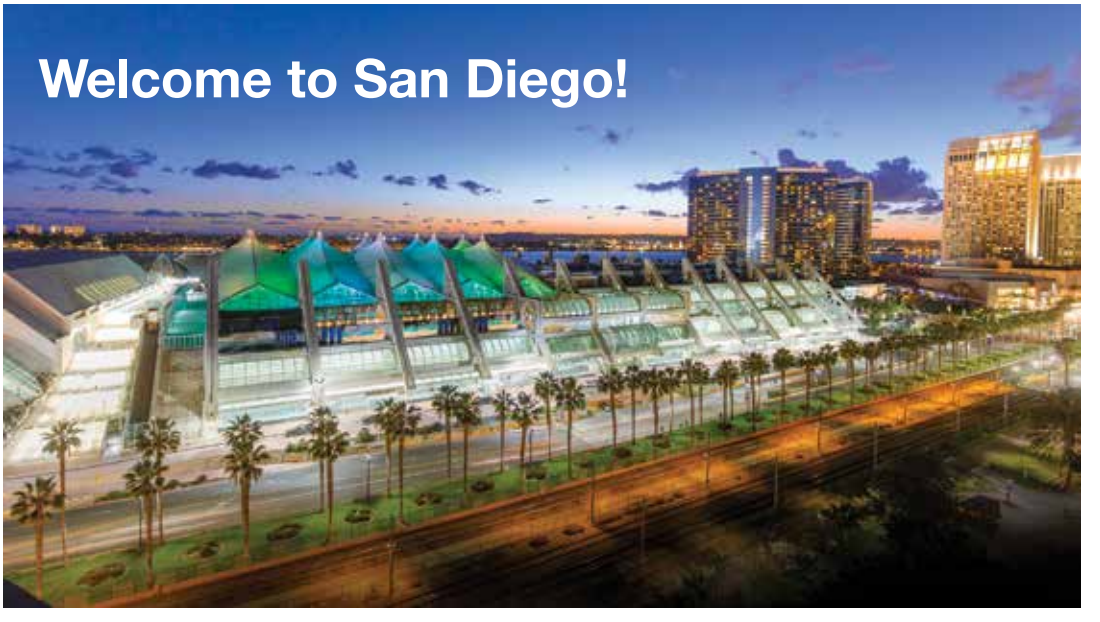
DIA 2019
GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

SHOW DAILY
Issue One
June 23, 2019



Sunday

9:00AM–12:30PM
Half Day Morning Preconference Short Courses*

9:00AM–5:00PM
Full Day Preconference Short Courses*

1:30–5:00PM
Half Day Afternoon Preconference Short Courses*

2:30–5:00PM
Professional Development Sessions

**Space is limited for Preconference Short Courses. Onsite Registration is available, but not guaranteed.*

Up Close and Personal

Get to know your fellow DIA members with Member Spotlights in each Show Daily. Today's issue features:

- **Jonathan Andrus**
- **Stella Blackburn**
- **Linda Bowen**
- **Gerald Dal Pan**
- **Munish Mehra**

Meet your *DIA 2019* Honorary Co-Chairs

Professor Guido Rasi, MD
Executive Director, European Medicines Agency
European Union

Professor Guido Rasi began his second term as Executive Director of the European Medicines Agency (EMA) on November 16, 2015. From November 2014 to mid-November 2015, Professor Rasi served as EMA's Principal Adviser in Charge of Strategy.

From November 2011 to November 2014 he was the Executive Director of EMA and a member of its Management Board in the three years prior.

Joanne Waldstreicher, MD
Chief Medical Officer
Johnson & Johnson

Dr. Joanne Waldstreicher has oversight across Johnson & Johnson pharmaceuticals, devices, and consumer products for safety, epidemiology, clinical and regulatory operations transformation, collaborations on ethical science, and technology and R&D policies, including those related to clinical trial transparency and compassionate access.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To learn how the gold standard of IRB review can transform your clinical research,
visit WIRB-Copernicus IRB Group in **booth #1105 in the exhibit hall**.

Advancing Discovery Science for Public Health Impact

Monday, June 24
8:00-10:00AM
Ballroom 20

Through the keynote speech, *Advancing Discovery Science for Public Health Impact*, Gary H. Gibbons, MD, Director of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), will address the value of implementation science that turns discovery science into improved population health, as well as the innovation of evidence-based initiatives in the treatment of chronic disease, to balance the scales of health equity in all populations.

Dr. Gibbons oversees the third largest institute at the NIH, with an annual budget of approximately $3 billion and a staff of nearly 2,100 federal employees, contractors, and volunteers. NHLBI provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Gary H. Gibbons, MD

Since being named Director of the NHLBI, Dr. Gibbons has enhanced the NHLBI investment in fundamental discovery science, steadily increasing the payline and number of awards for established and early stage investigators. His commitment to nurturing the next generation of scientists is manifest in expanded funding for career development and loan repayment awards as well as initiatives to facilitate the transition to independent research awards.

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, blood, and sleep disorders and enhance the health of all individuals. For decades, the NHLBI has been turning discovery into health and contributing to dramatic improvements in longevity and quality of life for citizens of the United States and abroad. Despite substantial reductions in morbidity and mortality from decades of improvements in prevention and treatment, chronic heart and lung diseases remain amongst the leading causes of death and significant challenges in disease burden and outcomes persist.

Member Spotlight: DIA Inspire Award Winners

Jonathan Andrus, Chief Business Officer, Clinical Ink

As Chief Business Officer, **Jonathan Andrus**, MS, leads Clinical Ink's solution management and compliance teams to help sponsors and CROs better leverage eSource, eCOA and ePRO data. With more than twenty years of experience, Andrus brings extensive expertise developing eClinical services that integrate data and technology to help life science companies optimize study execution. At Clinical Ink, he is responsible for P&L across Clinical Ink's products and services, and he is also focused on building relationships and forging strategic partnerships with sponsors, CROs, regulatory bodies, and clinical research professionals.

Andrus joined Clinical Ink from BioClinica where he led the eClinical Solutions Group to develop their current service offerings, including data management, quality management, implementation services and IWRS. Prior to BioClinica, Andrus worked in pharmaceutical consulting and with CROs focused on quality, data management, and validation. An active thought leader, blogger, and presenter, Andrus served as chair of the Society for Clinical Data Management (SCDM) in 2008 and 2013 and currently serves as the society's Treasurer. He is also an active member of DIA (North American Advisory Council and Annual Conference Data/Data Standards Track Chair) and ASQ. He earned his bachelor's and master's degrees from Temple University's College of Liberal Arts and Graduate School of Pharmacy and is a Certified Quality Auditor (CQA) and Certified Clinical Data Manager (CCDM®).

In your opinion, what is the greatest challenge in your field?

I believe that the greatest challenge in our field today is the use of technologies both at home and in the research site office that generate a great deal of data. Because of this, the profession of data management must transform. This role requires traditional data management practices, but it must also be coupled with practices that ensure data integrity and quality. Because these new types of data are voluminous and, at times, not collected in a well-defined format and structure, it requires data managers to be focused on the sources of data, the method of data transfer, and the technical and procedural controls in place with each of the sources to determine additional measures that may need to be taken to ensure compliance to needed protocol and regulatory requirements.

What do you like most and least about your job?

I love the people that I work with on a day-to-day basis, and I thoroughly enjoy strategizing and working with them on new products and service offerings. The thing that I like the least about my job is my commute! Our office in Pennsylvania is in the Philadelphia, PA suburbs, and I live in Lancaster County, Pennsylvania… I am 85 miles one way from my office. Lots of calls to colleagues, customers, and family occupy my time.

What advice would you give your younger self about to enter the "real world?"

I am fortunate enough to be the father of four children ranging in age from 15 to 22, and this has allowed me to give advice to a "version" of my younger self. My advice to my kids has been about the importance of making connections and being kind and friendly to everyone you have the opportunity to meet in life. Education is important, but connections and work ethic are much more important in the scheme of success in business. I have had the privilege of having hired numerous people over the years, and the trait that I have found to be most important in the success of individuals has been their drive and thirst to expand their skillsets and their motivation to volunteer for projects and jobs that have led to their rapid rise within an organization. The way that you treat others, putting others before yourself, and your willingness to be a servant-oriented leader are among the most important pieces of advice that I would give to my younger self and to others entering the "real world."

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Member Spotlight: DIA Inspire Award Winners

Linda Bowen, Head of Regulatory Policy and Intelligence, Seattle Genetics; Assistant Professor, RAQA Program, Temple University

Linda Bowen, MS, RAC (US, EU, CAN), FRAPS, has more than 35 years of experience in the BioPharma Industry, of which 25 years were spent in regulatory affairs. She is Head of Regulatory Policy and Intelligence at Seattle Genetics and is an Assistant Professor in the Temple University RAQA Program. She was previously Head of US Regulatory Policy & Intelligence at Sanofi and has held regulatory positions at Bayer and GSK.

Bowen is Chair of the DIA Regulatory Affairs Community and founder of the DIA Regulatory Intelligence Working Group. She was previously honored with the DIA's 2012 Excellence in Volunteer Leadership Award. She is a past two-term member of the RAPS Board of Directors, Chair of the NJ/NY RAPS Chapter, and a RAPS Fellow. Bowen is Program Chair for the 2019 RAPS Annual Convergence.

When did you realize you wanted to work as a regulatory professional?

I became interested in regulatory affairs while working in Quality Assurance. I ate lunch with the regulatory group and they attempted to explain what they did, and back then (in 1992) most regulatory affairs professionals were generalists, so what they did was...everything! I decided to attend evening classes

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Member Spotlight: DIA Volunteers

Stella Blackburn, Global Head of Early Access & Risk Management, Real World Insights, IQVIA

Stella Blackburn, MB BS, MA, MSc, is the Global Head of Early Access & Risk Management, Real World Insights, at IQVIA. Stella qualified in medicine from Cambridge University and Guy's Hospital and has an MSc in Epidemiology. Following a spell in hospital medicine, she has worked in PhV and Pharmacoepidemiology for over 30 years: in industry, at the European Medicines Agency and latterly at Iqvia. She developed the EMA's policy on risk management and was lead author of GVP V. She was involved in GVP VIII and was part of the core group implementing the "new" PhV legislation. Blackburn is an FRCP Edin, FISPE and FFPM, an Honorary Associate Professor at the London School of Hygiene and Tropical Medicine, and Visiting Scientist at MIT.

When did you realize you wanted to work in pharmacovigilance and pharmacoepidemiology?

It was purely by chance. I went to do occupational health at a pharmaceutical company and a separate part of the job was PhV for their products. I became fascinated by the subject and realized that I wanted to work in the field. One becomes a detective with the aim of working out what caused the adverse event. Was it a drug, the disease, something innate in the patient or just bad luck? Thirty years on and it is still fascinating.

In your opinion, what is the greatest challenge in your field?

People are chasing ever smaller risks without considering their importance to public health. Huge resources are spent on complying with the numerous regulations and not on looking at the safety profile. People are in danger of losing sight of why we do PhV—to protect patients and enable drugs to be used safely and effectively.

We should also be targeting benefits; risk is only half of the equation, identifying predictors of efficacy could be a game changer.

Where do you see your field going? What is your vision of the field in 2030?

I fear a totally automated system with computers talking only to each other as they receive, parse, and transmit data to each other. Data mining will raise signals, instant use of big data and automated systems will investigate, and label change will happen if required. No thought or intellect will be involved, and society and patients will be poorer.

What have you become better at saying "no" to? (Distractions, invitations, requests, etc.) What approaches or realizations helped you?

The realization that whatever I do now and however important or urgent it may seem at the time, it actually isn't. I am not resuscitating patients where life and death depends on speed and knowledge. Few things we do need instant answers, and in five years' time no-one will remember what the big issue was—or me.

Who would you have over for a dinner party, and what would you talk to them about?

I think a dinner party with Saki, Oscar Wilde, John Snow, Win Castle, and Leonore Davies would be interesting. Saki and Oscar Wilde are two of the most amusing writers I have come across, and so any conversation would be lively and entertaining. John Snow was fascinating in that he was the first to use epidemiological methods to investigate cholera outbreaks. He is known as the "father of epidemiology." He also anaesthetized Queen Victoria when she was giving birth to her last two children and wrote a paper on vitamin D deficiency—an amazing achievement for the son of a labourer. Win Castle was my mentor when I first started PhV and is one of the unsung greats in the field. Leonore Davies was my old headmistress. She came to the UK alone, aged 14, not speaking any English, on one of the last kindertransports from Vienna, and she was fascinating about life in Vienna and her subsequent career in the UK. And of course I would love to have my parents there. They had the most amazing dinner parties when I was a child and taught me to question everything and everyone!

How has DIA helped you?

DIA provided me with the opportunity to meet lots of interesting people with different backgrounds and knowledge. Parallel tracks at the annual meeting permit forays into unknown areas and new interests to be found. Bouncing ideas off

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Exhibitor List

DIA Show Daily advertisers listed in bold.

Company ..... Booth Number

Exhibit Hall Hours

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10AM – 6PM
Tuesday, June 25
9AM – 5PM
Wednesday, June 26
9AM – 4PM

– C

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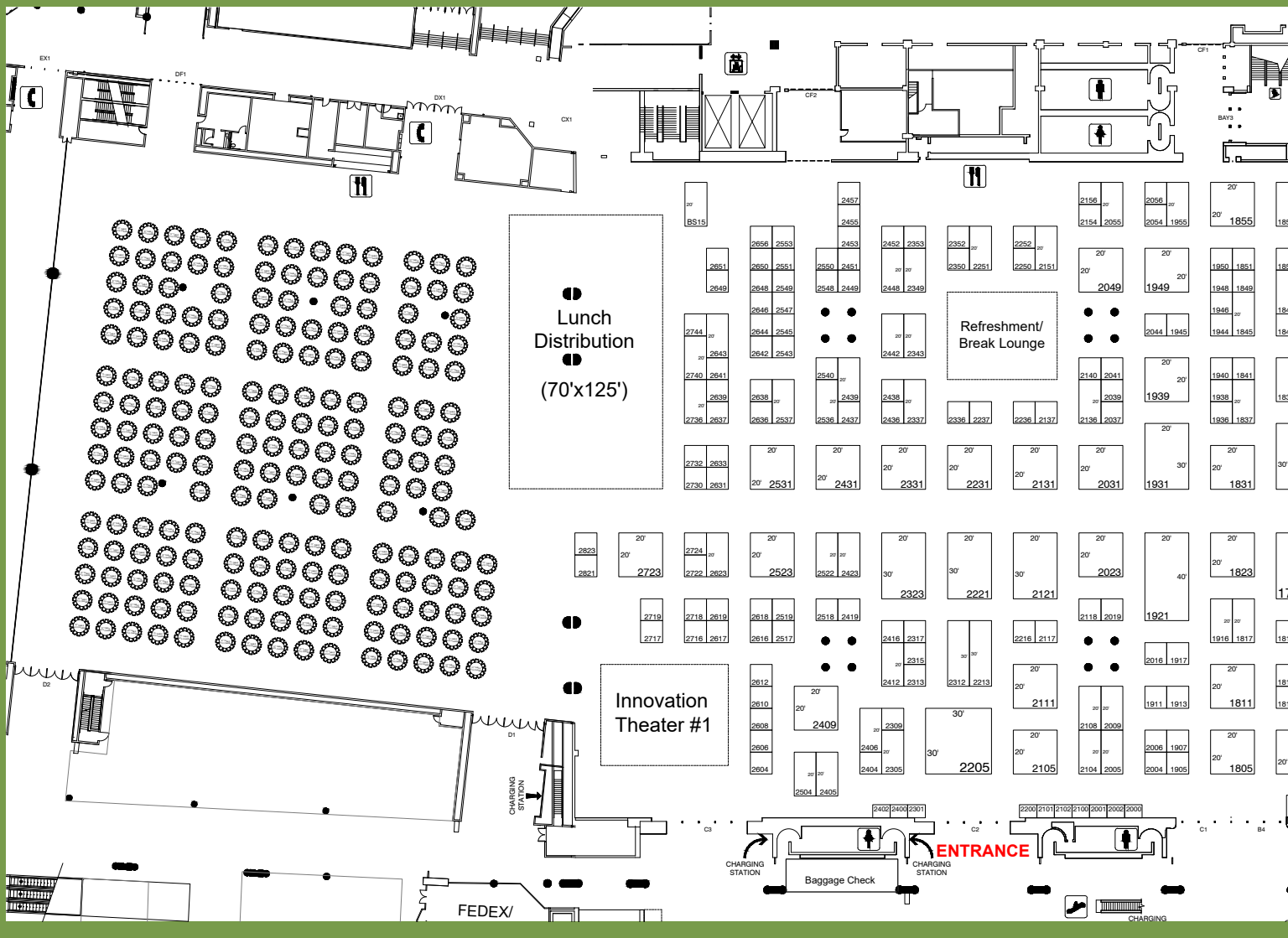

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Woodley Equipment Company 2131
WorldCare Clinical 524
WuXi AppTec 1416
XClinical Services America Inc. 1955
Yourway 517
YPrime Inc. 1851
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ZS 1300

– As of 6/17/19

Member Spotlight: DIA Fellows

Gerald Dal Pan, Director of the Office of Surveillance & Epidemiology, FDA Center for Drug Evaluation and Research

Gerald J. Dal Pan, MD, MHS, is Director of the Office of Surveillance & Epidemiology in FDA's Center for Drug Evaluation and Research, where he oversees adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. A member of the WHO Advisory Committee on the Safety of Medicinal Products, he served on the Council of International Organization of Medical Sciences and the International Council on Harmonisation. He received his MD from Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology from the Johns Hopkins University School of Hygiene and Public Health. Before joining FDA, he was a faculty member in Neurology at Johns Hopkins.

When did you realize you wanted to be an epidemiologist?

I first became interested in epidemiology during the first semester of medical school, in the Fall of 1982, when one of our professors spoke about his work in eradicating measles. I soon realized that epidemiology is a field that would allow me to combine my interest in medicine with broader public health issues using quantitative methods—a perfect combination for me.

Where do you see your field going? What is your vision of the field in 2030?

Informatics and the explosion of "big data" are transforming epidemiology, including pharmacoepidemiology. The challenge for the field is to learn how to use these data wisely by keeping in mind the fundamental principles of epidemiology.

What book are you currently reading and why?

I am re-reading Stephen Hawking's *A Brief History of Time*. In his explanations of relativity and quantum theory, Hawking brilliantly describes both the very small (sub-atomic particles) and the very large (the expanding universe). I find that re-reading a good book provides me with many more insights than the initial read.

What advice would you give your younger self about to enter the "real world?"

I would tell my younger self to think "out of the box" more.

How has DIA helped you?

DIA has provided me with opportunities to participate in important discussions about drug development with a broad group of stakeholders. Given the complexity of drug development and the many perspectives that various stakeholders bring to it, DIA's neutral forum has given me a 360-degree view of the drug development landscape.

Blackburn

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other professionals in the same field can produce results more quickly and link pieces of information.

It also allows me to give something back to the field I love. I hope that the odd bits of knowledge I have gained over the years can help the next generation in the same way various people helped me in the past.

Andrus

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Imagine a day without work, the internet, and any other obligations. What would you do?

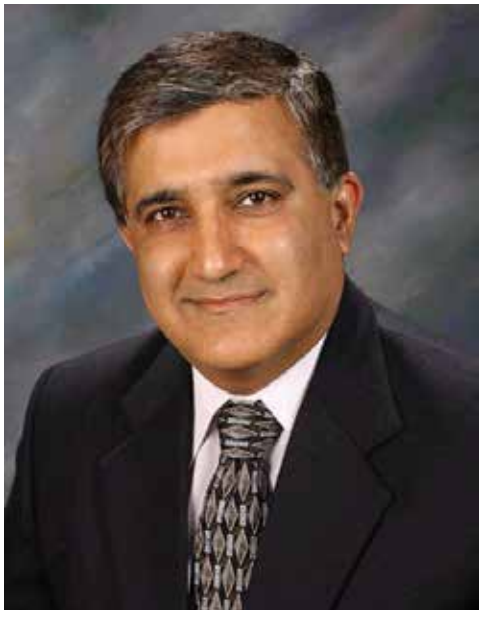
Without a doubt, I would spend the day with my wife at a Philadelphia Phillies or Eagles game (she is the diehard fan), followed by a nice a dinner and time out together. There is nothing better than being married to your best friend.

How has DIA helped you?

DIA has provided me with opportunities to expand my knowledge and experiences. The connections gained and friendships made have been incredibly valuable as well. The staff at DIA are wonderful, and I have been fortunate enough to have gotten to know them well, and I have had opportunity to present and share at DIA conferences, webinars, and workshops, and to participate on the DIA Advisory Committee.

Member Spotlight: DIA Community Chairs

Munish Mehra, Principal Biostatistician and Executive Director, Tigermed



Munish Mehra, PhD, MS, serves as Principal Biostatistician and Executive Director at Tigermed. During a career spanning over 30 years, he gained extensive experience in the design, analysis and reporting of phase 1 through 4 clinical trials across multiple therapeutic areas, including drugs or biologics for neurology, oncology, dermatology, cardiovascular, metabolic and endocrine, respiratory, GI, vaccines, women's health. Mehra has held positions of increasing responsibility at multiple CROs in the US, has founded a SMO and CRO in India, and expanded CRO operations for a US CRO in China. He has developed IDMC charters and supported IDMC's as unblinded biostatistician. He currently serves on several DMCs.

Mehra was awarded the DIA Global Inspire Excellence in Service Award at the *DIA 2018 Annual Meeting*. He currently heads up the DIA clinical research community and is actively involved on the biostatistics and GCP core committees. He has also authored numerous publications in peer reviewed journals and presented at numerous conferences.

Mehra holds a PhD in biostatistics, a MS in computer science from the University of Kentucky, as well as a MS in mathematics from the Indian Institute of Technology.

When did you realize you wanted to become a biostatistician and computer scientist?

Growing up in the 70s and 80s, I was fascinated by electronics and the ability to program computers. I had never heard of clinical research, let alone biostatistics. After studying science in high school, I pursued a five year undergraduate/graduate program at the Indian Institute of Technology with courses in engineering and a focus on statistics. This earned me an assistantship to the US to jointly do a PhD in statistics and a MS in computer science. In 1986, two years into the program, I was asked to program in SAS to analyze clinical data. As the saying goes...the rest is history.

In your opinion, what is the greatest challenge in your field?

The greatest challenge for biostatisticians involved in clinical research is to be able to take complex concepts such as statistical methods and explain them in simple, non-technical terms in order for people to understand the results from their perspective. With the explosion of the amount of data, there are more complex statistical models and computer algorithms, such as neural networks, for machine learning being applied. Understanding how these work, validating them, and explaining them to colleagues in simple terms is the greatest challenge for data scientists.

Where do you see your field going? What is your vision of the field in 2030?

I see biostatistics moving towards greater use of visualizing data. With the continuing increase in the number of statistical tables, figures, and listings the time and cost to generate, review, and interpret these has become prohibitive. Visualizing data using standardized static and dynamic displays that present data efficiently will allow companies developing medical products and regulators to evaluate these compounds together. The current process is sequential and inefficient. My vision for 2030 is for sponsors and regulators to review efficacy and safety of medical products collaboratively in real time using agreed-to displays.

What book are you currently reading and why?

21 Lessons for the 21st Century by Yuval Noah Harari, after reading *Sapiens* and *Home Deus* by him. I highly recommend all of his books, but if you are short on time just read *21 Lessons*.

What advice would you give your younger self about to enter the "real world?"

Take time to understand yourself by listening to what others, who are honest with you, tell you. Take self-assessments like the Myers-Brigs, DISC etc. Know your strengths and limitations. Focus on capitalizing on your strengths. Understand what excites you every day, what energiz-

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Exhibitor News

Exhibitor News features press releases submitted by exhibitors at the *DIA Global Annual Meeting* that advertise in the *publication*.

Cardiac Safety: The Promise of Artificial Intelligence (AI)

With recent advances in technology, computer science and informatics, new techniques in medicine became available, and existing tools and measurements were drastically enhanced.

Specifically, in the field of cardiac safety, we saw a change in technology and standard practice. The historical 10 seconds 12-lead ECG has served as the standard for the assessment of drug induced ECG effects, but it showed important limitations.

With the introduction of new technologies (biosensors, connected devices, implantable devices…), tools allow one to look at longer periods of monitoring and allow collecting more data that need to be processed. This will lead to analyzing the ECG recordings as a whole (time changes, beat morphologies changes, extraction of abnormal pattern) rather than just assessing a single isolated beat.

Technological enhancements allowed the refinement of tools to the newer ECG monitoring tools, of which we are already in the third-generation. Though artificial intelligence and deep learning are already established in other medical areas like radiology, they entered the field of clinical medicine only recently and carefully. This new technology will augment human intelligence to improve decision-making, resulting in optimal operational processes.

The alliance of technologies and science will for sure reshape the drug development process, and the use of continuous reading algorithms presents many benefits: improvement of cardiac biomarkers determination, reduction of variability… and will allow a reduction of the number of patients to be enrolled and, as a result, reduction of the cost of the research.

Banook Group is actively engage in the innovation pathway by working together with scientists and clinical researchers on new tools for classification, clustering and analysis of ECG data, with the goal of classifying with more accuracy continuous ECG recording. Stop at booth 2104 to share expertise with our team.

TransPerfect Life Sciences Takes Center Stage with a Theatrical Stakeholder Collaboration Workshop

TransPerfect Life Sciences returns with a workshop entitled "Setting the Stage for Effective Stakeholder Collaboration," as well as live demos of the award-winning Trial Interactive e-clinical platform, and insightful subject-matter expert booth talks.

The workshop, held on June 26 at 4:15 PM, will be led by Christine Morris, Executive Director of TransPerfect Life Sciences. Morris is taking a novel and artistic approach to the session—talent from North Carolina's Cary Playwrights' Forum will assist with stage adaptations of real-world clinical research scenarios, guiding attendees through empathy-mapping exercises and providing practical tools for stakeholder collaboration.

In addition, TransPerfect will preview new Trial Interactive e-clinical platform innovations. Join Head of Product Development, Jay Smith, at Booth 1838 on June 24 at 1:30 PM for "Mobile, Machine Learning, and More: Simplifying Clinical Processes." The Trial Interactive innovation team will be there to demo solutions that enable inspection readiness while reducing administrative costs and speeding timelines.

TransPerfect President and CEO Phil Shawe stated, "Centralizing the full clinical document lifecycle and maintaining inspection readiness are priorities for us. Our focus is on maximizing collaboration and simplifying workflows for study teams and utilizing best-practice technology to help improve and streamline trials."

New Innovation:

Trial Interactive 10.0 – Preview the latest platform release!

myTI –Experience mobile CRA reconciliation and enter for a chance to win a TMF Inspection-Readiness Workshop or a $100 American Express gift card.

TI GlobalLearn – Learn how study teams are adopting a compliance-focused learning management solution to deliver training on protocol, regulatory, and SOP compliance for risk reduction and operational excellence.

Clinical Document Collaboration – Study teams are rapidly adopting Trial Interactive's clinical content management solution to streamline document processes that flow directly to the eTMF and LMS.

Contact info@trialinteractive.com for more information.

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For more information, please visit http://www.axiommetrics.com/.

Bowen

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for my Master's Degree in Drug Regulatory Affairs, and the company I worked for at the time, Block Drug Company, gave me an opportunity to move to the International RA department while still in school. That was 26 years ago. My first submission was a NCE for the Australian market, so I had a lot of learning to do in a short period of time.

In your opinion, what is the greatest challenge in your field?

With the incorporation of automation into day-to-day regulatory processes, how can we prepare regulatory professionals to become strategic and critical thinkers with less of a focus on the operational side? Are we preparing RA professionals with the right skills?

What do you like most and least about your job?

What I love about my job is that I am challenged in new and different ways on a daily basis. What I dislike most about my position is that it is very hard for me to disconnect from the regulatory world. I am an information junkie. I am always afraid that I'll miss some important piece of information that will affect the company. Of course I know that won't happen, and as I get older I am learning how to take time for myself and my family on weekends, holidays, and vacation.

What is the first book you remember reading?

I was fascinated in grade school by the Encyclopedia Brown series of books. The first one I recall reading was, *Encyclopedia Brown Gets His Man*. The lead character in those books was Leroy "Encyclopedia" Brown, a child detective who solved neighborhood mysteries. Ironic that I would end up working in Regulatory Intelligence where we put our detective skills to work every day!

What advice would you give your younger self about to enter the "real world?"

To take advantage of every learning opportunity that presents itself. Repurposed skills from my days in Quality Assurance have presented themselves multiple times in my regulatory affairs career. And never be afraid to ask questions.

Imagine a day without work, the internet, and any other obligations. What would you do?

Visit close friends and relatives. As we get older, they are the constant in our lives.

Who would you have over for a dinner party, and what would you talk to them about?

My parents. I lost both of them to cancer, and there are so many things I would like to have discussed with them before they passed.

How has DIA helped you?

Specialty communities, such as the one I chair (Regulatory Affairs) are important to the membership of DIA. It helps build acumen, your network, and in my case, leadership skills. The communities provide an open forum to share best practices and discuss non-proprietary ideas and processes that support activities for emerging issues. With many members facing limited resources to travel or attend conferences, active participation in our community, and communities in general, is a great way to stay current with no additional costs–making the most of your DIA membership and network.

Mehra

Continued from page 12

es you, what do you like to do first over and above anything else every day when you get to work. Once you find something that you are really good at and you really enjoy doing, make that your career. Keep learning something new every day, even if it's reading for 15 minutes.

How has DIA helped you?

After becoming a DIA member early in my career, I chose to attend DIA conferences initially in the US, then in Europe, China, and India. I eventually chaired and organized conferences and webinars. This allowed me to meet a diverse group of people and become aware of opportunities I did not know existed. Recognizing the benefits of being a DIA member, I became actively involved with DIA's communities, realizing that even a small time commitment every month helped me build lifelong relationship with peers and mentors and increased my knowledge and skills. I often say the single best return on investment for my career has been my DIA membership.

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Exhibitor News

Exhibitor News features press releases submitted by exhibitors at the *DIA Global Annual Meeting* that advertise in the *publication*.

WCG Announces the Acquisition of Analgesic Solutions

WIRB-Copernicus Group®'s (WCG™) Clinical Services Division announces the acquisition of Analgesic Solutions, the global leader in the development of new pain medications and in the support of clinical trials in which pain is an indicator of an underlying condition. Analgesic Solutions joins the extensive family of WCG clinical services which facilitate and optimize the conduct of clinical trials. WCG's newest addition focuses on increasing assay sensitivity in clinical trials through consulting, innovative tools, data science, technology and specialized training.

"We are delighted to welcome Dr. Nathaniel Katz, the Founder and Chief Scientist of Analgesic Solutions, and his extraordinary team of clinicians and scientists to WCG," said Donald A. Deieso, PhD, Executive Chairman and CEO of WCG. "The intense public focus on developing alternatives to opioids for use in pain management, as well the organization's deep understanding of patients' subjective responses to pain, has made Analgesic Solutions one of the most sought-after solution providers in clinical research."

Laying the foundation for successful clinical research trials, Analgesic Solutions advises research sponsors on protocol design and development, regulatory and FDA submissions, and signal to noise optimization. Combining deep subject matter expertise with unmatched experience in data quality risk assessment, measurement error reduction, and data surveillance, Analgesic Solutions provides knowledge-based solutions that inform the conduct of clinical trials in which the measurement of pain is an endpoint or significant component. Since pain is a subjective experience, Analgesic Solutions teaches patients how to better describe their pain and clinicians how to better evaluate their descriptions. The company also provides central statistical monitoring and interventions to ensure that data produced and collected during trials are reliable and accurate with the goal of proactively protecting study outcomes.

To learn more about WCG Analgesic Solutions, please visit us in the Exhibit Hall at booth #1005.

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