# DIA 2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

# SHOW DAILY

**Issue Three**
**June 25, 2019**

## Tuesday

**7:00AM–5:15PM**
Attendee, Speaker, and Exhibitor Registration

**9:00AM–5:00PM**
Exhibit Hall Open

**9:00am–4:00pm**
Professional Posters Open (Exhibit Hall)

**3:30–4:00pm**
Annual Meeting of the Members (DIA Booth #1531 )

## Up Close and Personal

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

- **Matthew Reaney**
- **Birka Lehman**
- **Jeff Korn**


*With images from last year's gathering as her backdrop, DIA Global Chief Executive Barbara Lopez Kunz welcomed attendees to the DIA 2019 Global Annual Meeting Opening Plenary session.*


*In his Keynote Address, Dr. Gary Gibbons, Director of the National Heart, Lung, and Blood Institute at the US National Institutes of Health, illustrated the importance of collaboration and partnerships to advancing healthcare.*


*On June 24, hundreds of research professionals, patients, and community members participated in the 5th Annual Med Hero 5K to celebrate clinical research volunteers who make new medical treatments possible. This event is produced by CISCRP and is hosted in conjunction with DIA Global Annual Meeting.*


wcg™ Together, we pioneer.
To learn how the gold standard of IRB review can transform your clinical research,
visit WIRB-Copernicus IRB Group in **booth #1105 in the exhibit hall**.

# Member Spotlight: DIA Community Chairs

## Matthew Reaney, Scientific Lead, Patient Centered Endpoints, IQVIA

**Matthew Reaney**, MSc, is a Chartered and Practitioner Health Psychologist, a Chartered Scientist, a Fellow of both the Royal Societies of Medicine and Public Health, and an Associate Fellow of the British Psychological Society. He has recently joined IQVIA as a Scientific Lead in the Patient Centered Endpoints group, focusing on understanding and measuring patient-relevant outcomes and experiences in a scientifically sound way. This includes both outcome evaluation for clinical drug development and the support of patients in routine clinical practice. Reaney is particularly interested in understanding and embracing patient heterogeneity in defining outcome measures, such as benefit-risk and patient perception and preference, and improving healthcare through the careful measurement and feedback of relevant concepts. In addition, he is an active member of the Psychosocial Aspects of Diabetes and Behavioural Research in Diabetes study groups, a co-chair of the Drug Information Association Study Endpoints Group, and a lecturer on the psychology program at Royal Holloway University of London. Prior to this, Reaney held HEOR and PCE roles in consulting and pharmaceutical companies. He is married with three very active children aged between 7 and 12. While he used to enjoy playing a variety of sports, he now spends most of his spare time annoying his children by forcing himself uninvited into their activities as a vocal supporter, coach, and taxi driver.

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

Science, technology, and patient empowerment are not moving at the same rate. I am a big believer in all three of these things, but trying to get them working together to drive towards a scientifically credible outcome that is precise, reliable, timely, complete, non-burdensome, and meaningful for patients, regulators, and payers is very, very difficult indeed. We are starting to make some progress, but we are still a long way from making the most of the empowered and technologically rich environment of routine practice.

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

I love that we have an opportunity to listen and learn every day to patients, and that we have the skills to turn what we hear into outcomes and endpoints against which we can measure the benefit of interventions. I feel great about this. I am absolutely convinced, however, that the field of outcomes research—and particularly clinical outcome assessment—needs to adapt to the current environment and make the most of the connected environment in which many people live. Unfortunately, there are few decision makers who are looking at this with sufficient rapidity to blaze a trail that straddles good science and meaningful data. This frustrates me.

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

I only read one book as a child. It was called *Stig of the Dump* and was about a caveman trying to live in the (relatively) modern era. I often find the book analogous to the healthcare systems in which I now work!

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

I know what kind of answer you should give to this question.....but I have less interest in academic or clinical discussions in my spare time. Instead I would invite Tommy Cooper – and it would not be for a discussion. I would just ask him to talk so that I could listen and laugh, and laugh, and laugh.

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

DIA has a really exciting

set of Communities touching on broad and interesting topics. I would like to see greater collaborative research conducted among these Communities, with DIA sponsoring or rewarding those who help to drive the field of drug development forward through collaboration.

## Member Spotlight: DIA Fellows

### Birka Lehmann, Senior Expert, Drug Regulatory Affairs; Lecturer, Friedrich Wilhelm University, Bonn, Germany

**Birka Lehmann, MD**, was Head of Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices (BfArM) from 2011 to 2016. Lehmann studied Medicines at the Free University Berlin and trained at the Kinderklinik Norderney. Her working experience includes nine years of preclinical assessment in the 'Pharmacology and Toxicology' division of BfArM. She also served as head of the 'Decentralised Procedure' unit (1996-2002) and as deputy head of EU Division (2000-2002). From 2002 to 2006 she joined the European Commission, Directorate-General Enterprise and Industry as expert on secondment to the 'Pharmaceuticals' unit responsible for inter alia Marketing Authorisation and implementation of the Clinical Trials Directive. From 2006 to 2011, Lehmann was head of the division 3 Marketing Authorisation procedure at BfArM. She was also a member of the Paediatric Committee at the European Medicines Agency until the end of 2015.

**When did you realize you wanted to work in regulatory affairs?**

When I started to work in a National Competent Authority (BfArM), the interaction of legal and scientific topics are challenging and very interesting.

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

To bring the different stakeholder/stakeholder interests together for the benefit of the individual patients and public health

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

The development of science in the medicinal arena and the development of new medicinal products have to be in line with legal requirements with respect to the protection of public health. It is always a challenge to bring new treatment options to the patient in a safe and timely manner.

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

The mission of all competent authorities in the EU is to foster scientific excellence in the evaluation and

*Continued on page 6*

# Member Spotlight: DIA Staff

## Jeff Korn, Exhibits Manager, DIA Americas

**Jeff Korn** is the Exhibits Manager for the Americas at DIA. He has been at DIA since 2001, supporting the exhibits programs both regionally and in the Americas for most of his tenure, with a focus mainly on the exhibits at the Global Annual Meeting.

**When did you realize you wanted to be an exhibits manager?**

This was something that I honestly fell into when the previous manager retired. I had been working under her leadership for about ten years, and much of her responsibilities fell to me when she retired, and I've just sort of kept things rolling along since then.

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

Without question, it's juggling the many areas I'm responsible for, specifically in relation to the *DIA Global Annual Meeting*, from the onsite registrations system and the mobile app to managing the exhibit program, and a lot of other duties.

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

Make sure to keep a healthy balance between work and time for family, church, and hobbies, and don't let fear of the unknown keep you from making a change if you know there's a change you need to make.

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

It is my nature to want to help people, so I can't say that I have become better at saying no, but I am trying to work on it by talking through potential opportunities or situations with my partner and wise friends.

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

I would spend the day with my partner in my studio weaving, taking time to walk in nature, enjoying a nice dinner at a local establishment, and then settling in on the couch for a movie (and some knitting or spinning) before bed.

## Lehmann

*Continued from page 4*

supervision of medicines, for the benefit of public health. Setting standards and the development of guidelines, not only for the European Union, is a great challenge. More and early cooperation with external parties, in particular with patient representatives and healthcare professionals, is key – as is informing the public on the safety of medicines.

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

Be open, have no reservations. Also, it's a great challenge to work with patient communities in the interface between law and science, rather than working with patients directly.

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

Reading and communicating face-to-face with friends.

**How has DIA helped you?**

DIA has helped me understand the whole system of drug regulatory affairs—bringing science to benefit patients.

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

Giving me an opportunity to be involved in future, new issues.

# Tuesday's Innovative Theater Schedule

**9:45AM**

**DiagnoSearch Life Sciences – Theater 1**
Disruptive Innovation: 'Wide-Angle-Data' – Fully Integrated Platform with Advanced Analytics and Customized Algorithms for Real-Time Safety and Risk Management

**Covance – Theater 2**
Fixing the Patient Recruitment "Leaky Funnel"

**11:40AM**

**Veeva Systems – Theater 1**
Shortening Database Builds by 40-60%

**ArisGlobal – Theater 2**
Getting More Value From Your Data Through a Unified Regulatory Platform

**12:40PM**

**AMPLEXOR – Theater 1**
The Great Regulatory Catch-Up: Lessons from Big Pharma as Medical Device Manufacturers Succumb to New Reporting Rigor

**Bioclinica – Theater 2**
When EDC Is Not Enough: Automating Multi-Country Data Collection and Complex Workflows

**1:40PM**

**UBC – Theater 1**
Standardizing and Enhancing Registry Data to Improve Evidence Generation

**IBM Watson Health – Theater 2**
Real World Insights and Collaboration in Protocol Development

**3:30PM**

**PPD – Theater 1**
Have You Considered Market Access in Your Trial Design?

**Parexel and Microsoft – Theater 2**
Change the Way You Work: Transforming Regulatory Processes with Parexel and Microsoft

# Exhibitor List

*DIA Show Daily* advertisers listed in bold.

## Exhibit Hall Hours

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

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

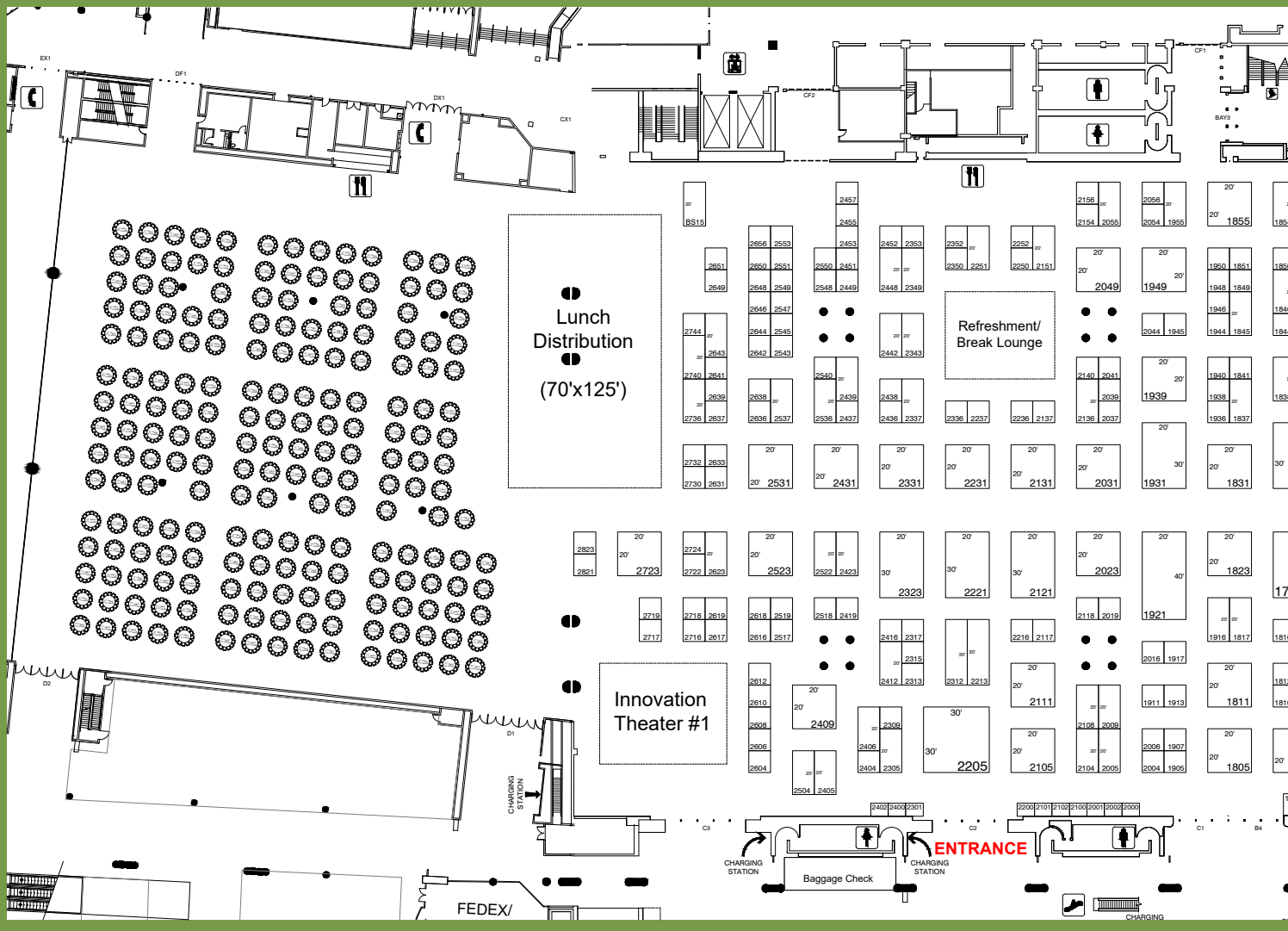
**# – C**



**D – F**



*Continued on page 8*



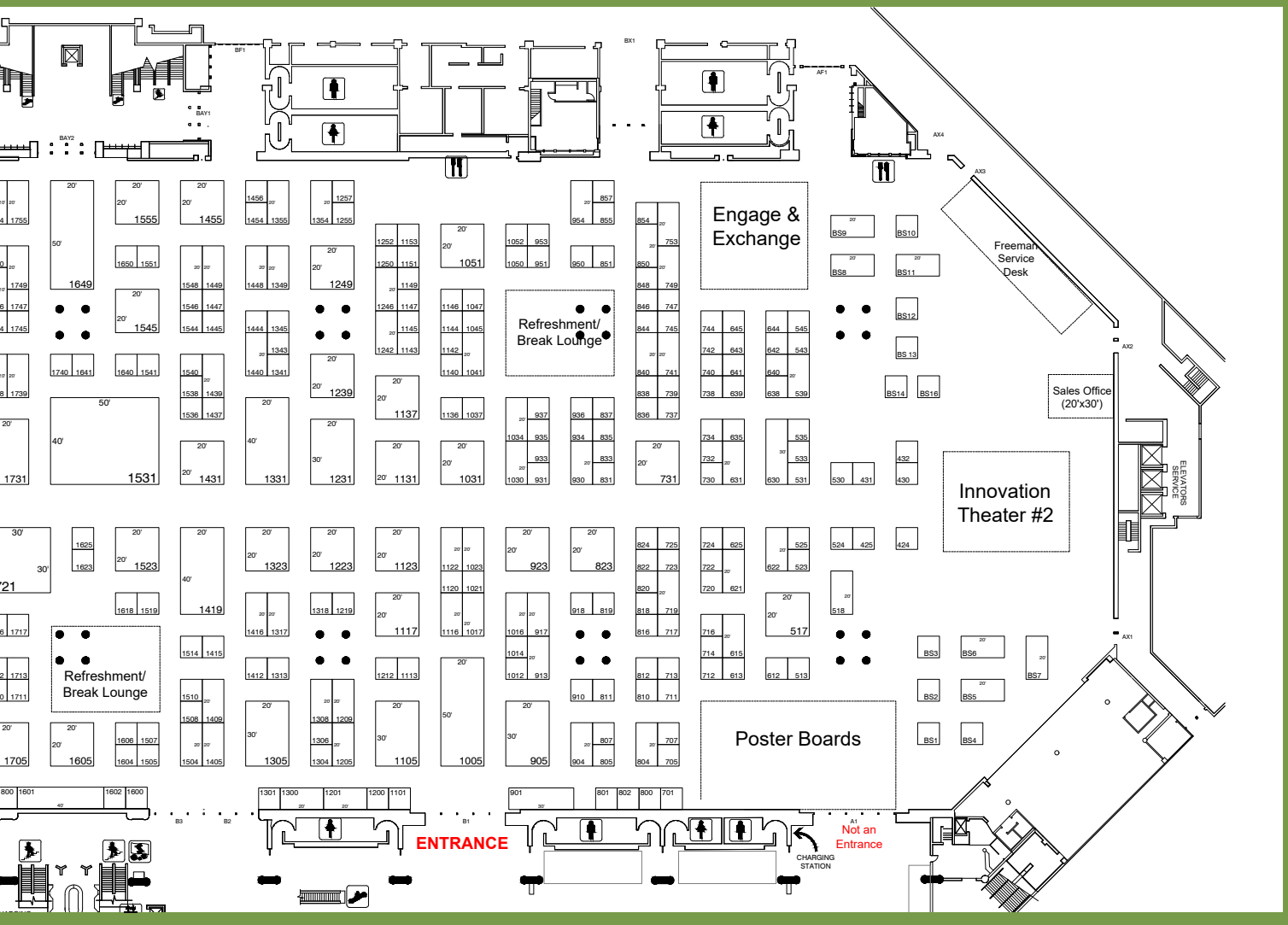

## Exhibitor List

*Continued from page 7*

EXTEDO, Inc. ..... 2041
**FDA ..... 1536**
FDA Quality and Regulatory Consultants, LLC ..... 1101
Firma Clinical ..... 1949
Flex Databases ..... 1037
FMD K&L ..... 724
FOCUS Investment Banking ..... 2606
Food & Drug Administration ..... 800
Frontage Laboratories, Inc. ..... 1437

**G – I**

G&L Scientific Inc ..... 1519
GCE Solutions Inc ..... 1625
Generis Knowledge Management Inc 741
Genetron Health ..... 2650
German Langauge Services ..... 523
Gilead Sciences, Inc. ..... 639
Global Instrumentation LLC ..... 720
GlobalCare Clinical Trials, LLC ..... 2436
Govig & Associates ..... 2656
Grant Thornton LLP ..... 1415
Greenphire ..... 2111
GXP Quality Systems, LLC ..... 846
GxPeople ..... 1200
Hangzhou Tigermed Consulting Co., Ltd. ..... 1405
HCL Technologies ..... 1455
HealthiVibe, LLC ..... 935
Huron Consulting Group ..... 1308
hyperCORE International ..... 2722
IBM Watson Health ..... 1123
ICON Clinical Research ..... 2121
Ideagen Plc. ..... 1544
Imperial ..... 1812
Indegene Inc. ..... 2651
Industry Standard Research ..... 1546
Inference Inc. ..... 723
Informa - Pharma Intelligence ..... 1034
Infuserve America ..... 2453
Innomar Strategies Inc. ..... 738
Innoplexus Holdings, Inc. ..... 2000
Innovaderm Research Inc. ..... 1343
InnovoCommerce ..... 2353
Insife ..... 2724
Insmed Incorporated ..... 835
Integrated Clinical Systems, Inc. ..... 1749
IntegReview IRB ..... 1917
Integron ..... 2406
International Dermatology Research Inc 831
International Drug Development Institute (IDDI) ..... 1151
InterSystems Corporation ..... 1354
inviCRO ..... 2536
Iperion Life Sciences Cloud ..... 819
IPHARMA / ChemDiv ..... 2637




IQVIA.....2205

**J – L**

JAF Consulting, Inc. .....950
Janus Clinical Research Institute....1747
Jazz Pharmaceuticals, Inc.....1257
Jeevan Scientific Technology Limited...1600
Joulé.....2117
K3-Innovations, Inc. .....953
Karma Oncology .....2550
Kayentis .....2612
Kinapse Ltd.....2719
Kinesys Consulting Ltd. .....1551
Klein Hersh International.....1944
KlinEra Global Services.....2718
Korea National Enterprise for Clinical Trials.....1540
LabConnect, LLC.....823
Leidos Life Sciences.....716
Lifelines Neuro Company.....1047
LifeScience Marketplace.....2100
LINEA System, LLC.....802
Lionbridge Life Sciences.....522
Litera Microsystems .....2309
LORENZ Life Sciences Group.....1439
LSK Global Pharma Services Co., Ltd.....2449
Luto Research Ltd.....2540

**M – O**

Machaon Diagnostics .....732
MakroCare.....1911 & 1913
Mareana Inc. .....818
Marken, Ltd.....1601
MarkLogic .....1800
Masimo.....1146
MasterControl, Inc.....731
Mayo Clinic .....2250
MD Connect.....717
Mebomine .....640
Medable .....2331
MedDRA MSSO .....1623
Medical Vigilance Solutions .....2740
Medicines Evaluation Unit .....2547
Medidata Solutions Worldwide.....1523
MEDIX.....1306
Mednet .....1031
Medpace .....BS6
MedPoint Digital, Inc.....2405
Medrio, Inc. .....2004
Mendel.ai .....801
MESM Ltd. .....2315
Metina PharmConsulting Pvt. Ltd....820
Ministry of Food and Drug Safety 1640
MonitorForHire.com .....2137
Montrium, Inc.....2349
Muv Inc.....1950
MyData-TRUST .....635
NACS, Inc. .....1618
National Disease Research Interchange...712
National Jewish Health .....1147

*Continued on page 10*

## Exhibitor List

*Continued from page 9*



*– As of 6/23/19*

# Tuesday'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.

**T-01: Use of Adverse Event Data to Develop an Artificial Intelligence Application for Assessing Seriousness**
Bruno Assuncao: Associate Director, Pharmacovigilance Innovation, Celgene
*Oral Presentation 12:00PM*

**T-02: Using Innovative Automation to Author Development Safety Update Reports and Enhance Cost-Effectiveness**
Nipa Parikh: Senior Director, PV Operations, Global Head Aggregate Reports/RMPs, Otsuka Pharmaceutical Development and Commercialization Inc.
*Oral Presentation 12:10PM*

**T-03: Development of an AI Approach for Identifying Adverse Events**
Danielle Abatemarco: PV Innovation Senior Specialist, Celgene

**T-04: Effect of Drug Safety Communications on Adverse Event Reporting in Multiple Sclerosis DMTs using the FAERS Database 2000-2017**
Hunter Davis: Medical Affairs/Medical Science Liaison Fellow, Genentech; Ernest Mario School of Pharmacy, Rutgers University

**T-06: Febuxostat Versus Allopurinol in Patients with Gout: A Real World Comparison**
Manfred Stapff: CMO, Trinetx

**T-07: FDA Developed Tool for Adverse Event Data Signal Detection in Clinical Safety Analysis**
Xin (Joy) Li: Mathematic Statistician, Office of Translational Science, CDER

**T-09: Structure and Target Based Statistical Tools for Safety Analysis**
Samir Lababidi: Statistician, FDA

**T-10: A Seamless Phase 2/3 Adaptive Design for Clinical Trials with a Continuous Endpoint in Asia**
Lien-Cheng Chang: Section Chief, Division of Medicinal Products, TFDA
*Oral Presentation 12:20PM*

**T-11: Subject Training is Needed For Key Terminology in Gastrointestinal Clinical Trials**
Elisa Conrad: Clinical Science Advisor, ERT
*Oral Presentation 12:30PM*

**T-12: Design and Analysis of Biosimilarity Based on Interval Estimations**
Chin-Fu Hsiao: Investigator, National Health Research Institutes, Chinese Taipei

**T-13: Academia's Challenges for Implementing an Investigator-initiated Clinical Trial Aimed at Developing A New Biological Drug**
Tetsuya Kusakabe: Professor, Osaka City University, Graduate School of Medicine

**T-14: Quality Management Using Six Sigma Tools For Clinical Research Sites**
Toshiko Ishibashi: Clinical Operation I, JAPAN, Clinical Operation Ono Pharmaceutical Co., Ltd.

**T-15: Natural History Studies: An Assessment of Current Trends in Design and Disease Research**
Juliane Mills: Director Scientific Affairs, Real World Solutions, PRA Health Sciences

**T-16: Generating Synthetic Control Patients Using Machine Learning for Alzheimer's Disease Clinical Trials**
Yannick Pouliot: Senior Computational Biologist, Unlearn.AI

**T-17: Streamlining Clinical Trials and Patient Experience Using Blockchain and Data Science Technologies**
Mohit Juneja: Co-Founder, Lyfescience

**T-18: Effectiveness of Patient Portals in Clinical Trial Recruitment**
Lauren Holmes: Global Trial Manager, Ernest Mario School of Pharmacy, Rutgers University

**T-19: Metadata Framework for Sharing and Developing Code Repository for Standard Analyses**
Hanming Tu: Vice President, IT Frontage Laboratories, Inc.

**T-20: Understanding Heterogeneity in Rheumatoid Arthritis Disease Progression by Using Word Embedding: An Electronic Health Record**
Ye Jin Eun: Senior Data Scientist, Janssen

**T-21: Characteristics of Expanded Access Programs Inclusive of Children in the United States**
Jit Sheth: Postdoctoral Medical Affairs Fellow, Alnylam Pharmaceuticals and Northeastern University
*Oral Presentation 12:40PM*

**T-22: Writing a Platform Master Protocol Using the Common Protocol Template**
Anthony Davidson: Scientific Writing Senior Associate, Eli Lilly and Company

**T-23: Adherence to Standardized INCI Labeling Practices in Twenty One Natural or Organic Global Consumer Baby Products**
Christopher Varghese: Post-Doctoral Fellow, Global Scientific Engagement, Johnson & Johnson, Rutgers University

**T-24: Should I Stay or Should I go? A Comparison of Primary and Secondary Research on Clinical Trial Retention**
Christina Cantrell: Senior Patient Insights Leader, Genentech, A Member of the Roche Group

**T-25: ClinLine.ru: The New Integrated Infomedia Russian Platform for all Parties Involved in Clinical Trials**
Oksana Karavaeva: ClinOps Director, IPHARMA LLC

**T-26: Demystifying the Patient's Experience: Use of Patient Journey Studies to Gather Valuable Qualitative Insight into the Patient**
Caroline Seo: Senior Analyst, Patient-Centered Outcomes, Pharmerit International

**T-27: Measuring the Patient Experience: Learnings from Real World Implementation to Improve Data Collection and Patient Engagement**
Renee Willmon: Manager, Behaviour Science, Self Care Catalysts

**T-28: The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety**
Andre Ghetti: Chief Executive Officer, AnaBios

**T-29: Python Optimization Tools for Remote Server Work**
Masaki Mihaila: Senior Programming Lead, Pfizer

*Continued on page 12*

# Tuesday's Professional Poster Session

*Continued from page 11*

**T-30: An FDA Analysis of Inspected Entities After Receiving Official Action Indicated Letters for GCP Violations**
Miah Jung: Pharmacologist, FDA
*Oral Presentation 12:50PM*

**T-31: Characterizing the Clinical Impact of Immunogenicity in Prescription Drug Labeling**
Daphne Guinn: ORISE Post-Doctoral Fellow, FDA
*Oral Presentation 1:00PM*

**T-32: Baseline Adjustment in Concentration-QTc Modeling: Impact on Assay Sensitivity**
Dalong Huang: Mathematical Statistician, CDER

**T-33: Compliance with FDA's Postmarketing Adverse Drug Experience Laws and Regulations**
Namita Kothary: Consumer Safety Officer, FDA

**T-34: Otsuka's Experience on eSubmission of Promotional Labeling and Advertising Materials via the eCTD FDA Gateway**
Joanne Hathaway: Manager, Global Regulatory Affairs, Promotion Compliance, Otsuka Pharmaceutical Commercialization & Development

**T-35: Considerations in Using Biomarkers as Efficacy Endpoints: The Review of Clinical Trials of Orphan Drugs Approved in Japan**
Tomoko Minamiguchi: Reviewer, Pharmaceuticals and Medical Devices Agency

**T-36: The South African Regulatory Environment: Challenges and Opportunities for a Reformed Regulatory Review Process**
Andrea Keyter: Deputy Director, Medical Devices, South African Health Products Regulatory Authority

**T-37: Regulatory Review Reliance Models: What are the Barriers and Enablers to the Successful use of These Models for Medicines?**
Neil McAuslane: Director, Centre For Innovation In Regulatory Science

**T-38: Agencies Strategies to Enhance the Review Efficiency of IND for Human Cell Therapy Products in Taiwan**
Meng Ting Tsai: Project Manager, Center For Drug Evaluation

**T-39: Use of Social Media in Clinical Trials: A Survey of IRB Chairs**
Susan Pusek: Director, Education Programs (Clinical/Translational Research), University of North Carolina Chapel Hill
*Oral Presentation 1:10PM*

**T-40: Comprehensive QOS and Established Conditions: Creating a Path for Flexible Regulatory Approaches to Post Approval CMC Changes**
Connie Langer: Regulatory Scientist, Pfizer Inc.

**T-41: Using Causal Inference Modelling to Predict Unbiased Treatment Response for Managed Care Organizations and Drug Manufacturers**
Denise Meade: Director, Product Management, IBM Watson Health
*Oral Presentation 1:20PM*

**T-42: Sample Size Re-Estimation in Action: Design Consideration, Charter Development, and Implementation of Analyses in a Trial with Adaptive Components**
Adam Hamm: Director, Biostatistics, Cytel

**T-43: Combining Tabular Data with Visual Display to Enhance Interpretation of Clinical Trial Data**
Teresa Curto: Associate Director, Biostatistics, Cytel

**T-44: A Real World Budget Impact Analysis of Apremilast or Biologic Treatment in Biologic-Naive Patients With Psoriasis**
Brian Ung: Manager, US Health Economics & Outcomes Research, Celgene Corporate
*Oral Presentation 1:30PM*

**T-45: A Decision Analytic Benefit-Risk Assessment Framework to Support Portfolio Prioritization Decisions**
George Quartey: Scientific Enablement Leader, Genentech, A Member of the Roche Group

**T-46: An Analysis of Healthcare Plan CAR T Cell Coverage Criteria for Medicaid Beneficiaries**
Landon Shupe: Post-Doctoral Fellow, Ernest Mario School of Pharmacy, Rutgers University

**T-47: Assessment of the Quality of Pharmacoeconomic Reports in Taiwan**
Shu-Mei Hsu: HTA Researcher TFDA/Center for Drug Evaluation

# Exhibitor News

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

## Truly Unified. Everything in one place. Single sign-on.

Enterprise software for small to mid-size. Focus on your study, not the technology.

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/.

# Exhibitor News

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

## 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, Bio-Telemetry, 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 BTRbusiness@gobio.com. The can-do staff at BioTel Research will be happy to assist you.

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

Should companies operating in the IO space look to other targets? Or, might there still be valuable opportunities discoverable through analysis of publically available drug pipeline and clinical trial data?

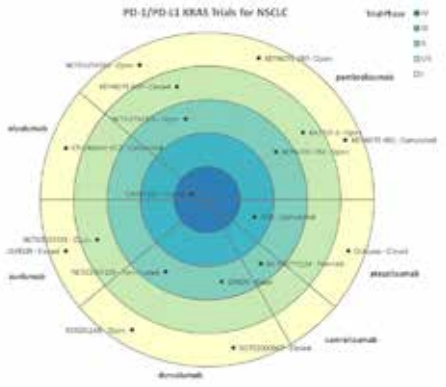
Earlier this year, analysts at BizInt Solutions and Citeline (Informa Pharma Intelligence) undertook a case study to investigate if using analysis and visualization tools to leverage drug pipeline and clinical trial data could help identify gaps in a crowded target area (PD-1/PD-L1.)

Searches were run on the Citeline Trialtrove® and Pharmaprojects® databases for all drugs and all industry-sponsored clinical trials for PD-1 or PD-L1 inhibitors. The results were visualized and analyzed using BizInt Smart Charts software tools to map areas of intensive trial activity and identify potential options for differentiation.

The results of this case study are being presented in a poster on Wednesday, "Identifying Gaps in Competitive Intelligence and Business Development Strategy: New Opportunities in the PD-1/PD-L1 Development Landscape" (W-27.)

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. BizInt Smart Charts Drug Development Suite software provides tools to integrate and create reports from leading drug pipeline, clinical trial, and biomedical literature databases. With VantagePoint-Smart Charts Edition, analysts can quickly create targeted visualizations -- including bullseyes, timelines, and bubble charts.

Citeline is the industry's most comprehensive, reliable and current global R&D intelligence suite of solutions. Pharmaprojects offers end-to-end tracking of the global pharma R&D pipeline, including company development trends, global development status, and therapeutic class status. Trialtrove provides a comprehensive, accurate and up-to-date source of pharmaceutical clinical trials data, supported by experienced industry analysts.



Come visit us in booth 937 (BizInt Smart Charts) and neighboring booth 1034 (Informa Pharma Intelligence) to learn more!

# 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.

# Casting Call for TransPerfect's Study Stakeholder Collaboration Workshop

M. Christine Morris, Executive Director, TransPerfect Life Sciences Solutions, will be holding auditions for her upcoming DIA Workshop "Setting the Stage for Effective Stakeholder Collaboration." The performance will be on Wednesday, June 26, from 4:15 PM to 5:30 PM at the San Diego Convention Center. We have 3–4 short scenes, and a variety of roles and participation opportunities are available.

The performances will consist of staged readings of clinical meeting planning scenarios, and scripts will be provided. All attendees will collaboratively build empathy maps for the play's protagonists/antagonists and be provided with real tools to bring back to their personal and professional lives. Memorization and staging will not be required for the performance. Hopeful casts of all ages are encouraged to attend.

Background:

"Last year, I had the honor of chairing my first DIA Workshop, in conjunction with my colleagues from the Cary Playwrights' Forum, where I sit on the board of directors. Inspired by my interactions with this collaborative community, it dawned on me that our personal endeavors may be useful in examining collaboration in a different context—improving clinical research stakeholder collaboration." – M. Christine Morris

Questions? Please contact M. Christine Morris at mmorris@transperfect.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.

## WCG Clinical Services Division Partners with Inspire to Improve Patient Recruitment in Clinical Trials

WIRB-Copernicus Group®'s (WCG™) Clinical Services Division has partnered with Inspire, the largest online community of patients and caregivers, to make clinical research more accessible to all patients, especially those suffering from rare and genetic-based diseases.

Together, using permission-based and opt-in approaches, WCG and Inspire will connect patients with clinical trial opportunities based on their areas of interest and self-identified disease states, giving those patients greater access to cutting-edge treatments and potentially life-saving therapies.

Inspire is a moderated online health social network, which is comprised of 225 individual communities, more than half of which are partnered with trusted US-based nonprofit patient advocacy organizations. Today, Inspire's total membership is 1.5 million members, and Inspire has more than 10 million active annual users.

A source of both practical advice and emotional support, the platform is particularly useful to patients with rare diseases, and their caregivers, who often struggle to attain an accurate diagnosis or to identify clinicians with specific knowledge of their disease. Inspire also helps biopharmaceutical research sponsors who are interested in making their clinical development programs more patient-centric by effectively and directly engaging and recruiting hard-to-find patients into clinical research, and in better understanding and serving the needs of patients.

"Patients are the heart of clinical research," said Brian Loew, co-founder and CEO of Inspire. "At Inspire, we are committed to advancing medical progress by actively engaging patients who possess an authentic desire to improve the quality of human health. We are proud to partner with WCG to expand our global network and to deliver even greater value to our existing clients and members."

WCG is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. By connecting the members of the clinical research ecosystem and optimizing their interaction, WCG decreases the length, cost and administrative burden of clinical trials. Inspire is the latest addition to WCG's fully-integrated, best-of-breed patient engagement solution, which includes the CenterWatch Clinical Trial Listing Service, ThreeWire Patient Enrollment and Retention Services, Patient iConnect Global Patient Recruitment Platform, and the Virgil Electronic Clinical Outcome Assessment (eCOA) and Patient Reported Outcomes (ePRO) Applications.

To learn more, visit WCG and Inspire in the Exhibit Hall, booth #1005.

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