

LINDY JONES

A Passion for Effective Clinical Research

With a personal motto of “let’s do it,” Lindy Jones inspires others with her vision of where Quintiles is headed. As global head of site management and therapeutic strategy at Quintiles, where she manages more than 4,000 people across multiple geographies, from CRAs to a team of more than 350 physicians, Ms. Jones outlines the journey to success and makes it real for people.

Ms. Jones is recognized by her colleagues as a creative innovator and problem solver. She always challenges the status quo, in particular looking at the conundrum of how to recruit the right patients to the right studies faster. Ms. Jones was one of the pioneers of Quintiles’ Prime and Partner Site program, which now delivers up to 50% of the patients into the company’s clinical studies. Recruiting more patients at fewer sites increases the support the sites receive and in so doing enhances the patient experience. She understands that listening to and responding to investigators’ needs are pivotal in driving high-quality research, and her efforts have resulted in Quintiles winning the Society for Clinical Research Eagle Award in 2013, 2014, and 2015.

Ms. Jones’ passion for the need for effective clinical research as an important treatment option is particularly apparent in her home country, the United Kingdom. She has led discussions with the regulators and government, including the recent Chancellor of the Exchequer and the Life Sciences Minister to ensure that clinical research gets the recognition and support it deserves.

Colleagues admire Ms. Jones for her capacity to inspire and engage across multiple stakeholders, saying she leaves an invaluable footprint by ultimately protecting patients and advancing clinical research worldwide. Despite her nu-

Determined. Team Player.



Lindy Jones leaves an invaluable footprint by ultimately protecting patients and advancing clinical research worldwide.

merous accomplishments and accolades, she is most respected for her untiring commitment to always keeping the patient at heart.

Ms. Jones, a nurse by training, has the well-being of patients as a fundamental focus and is a champion of patient outcomes.

“What we do matters,” Ms. Jones says. “I spent my early career at patients’ bedside so working on new medicines that may improve lives is meaningful and to affect change, results have to be delivered.”

What motivates her is the knowledge that she helps to connect the dots in the organization, and she has the ability to connect personally with employees at all levels of the organization.

“I love to move quickly and that means everyone has to stay aligned,” she says. “This requires a lot of two-way communications and a lot of support and encouragement at times too. It also means having to make tough decisions and challenge the norm when the business needs it.”

Ms. Jones retains the ability to connect personally with employees at all levels on a

Getting to know...

Lindy Jones

TITLE: Senior VP, Site Management and Therapeutic Strategy, Chair of EMEA LA Management Board

COMPANY: Quintiles

EDUCATION: MSc, Clinical Research, University of Wales Cardiff

FAMILY: Husband, Gareth; children Sara and Christian

HOBBIES: Boating, cooking, and wine sharing with friends

BUCKET LIST: Learn to golf; travel the French canals; improve at skiing

SOCIAL MEDIA: [f](#) [in](#) [You Tube](#) [g+](#)

global basis. This connection comes from the fact she has had a grass-roots career and has had the fortune to serve in many key roles. She is also able to spot talent, which she then develops and mentors. Quintiles in Europe has regularly been recognized as a Great Place to Work.

She is also a passionate believer in caring for employees’ well-being. Quintiles was named Britain’s Healthiest Company. She also is an advocate of corporate social responsibility, and as chair of the EMEA board she has made this a key objective for all of the country heads in the EMEA region.

Ms. Jones wants to be remembered as someone who made things happen and who developed future leaders. She works to be present and open, and she recognizes that some things are just tough.

“We have to support the team and make sure they have everything required in place to minimize risk,” she says. “You have to hold to your North Star of what you are trying to achieve and the path forward at all times.” **PV**

Inquisitive. Joyous.

DR. UBAVKA DENOBLE

Anything is Possible

Combining a deep understanding of the highly complex and regulated industry with remarkable technical and interpersonal skills, Ubavka DeNoble, M.D., ignites enthusiasm in everyone. Dr. DeNoble's journey to the executive committee of a leading CRO has been an interesting one. She attended medical school in Yugoslavia, traveled to the United States, and taught herself English. She began her career in the clinical research industry as a safety associate and worked her way up.

Today, Dr. DeNoble is building PAREXEL's customized BioPharm Unit, driving it to great heights of performance and success thanks to her passion for working with small-to-midsized biopharma companies. She has been a key driver for the BioPharm Unit's success, building infrastructure, developing strategy, and marketing the new delivery model. The unit has met or exceeded all business metrics and client satisfaction. Her accomplishments have been recognized at PAREXEL, winning the Executive Committee Leadership Award in 2013 and 2014 — the first time in the history of the company that the same individual received this award two years in row.

Her successful work with the unit has changed the way that small-to-midsized biopharma companies work with CROs. Previously, these small and midsized companies believed they should partner with companies of similar size. However, today, because of Dr. DeNoble and the strong team she has built, they're seeking the expertise of larger CROs.

A dynamic leader with a commanding presence, clients trust and respect Dr. DeNoble because she treats them as equal partners in the process and prioritizes their needs. When meeting with her clients around the world, she is instantly able to make a connection.

She can quickly identify clients' needs, draw the right conclusions, and navigate the best course of action. She is able to quickly articulate her vision and course of action. If there is a challenge, Dr. DeNoble will roll up her sleeves and dig in as far as she needs to get to the root cause and find a solution.

Making the possible happen requires leadership from the top, and she brings the drive needed to work through any challenge.

"If I'm working hard to meet the challenge, my team does the same, and we usually win," she says.

Getting to know...

Ubavka DeNoble, M.D.

TITLE: Corporate VP, Key Accounts, Phase II/III

COMPANY: PAREXEL

EDUCATION: M.D., Board Certified in Internal Medicine; Military Medical Academy Belgrade

FAMILY: Husband, son, daughter-in-law, and granddaughter

HOBBIES: Sailing, reading, and the constant enjoyment of visual art

BUCKET LIST: To learn how to play the piano, and to be an active volunteer in political campaigns for a new, younger generation of politicians

AWARDS/HONORS: Top performer, ClinTrials Research, 1998; Executive Committee Leadership Award, PAREXEL, 2013 and 2014

Driven to innovate by
PATIENTS

She is extremely insightful, and her ability to push the right buttons to do what is needed for PAREXEL and its clients is evident in everything she does.

Because Dr. DeNoble is so well-respected, she commands attention. She is able to fill a room and captivate an audience. When a meeting is announced, clients rearrange their schedules to ensure they get to hear her speak. They like her, respect her, and know that their time will be well spent.

She inspires and energizes others to give their best effort. Regardless of the situation, she remains positive, sees a light at the end of the tunnel, and looks at every situation as an opportunity to learn and improve.

She inspires by explaining the rationale for objectives to focus the team's thinking on "how" in order to generate the energy and ideas needed.

Dr. DeNoble has a clear vision for teamwork, customer service and innovative and dynamic approaches to solutions. And she always seeks to learn from others.

She has high expectations for herself and others, and works with her team to reach



Dr. Ubavka DeNoble has a distinct understanding of the highly complex and regulated pharmaceutical industry, as well as remarkable technical and interpersonal skills.

beyond their personal and professional goals while driving business for the company. She encourages and supports professional development, but believes personal development is equally important.

A talent catalyzer, Dr. DeNoble takes great pleasure in empowering others and helping others succeed.

She is factual and scientific but also intuitive, and sets very high expectations for her team and for herself, but always sees and makes optimal use of the human factor, which enables her to bring out the best in people.

As someone who cares about others, the toughest task for Dr. DeNoble is when she has to explain why the set of skills that individuals are bringing on board are no longer sufficient for the company's future mission.

"Separation of personal feelings from the business objectives at hand is the most difficult task and every single situation like this leaves you with deep scars," she says.

Her success as a woman in a field dominated by men has inspired many of her peers. Dr. DeNoble embraces the opportunity to support the Women in Leadership organization at PAREXEL. She generously shares her time and experiences, and gives advice on how to create a personal development plan. Mentoring rising female leaders who come from different geographies and cultures is a very satisfying part of her job.

"My goal is to help female leaders get around challenges they are confronted with during professional development," she says. "Reinforcement of self-confidence is fundamental for leadership trajectory."

She would like to be remembered as a person who leads by example, and who inspired, energized, and developed people. **PV**

Passionate. Relentless.

Craig Lipset is leading the transformation of clinical research and healthcare.

CRAIG LIPSET

Creating a Future State

A progressive force in the clinical space, Craig Lipset seeks and encourages innovation across an industry not generally known for its agility. Mr. Lipset makes it his business to stay on top of what innovators and innovative organizations are doing, whether those innovators are tiny start-up companies, medium-sized biotechs, or large pharmaceutical companies.

Mr. Lipset, head of clinical innovation at Pfizer, understands that innovating within a stringent regulatory framework requires diplomacy and a good sense of timing. A great idea is not enough; that idea must be discussed with the right people at the right time in the right manner. He knows that patience is required when bringing new ideas to the fore.

He is experimenting with mobile technologies, sharing data with participants through the use of Blue Button, examining beyond-the-pill solutions that take a holistic view for effective treatments, and creating ways to engage clinical trial participant alumni.

A prime example of his progressive approach is the Pfizer REMOTE trial. The trial — the Research on Electronic Monitoring of OAB Treatment Experience — was a U.S.-based participatory patient-centered (PPC) clinical study designed to assess the safety and efficacy of Detrol LA (tolterodine tartrate), a treatment for overactive bladder.

What was important about the trial was not that it was an industry first, but the team's commitment to sharing what worked and what did not.

"This initiative proved to be an important milestone helping colleagues to appreciate our ability to innovate in clinical trials without

compromising quality, safety, or ethical commitments," Mr. Lipset says. "And it helped to spark a collaborative community of clinical trial innovators across the pharma industry, with creative and energized peers across companies who believe that while we may compete on molecules, we can share tools that improve the overall patient experience and data capture. This work has continued to shape and influence our current mobile/wearable initiatives as well as those programs that engage patients as partners in our development programs."

One of the big challenges, Mr. Lipset says, is to take innovative opportunities from successful pilots to full-scale implementation across the industry's complex or-

ganizations.

"This approach may be less sexy than the typical perception of 'innovation,' but change management and scaling are critical to making innovation work and realizing an impact from what is otherwise just a good idea," he says.

Innovation, he maintains, thrives where there is urgency and frustration and flounders where there is comfort and fear.

His goals are to make lasting and visible change within his company and across the industry, and make it easier for patients to participate in clinical trials.


With unlimited resources he would advance trust, engagement, and participation of the public in clinical trials in the pursuit of new medicines. He believes these goals can be achieved through clarity of message, engagement in communities, and tools that help give those communities a sense of ownership over research priorities.

Mr. Lipset is passionate about patients and caregivers and believes that empowering them will prove to be a catalyst for improving outcomes and creating new and effective treatments in the future.

He was one of the first people to join the Walking Gallery started by activist Regina Holliday (a 2014 PharmaVOICE 100 honoree). Ms. Holliday began creating jackets after she lost her husband to kidney cancer; each jacket conveys a personal health story of its owner as a way to spark change.

A second-time PharmaVOICE 100 honoree, Mr. Lipset is a true leader in the transformation of clinical research and healthcare, and in enabling patient empowerment.

"I have had my own experiences as a patient that guide and influence my work every day," he says. "I embrace the idea that we are all patients at various points in our journey; we are too quick to allow artificial silos because one is playing the role of 'clinician' and another that of the 'patient.' These boundaries are temporary. We were born patients, we will die patients, and we will be patients and caregivers at various times in between."

He is a mentor for colleagues within Pfizer and recently joined the Pfizer faculty of an elective on pharmaceutical development for New York University's School of Medicine and Weill-Cornell Medical College, and enjoys the questions and fresh perspectives he hears from his teams. In addition, he mentors entrepreneurs at Blueprint Health, a New York-based health tech incubator. 

Getting to know...

Craig Lipset

TITLE: Head of Clinical Innovation, Global Product Development

COMPANY: Pfizer

EDUCATION: Brandeis University

FAMILY: His kids, who reboot his desire to always ask why and why not; and his wife, who gives him balance by being a perfect complement

BUCKET LIST: Play guitar with his daughter; travel Japan with his son

AWARDS/HONORS: DIA Outstanding Service Award, 2010; PharmaVOICE 100 Most, 2011; Pharmaceutical Executive Emerging Leaders, 2011; Partnerships Award for Clinical Trial Innovation, 2012; Pfizer Dare to Try Innovation Award, 2014

ASSOCIATIONS: TransCelerate BioPharma, oversight committee member; Foundation for Sarcoidosis Research, board member; MedStar Health Research Institute, board member; Drug Information Association, chair of the advisory committee of North America; Therapeutic Innovation & Regulatory Science, official journal of DIA, editorial Board; Blueprint Health, mentor

SOCIAL MEDIA:   

TWEET: @craiglipset

Driven to innovate by

OWNING THE FUTURE

Curious. Persevering.

Sandra Chase has implemented a highly successful clinical outreach specialist team to assist clinical study sites with patient recruitment.

Driven to innovate by
**CONSTANT
 IMPROVEMENT**

SANDRA CHASE

Looking at Clinical Research Through Many Lenses

ment. What started as a two-month pilot in October 2015, with one study from Astra-Zeneca, has since extended and expanded to studies that now reach across four product franchises. This is having a tremendous, positive impact on randomization rates because the outreach specialists are promoting the clinical trials to referring physicians who send patients to the study sites as highly probable candidates with a known medical history.

Under Ms. Chase's leadership and vision, the site optimization team has gone from six employees to become one of largest teams at Continuum Clinical with almost 40 employees.

Ms. Chase says if she had unlimited resources, she would make sure clinical trials were presented as viable treatment options to every patient who could benefit.

"Beyond helping bring new treatments to market, clinical trials offer so many patient benefits such as in-depth education about their health, more frequent testing and monitoring, and access to specialists who may not be available to them within their insurance plans," she says. "It would take a massive communications and advocacy enterprise reaching everyone from medical schools to health professionals, insurance companies, advocacy groups, patients, and many others." **PV**

Getting to know...

Sandra Chase

TITLE: VP, Patient Recruitment

COMPANY: Continuum Clinical

EDUCATION: BA, Journalism/Public Relations, University of Southern California

FAMILY: Son, Chase Bougeon

HOBBIES: Gardening, being outdoors, hiking, reading

BUCKET LIST: Hike the John Muir Trail

through Sierra Nevada in California; walk the Camino de Santiago in Spain; finish visiting all 50 states — only North and South Dakota, Arkansas, and Alaska to go

SOCIAL MEDIA: [in](#)

Sandra Chase has the ability to identify even the smallest ways to improve the patient experience in clinical trials. As VP of patient recruitment at Continuum Clinical, she is able to think outside the box for solutions to recruitment challenges. And she has been able to do that by looking at challenges through multiple lenses, taking in the perspective of sponsors, sites, and patients.

By implementing strong processes and spearheading industry-shaping initiatives, she is making a major impact on the company by growing site optimization, building the clinical enrollment specialist team, and introducing the clinical outreach specialist team.

Company leaders say Ms. Chase has been instrumental in growing the organization's site optimization services from strategy development to identifying key metrics that will help sites meet their enrollment goals. She has been a leader in training associates in protocol interpretation, and relationship management with site coordinators and investigators.

Colleagues say she is a patient recruitment veteran who is also a natural communicator. She is very engaging and shares that same enthusiasm when educating her team on new processes and trends that are occurring in the marketplace or around new business opportunities.

Her background as a healthcare public

relations expert shines through when she talks about innovative ways to reach patients. Her ideas always bring a sense of relevance and fun. She loves data and metrics but is always looking for clean, simplified ways to present the big picture to sponsors, rather than getting lost in the details.

Company leaders say Ms. Chase holds herself and her team to the highest standards. Her meticulous nature, vision, and ability to execute are just a few of her talents in the clinical research space. She trusts in her co-workers, and is committed to training and giving them new responsibilities and as a result many junior employees have thrived under her leadership. She is great at discovering what people excel at and what they like to do, and then encouraging them to take on new leadership roles themselves.

"I've found that having a path laid out helps people see the goal is achievable," she says. "I've found that good ideas become great ideas when others' thoughts and points of views are part of the process. As a leader, you have to have an open mind and welcome thinking that might be counter-intuitive at first, or may come from an unexpected discipline."

Ms. Chase has implemented a highly successful clinical outreach specialist team to assist clinical study sites with patient recruit-

DR. CHRIS SMYTH

Breaking Cultural Barriers for Innovation

Drawing on more than 20 years of experience in oncology development on both the sponsor and CRO side, Chris Smyth, Ph.D., is truly dedicated to advancing cancer research.

Dr. Smyth has led clinical research organizations and biopharmaceutical companies in both Europe and the United States, dealing exclusively in hematology and oncology drug development since 2003.

Dr. Smyth has a unique ability to understand the finer nuances and complexities of oncology research, specifically around hematologic malignancies, all with an ability to teach and translate this knowledge to others in an approachable and understandable way. His industry knowledge about developments such as immuno-oncology and new technologies, make him an expert on any topic at a moment's notice, and he actively works to translate these developments to new initiatives and innovations within the company.

His goal is to contribute to the development, and hopefully approval, of as many drugs for the treatment of cancer as he can.

Dr. Smyth joined Novella Clinical in early 2014 as managing director for the European and Asian operations and leader of its European headquarters in Stevenage, U.K. He has helped grow the company from a largely U.S.- and western EU-focused group to a truly global entity with more than 1,000 staff, re-

sponsible for all of ex-US operations.

"I work with great people, for a great company doing important work," he says. "It's a privilege to work in this industry."

He is steadily steering the business through a period of growth, ensuring it scales up as needed while still maintaining the culture and personal touch that Novella Clinical is known for.



Decisive. Dedicated.

Dr. Chris Smyth's depth of international leadership and oncology operations expertise is helping Novella Clinical to grow in new markets.

His experience from having lived in the United States and leading global clinical operations at the U.K. biotech company Antisoma, has helped him bridge the cultural gaps between the U.S. and EU offices, and afforded him with a unique perspective on how to effectively communicate with team members with all different backgrounds. Dr. Smyth also has been lucky enough to have traveled all over the world; he was born in Paraguay and has lived in Trinidad, Pakistan, Kuwait, Cyprus, Greece, Canada, and many other countries. The travel continued in his own career, which has taken him again all over the world, including New Zealand, Australia, South Korea, Taiwan, China, Singapore, South Africa, Argentina, Chile, and numerous places in both the United States and Europe.

Dr. Smyth says his experience working in Boston for Antisoma was a career highlight in terms of enjoyment, but at the same time challenging both personally, being away from family and friends, as well as professionally

Getting to know...

Christopher Smyth, Ph.D.

TITLE: Managing Director, European and Asian Operations

COMPANY: Novella Clinical, a Quintiles Company

EDUCATION: BSc, Biochemistry, University of Kent at Canterbury; MBA, Henley Management College; Ph.D., Reproductive Biology, University of Edinburgh

FAMILY: Wife and two daughters

HOBBIES: Running, triathlons, and following Saracens rugby and Liverpool soccer clubs

BUCKET LIST: Travel more and experience new cultures, go back to Botswana

SOCIAL MEDIA: [f](#) [in](#) [g+](#)

challenging to manage a global clinical operations team given that the U.K. and U.S. cultures can be quite different.

He says innovation requires collaboration as well as ensuring that the technology, people, and cultures are all aligned.

This concept of collaboration goes well beyond just one organization, with Dr. Smyth maintaining that by having the whole industry working together it would be possible to focus on moving forward and building on the work of others rather than wastefully replicating efforts.

As a manager, Dr. Smyth is highly dedicated to his team, believing strongly in the value of face time and in leading by example. He is often the first one into the office and last one to leave. Team members say he leads through encouragement and often with a humorous perspective.

For Dr. Smyth, the measure of success is happiness — both his and that of those around him.

He mentors in order to make a difference for someone by sharing his experience, which also allows him to develop as an individual.

The story of Ernest Shackleton, a polar explorer whose attempted crossing of the Antarctic failed, is for Dr. Smyth an epic story of endurance and leadership and it reminds him to never give up and illustrates what a good leader should be. **PV**

Driven to innovate by

EXCELLENCE

CHRISTINA HUGHES

Ahead of the Clinical Trial Services Curve

Christina Hughes is a master negotiator, strategic thinker, and creative leader who in just 10 years has contributed to Bracket's revenue growth of more than 650% by keeping the company on course by evolving the service offerings to keep pace with the changing marketplace. In recognition of her contributions she has risen in the ranks from project manager to her current role as VP, client services and business development operations.

A leader in both technology and business areas, Ms. Hughes is focused on transforming the clinical trials industry through the innovative use of Bracket technology, coupled with scientific expertise. She is directly responsible for delivering high-quality, client-centered electronic clinical outcome assessment (eCOA), rater training and quality assurance services.

Intense. Compassionate.



Christina Hughes has transformed her organization by significantly evolving service offerings for sponsors and trials to keep pace with the changing marketplace.

Climbing the promotional ladder from project manager in 2005 — running the largest multi-protocol study in the history of the company at the time — to currently overseeing more than 200 employees located across the globe with offices in the United States, Europe, and Asia Pacific has been her biggest career highlight to date, and also her most challenging achievement.

“We have instituted major change management initiatives to transform our culture and how we do business,” Ms. Hughes says.

Colleagues report that Ms. Hughes has a wonderful ability to lead her team in a manner that best positions the team members to succeed. She strikes the perfect balance between providing guidance while empowering team members to make decisions. She is a consummate team player, even with her direct reports.

“As a facilitator, I bring a multi-disci-

Driven to innovate by

UNMET
NEEDS

plinary team together to brainstorm what we're seeing in the marketplace and what we need to do to stay ahead of the curve,” she says.

Her leadership style has a significant positive impact on talent development within the organization.

“Personally, I can't be passionate about my work if there isn't some connection to helping others,” she says. “Regardless of how far removed our work might be from making a difference, I explain to my team how what we do connects them to improving the life of someone else.”

Coworkers say Ms. Hughes is a great negotiator and she is able to craft win-win solutions when faced with issues that seem at times to be unsolvable.

Notably, she considers the input of others before making decisions and then makes the decisions and sticks by them. Colleagues say they are inspired by Ms. Hughes' ability to be both decisive when faced with thorny issues, and willing to consider and weigh the input of others.

Ms. Hughes has a long list of achievements in her 10 years at Bracket, including successfully implementing initiatives that yielded a 25% reduction against baseline KPIs for sales to contract cycle, quality assurance (incident reports), and employee attrition; and developing the scale management and translation offering. ^{PV}

Editor's Note: As this issue was going to press, Ms. Hughes was named chief operating officer of AiCure, whose mission is to equip patients, researchers, and providers with the intelligence to understand the exact link between medication and health.

Getting to know...

Christina Nicole Hughes

TITLE: VP, Client Services and Business Development Operations

COMPANY: Bracket

EDUCATION: BS, Yale University; MBA, The Wharton School

FAMILY: Husband, Drew Gajan; children, Andrew, Genevieve, and Grier; parents, Pat and Chuck Hughes

HOBBIES: Enjoy anything British, pop culture, movies, and traveling — has visited more than 35 countries spanning five continents

BUCKET LIST: Complete a triathlon; climb Everest; travel to India, Nepal, Galapagos Islands, Morocco; attend Wimbledon, Kentucky Derby, Tour de France, World Cup Soccer Final Games — men's and women's

ASSOCIATIONS: Healthcare Businesswomen's Association (HBA)

SOCIAL MEDIA: [f](#) [in](#) [t](#)

TWEET: @chughesey07

DR. PHILIPPE SZAPARY

Driving Innovation Through Collaboration

A triple threat — that's how those who work with Philippe Szapary, M.D., describe him. A researcher, clinician, and teacher, Dr. Szapary has a clear focus: to collaborate with and lead teams that bring important medicines to patients living with immune-mediated diseases.

He considers being part of a large team of professionals who discovered and developed Janssen's Stelara, for patients with a number of immune-mediated diseases, including psoriasis, to be a career highlight.

An inspiring leader, Dr. Szapary is persistent without being overwhelming, is inclusive of diverse opinions, and does not shy away from challenges. While he always keeps in mind ethical considerations, Dr. Szapary questions the status quo to try to improve the industry standards of development in collaboration and consultation with other stakeholders, including health authorities.

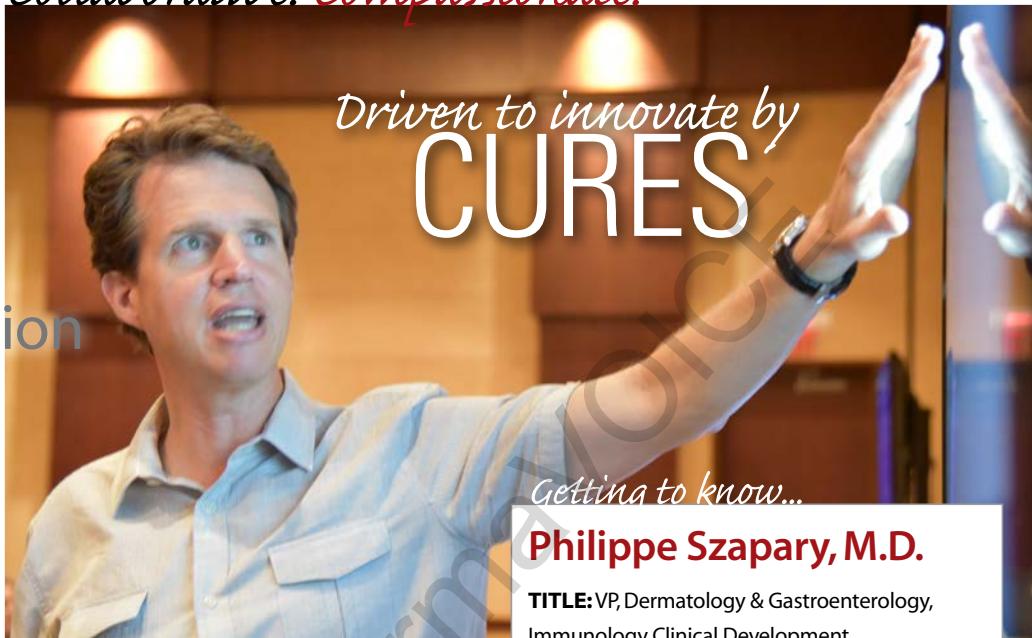
He is driven to achieve his objectives, strives for the highest quality in his work, while also looking for opportunities to help members of his team or when appropriate deferring to the expertise of others.

In a previous role as compound development team (CDT) leader for Stelara, he frequently assisted the clinical team with writing regulatory documents and publications, in addition to his duties to ensure that all of the research programs — ongoing and in development — were on track. He also helped the market access team develop the reimbursement dossiers, as well as supported the medical affairs team in building medical education materials and training Janssen colleagues on new data.

In this role as a leader, he was also able to inspire the Stelara CDT and Janssen immunology leadership to take on new Phase III programs for new indications at a time when resources were limited.

Today as VP of dermatology and gastroenterology, immunology clinical development, at Janssen, Dr. Szapary manages a group of 15 clinical scientists exclusively focused on

Collaborative. Compassionate.



Driven to innovate by
CURES

Getting to know...

Philippe Szapary, M.D.

TITLE: VP, Dermatology & Gastroenterology, Immunology Clinical Development

COMPANY: Janssen Research & Development LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson

EDUCATION: M.D., the University of Chicago Pritzker School of Medicine; Master of Science, Clinical Epidemiology (MSCE), University of Pennsylvania School of Medicine; Internal medicine residency at University of California, San Francisco

FAMILY: Wife, Allison Oler; three teenage children

HOBBIES: Traveling, cooking, triathlon, cycling

BUCKET LIST: Hiking in Bhutan and opening a bistro/gastropub on the West Coast

AWARDS/HONORS: Pharmaceutical Executive Emerging Pharma Leaders, 2011; Development team member 2011, U.S., and 2012, International, Prix Galien Awards for best biotechnology product, Stelara

SOCIAL MEDIA: [in](#)

Dr. Philippe Szapary is a strong clinical development leader who is also an innovative thinker.

developing next-generation therapeutics in inflammatory bowel disease and psoriasis. In this role, Dr. Szapary has enjoyed the breadth and diversity of activities, including participating in submission and approval processes, helping shape the regulatory landscape in pediatric drug development, and interacting with regulators on trial design and endpoints.

He also is leading a talent development initiative for the immunology development group and has been instrumental in establishing a framework to ensure that talent development is a systematic and embedded practice within the group, focused on enriching a future talent pipeline.

Working with an excellent team on successful products that make a real difference in patients' lives is the reason Dr. Szapary comes to work everyday. And he motivates others through challenges by exemplifying and instilling a unique quality of remaining calm.

"There's always time to overreact later," he says.

In fact, he argues that becoming distracted by the complexities of drug development is a roadblock to innovation.

He has a dynamic personality and whether he is presenting to hundreds or speaking with his team, Dr. Szapary has a remarkable ability to build relationships and networks at all levels and across the globe.

Colleagues describe him as authentic, honest, pragmatic, willing to speak his mind, and caring. These skills and characteristics have helped him to build strong relationships across functions — R&D, commercial, medical af-

airs, etc. — as well as with colleagues in regional and local country operating companies.

Dr. Szapary has also been able to develop collaborations with external experts that are based on a mutual sense of trust, competence, and a willingness to work toward solutions that benefit patients. He is committed to collaboration saying the sum is always greater than its parts.

Dr. Szapary continues to maintain his board certification in Internal Medicine and a clinic at University of Pennsylvania preventive cardiovascular program where he sees patients, including those with psoriatic disease, to assess and treat their cardiovascular risk factors. **PV**

Authentic. Visionary.



Amy Grahn is focused on the goal of bringing needed therapies to patients with rare and more common disabling diseases.

Working in an industry where there is the potential to help someone with an acute, chronic, or rare disease is what keeps Amy Grahn motivated.

Ms. Grahn brings an unparalleled commitment and dedication to advancing clinical research for patients and fostering Horizon Pharma's growth, as well as the growth of her colleagues.

She is a seasoned clinical development and operations professional, and her impressive track record with more than two decades of pharmaceutical industry experience spans from preclinical research to commercial roles, with a primary focus on clinical operations.

She joined Horizon Pharma in January 2009 as VP, global clinical development and operations, and was promoted to senior VP in 2010. She has worked tirelessly to help grow the company as employee No. 6 to more than 800 staff in the United States and Europe, and she was instrumental in building the clinical operations capability.

Over the course of her career, she has brought numerous medicines to market that have favorably impacted the health and well-being of patients. In particular, she cites the FDA approval of Duexis, a combination of ibuprofen and famotidine for pain, Horizon Pharma's first approved drug, as her career highlight to date.

Ms. Grahn is currently leading the Phase III clinical program for Actimmune (interferon gamma-1b) in patients with Friedreich's ataxia (FA). If the Phase III data are positive and Actimmune is approved by the FDA, it would represent the first-approved treatment for FA. She also is currently overseeing eight additional company-sponsored and investigator-initiated clinical studies and several academic collaborations.

AMY GRAHN

Clinical Perception

An exciting but difficult challenge for Ms. Grahn was the planning involved in the Phase III trial for glioblastoma multiforme. It required bringing top neurosurgeons together for consensus on a surgical approach to catheter placement for drug delivery via convection-enhanced delivery, then scoring their first cases and providing feedback to them. The study was extremely complex, integrating a device, drug delivery, neuroimaging, neuro-oncologists, and nurses in a comprehensive team to manage study patients.

"I had the privilege of working with an extraordinary group of medical professionals," Ms. Grahn says. "Unfortunately, FDA did not accept a progression-free survival endpoint at the time of the BLA submission."

She would like to be remembered for her role in giving a potential drug/intervention the best chance to demonstrate it is effective without constraint of poor quality or operational error in the conducting of a clinical trial.

Ms. Grahn is a strong leader who serves as a role model and who actively mentors other women in the pharmaceutical industry. In 2015, she was named a Healthcare Businesswomen's Association Rising Star for her dedication to advancing other women's careers.

"I try to push people out of their comfort zones to realize how much more they can contribute to the overall goal," she says. "A

Driven to innovate by

PATIENTS

collective is stronger than an individual so I try to cultivate team work and seek input from others."

She inspires by ensuring the target is clear and in focus, and often recognizing the efforts of her team members to demonstrate desired behaviors and achievements.

If she could give one piece of advice to her younger self it would be to be patient.

"I tend to push myself hard and expect others to do the same and keep up," she says. "I realize now that pausing at times and allowing others to catch up will accomplish the same goal in a less hectic way."

Ms. Grahn has drawn inspiration from both her parents. Her mother battled through breast cancer and has become an inspiration for

Getting to know...

Amy Y. Grahn

TITLE: Global Senior VP, Clinical Development and Operations

COMPANY: Horizon Pharma plc

EDUCATION: BA, Knox College; MS, Biochemistry, Illinois Institute of Technology

FAMILY: Mother and father; husband

HOBBIES: Competitive dressage (equestrian), Northwestern football and basketball, bike riding, hiking

BUCKET LIST: Achieve her United States Dressage Federation gold medal and freestyle bar in dressage; develop her yearling horse to become an international competition horse;

build a house on a lake; help her niece and nephews achieve anything their hearts desire

AWARDS/HONORS: Healthcare Businesswomen's Association Rising Star 2015

ASSOCIATIONS: American Society of Clinical Oncology, Healthcare Businesswomen's Association 2015, Women in Bio

SOCIAL MEDIA:  

others to seek treatment, including clinical trials, while her father sponsored others through their battle with alcohol addiction and battled both head and neck cancer and lung cancer for four years until he succumbed, but he always kept a positive outlook on life. She is also inspired by the physicians and healthcare practitioners who take care of patients and their willingness to do whatever it takes and have the confidence and commitment to try new treatments.

At a broader industry level, Ms. Grahn says there are so many developments that are pushing the boundaries: wearables that capture continuous data and feedback important information for understanding a treatment; leveraging electronic medical records as an "esource" for clinical trials.

On the preclinical, she is excited by side gene editing for animal knockout models such as CRISPR; and crowdsourcing such as Smart Patients and PatientsLikeMe to gain insight into patients' voices, what is important to them, and incorporating their voices into clinical trials.

Beyond her passion for mentoring and for patients, Ms. Grahn is active in numerous industry organizations, including Women in BIO and AVOCA, serving as an active panelist speaking about clinical development-related topics. 