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

SHOW DAILY

Issue Two
June 24, 2019

Speakers and attendees celebrate together at Sunday afternoon's Student and Emerging Professionals Forum to kick off their DIA 2019 experience.

Monday

7:00AM–6:00PM
Attendee, Speaker, and Exhibitor Registration

8:00–10:00AM Opening Plenary, Keynote Address, and DIAmond Session

10:00AM–6:00PM
Exhibit Hall Open

4:30–6:00PM
Opening Reception (Exhibit Hall)

Up Close and Personal

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

- **Jingsong Wang**
- **Joan Buenconsejo**
- **Richard Day**
- **Kim Quaintance-Lunn**
- **Nancy Dreyer**
- **Jessica Culp**
- **Mark A. Kryah**
- **Catherine Baldridge**
- **Chris Slawecki**

Who Owns Your Health Data?

DIAmond SESSIONS

Thought-provoking, worldwide issues deconstructed by acclaimed panelists representing multiple stakeholders from around the world in this growing ecosystem of life sciences.

#100 Who Owns My Health Data: Patients, Data, and the Future of R&D
Monday, June 24, 8:00–10:00AM
Ballroom 20
Part of Opening Plenary and Keynote

Consumers today are increasingly sensitive to how their data is used and monetized, largely in the wake of Facebook/Cambridge Analytica and other high-profile scandals. Use of personal health data is not immune from these concerns, from GDPR and California Consumer Privacy Act to the rise of state bills challenging ownership over personal health data even if de-identified. These consumer and policy trends are raising new questions for patients and medical providers and are challenging comfortable norms.

During this session, we will discuss the evolving relationship of patients and health data, from access and sharing to privacy and ownership. As well as the consumer and policy trends that may reshape expectations when personal health data is monetized. We will conclude our discussion with a conversation around the data dependence of drug development today and the implications for medical research tomorrow.


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Member Spotlight: DIA Inspire Award Winners

Jingsong Wang, CEO, Harbour BioMed

Jingsong Wang, MD, PhD, is the CEO of Harbour BioMed (HBM), a very promising biomedical start-up company in China. Before founding HBM, he was the Head of China Research and Development and of Translational Medicine, Asia Pacific, for Sanofi. Wang currently serves as the Chair of the China Regional Advisory Council, a role he has held since 2015. Under his leadership, DIA China established the annual *Drug Discovery Innovation Conference* (DDI) in 2015. This allowed the strategic expansion of DIA China's portfolio from late-phase development to early-stage product discovery and development. Dr. Wang has been an active DIA member since 2012 and has been on the program steering committee for the *DIA China Annual Meeting* from 2015-2019, and was Co-Chair of the *DIA China Annual Meeting* in 2016. Tribute to his leadership and dedication to DIA, as well as his strong influence to China's life-science innovation ecosystem, DIA China demonstrated a strong growth in both the Annual Meeting and DDI, attracting more than 3,000 and 700 attendees respectively. DIA's sphere of influence gradually expanded from MNCs-centered, to Chinese domestic biotech, start-ups, research hospitals, etc.

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

The healthcare field is emerging much faster compared to anytime in the history of medical inventions. But we still have a lot of unmet medical and patient needs that can only be addressed when the community (including researchers, physicians, and policy makers) decide to work together. This is happening more and more in recent years—the outcomes of which you see in some of the most advanced medicines and healthcare systems available today. Over the next decade, I can only anticipate this pace of R&D to grow faster and bring novel therapeutics to our patients. My vision for 2030 for all of us involved with DIA and beyond is to break breakthrough therapy for cancer patients. There are millions of patients suffering from various types of cancers, and only a collective and collaborative approach between academia, industry, physicians, patients, and policy makers is going to make this happen. And the time is now…

What do you like most and least about your job?

What I like the most about my job is that on a daily basis, I am working directly and indirectly with a large number of talented scientists and entrepreneurs focusing on developing innovative therapeutics to save lives and improve people's quality of life. It is the most rewarding job. As a physician and a scientist in the field of biotechnology, I constantly witness and am reminded of the suffering of the patients in need of breakthrough therapies. This is also the driver for me and my colleagues in the field to strive to discover and develop medicines that meet the needs of patients around the globe.

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

To excel in the biomedical field, you must have the desire and the dedication to help people in need and to serve humanity. Start with the work and the job at hand, establish yourself as the person your colleagues and your manager trust to be able to deliver what you are asked and have promised. At the same time, learn and work with colleagues outside your project and function. Participate in activities to enhance cross-functional collaboration and cross-industry community volunteer service to promote best practice sharing and operational excellence. Ultimately to become a leader and to generate greater positive impact for the industry and the people you desire to help.

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

That's a tough one… but one of the things I have become better at saying no to, especially since I started Harbour BioMed, is requests to work on new targets before delivering on older projects. Science is exciting and keeps us all motivated to find that new breakthrough, but it is also important to have the discipline of delivering on

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Member Spotlight: DIA Community Chairs

Joan Buenconsejo, Director and Biometrics Team Leader, AstraZeneca

Joan Buenconsejo, PhD, MS, is a Director and Biometrics Team Leader supporting the oncology therapeutic area within the Biometrics and Information Sciences at AstraZeneca. Prior to joining AZ, she was a statistics team leader at CDER, FDA. She is the chair of the DIA Statistics Community, North America. Buenconsejo received her Master's degree in Mathematical Statistics from University of California, Irvine, and a Master's degree in Public Health and Doctorate degree in Biostatistics from Yale University.

When did you realize you wanted to become a statistician with focus on biometrics?

As a child, I was always good in math, and when I had to choose my undergraduate major, applied mathematics was a no-brainer. After watching the movie *Outbreak* in 1995, I wanted to be an epidemiologist or in a related field, so applying to graduate school in Public Health seemed to be a great choice. While epidemiology classes were interesting, biostatistics courses gravitated towards me more. As a statistician in the biomedical field, I am always using my technical skills to answer important research questions and communicate findings that could impact people's lives. How cool is that?

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

Currently, businesses are transforming their organizations to be more digital and data-centric. Big data, machine learning, and artificial intelligence are at the forefront of these changes. Many statisticians are leading these changes given their technical expertise, problem-solving skills, and business acumen. I see excellent partnering with cross-functional members and continued growth in leadership, as statisticians expand their skills and embrace the changes. My vision for 2030 is the continued growth of the field of statistics as a core area for organizations that harness technology and data to improve decision-making.

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

I would tell my younger self not to worry about not knowing everything—that it is okay to make mistakes and to learn from those experiences. I would also tell my younger self to be curious and not to be afraid to ask questions. I would also encourage my younger self to network and to seek a mentor within the organization.

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

If I have a day to myself without work, internet, or driving my kids around activities, I would either be curled up in the sofa reading a romantic novel, or in my kitchen baking cupcakes. I would also take a moment to just breathe.

How has DIA helped you?

Through DIA, I have met many leaders in industry and regulatory agencies, not only within statistics, but also from other functional areas. Because of DIA's global presence and neutrality, there are numerous opportunities for me to learn from experts from different regulatory

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Member Spotlight: DIA Fellows

Richard Day, Professor of Clinical Pharmacology, University of New South Wales, Medicine, St. Vincent's Hospital, Sydney

Professor Richard Day, AM (MBBS, FRACP, MD), is internationally recognized for his research, leadership, and advocacy in support of quality use of medicines. He has been deeply involved in Australia's National Medicines Policy, culminating in his Chairmanship of the Pharmaceutical Health and Rational Use of Medicines Committee for the Federal Government (1999-2008), and is an active contributor to national resources such as the Australian Medicines Handbook and Therapeutic Guidelines. Day has published over 500 peer-reviewed papers and been cited more than 21,000 times. He was the first non-US President of DIA, and his many awards include Member of the Order of Australia AM (2000) and the AMA Distinguished Service Award (2009).

When did you realize you wanted to be a pharmacologist?

When I realized that the key to understanding variations in responses of my patients to their medications was understanding the dose response relationship. There's more to this relationship than meets the eye! I have used (and loved) this relationship ever since.

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

Personalising important therapies by using all the increasingly available and relevant information about my individual patients in an effective, efficient, and powerful way. And bringing to bear on the decisions regarding therapy for my patient, the power of the experiences of "similar" "real world" patients through the use of "Big Data"approaches.

What in your opinion is the biggest gap between research and practice in your field?

Implementation of all we know about achieving optimal results for an individual patient, and especially, bringing our patients 'along' with us so we reach a mutual understanding of what will be best for each individual. Helping our patients understand their illness and treatment options and then helping them to decide what's best for them and commit to the plan is a frontier that needs much more attention from us all.

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

Increasing personalization of therapy using the vast array of individual data available at the point of care.

What do you like most and least about your job?

Non-evidence based bureaucratic interventions and accretions impinging on ever more of our available time and energy.

What book are you currently reading and why?

The Shepherd's Hut by Australian author Tim Winton, author of *Cloudstreet*, *The Riders*, and *Breath*. Great story teller of "universal tales."

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

Reviewing too many research papers.....there are plenty of other "fish in the sea."

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

Select projects more judiciously.

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

Ride my bike early, coffee with mates, surf with Barb my wife, brunch, read, then nap, and then early dinner at our place, preferably a BBQ, with immediate family (three children plus partners and their eight children and "one on the way") followed by eight hours sleep.

How has DIA helped you?

I learnt so much about medicines development, working with global stakeholders and leaders, seeing the power of the free exchange of ideas, and experiencing the pleasure and effectiveness of working with enthusiastic and committed volunteers.

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

Continue as the leading forum for exchange of ideas and initiatives to improve human health globally while dealing with and contributing to solutions for our greatest global threat of climate change.

Member Spotlight: DIA Inspire Award Winners

Kim Quaintance-Lunn, Vice President and Head, Regulatory Policy, North American Regulatory Affairs, Bayer

Kim Quaintance-Lunn serves as Vice President and Head, Regulatory Policy, North American Regulatory Affairs, at Bayer. Kim joined Bayer in February 2014 to establish and lead the US regulatory policy function for the organization. She works with colleagues to analyze regulatory policy and advocate for changes in the regulatory environment, serves on global and US Regulatory Leadership teams, and assists in the development of regulatory strategies. Kim previously served as the Senior Director, Global Regulatory Policy and Intelligence at Eisai and as the Associate Director for Regulatory Affairs in CDER's Office of New Drugs. Kim began her career in the pharmaceutical industry working as a research scientist in drug metabolism at Pfizer.

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

From birth! But seriously, I had been working in the lab doing research and realized that I wanted to move in a new career direction. Translating the data I was generating into access for patients via regulatory approval held a definite appeal, and the rest, as they say, is history.

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

The greatest challenge in my view is the lack of harmonization among global health authorities. I will moderate that statement by saying that we should not harmonize for the sake of harmonization. We should harmonize to the best practice.

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Member Spotlight: DIA Inspire Award Winners

Nancy Dreyer, Chief Scientific Officer and Senior Vice President, IQVIA

Nancy Dreyer, MPH, PhD, is Chief Scientific Officer and Senior Vice President at IQVIA, focusing on generating real world evidence for regulators, clinicians, patients and payers through pragmatic trials and non-interventional approaches. She is a Fellow of DIA and the International Society of Pharmacoepidemiology, a member of the PCORI Clinical Trials Methods Advisory Panel, and a Standing Consultant to the National Football League Health & Safety Executive Committee. She holds an appointment as Adjunct Professor of Epidemiology at the Gillings School of Global Public Health at the University of North Carolina and has twice been named to *PharmaVOICE* magazine's annual list of 100 most influential and inspiring individuals in life sciences.

When did you realize you wanted to be a scientist working in public health?

My first job out of college was as a research assistant on a drug safety study—a challenging one where serious adverse events were discovered after females exposed in utero reached puberty. Lots of challenges creating a retrospective cohort of mothers, and contacting them to find out about any daughters, who then were in their late teens and twenties.

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

I expect we will see much greater use of real world evidence for label expansions. Recognizing the need for benchmark data to assure regulators and clinicians about comparative benefits and risks, the push for personalized medicine will demand more use of external comparators (aka historical controls) as patients and clinicians become less willing to risk randomization to placebos to determine their changes of receiving a cure.

What book are you currently reading and why?

Just finishing *Dreyer's English.* I want to see how my cousin got his book on *The New York Times* Best Sellers List.

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

It's not just about what work you do, but who you work with and company culture are equally important.

How has DIA helped you?

DIA has been a phenomenal way to meet intelligent, creative people who are driven to excel. I have met some wonderful people who inspire me to do more and try harder.

Get Social! Win Prizes and Make Connections

Stay connected with your colleagues from around the world and all the innovation happening in San Diego by following #DIA2019 on your social media channels. Search DrugInfoAssn to follow DIA.

Welcome to *DIA 2019!*

Member Spotlight: DIA Staff

Jessica Culp, Senior Manager, Meeting Operations, DIA

Jessica Culp, Senior Manager of Meeting Operations, has been with DIA since 2012. Jessica has managed the DIA Project Coordinator and Customer Services teams, and also supported the Specialty Meeting Exhibition Program. Jessica oversees internal and contract staffing for the DIA Global Annual Meeting, as well as the overall session management logistics, to ensure all needs are being met.

When did you realize you wanted to be involved in supporting the healthcare industry?

My focus had already been in the nonprofit realm, initially beginning with working in higher education. In my work, I've always appreciated the small impacts I can make on individuals for the better. DIA was a place I fell into, but, transitioning from higher education, I quickly found my place. The leadership from Sudip Parikh, Managing Director of DIA Americas, is truly inspirational. His passion for bringing cures to patients faster through the work we do is such a motivating force. In my time at DIA, I had a child that has significant health issues and needs. I'm now on the other side, being his patient advocate, and I see how my work at DIA to impact the healthcare industry has made the work I do for my son so important.

What do you find most challenging in your job?

The most challenging part of my job is making sure we're supporting all of our initiatives with a highly passionate staff that could use more hands. As we have been working, we've been growing our scope, tackling important areas that have needs, but doing it with the same staff team. I think we would be able to do more with more staff members to support new ideas and initiatives.

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

I would tell my younger self to be open and soak everything in. If you see something that you don't think is working, challenge and ask "why." But when you do that, have a solution to make it better.

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

I have been better at pushing back and saying "no" to "exceptions." I've grown more confident in the policies and procedures I've developed for our organization, so instead of just granting requests for exceptions, I've been better at asking individuals (both within and outside our organization) to follow our established procedures so there is consistency and logic in everything we do.

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

I would spend time with my family, making memories with my two children. Their favorite place lately has been the aquarium, so I would spend a family day with them there, going through the exhibits and watching them explore.

Free DIA WiFi

Complimentary WiFi service is available throughout the San Diego Convention Center. To utilize this service, simply connect to DIA Free WiFi and enter the password diaglobal. Once you accept the Terms and Conditions, you will be redirected to the DIA website.

Exhibitor List

DIA Show Daily advertisers listed in bold.

Exhibit Hall Hours

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Tuesday, June 25
9AM – 5PM
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9AM – 4PM

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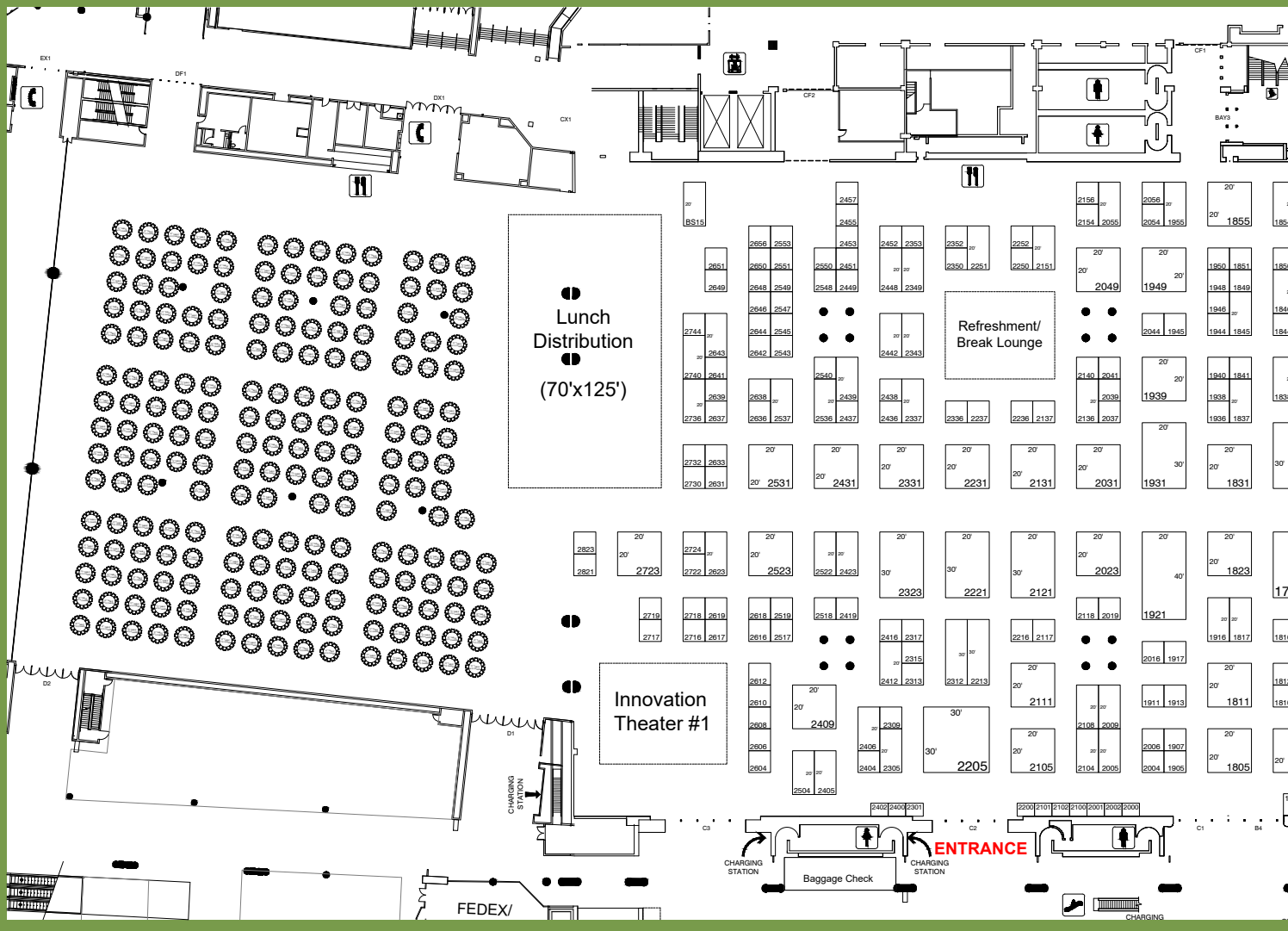

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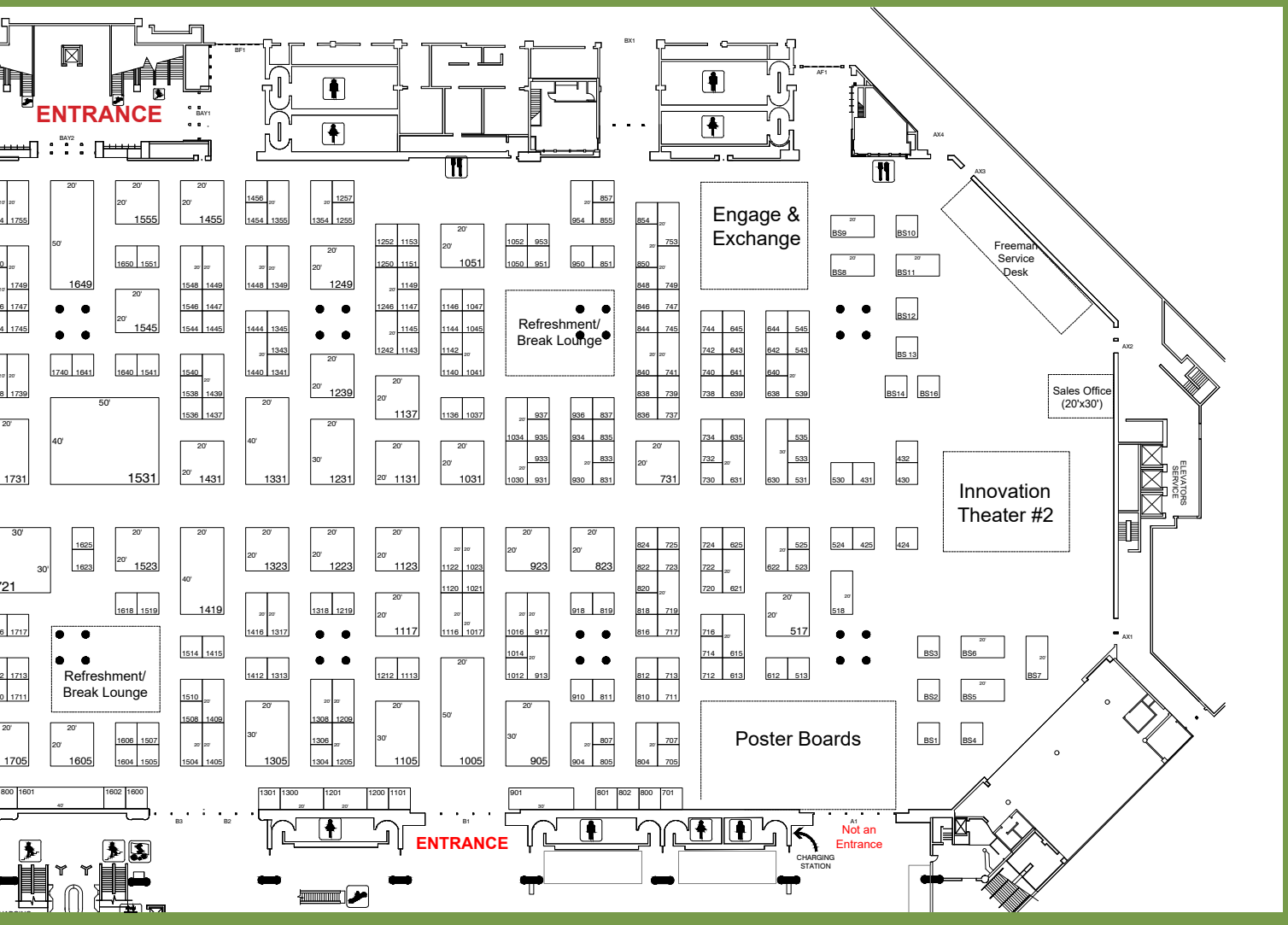

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Member Spotlight: DIA Community Chairs

Mark A. Kryah, Senior Advisor and COO, Pharmaceutical Project Management, Immunology, Eli Lilly and Company

Mark Kryah, BS, PMP, has been leading projects ranging from early to late phase development for 20 years, with extensive international, cross-cultural, and partnership experience. He has led multiple global development programs, consistently demonstrated an ability to build strong cross-functional working relationships, effectively managed operational complexity, and has delivered strong business results. For the last nine years, he has been a COO/Senior Advisor in Lilly's Bio-Medicines Business Unit, leading Phase 3 development and preparation for numerous registrations and launches across immunology, cardiovascular, and men's health products.

Mark has been involved with DIA for more than 15 years, contributing as a presenter and session chair at many DIA Annual Meetings. He served on the Annual Meeting Program Committee from 2013 to 2018, and is a member of the Project Management Core Committee, taking chair of the PM Community in 2018. He also serves on the DIA Community Leadership Council. Kryah obtained Project Management Professional (PMP) certification from the Project Management Institute (PMI) in April 1999 and currently maintains that designation.

When did you realize you wanted to manage projects ranging from early to late phase drug development?

After a number of cross-functional positions at Lilly, I had the opportunity to work on a late phase development team, which was at that time executing multiple post-launch studies across several indications. It was in this role, as a project manager—where the ability to see the big picture across the breadth of drug development, integration across many areas, influencing and leading teams to accomplish common goals, and where strong organizational, problem solving and communication skills are essential—that I realized I wanted to pursue pharmaceutical project management as a career. Fortunately, these are skills that come rather naturally to me, and it is a thrill for me to exercise them every day in work that brings improved therapies to patients around the world.

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

It's hard to walk down the street, communicate with a family member, friend or colleague, read something, anything, without being impacted or using some type of digital technology. It's everywhere. The rate of evolution of the science in healthcare is also incredible, due in many ways to leveraging the technology I mentioned above. However, I believe in the potential for broader application in our field, whether from operational perspectives, improving patient interactions, or from research innovations. Technology exists now that can reduce the time to bring new medicines to market, therefore reducing cost and time to bring new therapies to patients. I'd like to see our industry really accelerate the integration of science and technology in the next ten years.

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

Find those attributes, responsibilities, or skills that come naturally to you, and pursue a career path that exercises those strengths. Many people have high learning agility and the potential to learn a great many things, but I believe that when you enjoy most of what you are doing, and are good at it, then both you and your organization benefit! (Traveling the world or watching TV don't pay that well for most people.) Also, be positive, patient, and persistent in your pursuit of what you want.

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

Martin Luther King, Jr. It would be incredible to hear about Dr. King's journey, his passion, persistence, struggles, and visions in a life cut way too short.

How has DIA helped you?

Over the years, DIA has been a source of education and learning about the healthcare industry, in particular drug development. It has helped me grow and appreciate

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Monday's Student Poster Session

This year's Student Poster Program features students from various academic institutions from all over the world who will showcase their latest research from 10:00AM to 6:00PM in our Exhibit Hall. Student Poster presenters will be judged for their poster and onsite presentation on Monday, and will be recognized at the Student Poster Award Ceremony on Tuesday June 25.

M-01: Efficacy and Safety of Tyrosine-Kinase Inhibitors as First-Line Treatment in Advanced NSCLC Patients: A Network Meta-Analysis

Ismaeel Yunusa: Graduate Student, Massachusetts College of Pharmacy and Health Sciences

Oral Presentation 10:30AM

M-02: Impact of Patient Support Programs on the Performance of Adverse Drug Event (ADE) Signal Detection

Inyoung Lee: PhD Candidate, University of Illinois at Chicago

Oral Presentation 10:40AM

M-03: Systematic Evaluation of Randomized Controlled Trials on Nutraceuticals Containing Chinese Medicines for Diabetes Management

Junnan Shi: Student, University of Macau

Oral Presentation 12:40PM

M-04: A Review on Methodological Quality of Traditional Chinese Medicine's Clinical Trials' Design in 2016

Zhi Cui: Student, University of Macau

M-05: Data-driven Impact of Depression, Anxiety and Antidepressant Treatment on Clinical Outcomes for Type 2 Diabetes Mellitus

Elham Heidari: PhD Student, Health Outcomes Division, University of Texas

Oral Presentation 12:50PM

M-06: Evaluation of the Effect of Aegle Marmelos in a Murine Model of Trinitrobenzene Sulfonic acid (TNBS) Induced Coliti

Abhishek Mane: Student, Seth GS Medical College & KEM Hospital

M-07: Evaluation of the Anti-Anxiety Effect of Minocycline on Resident Intruder Model of PTSD in Golden Syrian Hamsters

Panini Patankar: Junior Resident, Seth GS Medical College & KEM Hospital

Oral Presentation 1:00PM

M-08: Improvement of Intestinal Dysbiosis With Exogenous Prebiotic Metabolites Reduces Intestinal Bowel Inflammation

Millicent Yeboah-Awudzi: Graduate Assistant and PhD Student, Louisiana State University

Oral Presentation 1:10PM

M-09: Disseminating Regulatory Self-Study Tools: A Study of the Efficacy and Promulgation of USC's Clinical Trial Quality Training

Advaita Chandramohan: Undergraduate Research Associate, University of Southern California

M-10: Study on Reducing Errors in Data Input to a Case Report Form

Hikari Ishii: Student, Waseda University

Oral Presentation 1:20PM

M-11: Barriers and Facilitators to Using Current and Revised Australian Product Information: Perceptions of Healthcare Professionals

Hsiu-Chun Tony Yuan: PhD Candidate (Pharmacy), The University of Sydney

M-12: Pharmacogenomics in Drug Labeling and Guidelines: An International Perspective

Christina Salama: Pharmacy Student, Saint John's University

Oral Presentation 1:30PM

M-13: Orphan Drug Demand Analysis in China - Empirical Forecasting Study of National Market from 2019 to 2028

Jiaqi Xu: Student, University of Macau

M-14: Biopharmaceutical Innovation: An Evaluation of Clinical Phase and Market Entry Period in Novel Drug Products

Ruoying Sheng: Student, University of Southern California

M-15: Global Supply Chain Issues Affecting Biopharmaceutical Manufacturers: An Analysis of FDA Warning Letters from 2013-2018

Sean Kerns: Graduate Researcher, University of Southern California

Oral Presentation 1:40PM

M-16: Impact of Different Randomization Techniques on The Statistical Efficiency in Clinical Trials

Jackline Kemboi: Student, African Institute For Mathematical Science (AIMS)-Rwanda

Oral Presentation 1:50PM

M-17: Sample Size Planning in Bioequivalence Trials: A Systematic Review of Methodology

Junior Sinclair Awounvo: Student, University of Bremen

Oral Presentation 2:00PM

M-18: Generic Medications: A Comparison on Drug Prices and a Cross Sectional Survey on Knowledge, Perception and Use

Cezar Manansala: Student, Centro Escolar University

Oral Presentation 5:10PM

M-19: An Evaluation of Comments to the CMS Proposed Drug Price Transparency in Direct-to-Consumer Television Advertising Rule

Achint Raince: Student, Ernest Mario School of Pharmacy

Oral Presentation 5:20PM

Quaintance-Lunn

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What is the first book you remember reading?

First book? Probably something by Dr. Seuss. But one of the first novels I remember reading, and falling in love with, is *To Kill a Mockingbird* by Harper Lee. I'm very excited to be able to see the adaptation of the novel on Broadway this summer!

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

First, work hard and do your best no matter what the task. Your work ethic reflects on who you are; I tend to hire for attitude and train for skills. Second, be open to opportunities. It may not be "the job" you want now, but it could be the stepping stone towards a future opportunity! And last, but perhaps most important, find your passion.

How has DIA helped you?

DIA offers so many opportunities, and I believe I have taken, and continue to take, advantage of all of them. There are the educational offerings, where you can increase your knowledge. DIA events offer the chance to network with other professionals and build relationships... I have met many people through DIA that I now consider not only professional allies, but also close friends. Finally, DIA has given me various experiences that have helped me grow as a professional. I am grateful for all the opportunities I have had over the years, and I am proud to be associated with DIA!

Kryah

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the importance of external focus, paying attention to how environmental events need to shape our internal strategies and plans. Just as importantly, if not more, DIA has given me the opportunity to develop a network of colleagues. Many of them have become friends with whom I can share experiences and learn from in the spirit of advancing the important work we do to develop new medicines for patients around the world who are waiting for improved care.

Buenconsejo

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agencies, academia, and industries, and to engage in scientific exchanges with them. Their annual meetings and statistics forums are exceptional with relevant and timely topics, and speakers that are recognized thought-leaders. The Communities within DIA are dynamic and are led by volunteers who are passionate about developing new programs and activities for members, disseminating relevant information through webinars, and fostering partnership and collaboration.

Member Spotlight: DIA Community Chairs

Catherine Baldridge, Principal Consultant and Owner, Essential Pharmacovigilance, LLC

Catherine Baldridge is a Safety and Pharmacovigilance Consultant with more than 15 years in the industry. She is an active DIA member, former Chair of the DIA CSP Community, and currently serves as a member of the DIA Community Leadership Counsel. Catherine received her undergraduate degree in Psychology at Hollins University, and her Masters of Science degree in Clinical Research and Health Evaluation from the University of Virginia. Catherine resides just outside Richmond, Virginia, and when not focusing on GvP/GxP activities, loves spending time with her friends and family at the beach.

When did you realize you wanted to work in clinical safety and pharmacovigilance?

I realized early on in my educational pursuits that I had a passion for helping the public in the health sciences. I took my first Clinical Research Coordinator job in a small psychiatric practice while I prepared to pursue a graduate program in the field. It was then that I realized how much effort went into the research and safety of the patients, who sought new and novel therapies through clinical trials, that I shifted my focus to clinical research. My interest in working to improve how the safety data was collected, monitored, captured, and reported grew from there!

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

The greatest challenge in safety and pharmacovigilance is generating cross-functional engagement, understanding, and alignment with the long-term goals and requirements for ensuring a compliant and effective PV system that will allow potential and developed products to reach and remain safely on the market. Short answer: getting buy-in and funding to support long-term needs. In some cases, we (i.e., PV) are an afterthought!

What in your opinion is the biggest gap between research and practice in your field?

The patients and researchers involved throughout the development stage are trained to report safety information in a way the general public is not. When I train new teams or inquire with seasoned colleagues "how many times have you reported an adverse reaction," I frequently find that people have experienced a product-related event but have not reported it. I believe we need to train our healthcare professionals and end-users (patients and their families) on their role in the continuous monitoring of the safety of each product.

What book are you currently reading and why?

I am currently reading *Chicken Soup for the Soul*. Being in a high pressure field with 24/7 demands and often high tension, it's nice to read a good uplifting and heartfelt story to remind me that we are all human, all going through "something," and that how we treat others will be our ending legacy.

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

Save your money! Just kidding (sort of!)... I would tell myself to slow down. I'm a very passionate person and have been in the work force since a very young age. This, coupled with my enthusiasm to learn, caused me to speed through career stages without taking a breath. I would tell myself that work will always be there, but family, friends, and personal health are the most precious!

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

I have become better at realizing my strengths and weaknesses, therefore am able to "say no" to projects in areas where I know there is a better suited individual to perform the activity than me.

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

Take my family camping, and I mean in a tent, not in a camper with a shower!

How has DIA helped you?

DIA was a resource for me when my access to global resources

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Member Spotlight: DIA Staff

Chris Slawecki, Senior Digital Copyeditor, DIA

Chris M. Slawecki has worked for DIA since 2002, with *Global Forum* and our *Driving Insights to Action* podcast channel among his chief responsibilities. Chris has contributed as a writer and editor across many different business settings, including proposals and subsequent contractual documentation for a government defense/aerospace contractor and for a mobile eBusiness consulting firm. Other, more creative writing experiences include serving for more than two decades as Senior Editor for the award-winning AllAboutJazz.com music website; as primary contributor to the Stax Records fiftieth anniversary celebratory blog; and as editor of the book *Puppy Mill Dogs SPEAK!*

When did you realize you wanted to be a writer and editor, especially in healthcare?

In my sophomore year of college. I had tried several different majors (honors, psychiatry, pre-law) but realized that regardless of my major, I always did best in English and enjoyed those classes the most. I must be an English major! I didn't realize I wanted to write about healthcare until I came to DIA and covered our first Rare Disease meeting. After that, I didn't just have a job at DIA. I had found my vocation.

What do you find most challenging in your job?

First, I am a wordsmith working in a scientific world. It's getting harder to adequately explain, describe, or express emerging science (such gene editing, for example) in plain language that an interested reader can understand but which still does justice to their complications. The other is that science and technology keep changing so quickly, but digital and social media can go only so fast. It's getting harder to keep up with the pace of change; by the time we get information out, there's often more and better information already out there.

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

There are many different ways to define or measure "success." Money is an important one, but it's still only one of them. Working hard at something you enjoy while trying to help others along the way brings its own quiet reward when you go to bed each night. And appreciate and hold onto those moments of beauty, small and large, in your life; they won't come around often enough or stay around long enough, so appreciate them when you've got them.

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

I just interviewed a clarinet player for a jazz magazine, and the interview began when we were swapping emails and he wrote, "It's increasingly evident that we only get so much time" so he wanted to tell his story. That stopped me in my tracks. I don't live and die by Facebook and network news like I used to. I have a hard enough time keeping up with my own life these days, and so the fewer distractions, the better for me. Trying to keep up – with the news, or with the Joneses – is a quick ticket to miserable for me.

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

Romp and walk with our Golden Retriever. A substantial nap on the sofa (both of us). Some nice Miles Davis, acoustic or electric depending on my mood, on the CD player in the kitchen while I make some BBQ or a big pot of chili. Wander in and out of the kitchen all day as friends and family arrive for a lovely dinner out in our backyard. And then off to some sort of outdoor concert in the park for the evening.

Baggage Check

There is an area in the Exhibit Hall C Lobby (near Starbucks) where you can check your belongings Monday-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:

Monday: 7:00AM–6:30PM
Tuesday: 7:00AM–6:00PM
Wednesday: 7:00AM–7:00PM
Thursday: 8:00AM–12:30PM

Wang

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what's currently important. More often than not, we get distracted by the next new thing and start working on that, resulting in delays in our current work. And it's not just science, it happens even when we have emails open while working on something else. So, I have learnt to say no to these distractions before delivering on current projects, be it science or emails.

How has DIA helped you?

DIA is a fantastic global platform to share knowledge and exchange ideas. Through this platform I have been able to access an unbelievable amount of high quality knowledge and information, and I've been fortunate to get to know an incredibly large number of highly talented colleagues and friends dedicated to address the patients' unmet medical needs; among them a huge circle of lovely volunteers around the world, serving the community in the interest of industry and patients.

Exhibitor News

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

Your phase I facility in Sydney Australia and the perfect place for your clinical study needs.

Scientia Clinical Research (SCR) is a not for profit and the only purpose-built clinical trial centre in New South Wales, Australia with extensive clinical trial expertise and state of the art facilities to perform early stage clinical trials from both first-in-human and first-in-patient studies through to proof of concept studies in healthy volunteers and patients across a wide range of therapeutic disciplines including oncology and haematology.

SCR is co-located within Prince of Wales Hospital, a tertiary teaching hospital, offering a full range of clinical specialities. Our facilities feature 30 inpatient beds with central cardiac monitoring and telemetry, 19 private consulting and outpatient rooms, an on-site pharmacy with a Grade C (EU GMP classification) manufacturing room, an on-site laboratory and a stunning view over one of our iconic beaches.

Our experienced & well-trained clinical workforce is globally recognised for high quality and timely data accepted by international regulatory bodies (e.g. FDA/EMA/PMDA/CFDA).

Australia has a fast regulatory approval scheme with no IND or equivalent required. This allows global customers to accelerate their development plans through subsequent regulatory filing in international markets including US and China. Furthermore, Australian regulations do not require Phase 1 investigational product to be manufactured in a cGMP facility.

The majority of our sponsors are multinational pharmaceutical and biotechnology companies from the US, China, Europe and South East Asia.

SCR has also access to a big population of Japanese, Chinese and Korean volunteers meeting the relevant criteria for ethno pharmacology studies.

Please visit us at our booth #807 to learn more about the services and other benefits working with us.

Get Social!

Stay connected with your colleagues from around the world and all the innovation happening in San Diego by following #DIA2019. Connect by:

- Uploading pictures to Instagram
- Live-Tweeting sessions and your experiences throughout the meeting
- Following new connections on LinkedIn
- Sharing what you've learned on Facebook

Search DrugInfoAssn to follow DIA.

Exhibitor News

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

Trial Interactive: Simplifying Site Monitoring Visits

CRAs carry the world on their shoulders. Essentially, they're the COO of study sites—ensuring everything runs smoothly, particularly as it applies to site monitoring visits and the reconciliation process. They must guarantee all documentation and data is current, compliant, and following protocols.

CRAs in the field have consistently reported two primary obstacles:

1. The effort to centralize the current state of the TMF and determine what to pursue during site monitoring visits
2. The documentation of on-site activity for TMF and CTMS records

These pains compound with complicated logistics (multiple site visits in single trips), manual and cumbersome planning processes, and time digging through site binders. E-clinical mobile technology offers relief:

- Site Monitoring Visit Prep – A CRA can easily assess the current state of the TMF at each site with a clear history of previous visits and simple views of activity between visits. Document statuses and tags make for easy sorting.
- Getting Documents into the TMF – Capture certified document images and import directly into the eTMF with a single click. No more chasing down scanners and copiers or lugging around portable scanners.
- Getting Documents to the Site – When a site is missing documents, CRAs can easily access and print the required documentation to add to the binder.
- Document Comparison and Verification – Cross-referencing and verification on spreadsheets is cumbersome. This task can be done in the palm of the CRA's hand, captured as part of the audit history, and reportable for the CTMS and future visits.
- CRA Activity – Captured automatically! No manual documentation, because CRA duties are logged by the system as performed. Plans write themselves, history is there for quick comparison, and current actions are added to the story for a real-time inspection-ready TMF.

Stop by Booth 1838 to experience mobile reconciliation. To learn more, contact us at info@trialinteractive.com.

15 Modules. 18 Years

Choose from any of Axiom Fusion eClinical Suite's 15 Modules

Headquartered in Toronto, Canada, Axiom delivers intuitive, powerful and cost-effective eClinical solutions and services focused around small to medium biotech, medical device and CROs. Services include: Data Management, Data Analytics, Biostatistics and Pharmacovigilance.

Axiom's eClinical suite, Fusion, delivers a powerful range of innovative end-user focused, unified functionality and 15 modules. Axiom serves as the Connected Hub for your entire clinical study data and operational needs. Fusion Delivers: EDC, DM, IWRS, CTMS, Inventory Management, IVR, Patient Portal, AE/SAE Tracking, Safety Database, Central Lab, Imaging, eTMF, and 24/7 Project and Clinical Data Reporting.

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

WCG Introduces a Transformational Solution for Clinical Research Sites

WCG SiteReady™ helps institutions and independent sites optimize their participation in clinical research

WIRB-Copernicus Group® (WCG™) introduces WCG SiteReady™, a first-of-its-kind solution aimed at increasing the efficiency and profitability of clinical research for institutions and independent research sites. WCG's newest offering helps researchers to optimize their performance, gain a competitive edge, and attract more opportunities for externally-funded clinical trials.

The trusted partner of 2,800 institutions, 195 academic medical centers and 140,000 global investigators, WCG develops solutions that give all members of the research ecosystem greater visibility into and control over their research. Combining proven processes and techniques with robust technologies already successfully deployed in the market, WCG SiteReady™ is a comprehensive, end-to-end solution that makes research more efficient, easier to manage, and more profitable for institutions and independent sites. WCG SiteReady™ reduces the administrative burden of regulatory compliance, streamlines contract and budget negotiation, accelerates study start-up, and increases patient enrollment in clinical trials.

"Opportunities for growth in clinical research are significant," said Jonathan Zung, PhD, WCG Executive Vice President. "Over the past two years, we helped the five largest institutions in our network to grow at annual rates exceeding 20%. Our clients achieved this growth by implementing efficiency measures while working to increase top-line revenue through new study acquisition. We have named this unique solution WCG SiteReady™."

Although the comprehensive offering is new, members of WCG's institutional and investigator site network have been using elements of the solution for several years and have achieved dramatic results, including: 20% reduction in operational cycle-times, 15% decrease in study costs, 30% improvement in ranking against peers, 40% reduction in clinical trial negotiating timelines, and 33% faster than average enrollment.

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

Monday's Innovative Theater Schedule

10:15AM

Advanced Clinical – Theater 1
Raising the Bar on Clinical Oversight to Reduce Risk and Ensure Inspection Readiness

ArisGlobal – Theater 2
Can Blockchain Technology Change Life Sciences?

12:15PM

IQVIA – Theater 1
When Context is Hard to Come By – The Emerging Value of External Comparators

Parexel – Theater 2
Transforming the Drug Development Journey Through the Patient's Eyes

1:00PM

Veeva Systems – Theater 1
Annual Industry Report: Trends, Insights, and Strategies to Improve Study Execution

WIRB-Copernicus Group – Theater 2
Getting the Most Out of Your Site Selection Strategy

1:45PM

Cognizant – Theater 1
Shared Investigator Platform: Innovating Clinical Trials Feasibility and Study Start Up

SAS – Theater 2
Smarter Clinical Trial Enrollment with Real World Data and Simulation Analytics

4:45PM

Appian – Theater 1
Accelerating the Regulatory Information Management Journey with Intelligent Automation

Deloitte Consulting – Theater 2
Reimagining Patient Safety

5:30PM

Statistics & Data Corporation – Theater 1
Artificial Intelligence and Machine Learning: Innovations in Clinical Trial Data Automation

Syneos Health – Theater 2
Dialing In the Optimal FSP Solution

Baldridge

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shrank due to a change in companies! I moved from a large global CRO to a small local organization and needed to have that global network of like-minded individuals for support and education in the safety and PV space. DIA reached out to me to help jump-start the CSP Community, and through that I've developed lasting friendships, expanded my professional network, and continue to improve on my education and understanding not only of the PV space, but of all of the other disciplines DIA supports. Being able to query someone in regulatory, quality, project management, or data management (any of them really), has been immensely helpful in my overall understanding of the complex network in drug/product development. DIA has helped me foster my passion for this industry, and I'm forever grateful for the friends and connections I've made through them. Thank you!

Exhibitor News

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

Conduct Clinical Trials in Participants' Living Rooms, Offices, U.S. National Parks, Etc.

Picture this: one of your clinical trial participants is vacationing near Denali National Park in Alaska. As they prepare in their hotel room for an adventure-filled day, there's a knock at the door. It's a PCM TRIALS nurse, ready to administer IP and collect labs for a rare disease oncology study. The nurse is a PCM TRIALS Certified Mobile Research Nurse (CMRN). The injection is done, labs are collected and the participant remained compliant.

At PCM TRIALS, we understand the struggles clients face when recruiting and retaining participants for clinical trials. Dropouts mean inefficiency, increased costs, delayed timelines and compliance issues that can jeopardize your trial.

The convenience of mobile nursing and direct-to-patient trials naturally attracts more participants, expands your trial's geographic reach and recruits more qualified participants. Whether it's at home, work, school, rehab centers or across the country, sponsors, CROs and site investigators can be confident that direct-to-patient visits are carried out with the same quality and care as on-site visits.

Because we employ our own CMRNs instead of subcontracting them, you gain more control and less risk during visits. Every PCM TRIALS nurse is trained, tested and certified as a CMRN in the principles of clinical trial research, GCP, IATA and trial-specific protocols. They understand the complex and unique requirements of mobile clinical research, and they adhere to our Standard Operating Procedures.

Our mobile nursing services are available globally. Since 2008, we've worked on 218+ protocols for 110+ sponsors and completed 22,600+ direct-to-patient visits. From the Alaskan wilderness to backstage at Broadway to a cross-country bicycle tour and beyond, PCM TRIALS is moving the needle on clinical research.

See for yourself today at Booth #1113 or contact us at info@pcmtrials.com, call +1.303.253.7470 or visit pcmtrials.com.

Exhibitor News

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

IMEDS Exploring Cross-Cutting Methods Research in Safety Studies

Program built on FDA's Sentinel network looks to move real-world data research to the next level

The Innovation in Medical Evidence Development and Surveillance (IMEDS) program at the Reagan-Udall Foundation for the FDA announces plans to increase focus on cross-cutting methods research, building on its position as the industry go-to for real-world post-market safety studies. IMEDS, a transformational public-private partnership, mobilizes data providers, drug manufacturers, researchers, and the FDA to accelerate research and answer critical patient safety and public health questions.

"Working with our industry partners has made it clear that more research is needed to improve the quality and breadth of real-world data for regulatory studies," says Dr. Carla Rodriguez-Watson, IMEDS' scientific director. "For example, there is a need to map and validate algorithms based on administrative codes for specific clinical endpoints – and to improve the accuracy of those algorithms."

Other potential focus areas for IMEDS will include better leveraging machine learning, AI and natural language processing to identify clinical endpoints, integrate patient reported outcomes, obtain insights from unstructured data, and develop new cluster detection methods to provide early detection of potential adverse events or new indications.

In engaging in this research, "IMEDS makes good on FDA's commitment to Congress and to the public to make tools and resources available to answer real-world safety questions affecting broad patient populations," says Jacqueline Corrigan-Curay, MD, JD, Director of the Office of Medical Policy, Center for Drug Evaluation and Research, FDA.

Created by a nonpartisan act of Congress, the Reagan-Udall Foundation for the FDA is an independent 501(c)3 not-for-profit organization charged with advancing regulatory science to help the FDA accomplish its mission. The Foundation works to improve America's public health through public-private partnerships that facilitate innovation, foster the use of real-world evidence and identify modern tools and policies to keep pace with today's rapidly evolving science.

Learn more about the Foundation and its work at www.reaganudall.org.

ePatch Revolutionizes Continuous ECG Data Collection in Clinical Trials

In the big data era, extended-wear Holter monitors are greatly enhancing the cardiac safety assessments in clinical trials. So, it is important to notice that not all extended-wear Holters (cardiac patch monitors) are the same. ePatch®, from BioTel Research, provides unique features that maximize patient compliance, setting it apart from all other cardiac patch devices.

Patient compliance for any skin-adhered medical device typically falters when perspiration causes the adhesive to fail, or when the patient removes the device because of skin irritation. For most cardiac devices, those situations terminate the recording.

ePatch is different. Its recording sensor is easily decoupled from its adhesive backing. If the backing has lost adhesion it is easily replaced with a fresh, adherent backing. And, if the study participant is experiencing skin irritation, unlike all other cardiac patches, the ePatch is easily converted to a small electrode format, allowing the irritated skin to breathe. In both cases, the recording session continues, successfully completing the study's data set.

BioTel Research is a highly experienced and dedicated global core lab that has completed thousands of clinical trials and provisioned tens of thousands of investigative sites worldwide. As part of the world's leading remote monitoring company, BioTelemetry, Inc. (Nasdaq: BEAT), BioTel Research combines cardiac safety testing and medical imaging for the advancement of biopharmaceutical development.

For more information about using ePatch in your next cardiac safety study, please visit gobio.com/epatch-studies, or contact us at +1.301.214.7628 or BTR-business@gobio.com. The can-do staff at BioTel Research will be happy to assist you.

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.

practical e-clinical solutions.

Built by clinical professionals, for clinical professionals.

SIMPLE: Quick implementation and user-friendly interface

COMPREHENSIVE: Full clinical research life cycle solutions and TMF services

MOBILE: Key eTMF processes at your fingertips

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