

> Instinctive *Innovators*

These experts in the clinical arena are evolving research and development practices, technologies, and development models to help bring new products to market faster, more cost-effectively, and with improved safety profiles.

Mitchell **KATZ**, Ph.D. • LEADING BY EXAMPLE

SUPPORTIVE. CHARISMATIC.

NAME: Mitchell Katz, Ph.D.

CURRENT POSITION: Executive Director, Purdue Pharma LP

DATE AND PLACE OF BIRTH: December 1954; Brooklyn, N.Y.

EDUCATION: Ph.D., Rutgers University, 1981; B.A., Brooklyn College, 1977

FIRST JOB: Retail assistant, Macy's

FIRST INDUSTRY-RELATED JOB: Principal scientist, Schering-Plough

PROFESSIONAL MENTORS: Dr. Morris Solotorovsky, Rutgers University; Dr. Paul Leibowitz, Schering-Plough

PROFESSIONAL ASSOCIATIONS: American Academy of Neurology; American Society for Microbiology; American Spinal Injury Association; Biotechnology Industry Organization; Drug Information Association; The American Association of Immunologists; The New York Academy of Sciences; New York Biotechnology Association

GIVING BACK: The Multiple Sclerosis Society and Alzheimer's Society

AWARDS: One of the top 20 leaders globally at Eisai selected to attend the Kellogg School of Management to receive an executive MBA; Johnson & Johnson Achievement Award for the development of the Orthoclone OKT3 Reference Laboratory to support U.S. transplant centers

WORDS TO LIVE BY: Let the data speak for itself

Dr. Mitchell Katz is a great mentor, role model, and leader and enjoys watching people grow successfully into new roles.



DID YOU KNOW?

Dr. Mitchell Katz has two sets of twins, twin boys and twin girls.



Vision, dedication, and passion are the qualities essential to leadership. In his 26 years of experience in pharmaceutical and biotech research and development, Mitchell Katz, Ph.D., has directed across functional areas as diverse as clinical operations, data management, statistics, and medical writing. He is very committed to achieving goals and works hard to make them happen.

By sharing his time and experience with others, Dr. Katz acts as mentor and role model. Since joining Purdue in June 2010 as executive director, he has built strong relationships internally and with his clinical outsourcing partners.

Dr. Katz leads by example and sets a bar that brings out the very best in his colleagues.

Dr. Katz's work ethic and motivation inspire his entire department to work efficiently and effectively. He has the drive and enthusiasm to improve clinical research significantly. Dr. Katz is focused on ensuring that quality data come from quality investigator sites to meet the standards that regulators are looking for and what the public expects from the scientific clinical community and pharmaceutical industry.

More than willing to share his time and his experience with others, his insights and thoughtful recommendations have value to everyone who works with him.

As part of a multifaceted approach to his profession, Dr. Katz speaks at many conferences. A leading voice in research and devel-

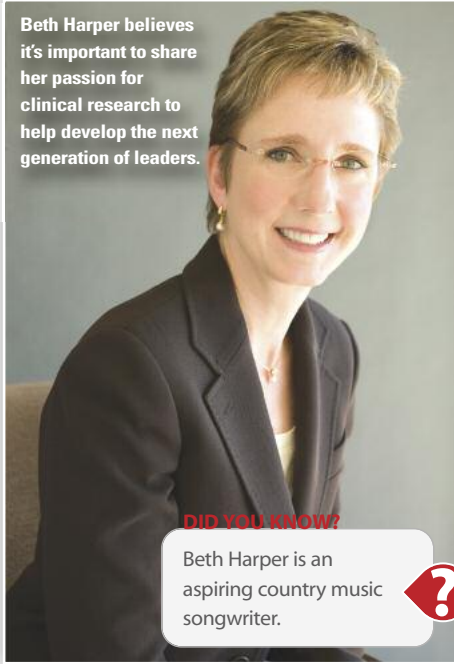
opment outsourcing strategy within the pharmaceutical industry, Dr. Katz has been a change agent for outsourcing strategy, first demonstrated at Eisai, and now at Purdue.

Naturally supportive, Dr. Katz likes to set people up to succeed and help talented people grow. He believes in sharing information, giving up his time to speak at conferences, networking, and contributing to moving best practices forward in the industry through collaboration with others.

Dr. Katz enjoys helping to get people with diverse opinions to reach consensus and collaborate when they might not have otherwise, or have gotten there as quickly. **PV**



Beth Harper believes it's important to share her passion for clinical research to help develop the next generation of leaders.



DID YOU KNOW?

Beth Harper is an aspiring country music songwriter.



Beth D. HARPER

A MODEL OF EXCELLENCE

ners, a consultancy focused exclusively on improving site and enrollment performance and enhancing sponsor-site relationships.

She traveled tirelessly around the globe to meet with clients needing help with various aspects of clinical trials operations.

More recently, she has applied her skills to Centerphase, where she focuses on optimizing protocols and applying years of lessons learned rescuing and rejuvenating studies to help sponsors get it right from the start.

The techniques she has helped to implement are making a measurable difference in enhancing and improving the predictability of study execution. Ms. Harper has exceptional customer relations skills and she is always prepared and insightful.

She is a well-known speaker in the industry and has extensively published in industry magazines. She is a well-known speaker in the industry and has extensively published in industry magazines.

One of her career highlights was being elected president of the Association of Clinical Research Professionals (ACRP).

Believing every day in clinical research is a challenge, she is willing to share her experi-

PERSISTENT. CURIOUS.

NAME: Beth D. Harper

CURRENT POSITION: Chief Clinical Officer, Centerphase Solutions Inc.

DATE AND PLACE OF BIRTH: March 1961, Madison, Wis.

EDUCATION: B.S., Occupation Therapy, University of Wisconsin; MBA, University of Texas

FIRST JOB: Corn de-tasseler

FIRST INDUSTRY-RELATED JOB: Occupational therapist/hand therapist and research coordinator

ALTERNATIVE PROFESSIONS: Cryptographer, linguist, or cultural anthropologist

PROFESSIONAL ASSOCIATIONS: Association of Clinical Research Professionals

CONNECTED VIA: LinkedIn

AWARDS: Alpha Eta Honor Society Inductee, 2007

WORDS TO LIVE BY: Touch passion when it comes your way; it's rare enough as it is; don't walk away when it calls you by name — J. Michael Straczynski

For more than 20 years, Beth Harper has been a model of excellence when it comes to improving clinical trials efficiency. She is completely dedicated to helping clients, particularly sponsors and investigative sites, overcome the intense challenges they face in clinical trials start-up and patient recruitment, and helping to educate them to make meaningful process changes to avoid stumbling blocks in the future.

Before joining Centerphase as chief clinical officer, she started Clinical Performance Part-

ences to help develop the next generation of leaders. She has served as an adjunct faculty at GWU for six years. **PV**



Yolanda P. DAVIS

A QUALIFIED VOICE OF AUTHORITY

Yolanda Davis' extensive clinical knowledge and experience have been instrumental in the growth of many data managers. Her character and motivation have inspired many to learn more and go further in the industry. She will go to great lengths to help others achieve their goals, and she takes a great deal of pride in sharing the joys of working in the clinical research field. Colleagues say they are inspired by her bright demeanor, charisma, and humor. Not only do her own internal teams appreciate her expertise, but she is looked to as a qualified authority by other clinical teams, sponsors, and external vendors. Those with whom she works say Ms. Davis is an incredible human being.

Currently, Ms. Davis is a clinical systems manager at Spaulding Clinical, a Phase I clinical trial facility. Most recently, she was manager, data management, at Comprehensive Neuroscience. **PV**



DID YOU KNOW?

Yolanda Davis walked through a cemetery every day to get to elementary school.



Yolanda Davis inspires others in the clinical field to achieve their goals.

INNOVATIVE. HARD-WORKING.

NAME: Yolanda P. Davis

CURRENT POSITION: Clinical Systems Manager, Spaulding Clinical

DATE AND PLACE OF BIRTH: July 1969; Miami

EDUCATION: B.S., Nutrition, Food and Movement Sciences, Dietetics, Florida State University

FIRST JOB: Cashier, Wendy's

FIRST INDUSTRY-RELATED JOB: Clinical research assistant

ALTERNATIVE PROFESSION: Elementary school teacher

PROFESSIONAL MENTORS: Jeff Veach and Lorraine Weatherspoon

PROFESSIONAL ASSOCIATIONS: South Florida Chapter of Associates of Clinical Research Professionals; Association of Clinical Research Professionals; Drug Information Association

GIVING BACK: Through her church to help the underprivileged community, providing food and clothing and tutoring for students

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: When you are happy at home you are happy at work

Annette **STEMHAGEN**, Dr.PH.

PUBLIC ADVOCATE

Annette Stemhagen, Dr.PH., senior VP, safety, epidemiology, registries and risk management, United BioSource Corp., has more than 30 years of public health epidemiological research experience, with 20 years in safety surveillance of pharmaceutical, biotech, and vaccine products.

Her specific expertise is in the design, implementation, and analysis of epidemiologic studies, registries, large streamlined safety studies, and actual use and observational studies for products in Phase IIIb and postapproval. Further, Dr. Stemhagen has designed and evaluated risk assessment studies, including more than 10 regulatory-mandated long-term safety studies. She has also developed risk intervention programs, risk management evaluation studies, and Risk MAPS/REMS.

Dr. Stemhagen has a can-do attitude and she is very passionate about the importance of the work she does to support clients' needs to provide patients with safe and effective medicines. Her optimistic outlook carries over into

the work she does; she believes solutions can be found for most challenges the industry faces.

Dr. Stemhagen is enthusiastic about epidemiology and furthering patient safety, and while she is a well-known thought leader in the industry, she always has time to help others with their needs.

She pushes herself and others to be their best to achieve their goals, both in their professional and personal lives. Her team is like a family whose members support each other with the same dedication Dr. Stemhagen brings to the field of drug safety.

Dr. Stemhagen leads by example, both with her team and the entire organization, demonstrating that a no-nonsense approach, hard work, and a good sense of humor really can make a difference. She is part of the driving force behind the culture of United BioSource and inspires those around her to be true to themselves and their field of training. **PV**



DID YOU KNOW?

Dr. Annette Stemhagen is a Philadelphia Wings indoor lacrosse fan.



Dr. Annette Stemhagen is one of the leading experts in the field of drug safety, periapproval studies, and risk management.

Alex **LANCKSWEERT**

PATIENT RECRUITMENT PIONEER



Alex Lanckswert's goal is to transform and simplify how GSK plans, develops, analyzes, and reports clinical trials.

DID YOU KNOW?

Alex Lanckswert was once listed as a deserter of the Spanish army. But since he never claimed his Spanish nationality, he was ultimately excused from military service.



Alex Lanckswert is a visionary leader focused on simplifying clinical trial operations at GlaxoSmithKline. He is well-known for his expertise in the performance and benchmarking world of clinical operations and has been frequently asked to speak at conferences on these topics. He was instrumental in driving key initiatives within GSK to improve the predictability and performance of clinical operations, specifically in achieving GSK's enrollment objectives and improving cycle time performance.

In his cur-

rent assignment at GSK as director, simplifying clinical development, he is leading a multimillion dollar change program with the goal of transforming and simplifying how the company plans, develops, analyzes, and reports clinical trials. He says overseeing this program, which has many moving parts, is one of the most challenging of his career.

Mr. Lanckswert says the interdependencies between clinical systems are as critical as the individual systems themselves and delivering fewer, better integrated systems and streamlined processes is not enough; he believes that to be successful, the fabric of the organization has to change, including its norms and the way it works.

Mr. Lanckswert is a hard-driving executive who holds very high standards for himself and others, inspiring others to do their best. He is an entrepreneurial leader who is able to navigate the policies, processes, partnerships, and politics to get difficult projects done.

His innovative use of technology facilitates data-driven decisions in an accessible and visual way and thus has changed the way Glaxo-

DEMANDING. FAIR.

NAME: Alex Lanckswert

CURRENT POSITION: Director, Simplifying Clinical Development, GlaxoSmithKline

DATE AND PLACE OF BIRTH: November 1972; Madrid, Spain

EDUCATION: B.A., Honors, European Business Administration, European Business School

FIRST JOB: Stacking shelves, manning cash register, sorting nails and screws at a home improvement retail store

FIRST INDUSTRY-RELATED JOB: Janssen Kyowa Hako, Tokyo

ALTERNATIVE PROFESSIONS: British army; entrepreneur

PROFESSIONAL MENTORS: Dr. Nicholas Edwards and Fraser Skirrow, Accenture; Dr. John Cavallito, Linda Meyerson, and Dr. Lynn Marks, GlaxoSmithKline

GIVING BACK: Habitat for Humanity; sponsoring an Ethiopian child through Save the Children

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: Great leaders inspire ordinary people to do great things in the face of adversity

SmithKline manages clinical trials. He has also been instrumental in improving his vendors' capabilities and has recently led the company's customer base to join together to create a market-leading industry benchmark. **PV**



Javier REVUELTA PÉREZ, Ph.D.

CLINICAL CHANGE AGENT

OPTIMISTIC. ENTHUSIASTIC.

NAME: Annette Stemhagen, Dr.PH.,

CURRENT POSITION: Senior VP, Safety, Epidemiology, Registries and Risk Management, United BioSource Corp.

PLACE OF BIRTH: Trenton, N.J.

EDUCATION: B.A., Biology, University of Pennsylvania, Masters and Doctoral Degrees in Epidemiology from the University of Pittsburgh Graduate School of Public Health

FIRST JOB: Working in a family catering business

FIRST INDUSTRY-RELATED JOB: Associate director, epidemiology, Ciba-Geigy

ALTERNATIVE PROFESSIONS: Professional chef or FBI agent

PROFESSIONAL MENTORS: Dr. Ronald Altman, New Jersey State Epidemiologist; Dr. Gerald Faich, friend and colleague; Patrick Lindsay, UBC mentor

GIVING BACK: Juvenile Diabetes Research Foundation (JDRF), the Barton Center for Diabetes Education, and Scottish Terrier Rescue

AWARDS: UBC Whatever it Takes! Award, 2005; DIA Board of Directors, DIA Outstanding Service Award; Fellow, International Society for Pharmacoepidemiology

WORDS TO LIVE BY: Do whatever it takes

Javier Revuelta Pérez, Ph.D., Pharm.D., doesn't just talk about change, he drives change by becoming extremely involved in the process to build consensus and enthusiasm from within the industry and among individuals.

Dr. Revuelta Pérez, executive director, clinical development in the internal medicine and women's health group at INC Research, has proven this throughout his career.

Part of his success as a change agent is his ability to quickly assess a situation and become an active participant. For Dr. Revuelta Pérez, who speaks five languages — Spanish, English, German, French, and Danish — and is a voracious learner, this come easy.

For example, in 2009, INC Research acquired the global clinical development unit of MDS Pharma Services, which required a substantial integration effort. He could either embrace change or quit. He chose to take on the challenge and was instrumental in the successful integration process, which included melding different cultures. He cites this integration as one of his biggest career highlights, noting that it was gratifying to find balance within the new entity.

In terms of industry challenges, he says the existing platforms that were designed to address the past challenges are inadequate because the science is advancing faster than existing structures can provide the required

Dr. Javier Revuelta Pérez has been an active leader in the integration of the global clinical development of MDS within INC Research over the past couple of years.



DID YOU KNOW?

Dr. Javier Revuelta Pérez at 11 was the top swimmer in his village — for the category under 13 — and went on to compete in the regional championships.



POSITIVE FOCUSED.

NAME: Javier Revuelta Pérez, Ph.D., Pharm.D.

CURRENT POSITION: Executive Director, Clinical Development, INC Research

DATE AND PLACE OF BIRTH: November 1972, Pamplona, Spain

EDUCATION: Pharm.D., Ph.D., MBA, University of Valencia, IE Business School

FIRST JOB: Bird control technician, Ibiza airport, Spain

FIRST INDUSTRY-RELATED JOB: CRA

ALTERNATIVE PROFESSION: Create a world-class center to reproduce and study endangered amphibian species around the world

PROFESSIONAL MENTOR: Dr. René Lardinois

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: Life brings you all opportunities, just have no hurries and no fears

ethical and regulatory answers. He believes past success is too self-rewarding and is limiting future disruptive success in many companies.

To transmit his experiences and knowledge, Dr. Revuelta Pérez has also taught clinical research and development to graduates who want to specialize in this area at COFM (Pharmaceutical College in Madrid) since 2006. Out of all of his accomplishments and career successes, he is most proud that through all the change he's experienced, he has never compromised his ethics or commitment to excellence. **PV**



Yolanda DAVIS • A DATA MANAGER'S DREAM



Yolanda Davis is a clinical research professional with 14 years of experience in all aspects of clinical operations, clinical monitoring, and data management for comprehensive drug development programs. Ms.

Davis currently serves as a clinical systems manager at Spaulding Clinical, where she is using her extensive experience with the implementation of GCP, ICH, and GCDM procedures and guidelines for Phase I through IV clinical research studies over multiple therapeutic areas. She has demonstrated skills with oral and written communication, project planning, teamwork, and mentoring and development of staff. It's the latter skill set that involves guiding young

clinical professionals to achieve their own goals that gives her a great deal of joy.

Ms. Davis is active in several industry organizations, including the South Florida Chapter of Associates of Clinical Research Professionals (SFACRP); the Association of Clinical Research Professionals (ACRP), and the Drug Information Association, which allows her to keep her finger on the pulse of what's happening in the field of data management.

Her dedication to the field inspires her colleagues and she is considered to be a great motivator. **PV**

Getting Personal with YOLANDA DAVIS

FAMILY: Husband; five children ranging in age from 6 to 16

HOBBIES: Reading, singing in the church choir

READING LIST: Tribal Leadership: Leveraging Natural Groups to Build a Thriving Organization; Created and Called: Discovering our Gifts for Abundant Living

FAVORITE MOVIE: The Color Purple

BUCKET LIST: Learning to sew

INSPIRED BY: Oprah Winfrey

FAVORITE SMARTPHONE APP: FSU sports

MOST UNUSUAL PLACE VISITED: A homeless camp under a Miami freeway

LIFE LESSONS: Be sure to achieve a good work and life balance

UNDER THE CLOAK OF INVISIBILITY: The Oval Office

TIME TRAVEL: Back to the time of Henry VIII and his Tudor Court

Dr. Annette STEMHAGEN • SAFETY EXPERT

Annette Stemhagen, Dr.PH., senior VP, safety, epidemiology, registries and risk management, United BioSource Corp., provides strategic consultative services to pharmaceutical and biotechnology clients in epidemiology, safety surveillance, and risk management. In addition, she assists other UBC groups in developing and implementing creative and innovative study design solutions to meet client needs.



a safety perspective, new products, particularly biotech products, require significant safety monitoring in actual clinical practice. She says methods to do this in a non-interventional way are evolving.

Dr. Stemhagen is active in the International Society for Pharmacoepidemiology and the Drug Information Association. In addition, she was appointed in 2004 as the first industry representative to the FDA Drug

Safety and Risk Management Advisory Committee, which she considers to be a true career highlight.

One of the most challenging and yet fulfilling assignments of her career came before the official designation of RiskMAPs and REMS. She and her team assisted pharmaceutical sponsors in designing and implementing one of the first complex controlled access programs that would protect patient safety and minimize risk so that an important therapy could be marketed. Dr. Stemhagen says there were no exact precedents, and the processes and implementation strategies they developed now serve as models in the marketplace.

She holds adjunct faculty appointments at both the University of Pennsylvania School of

Getting Personal with DR. ANNETTE STEMHAGEN

FAMILY: Husband; daughter

HOBBIES: Photography, cooking

READING LIST: Mysteries, medical and legal thrillers, and espionage

BUCKET LIST: Spend time in Greece

INSPIRED BY: Her daughter and husband

LIFE LESSONS: Blend intuition and scientific insight when designing periapproval programs

TIME TRAVEL: Back to a less frenetic time without BlackBerrys

Medicine Center for Epidemiology and Biostatistics and the Temple University School of Pharmacy. Dr. Stemhagen is a fellow of the International Society for Pharmacoepidemiology.

It is important to Dr. Stemhagen to assist others who in the earlier stages of their careers are dealing with the challenges and opportunities of conducting clinical and observational research for pharmaceutical and biotech products.

She has been a mentor for several masters and doctoral students at the universities where she has faculty appointments. Dr. Stemhagen says these experiences are mutually beneficial, as she learns a great deal from the students' perspective, as well as their more recent classroom experience. **PV**

Dr. Javier REVUELTA PÉREZ

BREAKING DOWN BARRIERS

Over the past two years, Javier Revuelta Pérez, Ph.D., Pharm.D., has managed the clinical operations, EMEA, at INC Research successfully and profitably.

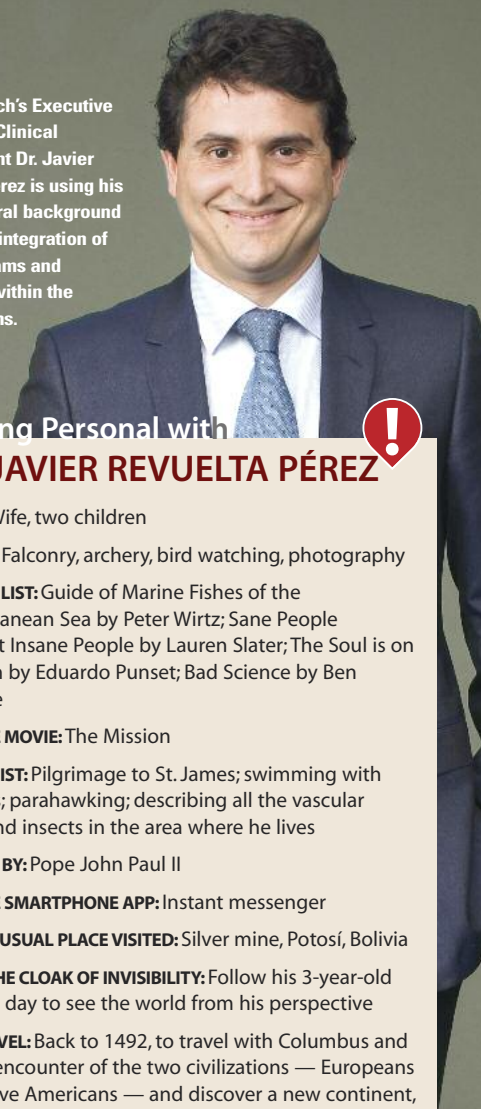
Dr. Revuelta Pérez, executive director, clinical development, used his past integration and restructuring experience to fully understand the tactics involved with integrating the two European clinical operations groups of MDS-GCD and INC during the year after MDS-GCD was acquired by INC in 2009. A key tenet of his success was his ability to get people focused on a single goal and enthusiastic about the positive outcomes of change rather than focusing on the negative.

Another example of driving change comes from Dr. Revuelta Pérez's leadership roles in industry organizations. He currently serves as the President of Asociación Española de Compañías de Investigación Clínica (AECIC), the Spanish CRO association. He has led lobbying activities that not only defend the interests of regional CROs, but also improve the clinical research environment in Spain. This role has also led him to participate on the European CRO Federation (EURCROF) European Legislation Working Group. Dr. Revuelta Pérez influences legislation on a broader basis to create a positive environment for clinical research in Europe.

Dr. Revuelta Pérez has published and presented different articles about research ethics, including several papers on harmonization and implementation of rules and practices across the different European ethics committees. He received positive feedback on his Ph.D. thesis at Valencia University, where he collaborated with other experts in different European countries to examine the compliance in Europe with the good clinical practice (GCP) norms from the International Conference on Harmonization (ICH). According to his colleagues, their work was considered groundbreaking at the time, as it revealed some wide disparities in the conduct of ethics committees. They found it corresponded closely to the different approaches taken by officialdom across the countries that make up the EU. In accordance with his approach, Dr. Revuelta Pérez also offered remedies in this area, which included establishing national systems in each EU member state to ensure effective protection of the population, correct scientific review, and administrative flexibility that would assist the development of clinical investigation in Europe.

More than 10 years later, Dr. Revuelta Pérez is experiencing firsthand this regionalization and globalization that is happening in clinical research and at INC Research. **PV**

INC Research's Executive Director of Clinical Development Dr. Javier Revuelta Pérez is using his broad cultural background to ease the integration of different teams and structures within the organizations.



Getting Personal with DR. JAVIER REVUELTA PÉREZ

FAMILY: Wife, two children

HOBBIES: Falconry, archery, bird watching, photography

READING LIST: Guide of Marine Fishes of the Mediterranean Sea by Peter Wirtz; Sane People Amongst Insane People by Lauren Slater; The Soul is on the Brain by Eduardo Punset; Bad Science by Ben Glodacre

FAVORITE MOVIE: The Mission

BUCKET LIST: Pilgrimage to St. James; swimming with dolphins; parahawking; describing all the vascular plants and insects in the area where he lives

INSPIRED BY: Pope John Paul II

FAVORITE SMARTPHONE APP: Instant messenger

MOST UNUSUAL PLACE VISITED: Silver mine, Potosí, Bolivia

UNDER THE CLOAK OF INVISIBILITY: Follow his 3-year-old son for a day to see the world from his perspective

TIME TRAVEL: Back to 1492, to travel with Columbus and see the encounter of the two civilizations — Europeans and Native Americans — and discover a new continent, new animal species, new plants, etc.

Beth HARPER • DRIVING CLINICAL INNOVATION



Beth Harper continues to drive innovation and change in clinical trials through her tireless efforts as chief clinical officer at Centerphase. Ms. Harper has been prolific in publish-

ing evidenced-based, groundbreaking research on topics such as fair market value, site selection, study feasibility assessment, recruitment planning, and site performance enhancement.

She believes one of the biggest challenges facing the industry is the lack of creative thinking and an unwillingness to challenge convention and the acceptance of a business-as-usual approach to conducting clinical trials.

She contributes back to the industry by participating in a number of programs. She previously served on the board for the Association of Clinical Research Professionals (ACRP) and is currently a member of ACRP's editorial advisory board. In her role as adjunct associate professor at George Washington University she mentors the next generation of clinical leaders.

Ms. Harper is passionate about her work and inspires her students, peers, and everyone in the industry.

She recently reconnected with a research professional from Chile at an international in-

Getting Personal with BETH HARPER

FAMILY: Husband of 26 years

HOBBIES: Mountain biking, hiking, beading, doing puzzles, reading, playing piano

FAVORITE MOVIE: When Harry Met Sally

INSPIRED BY: Her family

MOST UNUSUAL PLACE VISITED: Kota Kinabalu, Borneo

LIFE LESSONS: Nostalgia is a dangerous thing

vestigator's meeting. The colleague remembered Ms. Harper from a study coordinator training course that she had taught in Peru some 10 years earlier. She shared that it was because of this training program that she had pursued her career in clinical research to ultimately become the director of a site in Chile. To know that she had inspired someone to follow their passion was truly a memorable moment. **PV**

Dr. Mitchell **KATZ**

INSTINCTIVELY INNOVATIVE

The start of big pharmaceutical mergers was perhaps the first sign of desperation as companies began to chase pipelines, according to Mitchell Katz, Ph.D., executive director at Purdue Pharma. He believes the industry has to reinvent itself to be more streamlined and to base business on more new drug applications for smaller products, often in more difficult to treat diseases. Moreover, there have to be more compounds in play and the industry has to be better at translational medicine so it isn't afraid to kill products early on.

With his wealth of experience in pharmaceutical and biotech research and development, Dr. Katz has faced his share of industry challenges, and how he has dealt with them has culminated in his many achievements. He recognizes that within the industry there is a constant need to find new ways to be innovative and to look at new ideas differently.

Being involved in six successful new drug applications is a tremendous accomplishment. Dr. Katz's skill in global pharmaceutical clinical drug development and regulatory affairs has led to these career highlights.

He recognizes that working in emerging markets, particularly in challenging economic times, is the greatest challenge facing the industry today. Different standards of care and clinical practice, regulatory hurdles, and managing intellectual property in these environments completely changes how clinical trials are structured. Dr. Katz began his working life in the industry at Schering-Plough in 1984 as a senior scientist, moving on to progressively more senior positions. He joined Purdue as executive director in 2010.

Dr. Katz is setting his sights on establishing creative networks with industry leaders to share approaches in meeting the challenges of drug development and, in doing so, disseminate best practices.

He is charismatic and recognizes the importance of helping others succeed, after experiencing firsthand people taking an interest in him and believing in what he was doing. One of the most gratifying elements of Dr. Katz's career has been developing high-functioning and successful teams, and watching people grow successfully into new roles. **PV**

Getting Personal with **DR. MITCHELL KATZ**



FAMILY: Wife, Mary; four sons; four daughters

READING LIST: Blink: The Power of Thinking without Thinking by Malcolm Gladwell

FAVORITE BOOK: Three Centuries of Microbiology by Hubert Lechevalier and Morris Solotorovsky

FAVORITE MOVIE: The Godfather

BUCKET LIST: Travel with his family cross-country in an RV; resume teaching; purchase a Gibson guitar; take cooking and golf lessons

INSPIRED BY: People who have a passion for what they do and let it show

CONNECTED VIA: LinkedIn

MOST UNUSUAL PLACE VISITED: Duluth, Minn., in the winter for ice fishing

LIFE LESSONS: Never forget where you came from

UNDER THE CLOAK OF INVISIBILITY: To spend an hour of quiet time in the basement of his home where he would enjoy a good glass of wine and a cigar

TIME TRAVEL: Back to Colonial times to witness the signing of the Declaration of Independence

Dr. Mitchell Katz, Executive Director at Purdue Pharma, has set his sights on establishing creative networks with industry leaders to share approaches in meeting the challenges of drug development, and in doing so, disseminate best practices.



Alex LANCKSWEERT

CHANGING THE CLINICAL STATUS QUO



Alex Lancksweert believes in taking the initiative, grabbing empowerment, and challenging the status quo. His philosophy on life parallels his latest role as director, simplifying clinical development, at GlaxoSmithKline.

GSK's acknowledgement of his thought leadership and ability to drive change is evidenced most recently in assigning him the responsibility for streamlining the entire landscape of clinical trial systems and processes within GSK's clinical operations.

Mr. Lancksweert is acknowledged by colleagues, peers, and partners as a clinical operations executive who has a uniquely insightful vision for the way that advanced technologies can be used to improve clinical trials, and speed the delivery of drugs to market. Within the company, he has been successful in spon-

soring innovation projects that are driving step-change improvements in patient enrollment and site selection using advanced Web collaboration and predictive analytics technologies. Outside of the company, colleagues say he has championed the creation of a set of real-time industry benchmarks, leveraging operational data from a consortium of top global sponsors, that enable comparisons of clinical development productivity and cost efficiency.

Those he works with are inspired by his success in implementing these initiatives by working both within the company and externally with a network of partners, suppliers, and vendors.

For Mr. Lancksweert, influencing the design, development, and adoption of solutions that have enabled GSK to improve the reliability of clinical study recruitment plans and site selection decisions is a career highlight. Equally gratifying is building, witnessing, and contributing to the personal successes of the individuals he has hired, managed, and worked closely alongside with.

His current role has also been illuminating on a personal level as well. He says he has often failed to fully grasp the distinction between leading people and managing processes, but in this role he learned to appreciate that success will be less influenced by his

Getting Personal with ALEX LANCKSWEERT



FAMILY: Wife, Nikla Gibson; two daughters: Lorelai, 5, Chloe, 3

HOBBIES: Tennis, soccer

READING LIST: Goodnight Moon; Polar Bear; Strong Fathers, Strong Daughters: 10 Secrets Every Father Should Know by Margaret Meeker; Against All Enemies by Tom Clancy; Switch: How to Change When Change is Hard by Chip and Dan Heath

FAVORITE MOVIE: Gladiator

INSPIRED BY: Everyday people who defy the odds and who relentlessly forge forward in spite of all the obstacles, set-backs, discouragements, and hurdles that life throws at them

FAVORITE SMARTPHONE APP: BBC News

MOST UNUSUAL PLACES VISITED: Ruins of Angkor Wat in Cambodia; villages and cities of Rajasthan, India; the Buddhist shrines in Kyoto, Japan

LIFE LESSONS: It is easier to apologize than it is to ask permission

UNDER THE CLOAK OF INVISIBILITY: The corridors of power

TIME TRAVEL: Forward to find out what awaits his two daughters and to ensure that he and his wife prepare them for the trials, tribulations, and opportunities they will face in the future

individual contributions, than by aligning and motivating talented people around a common cause. Mr. Lancksweert says he has learned valuable lessons around the privilege and responsibility of leading people: getting them focused, creating a sense of urgency, and above all giving them the confidence and the empowerment to take action. **PV**

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Pharma**VOICE**

