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# Wednesday

**7:00AM-12:30PM**

Attendee, Speaker, and Exhibitor Registration

**9:00AM-4:00PM**

Exhibit Hall Open  
Professional Poster Presentations

**8:00-9:15AM**

**10:30-11:30AM**

**2:00-3:15PM**

**4:15-5:30PM**

Educational Tracks

## Up Close and Personal

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

- Terry Katz
- Michelle Rovner
- Casey Walker
- Lisa Mulcahy
- Alberto Grignolo
- Ling Su



# DIA 2019

GLOBAL ANNUAL MEETING  
SAN DIEGO | JUNE 23-27

# SHOW DAILY

Issue Four  
June 26, 2019



At the Awards Ceremony on Monday night, DIA welcomed our Fellows of DIA Class of 2019: Fellow Chair of DIA John A. Roberts, President and CEO, Cancer Genetics, Inc.; Fellow of DIA Birka Lehmann, Senior Expert Drug Regulatory Affairs, Germany; Fellow of DIA Gerald Dal Pan, Director, Office of Surveillance and Epidemiology, CDER; and Fellow of DIA Tatsuya Kondo, Chief Executive Emeritus, Pharmaceuticals and Medical Devices Agency, Japan.

DIA Americas Vice President and Managing Director Sudip Parikh addresses the Community Luncheon, which also hosted the Student Poster Awards.



Second place winner Millicent Yeboah-Awudzi and third place winner Panini Patankar with Nancy Pire-Smerkanich at the DIA 2019 Student Poster Awards. (First place winner Ismaeel Yunusa was unable to attend the ceremony.)



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## Member Spotlight: DIA Community Chairs

### Terry Katz, Director, Head of Global Data Management and Statistics at Merck Animal Health

**Terry Katz** is Head of Data Management and Statistics at Merck Animal Health. Previously he was Head of Biometrics at ImClone Systems, Senior Manager of Analysis & Reporting for PRA, and a Statistician at Schering-Plough. He holds Accreditation as a Professional Statistician, and Certifications as a Quality Engineer and in Six Sigma. He is Chair of DIA's GCP-QA Community, on the Core Committee for NJ CDISC User Group, and former Chair of Statistical Taskforce for the Animal Health Institute. Terry recently completed a three-month fellowship in Kenya to improve capacity to run oncology clinical trials.



#### When did you realize you wanted to be a statistician working in healthcare?

Healthcare as a focus started in High School when I was working at a pharmacy and radiology office. While earning a degree in Microbiology, I gained independent laboratory research experience in molecular biology, sequencing plasmids. My first taste of how to plan a designed experiment occurred while working in nephrology research and sparked an interest in exploring the statistical field. Graduate school provided the foundation in statistics, and leveraging my dual science and statistical backgrounds to design experiments for pharmaceutical development became my passion and career.

#### What do you like most and least about your job?

My current role is in veterinary medicine, which provides opportunity to work with all non-human species, therapeutics and vaccines in a wide variety of applications, from anti-infectives to autoimmune diseases to animal husbandry. Many of the experimental designs parallel those used when I worked in human medicine (oncology, cardiovascular, GI, and dermatitis). Some of the veterinary designs require more sophistication than human trials to accommodate clusters of animals in pens, location blocks within a site, and geographic regions to broadly test our products against various species of indigenous bacteria or parasites. Yet, the visibility of veterinary drug development in the industry is so limited that hu-

man-based researchers often naively dismiss veterinary as less challenging.

#### What book are you currently reading and why?

Most of the books I have read in the past few years have been non-fiction, and the subjects are varied. Most recently I read the *Immortal Life of Henrietta Lacks* (about the woman who was the source of HeLa), *Sisters of Sinai* (twins who discovered a palimpsest of the Gospels in the 1890s), *Code Girls* (American codebreakers during WW2), and *Into Thin Air* (about the 1990s Mt. Everest disaster). Currently I am reading *The Blue Nile* (discovery of one source of the Nile) and *Finding Everett Ruess* (a wilderness explorer lost in 1930's). Often, the true stories are more fantastical than the fiction novels!

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

On a warm sunny day with no obligations, hiking in the woods or visiting a National Park would be ideal. Long bicycle rides in the countryside,

or spending the day kayaking are also high on the list. When the weather turns colder, hiking can continue, or with enough snow, swapping the boots for skis.

#### How has DIA helped you?

I look at DIA as a forum for exchanging knowledge and ideas. I found that the Annual Meetings were a great place to determine which approaches were industry-standard, and a rare opportunity to gain FDA's and EMA's perspectives on acceptable new methods. To stay current with trends, I joined a couple of communities and volunteered for one project that became a many-year association with the GCP-QA Community. This Community provided professional networking, a chance to contribute to seminars and publications, and a leadership role as the Community Chair.

### Baggage Check

There is an area in the Exhibit Hall C Lobby (near Starbucks) where you can check your belongings Wednesday and Thursday. The San Diego Convention Center's cost of checking a bag is \$5 per item. Baggage Check will be available on the following days and times:

Wednesday: 7:00AM-7:00PM

Thursday: 8:00AM-12:30PM

## Member Spotlight: DIA Staff

### Michelle Rovner, Associate Director, Marketing and Global Community of Practice, DIA

**Michelle Rovner** brings a variety of experience to her role as the Associate Director, Marketing - Americas & Global Community of Practice Leader at DIA. She is responsible for the strategic planning and execution of DIA's marketing efforts and aligning global marketing best practices and standards throughout the organization. In her 20 years of marketing and communications experience, she has lead various public relations and marketing initiatives covering the government, for profit and non-profit business sectors. Prior to joining DIA, Rovner served as the public relations and social media manager at NextGen Healthcare. She also served under the Department Defense as a public affairs specialist for the Department of the Navy.

#### When did you realize that you wanted to work in marketing or support the healthcare industry?

I come from a military background. Marketing was very different for me because I was originally in public relations and public affairs for the US Department of Defense. After the Willow Grove base closed, I went to NextGen Healthcare as a public relations and social media professional, where I was really introduced to marketing because PR fell under the marketing department there. I literally took somewhat of a leap of faith and career path shift coming to DIA because I had always focused on public relations and really didn't have a lot of hands-on marketing experience under my belt at the time. Being part of something that's bigger than yourself has always been important to me. That's why I worked in the Department of Defense, in healthcare IT, and why I'm in the pharmaceutical sector now. It's more than a job for me;

it's making sure that whatever organization I work with is dedicated to a cause that's greater than just me.

#### What do you find most challenging in your job?

I wouldn't say that it's a challenge, but sometimes our hurdle is prioritizing work. As a marketer, you have a lot of clients; you are basically a central point of contact that touches every aspect of the business. Sometimes it's a matter of the triple constraint of cost, resources, and time. You level set expectations across the board to make sure that you're not "the no person," but you also can't be "the yes person." It's about level setting expectations, managing up, managing down, and making sure you stay focused on what's in the best interest of the organization.

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



Don't take yourself too seriously. Learn to laugh at yourself and to laugh at your mistakes. I don't mean that in a negative way, but being able to recognize that you're human. Learn from your mistakes. And perfection will always get in the way of progress.

#### What have you become better at saying "no" to? What approaches or realizations helped you?

I have really honed my approach to what I say yes to and whether or not it's an actual no. I try to find a compromise and an even balance that supports the person's ask, but has the business in mind, and is also what I can actually deliver. I don't want to stretch myself too thin but on the flip side I also don't want to be unsupportive. Being a shared service in an organization is about making sure you can come to a compromise that helps all, but doesn't sacrifice your team or the business needs.

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

I went skydiving a few weeks ago and in doing so I have found a new adrenaline fix. I am an adrenaline junkie who loves physical fitness and anything outdoors. So anything outdoors and fitness related that would give me my adrenaline fix, I'm all about!

*Student Poster presenter Millicent Yeboah-Awudzi discusses her work.*



## Member Spotlight: DIA Inspire Award Winner

### Casey Walker, Doctor of Pharmacy Candidate, Howard University

**Casey Walker** is currently a rising fourth-year Doctor of Pharmacy Candidate at the Howard University, College of Pharmacy. He previously served as a student chapter president of the Howard University DIA Student Chapter, an intern at the DIA office in Washington, DC, and a student poster presenter at the *DIA 2018 Global Annual Meeting* in Boston, Massachusetts.



#### When did you realize you wanted to become a pharmacy student?

I realized pharmacy was the career for me at the age of 14, after I observed my aunt at her pharmacy. There were a few of her patients who were victims of substance abuse, and seeing how my aunt provided care for them inspired me to discover methods to treat victims such as these with a career in pharmacy.

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

As many pharmacy students would probably agree, I think the most diffi-

cult aspect of pharmacy in this point of our lives is finding time to balance school, jobs, and molding our professional brands. We have a plethora of careers for pharmacists to choose from, and the competition to earn a position after graduation is fierce.

#### What advice would you give your younger self about to enter the “real world?”

If I could go back in time and give some advice to my younger self, I would encourage Young Casey to not put his eggs all in one basket and to be as financially conservative as possible.

(Student loans are real, and they are coming with a vengeance.) In addition, I would teach him the importance of

*Continued on page 12*

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## Member Spotlight: DIA Community Chairs

### Lisa Mulcahy, Owner and Principal Consultant, Mulcahy Consulting, LLC

**Lisa D. Mulcahy** has more than 25 years of experience in the pharmaceutical industry in the areas of Clinical Operations and Quality Management. More than 10 years ago, she became an independent consultant, focusing solely on Trial Master File (TMF) processes and management, assisting clients with assessment and improvement of their current state, development of future design, and implementation of systems for the management of electronic records of the TMF. She is experienced in the quality assessment of study-specific TMFs and an industry thought leader in the management of the TMF. She is also a frequent speaker and experienced workshop leader at TMF-related professional meetings.

Mulcahy is chair of the DIA Document and Records Management Community. She led the team of industry representatives who recently reviewed and revised the Framework for the Destruction of Paper, v2.0. She is a co-founder and a Steering Committee member of the volunteer team of industry representatives that created, maintains, and expands the TMF Reference Model.



#### When did you realize you wanted to work in clinical research documentation?

There was never a real intention on my part to go into the field of management of clinical research documentation. I spent the first half of my professional career in the management of clinical trials. I just happened to land in this specialty, which is one on the great spectrum of careers in pharmaceutical R&D, because I like order. I was drawn to the field because I had the desire to put consistent processes in place that people could easily follow around the management of the documentation—the type of documentation that proves that company procedures as well as regulations regarding patient safety and data integrity, were followed. I wanted to ensure that the documentation was in the right place at the right time and available for reference as well as for audit and/or inspection. Just goes to show you that, in the field of R&D, there are so many opportunities for your skillset and passion.

#### What do you like most and least about your job?

In my current position I am an independent consultant. I've held positions at the investigative site, Contract Research Organizations, a mid-size biotech company, and one of the largest pharmaceutical companies in the world. My current position allows me to help each of these different types

of companies to improve on their process for the management of clinical research documentation they create in support of their clinical studies. I meet such fantastic people who are searching to establish quality and consistency in their processes. Most of my projects are short, less than a year, so I do not get into slumps or ruts. There is nothing, absolutely nothing, I do not like about my job.

#### What is the first book you remember reading?

The first book I remember reading is a classic called *Little Bear* by Else Holmelund Minarik and Maurice Sendak. It was written in 1957. It is about a little bear who has the luxury of a support system, in the book it is Mother Bear who helps him prepare for adventures and, upon his return from these adventures, provides the warmth, safety, and the goodness of home. In retrospect, it captures how my own life has proceeded. I, like Little Bear, have been afforded the support of my parents, spouse, children, family, friends, and my professional managers, colleagues, and mentors to take personal and professional adventures and risks, which in turn has allowed to me continually grow in my skills and ability to have a positive impact on our industry.

#### What advice would you give your younger self about to enter the “real world?”

I would tell myself three things:

(1) It is easy to get into the rut of doing the same thing day after day; just meandering through and to try not to let this happen since this is not what life is about. Seek to intentionally soak in the little things that happen even on what might appear to be the most mundane of days. Some day when you look back, those little things were actually the big things that make such differences in your life.

(2) You are what you are when nobody is looking. Seek to be the best person you can be, not because you have to show it to others, but because you want to for your own sake and need.

(3) Educate yourself and then stand up bravely against what you think is wrong. Toleration of injustice, on any level, is destructive to the society in which you live.

#### How has DIA helped you?

I was just starting out as an independent consultant and I was given the advice to join DIA and a group of committed volunteers in the Document & Records Management Community, who were working together on a project. What I quickly learned was that the DIA was a platform for me to find and establish connections with other professionals, like me in my area of specialty, who were driven to improve the

*Continued on page 15*

DIA Show Daily advertisers listed in bold.

**Company.....Booth Number**

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# Exhibitor List

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Wednesday, June 26

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Symphony Clinical Research .....	2216
Synchrogenix Information Strategies, Inc. ....	1117
Syneos Health .....	1721
Synova Health .....	1602

Syneract .....	1931
Target Health Inc. ....	2305
Tata Consultancy Services .....	824
Technical Resources International, Inc.	1717
Techsol Corporation .....	2108
Telelingua Translations .....	1447
The Patient Recruiting Agency LLC .....	2437

**The Reagan-Udall Foundation**

<b>For the FDA .....</b>	<b>625</b>
Therapak, a VWR CATALYST Service ..	2317
Therapeutics Inc .....	1143
ThoughtSphere Inc. ....	1050
Total Clinical Trial Management .....	2055
<b>TransPerfect Translations .. 1731 &amp; 1838</b>	
Trial By Fire Solutions .....	910
TrialStat Solutions Inc .....	2633
Trifecta Clinical .....	1137
Trilogy Writing & Consulting GmbH ..	2251
UBC .....	1649
Uber Health .....	2618
uMotif Ltd .....	2545
Uppsala Monitoring Centre-WHO Collaborating Centre for IDM .....	838
UTMB Sealy Center for Vaccine Development .....	2457

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Validated Cloud Inc. ....	840
Veeva Systems, Inc. ....	2031
Verantos, Inc. ....	2400
Verified Clinical Trials .....	1014
Veristat Inc .....	1713
Versiti .....	2044
Viedoc .....	737
Viitai LLC .....	431
VirTrial .....	2056
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Vitalink Research .....	1201
Vitalograph Ltd .....	1817
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VivalNK .....	2438
WCCT Global .....	1445
<b>WCG Clinical Services .....</b>	<b>1005</b>
WebbWrites, LLC .....	1514
Welch Allyn .....	1936
Welocalize Life Sciences .....	1041
Whitsell Innovations, Inc. ....	1140
WIRB-Copernicus Group .....	1105
Woodley Equipment Company .....	2131
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XClinical Services America Inc. ....	1955
Yourway .....	517
YPrime Inc .....	1851
Zeal Technologies .....	2455
Zifo Technologies Inc .....	2350
Zigzag Associates Ltd .....	2016
ZS .....	1300

# Wednesday's Professional Poster Session

Life sciences professionals from all fields related to the mission of DIA will display their Professional Posters in the Exhibit Hall from 9:00AM to 4:00PM. There will also be Oral Presentations where select poster authors will deliver an overview of their work in the Poster Area.

## **W-01: A Real World Investigation of Finasteride and the Risk of Prostate Cancer**

Stephan Palm, Analyst, Clinical Sciences, Trinetx  
*Oral Presentation 12:00PM*

## **W-02: Improving Cost Effectiveness by Automating the Aggregate Report Scheduling & Distribution**

Jennifer Cichone, Otsuka Pharmaceutical Development and Commercialization Inc.

## **W-03: Development and Operationalization of a Method for Determining Adverse Drug Reactions from a Clinical Study Safety Data Set**

Fred Jerva, Pharmacovigilance, Astra-Zeneca

## **W-04: Reducing the Cost of Systematic Risk Assessments of Medical Products by Using a Modular Learning Risk Repository System**

Stephen Sun, Vice President, Quality Risk Management, Syneos Health

## **W-05: Design Thinking in Pharmacovigilance**

Ruta Mockute, PV Innovation Senior Specialist, Celgene Corporation

## **W-06: Healthcare Professionals' Knowledge and Adherence to the National Guidelines for Management of Pediatric Asthma**

Hamad Alyami, Assistant Professor, Najran University, Saudia Arabia

## **W-07: A General Framework for Utilizing Real World Data with Clinical Trials**

Xiaoyun (Nicole) Li, Principal Scientist, Merck & Co., Inc.  
*Oral Presentation 12:10 PM*

## **W-08: Using a Continuous Learning Risk Repository System to Drive Efficiencies in Identification of Clinical Protocol Risk Patterns**

Thaddeus Urban, Senior Clinical Data Manager, Syneos Health  
*Oral Presentation 12:20 PM*

## **W-09: Exploring Accuracy of Abdominal Pain Reporting with and Without Specific Instruction**

Alyssa Peechatka, Clinical Science Advisor, ERT  
*Oral Presentation 12:30 PM*

## **W-10: The Rise of Electronic Patient-Recorded Outcomes in Oncology (ePRO)**

Bhavish Lekh, Feasibility Manager, Synteract

## **W-11: Advantages of a Peer Mentoring Program in Clinical Operations**

Wen Liu, Principal Scientist, Merck & Co., Inc.

## **W-12: Relationship Between Efficacy and Discontinuation Rates in Clinical Trials of Moderate to Severe Crohn's Disease**

Austin Marrazza, Student, Pennsylvania State University

## **W-13: Best Practices for the Electronic Migration and Implementation of Clinician-Reported Outcomes Assessments in Clinical Trials**

Heather Romero, Clinical Scientist eCOA, MedAvante-ProPhase

## **W-14: Common Symptom Terminology is Frequently Misunderstood**

Rinah Yamamoto, Clinical Scientific Advisor, ERT

## **W-15: Patients are Uncomfortable and Unable to be as Honest When Discussing Depression Symptoms During Recorded Interviews**

Nadeeka Dias, Senior Scientific Advisor, ERT

## **W-16: Patient Understanding of Rescue Medication: Value of Patient Training on Reporting Rescue Medication Use**

Kelly Dumais, Clinical Science Advisor, ERT

## **W-17: Subject Training Substantially Improves Understanding of Key Terminology in Gastrointestinal Clinical Trials**

Michael Sadler, Clinical Science Advisor, ERT

## **W-18: Putting the Patient at the Center of Medical Information: A Patient-Centric Standard Response Letter Initiative**

Chelsea Aiudi, TESARO

## **W-19: Defining Excellence and Best Practices in Medical Information for AMCP Dossier Creation and Compendia Review**

Sally Stansbury, Medical Information Lead, Takeda

## **W-20: Building Patient Trust: Our Journey to "Radical" Transparency in Compassionate Use**

Christine Maccracken, Director, Patient Support, Janssen

## **W-21: Meaningful Patient Engagement: From Vision to Reality in the Rare Disease Space**

Linda Brennan, Director, Community Partnerships, Cystic Fibrosis Foundation

## **W-22: Tell Me More: Exploring Patient Perspective on the Benefits and Disadvantages of Drugs During Clinical Trials**

Alexis Miller, Senior Director, Regulatory Science and Policy, Sanofi

## **W-23: Evaluation of Publicly Available Patient Medical Education Videos on Breast Cancer**

Min Kyung (Amy) Kim, Post-Doctoral Fellow, Ernest Mario School of Pharmacy, Rutgers University

## **W-25: Bring Your Own Wearable (BYOW): Considerations for Clinical Research**

Marie McCarthy, Senior Director of Product Innovation, ICON plc

## **W-26: Educational, Gender, and Age Diversity in the Corporate Leadership of Fortune 500 Pharmaceutical Companies**

Michael Severo, Medical Affairs, Novartis Oncology; Post-Doctoral Fellow, Ernest Mario School of Pharmacy, Rutgers University  
*Oral Presentation 12:40 PM*

## **W-27: Identifying Gaps in Competitive Intelligence and Business Development Strategy: Opportunities in the PD-1/PD-L1 Landscape**

Matthew Eberle, Lead Developer, Analytics and Custom Solutions, BizInt Solutions, Inc.

## **W-28: Main Difference Between Quality Tolerance Limits and Key Risk Indicators**

David Lacagnina, President, The Eclinical Agency

# Wednesday's Professional Poster Session

*Continued from page 11*

**W-29: Single Pivotal Trial Characteristics Supporting Regulatory Approval of Non-Orphan, Non-Oncology Drugs in EU and US, 2012-16**

Vivien Jagalski, Regulatory Intelligence Professional, Lundbeck  
*Oral Presentation 12:50 PM*

**W-30: Analysis of Products Awarded the Rare Pediatric Disease Priority Review Voucher and the Impact of Advancing Hope Act**

Caitlin Skenyon, Regulatory Affairs Fellow, Northeastern University  
*Oral Presentation 1:00 PM*

**W-31: A Retrospective Analysis of Bridging Study Evaluation in Taiwan During 2011-2018: Focus on Multi-Regional Clinical Trials**

Hui-Chun Hong, Pharmacokinetic Reviewer, TFDA

**W-32: Evaluation of Branded Prescription Drug Facebook Messenger Responses to Consumer Requests for Product Information**

Alexandra Didonato, Post-Doctoral Fellow, St. John's University/Allergan

**W-34: FDA Advisory Committee Meetings: A Five Year Retrospective Analysis**

Lauren Aronin, Post-Doctoral Fellow, St. John's University

**W-35: Regulatory Flexibility in the Review of Biologics for Rare Diseases**

Julienne Vaillancourt, Rare Disease Liaison, CBER

**W-36: Prescribers' Perception of the PLLR when Making Clinical Decisions for Patients with Chronic Respiratory Conditions**

Victoria Quang, Post-Doctoral Fellow, Ernest Mario School of Pharmacy, Rutgers University

**W-37: Evaluation of ICH Q12 Implementation Readiness**

Lois Castellano, Senior Specialist, Global CMC Regulatory Affairs, Merck & Co., Inc.

**W-38: Defining the Methodology for Interim Analysis and Data Peek for Power in Late-Phase Research and Pragmatic Clinical Trials**

Thomas Wasser, Senior Principle Scientist, Biostatistics, Consult-Stat  
*Oral Presentation 1:10 PM*

**W-39: Using Synthetic Control Databases to Accelerate Indication-Specific Safety and Efficacy Evidence**

Colin Neate, Biostatistics Associate Director, Roche  
*Oral Presentation 1:20 PM*

**W-40: Practice of Interactive Visual Analysis of Clinical Trials for Different Roles**

Gaoyang Li, Lead SPA, Bayer, China

**W-41: Targeted Review of Adverse Events of Special Interest (AESI)**

Mary Nillson, Statistician, Eli Lilly and Company

**W-42: Performance of Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies**

Kun Nie, Clindata Insight, Inc.

**W-43: Calcitonin Gene Receptor Peptide (CGR) Antibodies: Real World Evidence on Acute Migraine Treatment**

Ria Westergaard, Clinical Pharmacist, Express Scripts  
*Oral Presentation 1:30 PM*

**W-44: New Methods for Analyzing Clinical and Cost Outcomes in Regulatory Affairs With Interactive Visual Analytics**

Sharon Hensley Alford, Offering Management, IBM Watson Health

**W-45: The Impact of US FDA Breakthrough Designation (BTD) on Global Access to Innovative Medicines**

Magdalena Bujar, Manager, Strategic Development, Centre For Innovation In Regulatory Science, United Kingdom

## Wednesday's Innovative Theater Schedule

### 9:45AM

**Salesforce - Theater 1**

Digital R&D: Accelerating Intelligent Innovation with IQVIA's Orchestrated Clinical Trials Platform, powered by Salesforce Health Cloud

**SAS Institute, JMP Division - Theater 2**

Semi-Automation of the Narrative Section of the Clinical Study Report for Oncology Studies

### 11:40AM

**IQVIA - Theater 1**

Clinical Development Innovation Through the Lens of Data Science

**ZS - Theater 2**

Designing with Confidence

### 12:40PM

**IQVIA - Theater 1**

The Digital Patient Experience

**Oracle Health Sciences - Theater 2**

The AI Revolution in Multivigilance

### 1:40PM

**Tata Consulting Services - Theater 1**

Enabling Perpetual Digital Transformation in Research & Development

**PRA Health Sciences - Theater 2**

The Importance and Impact of Age-Specific Content in Pediatric Studies

## Walker

*Continued from page 5*

networking, and how to navigate difficult situations.

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

If I could have a dinner party with three pop culture icons, I'd invite Stan Lee, Neil deGrasse Tyson, and Frederick Douglass to a dinner catered by Fogo de Chao and Jamba Juice. I'd love to hear their opinions

on entertainment, the cosmos, and philosophy, respectively.

**How has DIA helped you?**

DIA has helped me grow into the man I am today. After serving as a past student chapter president, a poster presenter, and an intern in the Washington DC office, I learned how different professionals can meet and exchange ideas to further advance drug development. DIA always provided a non-judgmental and encouraging environment for me to learn, and it gave me knowledge to share with my peers as well.

*DIA Global Inspire Award Winners received their honors at the Awards Ceremony on Monday night:*  
**Community Engagement:** Robert Paarlberg, Principal, Paarlberg and Associates, LLC; **Global Connector:** Deborah Chee, President, Korea National Enterprise for Clinical Trials, Korea; **Author of the Year:** Nancy A. Dreyer, Chief Scientific Officer, Real World and Analytic Solutions, IQVIA; **Community Engagement:** Francine Lane, Vice President, Global Transparency, TrialScope; **Excellence in Service:** Jingsong Wang, Founder, Chairman and CEO, Harbour BioMed.



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## PRODUCT & SERVICES SHOWCASE

### Altasciences Booth #2039



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### AMPLEXOR Life Sciences Booth #2431



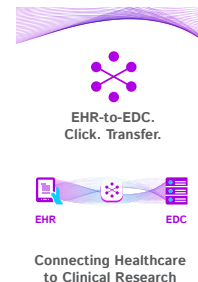
**RIMExpert**  
 RIMExpert is an integral part of AMPLEXOR Life Sciences Suite – the only regulated content management and compliance solution for the Life Sciences industry to support the entire product life cycle, from product nomination and development to submission and post-approval maintenance.

### BizInt Smart Charts Booth #937



Boost your competitive intelligence and business development strategy! Used by the top pharma companies for over 20 years, BizInt Smart Charts software helps you create targeted reports and visualizations from the leading drug pipeline and clinical trial databases – including Citeline Trialtrove, ClinicalTrials.gov, and EU Clinical Trials Register.

### Protocol First / Clinical Pipe Booth #2736



Clinical Pipe is an EHR-to-EDC connector, used as a productivity tool for clinical research. Instead of manual transcription from EHR-to-EDC, 30-70% of the data flows directly from EHR into the EDC database (e.g., Rave, InForm). This process eliminates transcription errors and SDV, and vastly reduces on-site monitoring visits.

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## Member Spotlight: DIA Fellows

### Alberto Grignolo, Corporate Vice President, Parexel

Alberto Grignolo, PhD, is a Corporate Vice President at Parexel, and established the firm's Japan Consulting Services during a two-year assignment in Tokyo. Grignolo has served as an adviser on human subject protection in clinical trials to the Institute of Medicine of the National Academy of Sciences, on the first Executive Committee of the Clinical Trials Transformation Initiative, as Chairman of the Regulatory Affairs Professional Society, and as President of FIDIA Pharmaceutical Corporation. He is a DIA Fellow, Editor of DIA's digital magazine *Global Forum*, and serves on the faculty of DIA's Regulatory Affairs: The IND, NDA, and Post-Marketing training course, which he has taught in Japan, China, Korea, Europe, and the US.

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

Reducing the costs, complexity and time currently needed to develop a new medicine, and therefore the price that many patients have to pay (or cannot pay) to use that medicine.

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

Technology and molecular biology are converging to such an extent and at such speed that by 2030 it will be possible to predict and prevent diseases at the fetal stage and in real life; gene editing and highly specific targeted interventions applied at the cellular level before the disease is even expressed will make most drugs as we know them today unnecessary and irrelevant.

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

Be open to considering the unexpected opportunity; don't judge others by their appearance; give everyone respect and the benefit of the doubt; apologize with sincerity.

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

I cannot imagine it. I would get up early in the morning and hurry to get to my next volunteering gig - because someone there needs me to show up and do something.

#### How has DIA helped you?

DIA has been for me (and continues to be) a "parallel universe" that is fully aligned with my values, has complemented my regular job, has enriched



my career, informed my perspectives, expanded my network, enhanced my learning, and fostered relationships with amazing people in our ecosystem. My life would be emptier without DIA.

#### What would you like to see DIA do for you in the future?

It's more about what I can do for DIA in the future, because what we do for DIA as volunteers comes back to us multiplied severalfold. I want to contribute in some ways to promoting better health for patients, within and outside of DIA.



DIA 2019 Student Poster presenters.

## Member Spotlight: DIA Fellows

### Ling Su, Professor and Director, Institute of Drug Regulatory Science, Shenyang Pharmaceutical University; Venture Partner, Lilly Asia Ventures

Ling Su, PhD, is a Venture Partner with Lilly Asia Ventures. He has over 25 years of experience in drug regulatory and development. He worked in various R&D management positions in the pharmaceutical industry, including as Medical Director at Merck, Pharma Development Director at Roche, VP for Clinical Research Asia Pacific at Wyeth, and as SVP and Head of Development China at Novartis. Prior to that, he worked in the Chinese regulatory agency and CDER, US FDA. Currently, Ling is also a professor in Regulatory Science in Shenyang Pharmaceutical University and serves as an advisor to the Chinese regulatory agency on numerous projects. He is a member of the Hong Kong Stock Exchange Biotech Advisory Panel. Ling is a Past President of DIA and currently is a Fellow of DIA and a member of DIA's Science and Policy Advisory Council. Ling holds BS in pharmacology from Shanghai Medical University, MS in Clinical Pharmacy and PhD in Epidemiology from University of North Carolina at Chapel Hill, USA.



#### When did you realize you wanted to be an epidemiologist and work in R&D?

When I was in graduate school pursuing a degree in clinical pharmacy, I attended a course in pharmaco-epidemiology and found it fascinating. I then went on to do a PhD in epidemiology.

#### What do you like most and least about your job?

Being primarily a consultant in drug development now, what I like the most is the opportunity to work with different people on different projects. What I like the least is receiving an urgent request phone call while on vacation.

#### What advice would you give your younger self about to enter the “real world?”

Not only knowing what you want to achieve as your immediate next step, e.g., in your current job, but also trying to explore what your next inspiration will be and what and how you need to be prepared for your next step.

#### Mulcahy

*Continued from page 6*

industry because we knew it could and should be done—thereby making the overall process for developing new medicines and devices more efficient. I have maintained so many of these early connections even today, 12 years later, as we continue to work

on projects that change how our industry works. Through projects managed via the DRM Community, I learned how to harness the great power of a group of volunteers driven to succeed in a common goal. Opportunities like this can be available to all DIA members; if one only wants to take the reins.

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

Perhaps do some leisure reading and go see an exhibit, or simply enjoy the quiet moment at home.

#### How has DIA helped you?

DIA has helped me tremendously in broadening my knowledge horizon and my professional network.

## Exhibitor News

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

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