Studied EXPERTISE

These distinguished thought leaders are using their clinical expertise to improve study design, patient safety, data outcomes, and overall research in their pursuit to bring innovative and efficacious medicines to those most in need.

CRAIG LIPSET

STANDING UP FOR PATIENTS

PATIENTS HAVE A POWERFUL ADVOCATE IN CRAIG LIPSET.

A recognized speaker and author on innovation in clinical trials and improving patient engagement in research, Mr. Lipset has recently been leading industry efforts around personalized medicine.

An entrepreneurial and innovative individual, Mr. Lipset is skilled at gathering smart people and great ideas together to capture and implement concepts of significant value.

He has been involved in starting two successful companies, Perceptive Informatics and Adnexus Therapeutics, enabling him to make an impact on the lives of patients managing life-affecting diseases. While at Adnexus, he advanced a novel therapy to a cancer research clinic for access by patients who had failed existing treatment options.

Today, as director of molecular medicine, clinical research, and e-health team member, at Pfizer, he continues that drive to improve the patient experience. For example, he serves as the technical architect and strategic lead for innovative clinical models for R&D, including initiatives making clinical trials participatory and patient-centric.

His goal is to raise the profile of the patient as a key stakeholder and voice in clinical research, while gathering knowledge to enable a future of personalized medicine.

Mr. Lipset says patients are increasingly empowered as participants in their health. They have access to their health information through health information technology, are self-tracking their health online and with mobile apps, and are engaging with one another through online resources, such as Health 2.0.

These trends present exciting opportunities to engage with patients in the search for new therapies. By engaging patients as true participants and partners in clinical research, the industry can bring necessary innovation to the clinical development process, Mr. Lipset says. For instance, partnering with patients to share health information — from self-reported data to genetic information — can produce learnings that enable new medicines and create the potential for personalized (or precision) medicine.

Mr. Lipset also gives back to patients and the community through his involvement on the board of directors of the Foundation for Sarcoidosis Research and as a founding member of Society for Participatory Medicine.

In addition, Mr. Lipset is chair, clinical research community, for the DIA and a member of their journal's editorial board. He has been recognized with the DIA's Outstanding Service Award for demonstrating a leadership role in information sharing and industry development. He has chaired numerous other industry consortia, including with PhRMA, and he has served on the editorial board of several relevant industry publications.

He lives and works by the motto, do the right thing, letting this guide and influence his decisions. ✦

Pfizer's Director of Molecular Medicine and member of the eHealth Team Craig Lipset made the decision to dedicate himself to the pharma industry, and that decision is validated every time a family member or friend confronts a life-affecting health issue.

DID YOU KNOW?

Craig Lipset had his genome scanned, which revealed a sensitivity to warfarin and suggested he will live to 100.

Entrepreneurial. Innovative.

NAME: Craig Lipset

CURRENT POSITION: Director of Molecular Medicine (Clinical Research) and eHealth Team Member, Pfizer

EDUCATION: MPH, Columbia University School of Public Health; B.A., Brandeis University

DATE AND PLACE OF BIRTH: July 1970, Brooklyn, N.Y.

FIRST JOB: Scooping ice cream

FIRST INDUSTRY-RELATED JOB: Study Manager for the Northern Manhattan Stroke Study at Columbia-Presbyterian Medical Center, New York

DREAM JOB: Improving the lives of patients (currently pretty close)

PROFESSIONAL MENTORS: Ralph Sacco, Columbia-Presbyterian Medical Center; Mark Goldberg, Parexel; John Edwards, Adnexus Therapeutics; David Lester, Pfizer; Aidan Power, Pfizer

PROFESSIONAL ASSOCIATIONS: DIA, Society for Participatory Medicine, Foundation for Sarcoidosis Research

CONNECTED VIA: LinkedIn, Twitter, and Pfizer's Think Science Now blog

WORDS TO LIVE BY: Do the right thing

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

The Trusted Process®

As a global CRO known for process-driven clinical research, we build trust into every step of your Phase I-IV trial.

Our regional experts blend a global perspective with an understanding of key local nuances to successfully manage your trial. Equipped with the knowledge of language, cultures and regulatory requirements in their location, our teams provide an unsurpassed level of strategic and tactical support in 40 countries worldwide.

Visit **www.incresearch.com/global** to find out how our Trusted Process® consistently delivers actionable results to make more informed and confident decisions on your drug development programs.

Cardiovascular | CNS | Endocrinology | Infectious Diseases | Oncology | Pediatrics | Respiratory | Women's Health

inc Research®

Therapeutic Foresight. Trusted Results.™

SUSAN BORNSTEIN CHANNELED DISCOVERY

IT'S AN INSATIABLE LOVE OF LEARNING IN THE LIFE SCIENCES THAT MAKES SUSAN BORNSTEIN STAND OUT.

Ms. Bornstein has a passion for clinical research and for driving the industry's adoption of a proactive approach to data management.

Whether she is developing a strategic approach to a clinical trial, encouraging her staff members to stretch themselves in new ways, or showing clients how to interact with clinical data to achieve results, Ms. Bornstein is constantly teaching and sharing her expertise.

The consummate clinical data junkie, Ms. Bornstein has been critical to the success of eClinical Solutions, a part of Eliassen Group, a provider of contract and direct-hire staffing solutions to corporations, government, and nonprofit organizations.

In just four short years, as executive VP, Ms. Bornstein has grown eClinical Solutions' team to include more than 200 employees and built a customer base of more than 40 pharma, biotech, and medical-device companies worldwide.

She has championed a truly best-of-breed approach to data management and the creation of an interactive data repository, which stores information from all phases and sources of a clinical trial. Next up, she would like to help more clients leverage their clinical data to positively impact patients' lives.

She maintains that the greatest challenge facing the industry is the increasing cost and complexity of trials due to the reality of unmet medical needs today. She would like to urge the industry to work collaboratively to streamline what it does without sacrificing safety and quality.

Ms. Bornstein laments the conservative nature of the industry, but is pleased there has been progress in data standardization, adoption of e-clinical strategies, and the proactive management of data and safety signal detection.

Ms. Bornstein regularly donates her time to community efforts by participating in Relay for Life. She also supports Eliassen Group's Devote a Day, in which employees are encouraged to take a day off from work to volunteer their time to a cause of their choice.

And she contributes to her town's Junior Jeopardy tournament, which not only satisfies her love of data, factoids, and trivia, but more importantly, raises money for the Friends of Dana-Farber Foundation.

Ms. Bornstein draws her own inspiration from her lifelong heroes: her grandparents. A working woman throughout her life, her grandmother inspired Ms. Bornstein to pursue her dreams of both career and family, while her grandfather ran his own pharmacy. Both held academics in the highest regard and encouraged her to always pursue her passions and share her infectious love of learning with others, philosophies which Ms. Bornstein lives by every day. ✦

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

Overachiever. Fun.

NAME: Susan Bornstein

CURRENT POSITION: Executive VP, eClinical Solutions

EDUCATION: MPH, Epidemiology and Biostatistics, Boston University School of Medicine, 1991; B.A., Biology, Clark University, 1988

DATE AND PLACE OF BIRTH: November 1965, Boston

FIRST JOB: Doing research on pregnancy screening tests at the Center for Human Genetics at Boston University School of Medicine

FIRST INDUSTRY-RELATED JOB: Data manager for a CRO

DREAM JOB: Secret agent

PROFESSIONAL MENTORS: Her grandparents

PROFESSIONAL ASSOCIATIONS: DIA, SCDM, CDISC, eClinical Forum, and MBC

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: Education is key to success — learn something new every day

Susan Bornstein, Executive VP, eClinical Solutions, has been a constant source of inspiration to everyone she has worked with in the life-sciences industry.

DID YOU KNOW?

While at Serono, Susan Bornstein won the CEO Award for globally implementing EDC.

We have a plan for that.

The CHC Group is your trusted partner in strategic communication and publication planning, management, and execution.

Translating medical discovery into clinical practice

www.theCHCgroup.com

CHC GROUP

CPS Complete Publication Solutions, LLC

CHC Complete Healthcare Communications, Inc.

CHC EUROPE

DR. MARLENE LLOPIZ-AVILES

ENERGY WITH A SMILE

CALMNESS AND DYNAMISM MIGHT SEEM LIKE STRANGE BEDFELLOWS, BUT THESE CHARACTERISTICS PERFECTLY DESCRIBE MARLENE LLOPIZ-AVILES, M.D. HER CALM DEMEANOR BECOMES THE AGREEABLE INTERFACE THAT IS THE DOORWAY TO THE ACHIEVEMENT-ORIENTED, NEVER-ENDING STOCK OF FOCUSED ENERGY THAT DR. LLOPIZ-AVILES USES TO DRIVE HER ORGANIZATION'S OBJECTIVES.

Her extraordinary capacity to handle multiple projects and devote the necessary time to oversee that all are moving in the right direction astounds all who work with her. A considered professional, Dr. Llopiz-Aviles researches each project thoroughly before starting it and always reaches the goals she sets for herself.

She keeps up with all the latest research, and is constantly thinking about how to improve health outcomes for everyone.

A social connector, Dr. Llopiz-Aviles spends a great deal of her time networking and speaking on Latin American issues around the world.

She has been influential in encouraging business leaders to expand their activities into Latin America because of its huge growth potential, and she is a tireless cheerleader for the pharmaceutical industry and Latin America.

A guiding light for professionals in the health field, Dr. Llopiz-Aviles willingly shares her knowledge, wisdom, advice, and wide network with partners and clients.

Her reputation as an ethical, open-minded, and disciplined individual is extensive. Colleagues applaud her compassion and her ability to detect when someone may need an extra bit of help. At the same time, they note, she can be tough when it comes to demanding excellence in the workplace.

One of the biggest professional challenges she faced was engaging with a group of people who resisted her coming on board; she had to work upstream to achieve the office's goals in the short term. Within six months, everything was in place and the office was functioning to its fullest capacity.

Dr. Llopiz-Aviles is regional director for Latin America with the international CRO

DID YOU KNOW?

Fluent in Spanish, English, and French, Dr. Marlene Llopiz-Aviles is also studying Italian and Japanese.

DR. BARBARA MARINO

INSIGHTFUL OUTCOMES

THE ABILITY TO UNDERSTAND SPONSORS' CLINICAL TRIAL NEEDS PROVIDES BARBARA MARINO, PH.D., WITH A UNIQUE PERSPECTIVE THAT ENABLES HER TO HELP GUIDE DECISIONS ON NEW PRODUCT OFFERINGS AND DESIGN TOOLS.

Dr. Marino, senior scientist, director of outcomes and study design, at PHT, is pioneering clinical research and measurement authority on the design and implementation of clinical trial protocols using ePRO to collect clinical data. She provides leadership to marketing, product development, sales, and technical services.

Dr. Marino is a groundbreaker and is helping sponsors to adopt PRO and ePRO to improve patient safety and the way clinical trials are conducted.

The cut and thrust of working in a small company environment, which requires an ability to wear many hats and work in all aspects of the business, clearly suits Dr. Marino.

What is most remarkable about Dr. Marino's business and acumen is that until she joined PHT 10 years ago, she had spent her whole career in an academic medical center.

She says the greatest highlight for her has been working with PHT's Founder and Chief Scientific and Quality Officer Steve Raymond, whose genius and passion for the work is inspiring. Mr. Raymond, she says, also supports her to reach as far as she can.

Having spent much of her career as a nurse researcher, which entailed developing plans to measure outcomes of care, Dr. Marino has been on the delivery end of the healthcare system. She says the biggest challenge for the industry is to find a solution that results in affordable and effective healthcare for all Americans.

As Senior Scientist, Director of Outcomes and Study Design, at PHT, Dr. Barbara Marino is a vital bridge between meeting sponsors' needs in clinical research and ePRO technology.

An active and involved member of society, Dr. Marino has contributed to National Public Radio; Bike and Build, for which her daughter participated in a Providence, R.I., to Seattle ride to promote affordable housing; the Dana Farber-Pan Mass Challenge; and the Mount Washington Observatory's Seek the Peak to raise money for the observatory. ✦

Organized. Goal-Directed.

NAME: Barbara Marino, Ph.D.

CURRENT POSITION: Senior Scientist, Director of Outcomes and Study Design, PHT Corp.

EDUCATION: Ph.D., Educational Psychology, University of Washington, 1984; M.N., Maternal-Child Nursing, University of Pittsburgh, 1974; B.S., Nursing, University of Pittsburgh, 1970

FIRST JOB: Staff Nurse at Magee Womens Hospital, Pittsburgh

FIRST INDUSTRY-RELATED JOB: Associate Scientist, PHT

DREAM JOB: Marine biology or a neurologist

PROFESSIONAL MENTORS: Valdo Arnera and Steve Raymond

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: There are always choices

DID YOU KNOW?

Dr. Barbara Marino performed with her daughter in 12 community theater productions for six years until her daughter was 12.

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

Dr. Marlene Llopiz-Aviles, Regional Director for Latin America at Venn Life Sciences, sets an exemplary standard of commitment, leadership, and teamwork.

Venn Life Sciences. She says her appointment as country manager in Mexico for a large CRO some years ago truly helped to define her career. Further aspirations include a position, such as VP for the Americas at a major CRO or as a medical director for an international pharmaceutical company in Mexico.

Her energy overflows from her daily activities at Venn Life Sciences into other societies and associations, where she actively promotes improvements and best practices that affect the entire industry.

Fluent in Spanish, English, and French, Dr. Llopiz-Aviles is also studying Italian and Japanese.

She looks up to those who work ethically and look out for their employees, while always encouraging the staff whose team efforts are necessary for personal and company gain and accomplishments.

But it is her parents who are her greatest inspiration. They left Cuba in 1960 without a dime in their pocket and without a job and started in New York. Both have withstood many trials and tribulations in their lifetime, but they showed Dr. Llopiz-Aviles that nothing is impossible if you set your mind to it. ✦

SEE DIGITAL EDITION FOR BONUS CONTENT
WWW.PHARMAVOICE.COM

Committed. Organized.

NAME: Marlene Llopiz-Aviles, M.D.

CURRENT POSITION: Regional Director for Latin America, Venn Life Sciences Ltd.

EDUCATION: MPH, Harvard, 2003; M.D., Universidad Anahuac Medical School, 1986; B.A., Honors, Biology and Biochemistry and Pre-Medical Studies, Austin College, 1980

DATE AND PLACE OF BIRTH: October 1958, Havana, Cuba

FIRST JOB: National Institute of Public Health, Mexico City

FIRST INDUSTRY-RELATED JOB: Country Manager, Quintiles Transnational, Mexico

DREAM JOB: Architect

PROFESSIONAL ASSOCIATIONS: AMEIFAC's Board of Directors (Association of Medical Professionals in the Pharmaceutical Industry); Global Science, Global Technology, and Society Group; Scientific Organizing Committee for the 7th Latin American Congress in Clinical Research; American Society for Microbiology; American Association for the Advancement of Science; Society of Clinical Trials; American Federation for Medical Research; Infectious Diseases Society of America; International AIDS Society; HIV Medicine Association and American Public Health Association; DIA; and Club Harvard de México

CONNECTED VIA: Facebook and LinkedIn

WORDS TO LIVE BY: Work hard enough to enjoy the pleasures of life and provide more than you ever had for your children — satisfaction guaranteed

MARYANN SZABO

SIGHTS ON SITES

WHATEVER PROJECT MARYANN SZABO TAKES ON SHE DOES SO WITH TIRELESS DEDICATION AND A STRONG WORK ETHIC.

Her understanding of the intricacies involved in managing clinical trials is second to none. She knows exactly what site monitors and regional managers experience on a day-to-day basis and draws on this to inform her decisions, fully understanding the impact they will have in the field and on her team.

She played an integral role in establishing Kforce Clinical Research's flexible resourcing partnership with Roche. She saw a need to improve the monitoring process and pushed hard to initiate the change.

Integrating Kforce and Roche monitors within the initial study was certainly not easy but within the year the project was a success. By the end of the trial, investigators and management could not distinguish between the two companies' monitors.

Maryann Szabo, Head of Site Management and Study Support at Roche, considers nothing more rewarding than being a part of improving a patient's quality of life.

Roche considers this alliance one of its best practices and recognized Ms. Szabo for her hard work with its knowledge-sharing award.

In her new role, Ms. Szabo's responsibilities have expanded from site management to include site development and study support — certainly a full load.

With the Roche/Genentech integration, her regional management group has grown from seven to 14 people and she is now attempting to incorporate territory development into the site development group.

While this will be an exciting challenge for her, those who have worked alongside her don't doubt her ability to tackle it successfully.

Ms. Szabo finds enormous reward in following the clinical trial process from beginning to end, an experience that helped her see the value that successful trial monitoring can bring to patients' lives.

She rates the opportunity to develop a successful drug from first-dose in humans to NDA approval as the highlight of her career so far.

She takes seriously her role in helping to improve the lives of patients, and her goal remains to continue to focus on developing and delivering the best medicines for patients. For colleagues, Ms. Szabo's lasting impression is her dependability and results-driven approach to her work.✦

SEE DIGITAL EDITION FOR BONUS CONTENT
WWW.PHARMAVOICE.COM

Determined. Honest.

NAME: Maryann Szabo

CURRENT POSITION: Head of Site Management and Study Support, Roche

EDUCATION: B.S., St. Josephs College, 1996; Associates Degree, R.N., Passaic County Community College, 1981

DATE AND PLACE OF BIRTH: Feb. 2, 1959, Perth Amboy, N.J.

FIRST JOB: Graduate nurse

FIRST INDUSTRY-RELATED JOB: Study coordinator

DREAM JOB: Astronaut

PROFESSIONAL ASSOCIATIONS: DIA, New Jersey State Nurses Association

CONNECTED VIA: LinkedIn

WORDS TO LIVE BY: You are your only limitation

DID YOU KNOW?

Maryann Szabo played the part of Lieutenant Rooney in a high school play of Arsenic & Old Lace.

DR. SILVIA ZIEHER RAISING THE BAR

A TIRELESS CAMPAIGNER FOR RAISING GOOD CLINICAL RESEARCH STANDARDS WITHIN LATIN AMERICA, SILVIA ZIEHER, M.D., HAS PLAYED A KEY ROLE IN PROMOTING THE CAPABILITIES OF LATIN AMERICA AS THE NEW HUB FOR CLINICAL STUDIES AND A CENTER FOR GCP STANDARDS.

Dr. Silvia Zieher, Senior Director, Clinical Operations Latin America, at INC Research, continuously and tirelessly campaigns to raise good clinical research standards within the Latin American regions.

DID YOU KNOW?

Dr. Silvia Zieher has a small farm where she grows blackberries and houses a few animals.

Integrity. Motivated.

NAME: Silvia Zieher, M.D.

CURRENT POSITION: Senior Director, Clinical Operations Latin America, INC Research

EDUCATION: M.D., University of Buenos Aires, 1986

DATE AND PLACE OF BIRTH: March 1963, Buenos Aires, Argentina

FIRST JOB: University teacher

FIRST INDUSTRY-RELATED JOB: Freelance monitor in a pharma company

DREAM JOB: Author

PROFESSIONAL ASSOCIATIONS: DIA; VP, Argentine Chamber of CROs Association; Professor of Universidad Abierta Interamericana; Argentine Medical Association; Universidad Austral; University of Buenos Aires

CONNECTED VIA: LinkedIn

WORDS TO LIVE BY: Discover and explore new areas, take care of your family, and help others develop themselves

She has achieved this through her roles on government bodies and in industry.

Since the mid-1990s, the growth of the outsourcing industry has opened up several major business and professional development opportunities to pharmaceutical companies, enabling them to reach emerging regions such as Latin America for clinical research, Dr. Zieher says.

Dr. Zieher participated in the GCP expert working group under the PAHO coordination that published the GCP: Document of the Americas, which is one of the foundational guidelines for new regulations in Latin America.

She literally wrote the book — or chapter — on GCP and Clinical Research Standards in Latin America for the Good Clinical Practice: A Question & Answer Reference Guide.

In her recent revisions, she outlines the latest regulatory requirements in Latin America.

In addition, Dr. Zieher was awarded the Clinical Research Professional of the Year in 2009 by GCPj/Scrip.

In various capacities, Dr. Zieher has been helping companies understand the intricacies of Latin American markets.

She has tackled a huge expansion project in the region when she took overall responsibility for research in 2007. This involved establishing a new office in Brazil and expanding operations in five offices and other countries through partner CROs. This required Dr. Zieher to harmonize activities and develop new staff, tasks she rates as her most important assignments to date.

Dr. Zieher has been a standout leader at INC Research since the company acquired the Phase II through IV operations (Global Clinical Development) of MDS Pharma Services in July 2009. She was instrumental during the transition period in ensuring existing trials continued seamlessly, while incorporating the company's trusted process methodology of managing clinical trials. And thanks to her regional expertise she has been hugely successful at expanding INC Research's services and awareness in Latin America.

She has contributed to the implementation and supported the recruitment of professionals to offer various functional outsource services, including site contract and budget negotiation, regulatory document (electronic trial master file) processing, and site payment administration services.

Some recent accomplishments include leading a clinical operations team that was able to deliver significant results for various clinical trials and therapeutical indications. Among these studies was a Type 2 diabetes program for one antidiabetic drug for which 400 patients in Argentina, Peru, Mexico, Chile were enrolled. Another example, was a Phase II study that was successfully completed with 147 osteoporosis women randomized in four months in Argentina. This cohort of patients made up 67% of the study global sample.

She also led a clinical operations team for a study that enrolled a total of 266 pediatric patients in two months for a Phase III vaccine study in Peru.

The results of this study are intended to contribute to the registration dossier of a pediatric vaccine in infants.

In the world beyond clinical research, Dr. Zieher says she is concerned about social inequity and marginality in many societies but mainly in developing countries such as Argentina; threats to global peace in several world areas; and the environmental damage that the world is experiencing with devastating consequences if no quick and effective measures are taken.

But she draws hope from those who fight for survival in challenging and difficult conditions in Latin America and other regions. Their attachment to life and faith is an inspiration. ✦

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

Knipper®

Healthcare Marketing Solutions

What's driving your sampling ROI?

REACH YOUR SAMPLING DESTINATION WITH KNIPPER

Call 1888-KNIPPER or email us at info@knipper.com

www.knipper.com

MARKETING SOLUTIONS

- Consultative Needs Assessment
- Personalization/Mailing List
- Post/Shipping Services
- Direct Mail
- Pick 'n' Pack/Bulk
- Fulfillment Services
- MyPharmaRep.com™

SAMPLING SOLUTIONS

- Traditional Sampling
- Alternative Sampling
- Adherence Programs
- E-Sampling - MySampleCloset.com™

COMPLIANCE SOLUTIONS

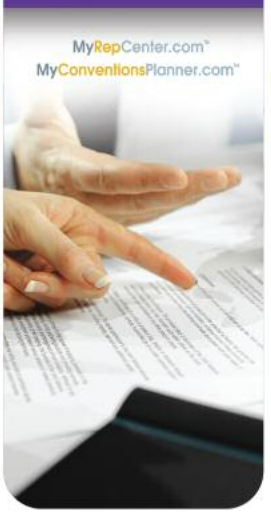
- Recalls/DDL's
- Sample Accountability
- Prescriber Validation
- Regulatory and Compliance Consulting

INFORMATION SOLUTIONS

- Application Development
- Database Management
- Web-based Reporting
- AMA DBL

SALESFORCE SOLUTIONS

- SalesForce Distribution
- Electronic Rep Ordering
- MyRepCenter.com™
- MyConventionsPlanner.com™



www.knipper.com

DR. VIJAI KUMAR

CLINICAL PIONEER

TAKING A RISK AND STEPPING OUT OF HIS COMFORT ZONE PROVED TO BE A CAREER ALTERING DECISION FOR VIJAI KUMAR, M.D.

In 1988, Dr. Kumar left the comfort of corporate America to start a consulting career and founded the first site management organization in India, helping to champion the placement of sites throughout the country for global clinical trials.

His work with regulatory authorities has been integral to making India one of the foremost nations for clinical research today. Specifically he was involved in the process of drafting guidelines for clinical research, which helped establish India as a credible, legal, and effective location for the conduct of global research.

He has helped develop and publish a number of key market research studies analyzing key issues in the Indian clinical research market, including a survey on the informed consent process and patients' experiences with clinical trials, as well as a survey on the motivations of physicians involved with clinical research.

He has helped to effectively promote the concept of conducting high-quality and expedient clinical trials in India to accelerate FDA product approval to the global pharmaceutical industry. In addition, he has trained numerous clinicians, IRB members, and others in good clinical practices. His extensive experience conducting global research has undoubtedly accelerated the advancement of new therapies and led him to become an authority on the drug development industry. In fact, many respected drug development professionals consider Dr. Kumar to be the father of clinical research in India.

Dr. Vijai Kumar, President and Chief Medical Officer, Excel Life Sciences, is an internationally renowned thought leader who has made significant contributions to the clinical trial industry.

One of his greatest achievements in his capacity as president and chief medical officer of Excel Life Sciences (ELS) was when the ELS team enrolled the highest number of patients globally in successive trials for FDA approval.

Dr. Kumar takes a real interest in educating his employees and colleagues in an effort to advance not only the company that he works for, but the clinical research enterprise in general.

Dr. Kumar had been a member of the medical committee of the OPPI (Organization of Pharmaceutical Producers in India) from 1984 to 1988, during which time he presented the industry perspective and concerns to the regulatory agency.

He was invited by the WHO to participate as a faculty member in the clinical monitors workshop in Thailand for the development of drugs used in tropical diseases.

And he has presented numerous papers on clinical research and related issues in Asia, Europe, and the United States. ✦

SEE DIGITAL EDITION FOR BONUS CONTENT
WWW.PHARMAVOICE.COM

DID YOU KNOW?

After taking a sleeping pill, Dr. Vijai Kumar had to be carried to the lounge when an aircraft developed a technical snag.

Friendly. Fair.

NAME: Vijai Kumar, M.D.

CURRENT POSITION: President and Chief Medical Officer, Excel Life Sciences

EDUCATION: M.D., University of Delhi, India; M.B.B.S., Armed Forces Medical College, Pune, India

DATE AND PLACE OF BIRTH: July 20, 1946, Hyderabad, India

FIRST JOB: Research fellow, Department of Defense, India

FIRST INDUSTRY-RELATED JOB: Medical Advisor, Sandoz

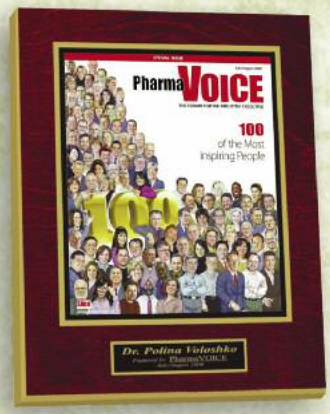
DREAM JOB: Airline pilot

PROFESSIONAL ASSOCIATIONS: ACRP, DIA, APPI

CONNECTED VIA: LinkedIn

WORDS TO LIVE BY: Don't ignore people on your way up because you'll meet them on your way down

A Pat On The Back You Can Hang On The Wall!



Celebrate your achievement and honor of appearing in PharmaVOICE by mounting your feature on a hand-made plaque!

Made Of 3/4" Birchwood
Hand Stained In A Rich Mahogany
Matted In Black And Gold For Emphasis
Gold-trimmed Edges
Engraved Brass Plate
100% Guarantee on Quality and Workmanship

To get your own plaques made, Call Janine Crouch

IN THE NEWS
Where News Never Gets Old.
8517 Sunstate Street, Tampa, FL 33634
P.O. Box 30176, Tampa, FL 33630-3176

1-800-548-3993 ext. 3022
www.inthenewsonline.com

Executing Global Clinical Trial Operations

How to globalize your study for clinical success

September 28 - 29, 2010

Embassy Suites Washington DC - Convention Center

HIGHLIGHTS

STATE OF THE INDUSTRY ADDRESS

Mitchell Katz, PhD
Purdue

SPEED OF RECRUITMENT

Peter Carberry, MD
Astellas

CLINICAL PARTNERS

Raymond Panas, PhD
Sucampo Pharmaceuticals

REGIONAL REGULATIONS

Gene Wright, PharmD, PhD
CombinatoRx

EMERGING MARKETS

Aleksander Skuban, MD
Otsuka America

ETHICS

David Perlman, MD
Penn Center for Bioethics

Special Coverage on:

- ✓ **The Economics** of Global Trials and **SPA**
- ✓ **Regulatory Updates** with invited speaker Ni Khin, MD, Medical Team Leader, **US Food & Drug Administration**
- ✓ **Patient Recruitment: 3-Part Section on** Recruitment Speed, Globalizing your Study, Social Media & Communication & Privacy

Hot Topic Discussions:

- ✓ Managing Global Clinical Studies During an Acquisition
- ✓ Cultural Impact on Study Execution
- ✓ Optimizing Resource Utilization
- ✓ Using Data Mining Techniques to Identify Patient Locations

Featured Panels:

- ✓ How to Investigate and Identify the right KOL and CRO for your trial implementation
- ✓ It's A Team Effort! Best Practices in Executing Global Trials with Sponsors, CROs and Investigators

Round Tables by Region:

Latin America • Eastern Europe • China
Korea • Europe • India • Japan

Executive Sponsor:

Acurian
Predictable Patient Recruitment

Supporting Organization:

Inter-American Foundation for Clinical Research

Media Partner:

PharmaVOICE

Presented by:

THEconferenceFORUM

TO REGISTER, VISIT WWW.THECONFERENCEFORUM.ORG OR CALL 646-350-2580

PharmaVoice subscribers get an additional 10% discount when using key code PVGCT

SUSAN BORNSTEIN •

THE CLINICAL DATA DETECTIVE

Getting Personal with SUSAN BORNSTEIN

FAMILY: Husband and two daughters

READING LIST: The Five Dysfunctions of a Team and The Five Temptations of a CEO by Patrick Lencioni

HOBBIES: Restaurant owner, exercise, soccer and dance mom, and travel

GIVING BACK: Pan-Mass Challenge, Relay for Life, cancer societies

BUCKET LIST: Travel to new places and visit other cultures

INSPIRATION: Grandparents

TOP IPOD DOWNLOADS: Usher, Lady Gaga, Justin Bieber, Taylor Swift, top 40 pop songs, Earth, Wind & Fire, Chicago, and Madonna

MOST UNUSUAL PLACES VISITED: Venice and Athens

LIFE LESSONS: Live life to be the best that you can be and enjoy every day; laugh as many times as you can; be flexible, don't forget the sway; and don't sweat the small stuff

UNDER THE CLOAK OF INVISIBILITY: Watch her kids

If you asked the 7-year-old Susan Bornstein what she wanted to be when she grew up, she would say a spy for the CIA. She was intrigued by the facts and figures, the secrets and code cracking, and the potential to discover something previously unknown along with the accompanying adrenaline rush.

Not long after, she became passionate about pursuing a career in medicine, drawn to the science, the innovation, and the possibility of helping others, and for all the same reasons why being a secret agent appealed to her.

With those forces in play, it's no wonder she would find her true calling as a clinical data detective.

After receiving her MPH from Boston University School of Public Health, Ms. Bornstein stepped into several roles that allowed her to meld her love of fact-finding and medicine. Among these were data analyst at the Center for Human Genetics at Boston University; worldwide senior director of data management at MTRA/AAI Pharma; and program director in the neurology global product development unit, and worldwide director of data management at Serono.

While at EMD Serono, Ms. Bornstein led the company's global implementation of EDC, and she received the CEO award for that achievement, a true career highlight.

In 2006, she joined Eliassen Group to lead the launch of the eClinical Solutions division. In this role, she found she could best satisfy both her inner CIA spy — maybe minus the trench coat, but with magnifying glass in hand — and her love of medicine by providing end-to-end clinical data management, EDC implementations, SAS programming, technical consulting, clinical data repository solution, and training services for the biopharma industry.

Ms. Bornstein's industry contributions include serving on the SCDM board of directors where she collaborated on launching the good clinical data management practices (GCDMPs), which laid the foundation of data management as a discipline. She also served on the electronic clinical forum steering committee. Over the years, she has been active in the e-clinical forum and regularly presents at DIA's annual conference.

Between serving as executive VP and head clinical data detective at eClinical Solutions and aiming for the next belt in her karate class during her free time, Ms. Bornstein has been able to keep her adrenaline up and her CIA spy cravings at bay — for now. ✦

DR. VIJAI KUMAR •

GLOBAL CONNECTOR

India's growing reputation as a hub for clinical research has much to do with the work of one man: Vijai Kumar, M.D.

For more than 30 years, he has contributed significantly to the clinical research enterprise in India and throughout the world.

After moving into the sphere of consulting pharmaceutical physician, Dr. Kumar became instrumental in assisting multinational pharmaceutical companies in developing entry strategies to the Indian clinical research enterprise and in obtaining regulatory approval of new products.

One of Dr. Kumar's greatest strengths is understanding how his organization can continue to improve its service proposition and meet evolving clients needs. He has achieved this through some very challenging assignments.

Among these was setting up a site management organization in Asia in a pharmaceutical industry-sponsored research-naïve region. Dr. Kumar needed to talk to all of the global drug development stakeholders to ensure they appreciated the need to support busy and inexperienced clinicians participating in global drug development while at the same time assuring sponsors of data quality and data integrity.

Today, Dr. Kumar brings his insights to Excel Life Sciences (ELS), a U.S.-based, India-focused, provider of comprehensive clinical trial management services, focusing on site performance, patient enrollment, on-time study completion, and data quality and integrity.

Though focused on improving and expanding the clinical research enterprise in India, Dr. Kumar is also setting his sights on facilitating clinical development programs of non-U.S. companies in the United States. ✦

Getting Personal with DR. VIJAI KUMAR

FAMILY: Wife, Nandini; Son, Abhijit; Daughter, Gitanjali

READING LIST: John Grisham

HOBBIES: Assisting his wife in the garden, meeting with former medical school and work colleagues, reading medical history and travel books

GIVING BACK: American Cancer Society (as a cancer survivor); National Public Radio

BUCKET LIST: Attend the 50th class reunion of his medical school in 2013; ensure Excel Life Sciences is one of the primary service providers in India by 2012; be one of the first service providers to help Indian pharma companies conduct clinical trials in America for FDA approval of a new drug

INSPIRATION: Cancer survivors, disabled individuals

SCREENSAVER: His granddaughter

MOST UNUSUAL PLACE VISITED: Leh, the capital of Ladakh, 14,000 feet in elevation, the Indo Chinese border

LIFE LESSONS: In preparation for each day, he follows his father's advice, having a healthy breakfast and wearing comfortable shoes

UNDER THE CLOAK OF INVISIBILITY: Fly like a bird and observe everything below

CRAIG LIPSET • INVENTING THE COURSE

Change is pervasive in the industry, but for Craig Lipset change should never mean paralysis. As director of molecular medicine, clinical research, at Pfizer, he says one of his major challenges is to motivate colleagues to stay focused on the work and opportunity before them, and avoid being distracted or paralyzed by changes that are often beyond their control.

Among the big issues he sees for the industry are scaling and adjusting to new revenue models for products, such as the impact of personalized medicine, emerging markets, and comparative effectiveness; the need to find new sustainable R&D models that fit these potential revenue streams; and, particularly for larger organizations, how to encourage innovation.

This area — encouraging innovation — is one where Mr. Lipset excels. He was recently one of four winners of Pfizer's Breakthrough R&D Idea Challenge for a proposal to improve the company's support for innovation. He has also recently begun blogging at Pfizer's Think Science Now as a platform for sharing and discussing innovation in clinical research.

On a broader front, the issues of global health and economic instability, while not strictly within the scope of the industry, have a direct impact on pharma, and Mr. Lipset says it is vital that decision-makers find ways to ensure the sustainable delivery of healthcare on a global basis, noting that emerging markets must be more than charities.

During his career, Mr. Lipset has helped to oversee substantial change that has improved patient care and patient involvement in their own health. He's also had his fair share of defining moments in the industry — from two successful start-ups — Perceptive Informatics and Adnexus Therapeutics — to winning the DIA Outstanding Service Award. ✦

Getting Personal with CRAIG LIPSET

FAMILY: Wife, Shani, son, 7;, daughter, 4; golden retriever and cat

HOBBIES: Managing son's T-ball team and playing with the latest gadgets

READING LIST: The Decision Tree by Tom Goetz

GIVING BACK: Board of Directors for the Foundation for Sarcoidosis Research

BUCKET LIST: Owning a red, 1965 Mustang convertible

INSPIRATION: Patients, including the work of Dave DeBronkart (ePatientDave), and Jamie Heywood (PatientsLikeMe)

MOST UNUSUAL PLACE VISITED: Havana, Cuba, and Tasmania

LIFE LESSONS: Do what you love: money will follow

UNDER THE CLOAK OF INVISIBILITY: Stay at home and observe the dog

DR. MARLENE LLOPIZ-AVILES • COMMITTED TO MAKING A DIFFERENCE

From childhood, Marlene Llopiz-Aviles, M.D., knew she would become a medical doctor. Having accomplished this goal, she continued her studies to work on research to find cures for all types of diseases, as well as translate clinical studies in several languages.

Her dedication and hard work is driven not for the prestige or accolades that may accompany such a career, but purely to help others by striving to find solutions to the many health problems that plague her community, as well as humanity in general.

Dr. Llopiz-Aviles has always considered the welfare and well-being of others her primary concern. This quality has permeated every area of her life and medical career.

Dr. Llopiz-Aviles has extensive experience in all areas of clinical research, developing new resources and programs for providing adequate public health strategies for women, children, adolescents, and migrant workers. She has worked in Phase I to IV trials, written trial protocols, and acted as a medical papers translator.

As an alumna from the Harvard School of Public Health, Dr. Llopiz-Aviles has been instrumental in organizing her fellow alumni and engaging them in activities far from Boston. During the second global Harvard alumni meeting that took place in Mexico City in 2004, Dr. Llopiz helped organize a School of Public Health gathering, using her contacts, time, and energy to contribute to the program's success.

In recognition of her professional accomplishments, Dr. Llopiz-Aviles was nominated twice for the most prestigious Harvard School of Public Health award — Alumni Award of Merit — for her contributions to the field of public health. She has also been nominated for the Austin College Leadership Award.

Gaining her master's in public health is a true career highlight for Dr. Llopiz-Aviles, who received her degree at age 43. It was, she says, extremely difficult but nonetheless, very rewarding. It showed her children that anything is possible at any age, though she acknowledges it requires a support system from her family.

Demonstrating her commitment to health, Dr. Llopiz-Aviles actively participates and works closely with leading governmental and private institutions in Mexico for the betterment of country-specific health needs. ✦

Getting Personal with DR. MARLENE LLOPIZ AVILES

FAMILY: Married for 25 years to Hector Ruiz; two children, Alejandra, 21; and Gustavo, 19

READING LIST: Patricia Cornwell, Karen Slaughter, and any novel on pre-Hispanic history

HOBBIES: Reading, fishing

GIVING BACK: Promoting Latin America academically, professionally, and culturally

BUCKET LIST: Return to Cuba, visit Paris again

INSPIRATION: Her parents

TOP IPOD DOWNLOADS: The Beatles, Gloria Estefan, Ricky Martin, instrumental music

SCREENSAVER: A picture of her children with big smiles at a beach resort when they were small

MOST UNUSUAL PLACE VISITED: A secluded stream for trout fishing

LIFE LESSONS: Never think you're too old to accomplish your career goals and achieve your dreams — her father

UNDER THE CLOAK OF INVISIBILITY: Tap the great minds of renowned scientists

DR. BARBARA MARINO • TEAM PLAYER

Getting Personal with DR. BARBARA MARINO

FAMILY: Two daughters, a son-in-law, and a granddaughter

READING LIST: Wolf Hall by Hilary Mantel; National Geographic; Backpacker magazine

HOBBIES: Hiking, backpacking, reading, cooking, theater, cycling

GIVING BACK: NPR, Bike and Build, Dana-Farber Pan-Mass Challenge, Mount Washington Observatory's Seek the Peak

BUCKET LIST: Raise bees; run a hostel for hikers on the Appalachian Trail; live in a home off the grid; win the lottery so her daughters can spend more time with their families and less time working

SCREENSAVER: A photo of spring flowers in Disneyland

MOST UNUSUAL PLACE VISITED: Tanzania

LIFE LESSONS: Live in the moment

UNDER THE CLOAK OF INVISIBILITY: Visit the Oval Office

When Barbara Marino, Ph.D., joined the ePRO provider PHT Corp. 10 years ago, she came directly from a hospital setting, where she worked with clinical and administrative teams to evaluate patient outcomes.

Thus she came to PHT with a deep insight into the needs of healthcare providers using patient outcomes data to inform policy decisions.

Her experience in working with a multi-faceted team has enabled Dr. Marino to interface with PHT's account executives and pharma clients to bridge science and technology as sponsors seek to optimize their investment in ePRO.

In her role as senior scientist, director of outcomes and study design, at PHT, Dr. Marino has been instrumental in developing partnerships and supporting a new consulting service within the company for the purpose of meeting the requirements of the FDA's PRO Draft Guidance.

She has also been instrumental in helping software engineers improve data deliverables for sponsors, develop better designed tools for internal use, and enhance productivity for PHT staff.

In addition, Dr. Marino has been responsible for the preparation and project management of a multi-million dollar grants program through the National Institutes of Health; she has also prepared submissions to and made presentations at functions related to the pharmaceutical industry and FDA regulations.

Dr. Marino joined PHT in 2000 as an associate scientist, from her role as a nurse researcher at Children's Hospital in Boston. She was with Children's Hospital for 16 years, starting as research coordinator and assistant data manager, then as a clinical specialist in infant and family development.

In addition, Dr. Marino was an instructor at the Graduate School for Health Studies, Simmons College. ✦

DR. SILVIA ZIEHER • LATIN INSIGHTS

A recognized expert in Latin American clinical research, Silvia Zieher, M.D., senior director, clinical operations Latin America, at INC Research, has become the go-to person for the region.

Her reputation for maintaining high standards for clinical trials in Latin America led to her being asked to participate in government-sponsored educational programs aimed at investigators.

Dr. Zieher is volunteering her time to give lectures in several educational programs on GCP standards and requirements such as the Intensive Course on Regulations for Clinical Trials 2010 organized by the Oncology Institute, Angel H. Roffo Faculty of Medicine, University of Buenos Aires. This course is free for attendees, mainly oncologists.

Her active involvement in academic and industry organizations is nothing short of astounding. Since 2007, Dr. Zieher has served as the VP of the Argentine Chamber of Contract Research Organizations (CROs) and has become a sought-after spokesperson for promoting clinical research participation. She was re-elected in 2009.

She is a professor at the Magister of Clinical Pharmacology in the Universidad Abierta Interamericana (UAI), Argentina, and she contributes to many academic organizations.

As a representative of the Latin American Federation of Pharmaceutical Industry (FIFARMA) in the Pan-American Health Organization (PAHO) Working Group on Good Clinical Practices for the Pan American Network for Drug Regulatory Harmonization from 2000 to 2004, she participated in meetings involving regulators from the Americas — i.e., FDA, Administracion Nacional de Medicamentos Alimentos y Tecnologia Medica (ANMAT) — and representatives from the national and international pharmaceutical industry in Latin America. The GCP: Document of the Americas is a regulatory guideline that was published as a result of the activities of this GCP Experts Working Group. This GCP guideline is the foundation document for all new regulations in Latin America.

Dr. Zieher served as chairman of the Scientific Program Committee of the 5th Latin American Congress of Clinical Research, DIA and SAMEFA held in Buenos Aires.

She is on the Scientific Committee for this year's Latin American DIA conference in November and is the director for the regulatory tutorials in the region. She is organizing educational sessions designed to instruct the audience how to avoid risk and delays in the drug development process by understanding submission processes for study protocols and the increasingly complex regulatory structure.

And she is participating as chapter chair of the DIA PEACH book initiative for Computerized Systems in Clinical Research: Current Data Quality and Integrity Concepts. ✦

Getting Personal with DR. SILVIA ZIEHER

FAMILY: Husband and two daughters

READING LIST: Mario Vargas Llosa, Carlos Fuentes, Jose Saramago, Julio Cortazar

HOBBIES: Reading, countryside touring

GIVING BACK: Supports charitable home, Province of Buenos Aires

BUCKET LIST: Write a book

INSPIRATION: Underprivileged individuals

TOP IPOD DOWNLOADS: Latin American music

MOST UNUSUAL PLACE VISITED: Kansas City

LIFE LESSONS: Rather than conveying sensitive information by e-mail, build relationships by communicating on a personal level

UNDER THE CLOAK OF INVISIBILITY: Observe Earth from space

MARYANN SZABO • STRAIGHT SHOOTER

When colleagues think of Maryann Szabo, the acronym WYSIWYG comes to mind: what you see is what you get.

Though a straight shooter who calls 'em as she sees them, she is also an extremely supportive and empathetic person. It is evident in her management style how much she values the personal interactions with her team.

People know they can rely on her and that as head of site management and study support at Roche, when she says she'll handle it, she means it.

Her reports know that she will never expect anything more or less of them than what she would expect of herself. In fact, she says the best advice she ever received was just that: never ask anyone to do what you're not willing to do yourself.

Ms. Szabo has always said she belonged in the medical field. Starting as a candy striper, she quickly realized she enjoyed working with nurses and patients. After working in coronary care for several years as a nurse herself, she transitioned into the pharmaceutical industry. At the beginning of her career with Roche, she worked on the Xenical drug trials and monitored all of its trials, from Phase I through Phase III.

She is excited by the opportunities presented by genetic drug development to revolutionize medicine and provide new therapeutic treatment for diseases.

But how patients will access those medicines does concern her. Ms. Szabo says she recently read an article that some 47 million U.S. residents have no health insurance, and the numbers keep growing. Workers continue to struggle to pay higher premiums, deductibles, and co-payments, forcing many to delay getting needed medical care or worse, to decline coverage for themselves or their families because of cost.

Beyond her passion for healthcare, Ms. Szabo is committed to conservation, saying she values the complexity of the natural world, and that everyone needs to pay more attention to preserving it. ✦

Getting Personal with MARYANN SZABO

FAMILY: Dog, Mimi

READING LIST: James Patterson

HOBBIES: Reading and classic movies

GIVING BACK: Donations to cancer charities

BUCKET LIST: Appreciate Egyptian pyramids from a vessel cruising the Nile

INSPIRATION: Her family and friends

TOP IPOD DOWNLOADS: Opera and Reggae

SCREENSAVER: Mimi, her dog

MOST UNUSUAL PLACE VISITED: The Winchester Mystery House, San Jose, Calif.

LIFE LESSONS: Never ask anyone to do what you're not willing to do yourself

4th annual event

world DrugSafety congress EUROPE 2010

Safety assured

14 - 17 September 2010, Millennium Gloucester Hotel, London, United Kingdom

A-list industry experts

Dr Susan Graver
Group Director - Global Pharmacovigilance and Epidemiology
Bristol-Myers Squibb

Prof Philippe Van der Auwera Global Head of Safety Risk Management and EU-QPPV
F-Hoffman La Roche

Dr Beverley Forsythe
Principal Safety Physician R&D, Clinical Development, Patient Safety
AstraZeneca

Dr Larry Johnson
Executive Director, Global Safety Head of Therapeutic Area Safety
Amgen

...plus representatives from the MHRA, Afssaps and other key regulatory agencies

Sponsors: PRA International, ORACLE HEALTH SCIENCES, UBC, 13 drug safety, PHASE•FORWARD

Addressing the key challenges for safety professionals Worldwide

Pre & post conference workshops

14 September 2010
Observational studies in post-approval safety: benefits and challenges

17 September 2010
Designing and implementing an effective risk management system

World Drug Safety Congress Europe 2010

To register or to request a brochure:
Tel: + 44 (0) 207 608 7055

Online:
www.healthnetworkcommunications.com/2010/safety

Quote PV01 as your voucher code

Produced by: healthnetwork COMMUNICATIONS

For more info visit www.healthnetworkcommunications.com/2010/safety