemented technology solutions across the clinical spectrum seeking to improve the processes around capturing and analyzing clinical trial data.

He has always been ahead of his time in terms of strategic thinking on the future directions of key technologies, which underlie the improved efficiency performance of clinical trials — not just from a pure technology point of view but also from a usability point of view.

He not only understands the technology itself, he understands what it takes to implement the technology in a way that truly adds value to the research process.

Driven by the unknown, Dr. Muehlhausen thrives on finding solutions for problems that aren't even known yet.

""I have been in this industry since 1998 and have never had a boring day," he says. "Sometimes it feels like being on the starship Enterprise — exploring strange new worlds and boldly going where no one has been before."

His goals include eliminating paper diaries and establishing more standards to reduce inefficiencies in the clinical trial process. He believes technology, specifically mobile technology, will be at the center of the new processes and offers tremendous new opportunities to reach out to patients directly. He is glad to be part of a team at ICON driving this game-changing agenda and making meaningful contributions via scientific research and collaborations

However, he recognizes there is much that needs to be done to get clients to embrace new technologies and processes.

"It is still unclear to me why anyone would collect daily diary data on paper and expect to get anything meaningful out of this exercise," he says. "I often hear that paper is cheaper than an eDiary. I know this is often not the case, and if we consider the quality of the data being collected, this approach is certainly not cheaper. If daily diary data are not important enough to capture properly, i.e. electronically, then why capture the information at all."

DRIVEN TO INNOVATE BY CURIOSITY

Dr. Muehlhausen regularly collaborates with regulatory autorities and ePRO consortium to drive research on equivalence testing, which will support the acceptance of BYOD (bring your own device) models in ePRO. His collaborative inspirational style of conducting business has inspired peers in the industry and spawned further consortia that have motivated pharma and CRO technology partners to work together to remove obstacles in order to move toward a leaner clinical trial.

In addition, he has been a member of various working groups in DIA and ISPOR to drive change.

One of his most inspiring challenges was directing the ePRO consortium during the inaugural phase as it involved managing expectations and apprehensions of five competitors.

"The expectations of the industry and my own goals for the consortium were rather ambitious," he says. "With integrity and a sense of humor — I know I am German, but we can be humorous too — we managed the group well and achieved quite a bit. We managed to convince five additional competitors to join the initiative and now the ePRO consortium represents the vast majority of the players and does excellent work in collaboration with the PRO Consortium."

Reducing inefficiencies is another industry priority and Dr. Muehlhausen believes that adoption of standards is the easy initial step. New regulations allow for reduced source document verification and risk-based monitoring. Adaptive clinical trial design and simplifying protocols by only capturing data points that will be used for efficacy or safety are other opportunities to reduce costs and timelines.

To drive innovation, Dr. Muehlhausen has gathered the best and brightest in the industry and developed an innovation process within ICON that includes every employee.

Late last year, ICON deployed SPARK to manage challenges and ideas within the company, and the plan is to open this up to external partners.

Everyone in ICON can put forward an idea and invite colleagues to provide comments and support.

"I am a strong believer in crowdsourcing and SPARK brings all of us together to collectively address issues and develop solutions and visions for future challenges," he says.

Advice to a younger self would be to take the challenges as they come — Hakuna matata style — as there is an endless supply of tasks to be mastered.

"Life is too short to not have fun and enjoy every day," he says. PV

DR. MICHAEL GIBERTINI

Pragmatism Meets Vision

DRIVEN TO INNOVATE BY NEED

There is almost always a best option for any research study that, with an open-minded attitude, reveals itself quickly. Michael Gibertini, Ph.D., has a gift for seeing just what that possibility is. At the same time, Dr. Gibertini strives to gather information from all quarters and remains open that his initial read can be updated with fresh ideas and new approaches.

With more than 30 years of industry experience, Dr. Gibertini is known as one of the top clinical development experts in the CNS research field, where he is a thought leader in scientific and therapeutic content, data analytics, and operational strategy.

Combining visionary leadership with a pragmatic and highly strategic approach to operations, Dr. Gibertini has helped INC Research become an industry leader.

He has advanced trial design, external surveillance, critical path planning, data analytics, and other areas of clinical development. Many of his innovative ideas have become reality and are now practiced by multiple sponsors throughout the industry. He led the growth of INC's CNS unit from 150 people to more than 830 through an ability to amass and motivate talented employees.

Now as president of clinical development at INC Research, he is taking his work with the CNS unit into the broader company and is focusing on growing INC Research's clinical development units into the most effective engines for drug development in the industry. He is responsible for driving the growth of INC's therapeutic offerings globally, enhancing the company's focus on therapeutic foresight and continuing to drive a differentiated business model through thought leadership and delivering excellence in clinical development.

DECISIVE. OPEN-MINDED.

With a focus on the scientific integrity of each study, Dr. Michael Gibertini provides the entire organization with a purpose for being and empowers others to achieve success.

He continually looks for ways to use technology, streamline operations, and deliver breakthrough clinical development process improvements. Dr. Gibertini describes his role at INC as one that is perfectly tuned to his aptitudes and experiences.

Driven by patient need, Dr. Gibertini cares about people, processes, the compounds INC helps develop, and bringing those medicines to people around the world. Over the past 10 years in leading the CNS unit, Dr. Gibertini and his team have been involved in the pivotal trials responsible for new drug approvals and in the process have grown INC's business more than 10-fold.

"Seeing my efforts contribute to better medicines for patients suffering from CNS disease is most gratifying," he says.

With a commitment to promote and encourage creativity throughout the organization, Dr. Gibertini works across INC's therapeutic units to collect best practices, share ideas, and assess new ways to optimize clinical research. And he encourages other leaders within the organization to collaborate and share best practices to help spread knowledge and increase productivity on a larger scale.

He is a go-to person on many issues and is respected throughout the company and within the industry. A superb strategist, Dr. Gibertini encourages others to implement thoughtful change, always balancing the need for continuous improvement with the importance of making evidence-based and decisions toward change.

He has an uncanny ability to find new ways to address challenges and find solutions, and he always strives to achieve success without being deterred by obstacles. His innovative approach creates greater value for clients and enhances drug development for sponsors and patients.

Colleagues describe him as an inspirational leader and clinical innovator. As a leader, Dr. Gibertini fosters independence and growth among all members of his team. He gives people the latitude to find the best ways to overcome obstacles, and empowers them to meet challenges and produce optimal results. He inspires others by always being available as a touchstone and to offer support and guidance based on his own experiences.

He says innovation arises when teams recognize a problem that really needs solving.

"My role is to help teams distinguish those challenges that need an innovative solution from those that do not," he says.

First, though, the organization needs to have a culture that fosters innovation, rewards risk-taking, and leaders who can see and nurture innovations that are likely to succeed and quickly cull the rest.

Colleagues say one of his greatest assets as a leader is his ability to create buy-in from new team members and earn their trust and respect quickly. And while he is never afraid to make a decision, he always weighs the pros and cons, remaining calm under pressure and thoughtful in his approach to the task at hand.

Dr. Gibertini believes it is critical to recruit people who have an aptitude for clarity of purpose and proactivity since such people can respond to a leader's fundamental focus and get inspired to lend their talents and energies toward a worthwhile endeavor. PV

GETTING TO KNOW...

Michael Gibertini, Ph.D.

TITLE: President, Clinical Development
COMPANY: INC Research
EDUCATION: Ph.D., University of Houston; B.A., Northwestern University
FAMILY: Wife, Kari Nations, Ph.D.; two children, Anna and Kincaid
HOBBIES: Scuba diving, golfing, camping
SOCIAL MEDIA:

I am Michael Gibertini

I've helped INC become a recognized leader in CNS research

Making drug development effective and efficient

Helping new treatments to get approved

So that patients worldwide can get the medicines they need, sooner

I am INC Research

Congratulations to Michael Gibertini, PhD, President, Clinical Development, for being named in this year's PharmaVOICE 100. To learn more about how his leadership helps you connect with the specialists you need to run your trials, visit **increasearch.com**

inc Research®

CONSCIENTIOUS. RELIABLE.

DR. MARTINE DEHLINGER-KREMER

A Global Perspective

Dr. Martine Dehlinger-Kremer has pushed her team to reach beyond their comfort zone and embrace improvements to trial processes without sacrificing quality.

During her career, Martine Dehlinger-Kremer, Ph.D., has witnessed an evolution in the complexity of trials and the impact of global trials on innovation in the industry. It is a change that she believes is to the benefit of patients and products, because drugs are developed for worldwide use. As a result, she says it is essential to have professionals with global regulatory knowledge to support the development of tomorrow's treatments.

For the past year, Dr. Dehlinger-Kremer has been developing SynteractHCR's global medical and regulatory department. Her focus is on setting up new processes to make the organization even more proficient and efficient for the benefit of clients and for the benefit of drug development.

She is a proponent and advocate for alignment among the various regulatory bodies in different countries, because alignment in regulations will help to improve safety, increase efficiencies, and help to reduce costs as well as aid in getting drugs approved and to market globally, thereby bringing much-needed medicines to patients who need them, the world over.

Her contribution to innovation is extensive. She was involved in the second-ever orphan drug designation in Europe. She has also been involved in biosimilars from the outset in Europe in the 1990s helping to define guidelines when none existed. One of the first products she worked on was somatropin, a human growth hormone.

Dr. Dehlinger-Kremer has participated in more than 100 new drug applications (NDAs) and marketing authorization applications (MAAs), in the maintenance of products on the market, and in numerous clinical studies across all phases.

Before joining SynteractHCR, Dr. Dehlinger-Kremer was global VP of regulatory affairs at ReSearch Pharmaceutical Services (RPS).

Among the accomplishments she is most proud of is setting up service areas from scratch, including a regulatory department, a pediatric franchise, a study start-up group, and electronic tools.

In addition, she has influenced the standards, protocols, and number of trials conducted for drugs being administered to children, working alongside various stakeholders and authorities to help improve clinical research for the pediatric population. Her experience in this area includes serving as the chair of the Pediatric Working Group of the European CRO Federation (EUCROF) and as the lead member of the Pediatric Franchise at RPS.

She has also written several articles on the need for improved pediatric research, communications between regulatory bodies, investigative sites, and biopharma companies regarding children's research and she has influenced changes in the industry. Because she is such a renowned expert in this field, Dr. Dehlinger-Kremer is frequently asked to deliver conference presentations and webinars and has moderated panels regarding the topic of children's research to expand exposure for the unique nuances of this type of research.

"My hope for the future is that all sick children are treated with appropriate medicinal products, which have been approved for their respective disease and age group," she says.

Always with a focus on innovation, she has pushed her team to reach beyond their comfort zone and embrace improvements to processes without sacrificing quality. But she never asks team members to do anything that she wouldn't ask of herself.

"As a leader, I carry several responsibilities, but I do not set myself above my teams," she says.

Living with an ethos of enjoying every moment, Dr. Dehlinger-Kremer truly enjoys her job, saying it's fantastic to be able to contribute to the development of new medicines, to influence pediatric research, and thus to contribute to the improvement of medical treatments worldwide.

She inspires others by setting a good example, providing a safe environment for her reports to bring up their ideas, and sharing from her own experiences. Innovation is important, she says and so she encourages other to follow innovative and progressive ideas.

She devotes considerable time to mentoring her team members and as a result they are better equipped to embrace change that comes with our growth as an organization.

"I make them aware of the opportunities they have in the clinical research field, how important their contributions to the development of new medicines are, and thus, how important their daily work is for humanity," she says. "I also support them in challenging situations and let them know they can always count on me. Overall, I give them confidence in themselves." PV

DRIVEN TO INNOVATE BY

IMPROVEMENT

GETTING TO KNOW...

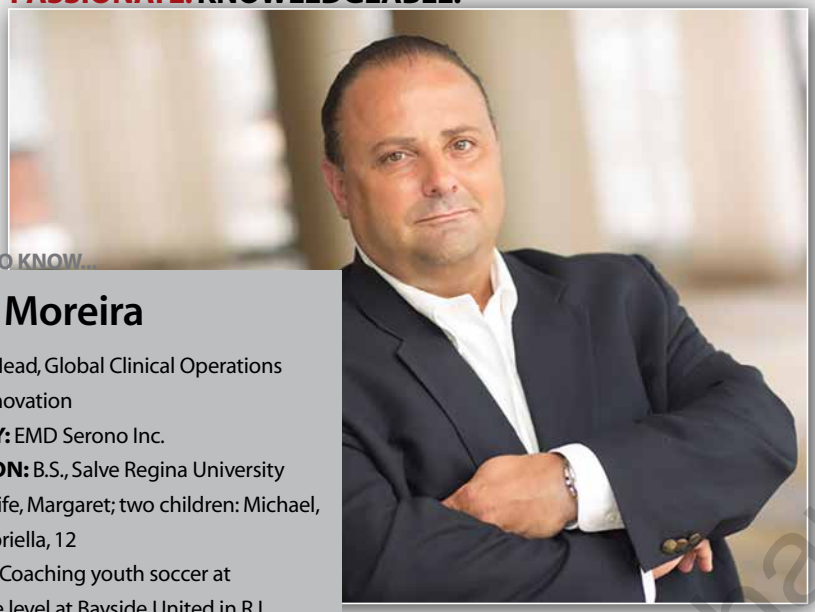
Martine Dehlinger-Kremer, Ph.D.

TITLE: Global VP, Medical and Regulatory Affairs
COMPANY: SynteractHCR
EDUCATION: Doctorate in Sciences, the University of J.W. Goethe; Diploma of Advanced Studies in neurophysiology, the Louis Pasteur University; Master of Science, the University Moulin de la Housse
FAMILY: Husband, Michel; daughter, Céline, 11
HOBBIES: Reading, movies
BUCKET LIST: Improve pediatric research
ASSOCIATIONS: EUCROF, European CROs Federation; BVMA, German CRO Association; The Organisation for Professionals in Regulatory Affairs (TOPRA); member of Working Group "How to establish communication between EnprEMA, networks and industry" of EnprEMA; the European Network of Paediatric Research at the European Medicines Agency
SOCIAL MEDIA:

PASSIONATE. KNOWLEDGEABLE.

PAULO MOREIRA

Putting Patients First



Paulo Moreira is focused on education and bringing along the next generation of drug developers, while ensuring that patients are aware and well-informed about the contribution they are making to the development of new medications.

GETTING TO KNOW...

Paulo Moreira

TITLE: VP, Head, Global Clinical Operations External Innovation
COMPANY: EMD Serono Inc.
EDUCATION: B.S., Salve Regina University
FAMILY: Wife, Margaret; two children: Michael, 15, and Gabriella, 12
HOBBIES: Coaching youth soccer at competitive level at Bayside United in R.I.
BUCKET LIST: Complete his quest to see and visit all 50 States — 10 remaining; write a book; patent an invention
AWARDS/HONORS: President's Award; LEAD Award; several Value Awards
ASSOCIATIONS: Clinical Trial Transformation Initiative (CTTI); Society for Clinical Research Sites (SCRS); DIA; Linking Leaders
SOCIAL MEDIA:

A career highlight for Paulo Moreira was being in a hospital room watching a patient being dosed with an investigational medicinal product he helped to develop and test. It's this patient-centricity that defines Mr. Moreira's approach to clinical research and clinical trials.

For Mr. Moreira, the goal is quite simple: it's all about the patient. He wants to help put new medicines on the market that will make a difference in people's lives, see the eradication of at least one form of cancer, and continuously make rare diseases even rarer. And if he had a super power it would be to fight very small villains — viruses and bacteria.

Each day he goes to work knowing that patients are waiting for answers. He stays firmly focused on patient safety and what is in the best interest of the person receiving the therapies and medicines that EMD Serono is developing.

Mr. Moreira doesn't just talk the talk, he legitimately walks the walk. One of the organizations he is most passionate about is CISRP's AWARE for ALL Campaign. Besides supporting the organization through his company financially, he passionately advocates bridging the gap between his trial teams and the patients at patient education events. In this atmosphere, he encourages his teams to thank, recognize, and support the patients enrolled in the trials, and he recognizes the benefit for his trial teams to learn from the patients first hand by speaking with them about their personal experiences.

Mr. Moreira's passion and vision are to change the industry by continuing to engage patients, educate communities, and build a culture of transparency. By doing so, patients feel that they are not only getting drug treatment, but they are also involved in making a difference in the disease or illness from which they suffer. In this light, they will continue to engage in the trials companies need to develop treatments for patients.

An excellent motivator, Mr. Moreira's energy spills over to those who work with him. He believes inspiring others begins with being genuine and authentic. He values and respects those around him and continuously invests the time to help them succeed.

He says having a vision is the beacon that provides the guiding light to drive innovation. But innovation cannot be forced — it requires time and opportunity. To innovate, Mr. Moreira believes in building relationships, seeking input, and trying to connect the dots.

"If you come up with nothing, don't simply give up, come back to it later," he says. "Never give up on ideas no matter how crazy they may seem at first."

It's important for leaders to be open-minded and courageous when implementing new ideas, and they need to remember that the most truly innovative ideas do not have an ROI established yet, so that shouldn't be the first thing you ask for.

Mr. Moreira lives every day with a few simple rules, which he calls the Seven "Ls" of life.

"It starts with live your life with purpose," he says. "Love what you do and do it with passion. Laugh often. Lend your time, your expertize, and your resources to those in greater need than you. Lead the way, don't wait. Listen and pay attention to others and to what goes on around you. It concludes with legacy — this one has to do with perseverance and having an impact in everything that you do."

New ideas and taking risks inspire Mr. Moreira and if he could travel in time it would be to the time of the discoveries, when people got into wooden boats and followed leaders to cross the oceans. PV

DRIVEN TO INNOVATE BY
EXCELLENCE

PATRICK HUGHES

Advancing Clinical Trials

Patrick Hughes knows the clinical trials industry inside out. From data monitoring and trial management, to clinical payment technologies, his experience has touched all corners of the clinical research and pharmaceutical markets, making him one of today's most highly respected advisors and mentors.

Renowned in the industry for recognizing technology solutions that truly make a difference and disrupt traditional practices and processes, Mr. Hughes has spearheaded the research, product development and commercial launch of some of the most exciting technologies on the market.

Above all, he is dedicated to understanding the real challenges that impact sponsors and CROs, while inspiring the industry to step away from the traditional and embrace new thinking and ways of approaching clinical processes. Maintaining a customer-based focus in the development of game-changing technologies allows him to inform the creation of solutions that improve the clinical trial process for everyone involved.

A true testament to his aptitude in clinical trials is his ability to recognize technologies that can not only improve and simplify processes for all parties involved, but that are also genuinely exciting and make great strides in instilling innovation across the industry, resulting in better, faster, and more cost-effective studies.

At ClinPhone he was instrumental in taking an unknown technology, interactive voice response systems (IVRS), from limited usage to virtually 100% buy-in in late Phase clinical trials today. During his tenure at ClinPhone, the company achieved two Queen's Awards for Innovation and Growth and Best UK Company in Confederation for British Industry (CBI) Awards in the same year.

He was also one of the early advocates of bring your own device (BYOD), spotting the revolutionary potential in ePRO and eCOA before it became a hot topic in clinical trials and mobile healthcare. He has also held executive positions at ERT and Exco InTouch, where he further cemented his success in finding and taking new eClinical technologies to market.

Now at CluePoints, Mr. Hughes has been key in helping drive an industrywide shift toward risk-based monitoring practices and getting the industry to sit-up and take notice of a new way of objectively and independently determining the quality and integrity of clinical trial data. He is helping CluePoints become the name in technology to enable risk-based monitoring and data quality oversight.

"By interrogating clinical trial data using a comprehensive suite of statistical algorithms, in the same way that the finance industry does to keep its customers safe, we are increasing data quality and integrity, protecting patients, and de-risking clinical trials," he says.

Mr. Hughes believes the challenge is to constantly evolve the solution by responding to customer needs, ideas, and suggestions. The team at CluePoints is challenged every day to improve the user experience and find enhancements that are valuable. These suggestions are added to a requirements list that is prioritized and then developed using product development "sprints." In this way the innovation is continuous and the product is changing at a rapid rate, he says.

In addition, Mr. Hughes is a regular advisor to investment companies, private equity firms, industry investors, and CROs, helping them to identify new opportunities to make clinical trials more cost and resource efficient.

When it comes to providing inspiration, Mr. Hughes says the only way he knows is to demonstrate to others how doing things in a certain way will result in a successful outcome.

"You can't inspire others unless they see you rolling up your sleeves and doing it yourself," he says. "I am constantly challenging others to do better or more and I can only imagine what they call me over the water cooler. Actually, I don't have to imagine, they usually tell me."

His main concern is whether he has conveyed his ideas or given direction and advice in a way that allows his colleagues to perform to the best of their ability. Encouraging innovation means ensuring people aren't afraid to fail. He says while rigorous and objective analysis of clinical trial data will play a significant role in data quality oversight and risk-based monitoring, it isn't obvious yet how this will be universally adopted.

As a result, CluePoints has been trying many different ways to discover how users will best interact with the signals and indicators of risk.

"We will ultimately find role-specific techniques to deliver the value in the software," he says. "If we weren't prepared to get it wrong from time to time, but hopefully not too often, then the product wouldn't end up being as great as it is."

Professionally, his goals remain to continue to be successful, to continually challenge himself and others, and always, always to have fun. PV

COMPETITIVE. SELF-DEPRECATING.

Patrick Hughes works relentlessly to understand the pharmaceutical and clinical trial sectors' needs from the ground up and has a steely determination to facilitate change.

DRIVEN TO INNOVATE BY

EXCITEMENT

GETTING TO KNOW...

Patrick Hughes

TITLE: Chief Commercial Officer
COMPANY: CluePoints
EDUCATION: B.Sc. and PGCE, University of Newcastle Upon Tyne
FAMILY: Wife, Claire; sons, Samuel William Maximus, 5; Harrison Alexander Maximilian, 2
HOBBIES: Manchester United football fan, , running half marathons, playing football and tennis
BUCKET LIST: Attend marquee sporting events around the world — cricket in Australia, World Cup, Olympics, Superbowl
AWARDS/HONORS: SCRIP Award 2014; awarded scholarship by the Department of Trade and Industry in UK to study business-to-business marketing strategy at Kellogg School of Management, Northwestern University, Illinois
ASSOCIATIONS: Chartered Institute of Marketing, Fellow of the Institute of Direct Marketing
SOCIAL MEDIA:
TWEET: @pdchughes

KARA DENNIS

Getting to Yes in mHealth

HARD-WORKING. OPTIMISTIC.

Kara Dennis leads Medidata's pioneering efforts to enable mHealth-powered clinical trials and patient-centric research, opening doors for a new era in data collection.

GETTING TO KNOW...

Kara Dennis

TITLE: Managing Director of Mobile Health
COMPANY: Medidata Solutions
EDUCATION: MBA, Harvard Business School; M.A., Columbia University; B.A., Yale University
FAMILY: Husband, Patrick; daughter, Marie, 21 months
HOBBIES: Playing with daughter, hiking
BUCKET LIST: Hike Zion National Park, Utah; travel
AWARDS/HONORS: Healthcare Businesswomen's Association (HBA) Rising Star
ASSOCIATIONS: HBA
SOCIAL MEDIA:
TWEET: @KaraNDennis

Kara Dennis is an mHealth expert today, but she may not have had the drive to be successful if it weren't for her earlier teaching experience with middle school students in Harlem.

Working for Teach for America for two years right out of college was the hardest thing she's ever done, but it was equally challenging and exhilarating. She enjoyed seeing the power that affirmation and encouragement could have to turn kids around, yet she met with many failures as well. She says she learned to cope with stress and handle very difficult situations thoughtfully, calmly, and with deliberation. This experience set the foundation for the determination, optimism, and authenticity that make her the leader she is today.

Recently named a Rising Star by the Healthcare Businesswomen's Association (HBA), as managing director of mobile health at Medidata, Ms. Dennis now leads the company's pioneering efforts to enable mHealth-powered clinical trials and patient-centric research, opening doors for a new era in data collection.

Collaborating closely with Medidata's CEO Tarek Sherif, President Glen de Vries, and Chief Operating Officer Mike Capone, she spearheads initiatives to increase the adoption of mobile sensors, wearables, and apps in clinical trials — and, in doing so, to enable a new model for drug development that aligns patient needs with faster study execution and reduced costs. Her efforts aim to help customers transform their research programs by collecting high volumes of objective, high-quality data that provide continuous, actionable insight into patient well-being and disease progression.

For example, Medidata's recent collaboration with GlaxoSmithKline assessed the impact of unifying mobile health (mHealth) tools with cloud-based technologies in a clinical trial setting. This innovative joint initiative is demonstrating that mHealth technologies have the power to collect high volumes of critical, objective data — generating more than 18 million data points per subject per day — that are not only reliable, secure, and analysis-ready, but provide unparalleled insight into the well-being of patients in real time.

In addition, Ms. Dennis has directed several other key mHealth initiatives at Medidata. Among them are Medidata's first sponsored trial, which evaluated whether mHealth tools can increase the rates of therapy adoption and drive better health outcomes for people with Type 2 diabetes, and a collaboration with Garmin International Inc. to integrate its vívofit activity tracker with the Medidata platform and explore the feasibility of using the vívofit in clinical trials. Most recently, Ms. Dennis led the development of an open-source connector linking Apple ResearchKit with the Medidata platform to map data generated by ResearchKit apps into Medidata's secure, regulatory-compliant environment.

She does not plan on stopping with just these accomplishments. Because she has a deep understanding of sponsors' frustrations around the limited data available from traditional clinical research, according to colleagues, she spends every day focused on challenging the status quo to help get the most out of clinical trial technology and processes.

DRIVEN TO INNOVATE BY
CURIOSITY

Ms. Dennis' passion and excitement for transforming trials is evident in how she approaches the most difficult issues and challenges in mHealth, each of which she views as an opportunity to do something differently, to do it better, and to set the pace for the future.

She truly believes that the remote, continuous observation of patients using mHealth technology and wearable devices will enable researchers to collect richer clinical information without generating additional costs and provide a more nuanced picture of patient health.

She inspires herself and her team members by always striving to get to "yes." She encourages deep discussions with clients to fully understand their needs and to discover a way to innovatively solve their problems.

"By taking the perspective that the answer to any question or challenge is always yes, we can figure out how to get to a solution, and that thought process forces innovation," Ms. Dennis says. "By saying 'yes we can,' we are forced to think differently to get to a new end result. This approach becomes a much more productive innovation dialogue."

And in a world that continues to rely heavily on the connectivity of countless devices and the cloud, as well as a shift toward a more patient-centric healthcare model, Ms. Dennis will be leading the charge for more effective and efficient clinical trials. PV