CELEBRATE
THE PAST–

INVENT
THE FUTURE

DIA 2014 50TH ANNUAL MEETING

FINAL PROGRAM

June 15-19
San Diego Convention Center
San Diego, CA
diahome.org/DIA2014

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WELCOME TO SAN DIEGO

MESSAGE FROM DIA'S GLOBAL CHIEF EXECUTIVE

Dear Colleagues,

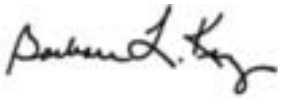
The traditional gift to celebrate a fiftieth anniversary is something made of gold. It is my pleasure to welcome to you the golden sunshine of San Diego and thank you for joining us to celebrate our DIA 2014 50th Annual Meeting. As we come together to address significant challenges in human health and reflect on our collective accomplishments over the past 50 years, the theme of this year's meeting could not be more appropriate. We welcome you to *DIA 2014 50th Annual Meeting to Celebrate the Past – Invent the Future*.

This Annual Meeting brings together catalysts and leaders from all parts of the health ecosystem. For example, keynote speaker Jamie Heywood, PatientsLikeMe Co-Founder and Chairman, has helped lead the way in understanding patients' therapeutic needs and in employing technology and entrepreneurship to meet them. Our educational offerings are organized into tracks and led by experts who will not only explore evergreen interest areas such as clinical operations and regulatory affairs, but more recent developments such as regenerative medicine, global health outcomes and economics, and therapies for rare/orphan diseases.

This Annual Meeting marks an important milestone in our efforts to foster innovation by providing forums for industry, regulators, patients, and other stakeholders to exchange information and discuss health products, technologies, services, and related issues. This exchange of information and perspectives is encapsulated in the first-ever selection of two DIA Annual Meeting Co-Chairs who are established leaders in their respective domains. I invite you to read their biographies on the right to learn more about our distinguished Co-Chairs.

On behalf of the DIA Board of Directors and all of our Annual Meeting program volunteers, exhibitors and poster presenters, patient advocates and students, thank you very much for attending our celebratory *DIA 2014 50th Annual Meeting*.

Sincerely Yours,



Barbara L. Kunz
DIA Global Chief Executive

PROGRAM CO-CHAIRS

Freda C. Lewis-Hall, MD, FAPA

Chief Medical Officer and
Executive Vice President
Pfizer Inc

As Pfizer's Chief Medical Officer, Freda Lewis-Hall leads Pfizer Medical, the division devoted to the safe, effective, and appropriate use of every Pfizer product, from its first use in a clinical trial until its last use anywhere in the world. In September 2010, Dr. Lewis-Hall was appointed by the Obama Administration to the inaugural Board of Governors for the Patient-Centered Outcomes Research Institute, which is charged with prioritizing and directing a range of research programs to improve the nation's quality of health care. She also serves on the boards of The Institute of Medicine's Forum on Drug Discovery, Development, and Translation; The Foundation for the National Institutes of Health; The Harvard Medical School Board of Fellows; the Society for Women's Health Research; and the American Heart Association's "Power to End Stroke" initiative. She is a Fellow of the New York Academy of Medicine and the American Psychiatric Association. Dr. Lewis-Hall was chosen as 2011 "Woman of the Year" by the Healthcare Business Women's Association. She has been named as one of the nation's 75 Most Powerful Women in Business by Black Enterprise magazine and among the 25 Most Influential African-Americans in health care by Black Health magazine.

Rear Adm. (ret)
Sandra L. Kweder, MD, FACP

Deputy Director, Office of New Drugs
CDER, FDA

Sandra L. Kweder graduated from the University of Connecticut in 1979 and attended the University of North Carolina's School of Public Health in Chapel Hill. She was commissioned in the U.S. Public Health Service in 1980 upon entering the Uniformed Services University of Health Sciences (USUHS) and retired her uniform in 2013. Following internal medicine training at Walter Reed Army Medical Center she joined the U.S. Food & Drug Administration (FDA) as a medical reviewer in the Division of Antiviral Drugs early in her career to address the growing field of HIV drug development. She has since held a number of positions, including leadership of the Division of Postmarketing Surveillance & Epidemiology and the Office of Antimicrobial Products and spent two years on sabbatical at Brown University as a clinical fellow in Obstetric and Consultative Medicine. She has been Deputy Director, Office of New Drugs (OND) in FDA's Center for Drug Evaluation & Research (CDER) since 2002.

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SCHEDULE AT-A-GLANCE

As of 3/20/14. Schedule subject to change.

SATURDAY JUNE 14

Registration Hours:

9:00AM-5:00PM Exhibitor Registration

SUNDAY, JUNE 15

Registration Hours:

8:00-9:00AM Registration for Full Day, Morning Preconference Tutorials*
8:00AM-6:00PM Exhibitor Registration
12:30-1:00PM Registration for Afternoon Preconference Tutorials*
3:00-6:00PM Attendee and Speaker Registration

Schedule:

8:30AM-12:00PM Half Day Preconference Tutorials*
9:00AM-5:00PM Full Day Preconference Tutorials*
1:00-4:30PM Half Day Afternoon Preconference Tutorials*
4:00-5:00PM DIA 2014 50th Annual Meeting Orientation and Networking

**Space is limited for Preconference Tutorials, therefore preregistration is strongly recommended. Availability for onsite registration is not guaranteed.*

MONDAY, JUNE 16

Registration Hours:

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

Schedule:

7:30-8:20AM DIA 2014 50th Annual Meeting Orientation/Networking and Coffee
7:45-8:30AM Coffee and Breakfast Breads
7:45AM–2:30PM Student Poster Session (Sails Pavilion Lobby)
8:30-10:00AM Educational Opportunities
90-minute Offerings (8:30-10:00AM)
8:30-10:00AM Student Forum
9:30AM-6:00PM Exhibit Hall Open
10:00-11:00AM Coffee Break
11:00AM-12:30PM Educational Opportunities
90-minute Offerings (11:00AM-12:30PM)
12:30-2:30PM Lunch & Exhibit Hall Innovation Theater Presentations
2:30-4:00PM Plenary Session & Keynote Address
4:00-6:00PM Opening Reception and DIA's 50th Anniversary Celebration
4:30PM Student Poster Award Ceremony (DIA Booth #1531)

TUESDAY, JUNE 17

Registration Hours:

7:00AM-5:00PM Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15-8:00AM Coffee and Breakfast Breads
7:15AM-4:00PM Professional Poster Session #1 (Sails Pavilion)
8:00-9:30AM Educational Opportunities:
60-minute TURBO Offerings (8:00-9:00AM)
90-minute Offerings (8:00-9:30AM)
9:00AM-5:00PM Exhibit Hall Open
9:30-10:30AM Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30AM-12:00PM Educational Opportunities
60-minute TURBO Offerings (10:30-11:30AM)
90-minute Offerings (10:30AM-12:00PM)
11:30AM-1:30PM Lunch & Exhibit Hall Innovation Theater Presentations
1:30-3:00PM Educational Opportunities
60-minute TURBO Offerings (1:30-2:30PM)
90-minute Offerings (1:30-3:00PM)
1:30-3:30PM Exhibit Guest Passes
2:30-3:30PM Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30-5:00PM Educational Opportunities
60-minute TURBO Offerings (3:30-4:30PM)
90-minute Offerings (3:30-5:00PM)

WEDNESDAY, JUNE 18

Registration Hours:

7:00AM-5:00PM Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15-8:00AM Coffee and Breakfast Breads
7:15AM-4:00PM Professional Poster Session #2 (Sails Pavilion)
8:00-9:30AM Educational Opportunities
60-minute TURBO Offerings (8:00-9:00AM)
90-minute Offerings (8:00-9:30AM)
9:00AM-4:00PM Exhibit Hall Open
9:30-10:30AM Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30AM-12:00PM Educational Opportunities
60-minute TURBO Offerings (10:30-11:30AM)
90-minute Offerings (10:30AM-12:00PM)
11:30AM-1:30PM Lunch & Exhibit Hall Innovation Theater Presentations
1:30-3:00PM Educational Opportunities
60-minute TURBO Offerings (1:30-2:30PM)
90-minute Offerings (1:30-3:00PM)
1:30-3:30PM Exhibit Guest Passes
2:30-3:30PM Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30-5:00PM Educational Opportunities
60-minute TURBO Offerings (3:30-4:30PM)
90-minute Offerings (3:30-5:00PM)

THURSDAY, JUNE 19

Registration Hours:

8:00-11:00AM Attendee and Speaker Registration

Schedule:

8:15-9:00AM Coffee and Breakfast Breads
9:00-10:30AM Educational Opportunities
60-minute TURBO Offerings (9:00-10:00AM)
90-minute Offerings (9:00-10:30AM)
10:30-10:45AM Coffee Break
10:45AM-12:15PM Educational Opportunities
90-minute Offerings (10:45AM-12:15PM)

MONDAY, JUNE 16 HIGHLIGHTS

Opening Reception and DIA's 50th Anniversary Celebration
Exhibit Hall
4:00-6:00PM

OPENING PLENARY SESSION
2:30PM | BALLROOM 20

Keynote Speaker: Jamie Heywood
Co-Founder and Chairman, PatientsLikeMe
Founding Director, ALS Therapy Development Institute (ALS TDI)

"Celebrate the Past - Invent the Future: that future where patients will be partners in a new way with industry and health care, where they meet them as equals."

Jamie Heywood is one of the foremost practitioners using technology to transform the future of health care. He is the founder of PatientsLikeMe, an innovative web community, that allows patients to pool their experiences of disease and treatment. He also founded ALS TDI, the world's first nonprofit biotechnology company, following his brother Stephen's diagnosis of ALS (Lou Gehrig's disease) in 1998.

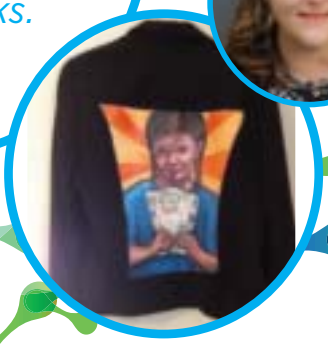
Since then, ALS TDI has broken new ground on many fronts and has become recognized as one of the most promising and innovative research organizations. Its achievements include an industrialized therapeutic validation process and one of the world's leading ALS drug discovery programs. It was the first organization to run an open research program, posting the results of its studies in real time.

Jamie is a leader in engaging patients, understanding their needs, and in applying entrepreneurial smarts and drive to improving the treatment and delivery available to them. He is a passionate believer in transparency and collaboration.

Jamie's work has been the subject of *His Brother's Keeper*, a book by Pulitzer Prize-winning author Jonathan Weiner, and *So Much So Fast*, a Sundance award-winning documentary. He has also been profiled in *The New Yorker* and *60 Minutes*.

THE WALKING GALLERY | 4:00-6:00PM

We are the Gallery that walks. We are the Patients that wear our stories on our backs.



Join us during the Opening Reception and DIA's 50th Anniversary Celebration as we host a gathering of The Walking Gallery, a patient empowerment movement founded by Artist Regina Holliday. Walking Gallery Members will be onsite in the Exhibit Hall.

Meet Regina Holliday, artist and creator of The Walking Gallery at the DIA Booth #1531.

#225 & #252 The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances, and Precision Medicine (Part 1 and Part 2) Tuesday | 8:00-9:30am & 10:30am-12:00pm

Ellen G. Feigal, MD, MSc
Senior Vice President
Research and Development
California Institute for
Regenerative Medicine (CIRM)

Kenneth A. Getz, MBA
Director of Sponsored Research
Tufts Center for the Study of
Drug Development
Chairman, CISCRP

Annalisa Jenkins, MBBS, MRCP
Former Executive Vice
President, Head of Global
Research and Development
Merck Serono

Kenneth I. Kaitin, PhD
Professor and Director
Center for the Study of Drug
Development, Tufts University
School of Medicine

David G. Shoemaker, PhD
Senior Vice President
Research and Development
Rho Inc.

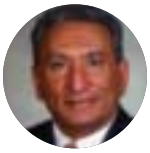
Peter Tippett, MD, PhD
Chief Medical Officer and
Vice President
Verizon Enterprise Solutions

Bruce M. Wagman, MBA, RN, RAC
Regulatory Affairs and
Quality Assurance
Prometheus, Inc.

Scott Whitcup
Executive Vice President
Research and Development
Allergan Corporation

#259 Collaborating to Streamline Drug Development: Case Studies of What Works (and What Doesn't)

Tuesday | 1:30-3:00pm



Dalvir Gill, PhD
Chief Executive Officer
TransCelerate Biopharma Inc.

Ann Meeker-O'Connell, MS
Senior Director, QA Clinical
Strategy Team Lead
Janssen Pharmaceuticals, Inc.

Douglas J. Peddicord, PhD
Executive Director
Association of Clinical
Research Organizations

Christine K. Pierre, RN
President
Society for Clinical Research Sites

Pamela Tenaerts, MD, MBA
Executive Director
Clinical Trials Transformation
Initiative (CTTI)
Duke Translational Medicine Institute

#350 The Patient Point-of-View: An Unrehearsed but Revealing Conversation to Rectify Patient Enrollment

Wednesday | 10:30am-12:00pm

Christopher J. Hoyle, MBA
Executive Director
Elite Research Network

Christine Pierre, RN
President
Society for Clinical Research Sites

T.J. Sharpe
Cancer Blog Author
www.philly.com

Win a $100 VISA Gift Card!

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Snap an Annual Meeting shot while in San Diego, upload to Instagram, and tag **#DIA2014** and **@DrugInfoAssn**

GLOBAL REGULATORY PRESENCE

The Global Regulatory Track is the keystone of the DIA 2014 50th Annual Meeting, giving you the rare opportunity to interact with global regulators to share knowledge and discuss keys issues in the industry. Attend one of the 12 offerings available in this year's program and join high-profile officials from a variety of global and regional regulatory agencies to discuss the latest initiatives and challenges faced in the review of drugs, diagnostics/devices, biologics, and more.

#121 & #144 New Approaches to International Collaboration Between Regulators (Part 1 and Part 2) Monday | 8:30-10:00am & 11:00am-12:30pm

Dirceu Brás Aparecido Barbano
Director-President
Agência Nacional de Vigilância Sanitária (ANVISA), Brazil

Emer Cooke, MBA
Head of International Affairs
European Medicines Agency
European Union

Margaret A. Hamburg, MD
Commissioner
FDA

Murray M. Lumpkin, MD, MSc
Deputy Director
Regulatory Affairs, Global Health and Integrated Development
Bill and Melinda Gates Foundation

Tatsuya Kondo, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Lembit Rago, MD, PhD
Head, Regulation of Medicines and other Health Technologies
World Health Organization (WHO), Switzerland

Guido Rasi, MD
Executive Director
European Medicines Agency
European Union

John Skerritt
National Manager
Therapeutic Goods Administration (TGA), Australia

Aiping Zhang
Inspector General, Department of Drug & Cosmetics Supervision
China Food and Drug Administration (CFDA), China

#216 CDRH Town Hall Tuesday | 8:00-9:30am

Christy L. Foreman
Director
Office of Device Evaluation
CDRH, FDA

Alberto Gutierrez, PhD
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
CDRH, FDA

Janet Jenkins-Showalter
Senior Regulatory Group Director
Regulatory Policy and Intelligence
Genentech, A Member of the Roche Group

Kirsten H. Paulson, MS
Senior Officer
Medical Device Initiative
The Pew Charitable Trusts

Jeffrey Shuren, JD, MD
Director
CDRH, FDA

#224 Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall Tuesday Tuesday | 8:00-9:30am

Masura Hiraiwa
Director
of Planning and Coordination, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Tatsuya Kondo, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Tetsuo Nagano, PhD
Executive Director,
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Nobumasa Nakashima, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Hiroshi Yamamoto, MS
Chief Safety Officer,
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#251 Europe Town Hall Tuesday | 10:30am-12:00pm

Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency
European Union

Professor Michel Goldman, PhD, MD
Executive Director
Innovative Medicines Initiative (IMI)
Belgium

Guido Rasi, MD
Executive Director
European Medicines Agency
European Union

Christa Wirthumer-Hoche, PhD
Head
Institute Marketing Authorisation and Lifecycle Management,
Austrian Medicines and Medical Devices Agency (AGES), Austria

#273 Introducing CDER's Office of Pharmaceutical Quality **Tuesday | 1:30-3:00PM**

Christine M. V. Moore
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science
CDER, FDA

Russell Wesdyk, MBA
OPS Scientific Coordinator
Office of Strategic Program
CDER, FDA

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research (CDER)

#279A Asia Town Hall **Tuesday | 1:30-3:00PM**

Nobumasa Nakashima, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)
Japan

Tatsuya Kondo, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Ming-Kung Yeh, PhD
Director-General
Taiwan Food and Drug Administration (TFDA), Taiwan

Representative Invited
Joint Secretary
Ministry of Health and Family Welfare, India

#349 An International Approach to Benefit-Risk Assessment of Medicines: An Evaluation by a Consortium of Established Agencies **Wednesday | 10:30AM-12:00PM**

Raymond S.B. Chua, MD, MBA, MPH, FRCP
Group Director, Health Products Regulation Group, Health Sciences Authority, Singapore

Petra Doerr, PharmD
Head of Communication and Networking, Deputy Director
Swissmedic, Swiss Agency for Therapeutic Products
Switzerland

Barbara J. Sabourin, FACP
Director General
HPFB
Health Canada

John Skerritt
National Manager
Therapeutic Goods Administration (TGA)
Australia

Stuart Walker, PhD
Founder
Centre For Innovation In Regulatory Science (CIRS)
United Kingdom

#414 & #426 CDER Town Hall (Part 1 and Part 2) **Thursday | 9:00-10:30AM & 10:45AM-12:15PM**

Thomas W. Abrams, MBA
Director
Office of Prescription Drug Promotion
CDER, FDA

John K. Jenkins, MD
Director
Office of New Drugs
CDER, FDA

Rear Adm. (ret) Sandra L. Kweder, MD
Deputy Director
Office of New Drugs
CDER, FDA

Capt. Justina A. Molzon
Associate Director for International Programs
CDER, FDA

Christine M. V. Moore
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science
CDER, FDA

Gerald J. Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology
CDER, FDA

Nancy D. Smith, PhD
Adjunct Professor
Temple University, FDA Alumni

PATIENT ADVOCATE FELLOWSHIP PROGRAM

DIA understands that patients play a key role in the drug development process. Patient advocates are increasingly influencing all stages of the drug development and regulatory process, and industry and regulators are establishing and expanding patient engagement programs within their organizations. DIA provides the perfect forum for patients to not only network and learn from experts from around the world, but also to participate in the process of bringing safe and effective therapies to market.

Eighteen patient representatives, chosen through a competitive process, will have opportunities to develop, strengthen, and support collaborations with policymakers, industry, academia, and health professionals by taking part in all facets of the DIA 2014 50th Annual Meeting. The Annual Meeting provides a forum for sharing best practices, stimulating cooperation, and facilitating a two-way dialogue across the entire global health care community.

Visit booth #1739 to meet the Patient Fellows and join the conversation about the patient perspective. Follow #DIA2014Patients for real-time updates.

Class of 2014 Patient Advocate Fellowship Organizations:

Us TOO Prostate Cancer Education & Support

Foundation for Prader-Willi Research
Working Toward an Independent Future

Erdheim-Chester Disease Global Alliance

Tuberous Sclerosis Alliance

National Foundation for Ectodermal Dysplasias

Batten Disease Support and Research Association

The CFIDS Association of America
Leveraging patient-centered research to cure ME/CFS

TSC Canada

Kennedy's Disease Association
www.kennedysdisease.org

dravet.org
dravet.ca

FSR
Foundation for Sarcoidosis Research

Myotonic Dystrophy Foundation

Parent Project Muscular Dystrophy
LEADING THE FIGHT TO END DUCHENNE

TargetCancer

Answering T.T.P.
Thrombotic Thrombocytopenic Purpura Foundation

INNOVATION THEATER PRESENTATIONS | Exhibit Hall

Solution Provider presentations will be made available in the Innovation Theater located in the rear of Exhibit Hall, near aisle 1200. Participating exhibiting companies will showcase their expertise and solutions in this year's schedule. Additional presentations to be announced.

#145 "Organizing for Change"... Lessons Learned in Preparing a Global Organization for Innovation
Monday, June 16 | 1:00-2:00pm

#253 Risk-Based Monitoring - Seeing the Forest for the Trees When Designing and Deploying an Enterprise Process
Tuesday, June 17 | 11:45am-12:30pm

#254 Industry's Largest eTMF Survey: Benchmarks and Insights
Tuesday, June 17 | 12:45-1:15pm

#279B Reaching the Tipping Point of Innovation
Tuesday, June 17 | 2:45-3:15pm

#351 Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP Clinical
Wednesday, June 18 | 11:45am-12:15pm

#352 Data Transparency and Sharing: Research Benefits, Risks and the Future
Wednesday, June 18 | 12:30-1:15pm

EDM & eSUBMISSIONS PAVILION | Exhibit Hall Section 530-547

This Pavilion in the Exhibit Hall features organizations focused on Electronic Document Management (EDM) and eSubmissions. Your one-stop shop!

2014 Confirmed Participants:

HURLEY CONSULTING ASSOCIATES LTD.

MEMBERSHIP & VOLUNTEER ACTIVITIES

DIA Member Lounge

Are you looking for a space to relax or connect with other DIA members? Stop by DIA's Member Lounge located in the Sails Pavilion. This exclusive lounge offers DIA members a place to take an important call, charge their device, utilize a workstation, or just relax. Free wi-fi is also available in the Member Lounge. While there, fill out DIA's Member Benefits Survey to be entered into a drawing for a free Apple iPad Mini.

DIA Scientific Working Groups (SWGs)

SWGs create a neutral, noncompetitive environment for professionals to bring their expertise to special projects that advance the science of medical product development. Stop by the **DIA Booth #1531** to learn more about the current SWGs:

- Adaptive Design
- Bayesian Statistics
- Biosimilars
- Comparative Effectiveness Research
- Missing Data

Join a DIA Community

This exclusive DIA member benefit helps members stay connected even after the meeting ends! Continue the networking and information sharing on DIA's online member Communities in ConneX. With over 30 different topic-specific areas to choose from, DIA Communities keep you connected.

- Interact with colleagues from many different disciplines from around the globe 24/7
- Keep up to date on hot topics and community-generated content and programming
- Share best practices, knowledge resources, articles and more

DIA Community Corner

Throughout the year, 30+ DIA Member Communities connect and network online to exchange knowledge in a neutral and multidisciplinary environment. DIA meetings like the DIA Annual Meeting give unique opportunities for Community members to interact face-to-face, and allow non-members an opportunity to get a taste of what Communities have to offer.

BECOME A DIA MEMBER TODAY!

Scan to learn more about the perks of becoming a DIA Member.

DIA Community Networking Area

Take advantage of a specially designated area for DIA Communities in the Exhibit Hall. This special seating area will allow Community members and those interested in learning more about DIA's Global Communities, to network with colleagues. Each table will include a sign related to a specific Community topic area. **Look for the designated area in the back left side of the Exhibit Hall, near the 2600 aisle**.

Tuesday DIA Community Lunch | 12:30-1:30pm

The Tuesday lunch break in the DIA Community Networking Area will include a welcome from the DIA Community Leadership Council, an introduction of the Community Chairs and some exciting updates about ConneX, the online platform for DIA's Communities. This will be one of the best chances to learn more about the Communities, volunteer opportunities, and to connect face-to-face with virtual participants.

Breakout Offerings Developed by DIA Communities

Many of the Communities are also bringing discussions and topics from online discussions directly to the Annual Meeting. Here is a list of offerings developed by DIA Communities:

- #103 Does One Size Fit All? Understanding the Impact of Cultural Differences Across the Globe
- #134 Fact or Fiction: Patient Engagement in the Drug Development Process
- #209 Communicating Clinical Trial Results: Targeting the Patient Audience
- #247 Impact of Bayesian Methods in Drug Development with a Focus on Comparative Effectiveness Research
- #274 Unraveling Evidence-Based Medicine: A Scientific, Ethical, and Socio-Political Analysis
- #298 Assessing Comparative Effectiveness Research Feasibility and Interpretability A Priori
- #314 The Legal, Ethical, and Commercial Issues Impacting the Development and Accessibility of Pediatric Medicines
- #365 EU Clinical Trial Data Transparency Debate: Where Are We?
- #367 & 393 Clinical Study Risk Management: What Does It Really Mean and How Do You Do It? (Part 1 and Part 2)
- #379 Project Management Plays Critical Roles in the New Challenging Environment
- #383 Powering Up Communications: Improving the Information Exchange Between Patients and Industry
- #398 Pediatric Trials: Improvements through Bayesian Methods, Adaptive Designs, and Modeling/Simulation

Annual Meeting Orientation and Networking, Room 6A

Is this your first time at the DIA Annual Meeting or would you like to learn more about this year's event and how to optimize your networking opportunities? Bring your business cards to network with fellow Annual Meeting attendees while learning how to make the most of your experience at the DIA 2014 50th Annual Meeting.

Sunday, June 15 | 4:00-5:00PM
Monday, June 16 | 7:30-8:20AM

Extended Refreshment Breaks

Meet with your colleagues each morning for coffee and breakfast breads in the Sails Pavilion of the San Diego Convention Center.

Monday, June 16 | 7:45-8:30AM
Tuesday, June 17 | 7:15-8:00AM
Wednesday, June 18 | 7:15-8:00AM
Thursday, June 19 | 8:15-9:00AM & 10:30-10:45AM

Mid-morning and mid-afternoon breaks will also be held in designated areas of the Exhibit Hall.

Monday, June 16 | 10:00–11:00AM
Tuesday, June 17 | 9:30–10:30AM
Tuesday, June 17 | 2:30–3:30PM
Wednesday, June 18 | 9:30–10:30AM
Wednesday, June 18 | 2:30–3:30PM

Extended Lunch Hours

Enjoy extended lunch hours to visit more than 450 exhibiting companies in the Exhibit Hall.

Monday, June 16 | 12:30-2:30PM
Tuesday, June 17 | 11:30AM-1:30PM
Wednesday, June 18 | 11:30AM-1:30PM

Opening Reception and DIA's 50th Anniversary Celebration

We invite you to network with over 7,000 attendees at the Opening Reception and DIA's 50th Anniversary Celebration in the Exhibit Hall. See old friends and make new acquaintances, while visiting more than 450 exhibiting companies. While you browse, be sure to use the complimentary beverage coupon which is provided to all non-exhibiting participants.

Monday, June 16 | 4:00-6:00PM

Students and Student Poster Session

Student attendees are encouraged to attend the DIA 2014 Student Forum: *Maintaining Your Career - Continuing Education and Changing Your Track.* This is a great opportunity to network with other students that are attending this year's DIA Annual Meeting. This forum will be held on Monday from 8:30-10:00AM in room 1A, see session #120 for more information.

Student Networking Area
A dedicated area is located in the rear of the Exhibit Hall (near the lunch voucher exchange) for students to network, plan their day, and meet for lunch.

Student Poster Session
Eighteen students from around the world will be showcasing their research in this year's Student Poster Session. Posters will be located in the Sails Pavilion Lobby of the Convention Center. In addition, join us at 4:30PM in the **DIA Booth #1531** as we present the awards for the first-, second-, and third–place student poster winners. See page 111 for this year's student poster presenters.

Monday, June 16 | 7:45AM-2:30PM

Professional Poster Sessions

A selected group of Professional Poster presenters will share their research results in various topics. There will be two dedicated times with different posters available for view. Posters will be displayed in the Sails Pavilion. See page 111 for a listing of this year's Professional Poster presenters:

Session #1: Tuesday, June 17 | 7:15AM-4:00PM
Session #2: Wednesday, June 18 | 7:15AM-4:00PM

Exclusive opportunity for first time attendees! Select best Professional Poster from this year's program for a chance to win a Kindle Fire HD

"My first DIA experience was perfect! The quality of the pre-workshop seminars, booths, and social networking events really helped ground me in my expanding career."

Sukh Chugh, MBA,
Senior Business Relationship Manager, Allergan, Inc.

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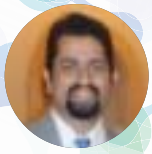

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FDA

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GENERAL INFORMATION

Accessing Presentations
To access presentations, visit diahome.org/DIA2014 for more details.

Baggage Check
There will be an area in the Exhibit Hall D Lobby reserved for attendees to check their belongings ($3.00 per item) Monday through Wednesday. Please note that Baggage Check will be relocated to Exhibit Hall C Lobby on Thursday. The Baggage Check will be available at the times listed below:

Monday, June 16 | 7:00AM-6:30PM
Tuesday, June 17 | 7:00AM-6:30PM
Wednesday, June 18 | 7:00AM-6:30PM
Thursday, June 19 | 7:00AM-1:00PM

Business Center
FedEx is the official business center for the San Diego Convention Center, providing full service business needs. Their phone number is 619-525-5450. The FedEx office retail storefront is located in Lobby D (street level) of the Convention Center. Their hours will be as follows:

Saturday, June 14 | 9:00AM-5:00PM
Sunday, June 15 | 9:00AM-5:00PM
Monday, June 16 | 8:00AM-5:00PM
Tuesday, June 17 | 8:00AM-5:00PM
Wednesday, June 18 | 8:00AM-5:00PM
Thursday, June 19 | 8:00AM-5:00PM

Career Center
DIA's interactive Career Center, located in the Sails Pavilion, is your premier resource for online employment connections! Looking for the perfect fit? The DIA Career Center offers employers targeted access to quality industry professionals, quick and easy job posting, online job activity reports, and access to the National Healthcare Career Network of over 60 top health care associations and professional organizations. Job seekers receive FREE and confidential resume posting, automated weekly email notification of new job listings, and the ability to save jobs for later review.

To find a job or fill a position, visit **diahome.org/DIACareerCenter**

WiFi and Cyber Café
The San Diego Convention Center provides free basic wireless internet access in the Exhibit Hall Lobby (ground level) of the Convention Center. To utilize this service, simply connect to Complimentary WiFi, open your browser and follow the on screen instructions. To supplement this service, DIA is also providing free wireless internet access in the Sails Pavilion (upper level) of the Convention Center. To utilize this service, simply connect to **DIA 50th Annual**, then launch a browser and you will be authenticated on the wireless system. If you need assistance with the wireless service in either location, please call 619-525-5500.

DIA is also providing workstations in the Sails Pavilion for those who do not have laptop computers or other devices.

Dress Code
Dress code is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. The Convention Center may be chilly so bring a sweater or jacket; comfortable shoes are a must!

First Aid Center
First Aid is available for routine health problems and emergency care. The First Aid Center is located in the Exhibit Hall C Lobby. In case of emergency dial **5911** from any house phone or **619-525-5911** from your cell phone and provide the location of your emergency.

The Convention Center will dispatch medical personnel at once. Please do not dial 911. We also urge you to complete the emergency contact information card, which is available at Attendee, Speaker, and Exhibitor Registration, and keep it in your badge holder at all times.

Ask Me Stations
Ask Me Stations are located in key locations throughout the Convention Center. Should you need directional information, or need additional assistance, please do not hesitate to stop by one of the stations.

Lost and Found
Misplaced items will be stored at Attendee Onsite Registration, located in the Sails Pavilion, until the end of the event. Items remaining at the close of the DIA 2014 50th Annual Meeting will be turned over to the San Diego Convention Center Security. At that point, you can contact San Diego Convention Center Security at 619-525-5490.

Lunch Voucher Program
In order to provide you with a variety of food options and freedom of choice, a voucher program is being used for DIA's luncheon service. Your vouchers are included with your badge. Please keep your vouchers in a safe place, as replacement vouchers will not be issued. The voucher is redeemable for up to $15 (inclusive of tax) for food and beverage items, and must be provided at checkout.

Lunch vouchers are not redeemable for cash, and change will not be provided if your purchase is under $15.00. Only one voucher can be used per transaction and they are not transferable. Therefore, each participant will need to pick up his or her own lunch. Vouchers can be used in the Exhibit Hall only, and are valid between the hours of 12:30PM and 2:30PM on Monday, and 11:30AM and 1:30PM on Tuesday and Wednesday.

In order to expedite your lunch service each day, please reference the lunch voucher flyer included in your registration bag.

Name Badge
Name badges must be worn at all times in the Convention Center. Participants will incur a $25 fee for badge reprints. If you have misplaced your badge, you will be required to have a badge reprinted. Please visit Attendee Onsite Registration located in the Sails Pavilion. Identification will be required. Please note, allowing exhibitors to scan the QR code on the front of your badge will provide them with your contact information. No children under the age of 18 years will be allowed in the Exhibit Hall due to liability issues.

Private Social Functions Policy
DIA does not allow any hospitality functions to be held during any Annual Meeting offerings, scheduled Exhibit Hours, or social events. Therefore the hours noted below are the only hours acceptable for hospitality functions:

Saturday, June 14 | All times are acceptable
Sunday, June 15 | All times are acceptable
Monday, June 16 | Before 7:30AM and after 6:30PM
Tuesday, June 17 | Before 8:00AM and after 5:00PM
Wednesday, June 18 | Before 8:00AM and after 5:00PM
Thursday, June 19 | Before 9:00AM and after 12:15PM

Selection of Offerings
Seating for educational offerings is on a first-come, first-served basis. Attendees should be prepared with an alternate selection in the event that a room is filled to capacity.

San Diego, California's second largest city has so much to offer besides incredible weather. The bayside city is perfect for combining business and pleasure with an award-winning downtown Convention Center and superb array of amenities and attractions as abundant as its year round sunshine. After a day at the DIA Annual Meeting, enjoy an evening in downtown San Diego and the electric Gaslamp Quarter.

Restaurant and City Information Concierge

Over 100 restaurants are all situated within blocks of each other. A San Diego Restaurant and Information Center desk, located in the Exhibit Hall B Lobby, will be available to advise and assist you with all your San Diego needs. Save on restaurants, attractions, activities and more while you are in town. Visit www.meetmeinsandiego.com/coupons/SanDiegoCoupons.pdf for a list of participating businesses throughout San Diego. You can print the coupons, or simply show your convention badge to save.

Taxicab Service

Taxis and shuttles are easily accessible from the convention center, airport. major hotels, and downtown locations. Taxi service from San Diego Airport is approximately $15.00-$20.00 one way.

The list below are taxicab companies frequently used by travelers. Call directly to find the taxicab service that best suits your needs.

- Airport Yellow Cab of San Diego | 619-444-4444
- American Cab | 619-234-1111
- Orange Cab | 619-291-3333
- San Diego Cab | 619-226-8294/800-368-2947
- USA Cab | 619-231-1144

DIA Courtesy Shuttle

The DIA Shuttle arrives and departs from the Exhibit Hall Lobby (Harbor Drive) of the San Diego Convention Center. You must be registered at a DIA room block hotel in order to utilize the DIA Shuttle. A shuttle pass, provided at hotel check-in, must be attached to your name badge as verification that you are staying in a designated DIA hotel. If a shuttle pass was not provided at your hotel check-in, you can stop by the Housing Desk, located in the Sails Pavilion (next to Speaker Registration), and one will be provided, after verifying your registration at one of the hotels noted below.

Use of the shuttle pass will be strictly enforced.

The following hotels will be provided with a DIA courtesy Shuttle to and from the Convention Center in the morning and at the conclusion of each day's events.

- Bristol Hotel | 1055 First Avenue
- Embassy Suites Downtown | 601 Pacific Highway
- Hampton Inn by Hilton | 1531 Pacific Highway
- Horton Grand Hotel | 311 Island Avenue
- Hotel Indigo | 509 9th Avenue
- Residence Inn Downtown | 1747 Pacific Highway
- Sofia Hotel | 150 West Broadway
- US Grant | 326 Broadway
- W San Diego | 421 West B Street
- Westgate Hotel | 1055 2nd Avenue
- Westin Gaslamp | 910 Broadway
- Westin San Diego | 400 W. Broadway

The Hard Rock Hotel, Hilton San Diego Bayfront, Hilton San Diego Gaslamp, Manchester Grand Hyatt, Omni San Diego Hotel, San Diego Marriott Gaslamp and San Diego Marriott Marquis are within walking distance of the San Diego Convention Center.

San Diego Trolley

The Metropolitan Transit System (MTS) operates the San Diego Trolley and has made trip planning easy with fun places to go. In addition to the trolley, The Flyer, MTS bus route 992, directly services the airport and the downtown area. Trolley Stations are across the street from the Convention Center, providing convenient service around downtown and to Mission Valley hotels and shopping malls. Please visit www.meetmeinsandiego.com/dia/ for information on various routes, fares and schedules.

San Diego/Coronado Ferry

A passenger ferry runs regularly across San Diego Bay from downtown's Broadway Pier to Coronado's Ferry Landing. Visit coronadoferrylandingshops.com/san-diego-bay-ferry.htm for more information.

Stay Connected!

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TAKE YOUR DIA EVENT EXPERIENCE TO THE NEXT LEVEL!

Create your program agenda, network with attendees and exhibitors, plus connect to DIA resources, social media channels, member communities, and more.

Access the DIA 2014 App:
- Click on the Events Icon
- Select DIA 2014 50th Annual Meeting

Search for "**DrugInfoAssn**" in your app store, or scan to Download the FREE DIA app today!

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Inaugural Medical Heroes Appreciation 5K

Monday, June 16, 2014 | 6:45 to 8 AM | San Diego Convention Center Area

MEDICAL HEROES APPRECIATION ANNUAL 5K run and walk

CISCRP

Thank you for making the Medical Heroes Appreciation 5K a smashing success!

All proceeds from this event will support programs that educate and empower patients and the public about clinical research participation.

With your dedication and support, we can ensure that volunteers who give the gift of participation in clinical research are recognized and celebrated.

For 2015 Event Information or Sponsorship Opportunities:

Visit
www.ciscrp.org/med-hero-5k

Email
medhero5k@ciscrp.org

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CONTINUING EDUCATION

The DIA 2014 50th Annual Meeting is the premier event designed for individuals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related medical products. The Annual Meeting is intended to strengthen professionals' understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

LEARNING OBJECTIVES

At the conclusion of the DIA 2014 50th Annual Meeting, participants should be able to:

TRACK 01: CLINICAL OPERATIONS

- Identify the important current clinical trial issues and how they can be addressed with innovative solutions
- Discuss methods of reducing costs while maintaining quality in the management of clinical trials using new technologies and efficient best practices
- Describe how to ensure ethical and safe treatment of subjects in the modern trial arena

TRACK 02: PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

PROJECT MANAGEMENT

- Identify and describe product development/project management practices and project-related finance practices used in industry and project management practices within regulatory agencies
- Discuss new project management practices and systems used in global product development

PORTFOLIO MANAGEMENT

- Identify and describe product development portfolio management practices, portfolio asset strategy decision making methods, and associated tools
- Discuss new portfolio asset strategy decision making, management, and portfolio/product prioritization/optimization practices

STRATEGIC PLANNING

- Discuss project and portfolio management practices for strategic planning

TRACK 03: INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

- Identify innovative partnering models and unique outsourcing strategies that are shaping the way in which pharmaceutical and biotechnology companies work with contract research organizations (CROs) and other service providers, academia, co-development partners, and other organizations

TRACK 04: NONCLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT

- Explain some of the latest nonclinical technologies and approaches for assessing the safety of pharmaceutical products
- Discuss recent advances in coping with particularly challenging issues that arise in the early phases of novel pharmaceutical development
- Describe current strategies for designing successful early clinical pharmacology and clinical trials
- Identify information needed to facilitate successful early interactions between regulatory agencies and other stakeholders such as key opinion leaders and patient advocacy groups

TRACK 05: REGULATION OF PRODUCT ADVERTISING AND MARKETING IN AN EVER-CHANGING WORLD

- Discuss the current regulatory landscape related to advertising and promotion

TRACK 06: MEDICAL COMMUNICATION, MEDICAL WRITING, AND MEDICAL SCIENCE LIAISON

- Identify opportunities to collaborate and meet the expectations of multiple, global regulatory authorities, health care professionals, patients, payers, and other customers
- Discuss successful communication channels across medical writing, medical communications and medical science liaisons

TRACK 07: PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH

- Discuss best practices for technologies and processes in clinical research
- Describe novel uses of existing/emerging technologies and processes
- Identify how technical and procedural innovations transform the clinical trials life cycle

TRACK 08: REGULATORY AFFAIRS AND SUBMISSIONS

- Discuss the latest global regulatory trends and developments that impact the industry

TRACK 09: MEDICAL DEVICES, IN VITRO DIAGNOSTICS, AND COMBINATION PRODUCTS

- Discuss how to further enhance the abilities of drug companies to meet the regulatory challenges created by innovate drug delivery, companion diagnostics and personalized medicine

TRACK 10: PUBLIC POLICY/HEALTH CARE COMPLIANCE/LAW

- Discuss implications and recommendations raised in current topics in health care compliance, public policy, and law

TRACK 11: INNOVATIVE APPROACHES TO ENSURING QUALITY IN CLINICAL TRIALS AND COMPLIANCE TO GOOD CLINICAL PRACTICE (GCP)

- Describe innovative approaches being used to manage GCP compliance and ensure quality in the development of new therapeutics in a changing international regulatory landscape

TRACK 12: PHARMACEUTICAL QUALITY

- Explain how to apply fundamental and advanced scientific and regulatory approaches to current and emerging pharmaceutical quality issues, including a strong emphasis on global harmonization efforts within and outside the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

TRACK 13: COMPARATIVE EFFECTIVENESS RESEARCH/GLOBAL HEALTH OUTCOMES AND ECONOMICS

- Describe current issues in measuring and communicating the medical need, health impact, and economic value associated with medical interventions
- Evaluate treatment heterogeneity and comparative effectiveness research (methods and applications)

TRACK 14: CLINICAL SAFETY AND PHARMACOVIGILANCE

- Discuss a broad array of concepts and tools (traditional and new) that support participants' pursuit of excellence in patient safety, for both investigational and marketed health care products

TRACK 15: STATISTICAL SCIENCE AND QUANTITIVE THINKING

- Identify innovative statistical solutions to issues associated with the evidence and regulatory review of drugs, diagnostics/devices, and biologics
- Describe relevant application of statistical science and quantitative thinking to the development of new therapeutic biologics, drugs, and diagnostics/devices

TRACK 16: PROFESSIONAL DEVELOPMENT

- Discuss ways to foster advancing therapeutic innovation and regulatory science through professional development and educational efforts

TRACK 17: RARE/ORPHAN DISEASES

- Identify the unique challenges, opportunities, and strategies that will help to shape a better future for the successful discovery and development of orphan drugs and novel treatments for rare diseases
- Examine the role of basic, translational, and clinical researchers, drug/device companies, governmental agencies, patient advocacy organizations and patients in novel therapy development
- Recognize the impact of rare/orphan diseases on patient well-being and health care systems

TRACK 18: GLOBAL REGULATORY

- Discuss key initiatives, changes, and challenges of various global regulatory agencies with the review of drugs, diagnostics/devices, and biologics

TRACK 19: EXECUTIVE PROGRAM

- Identify shifts in pharmaceutical R&D
- Discuss the impact of these changes on the R&D landscape
- Examine the role of small and specialty pharma in the discovery, development, and commercialization of new medical products

TRACK 20: LATE-BREAKING TOPICS

- Discuss late breaking, hot topics in the pharmaceutical, biotechnology and/or medical devices industry

Select program offerings (including sessions, forums, workshops, symposia, *TURBO* offerings) have been approved for *AMA PRA Category 1 Credits™* and may also offer pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs) and will be clearly identified in the program with the statement of CME, Pharmacy, Nursing, and PMI. IACET continuing education units (CEUs) are offered for all program offerings.

*Continuing education credits are **not available** for the Opening Plenary Session on Monday afternoon, Power Up! session on Tuesday afternoon, Student or Professional Poster Sessions, or Innovation Theater. Learning objectives for each program offering will be shown in the meeting rooms.*

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS

Accreditation Council for Continuing Medical Education (ACCME)

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. PIM is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation

The Postgraduate Institute for Medicine designates this live activity for a maximum of 18 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Council for Pharmacy Education (ACPE)

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 18 contact hours or 1.8 continuing education units (CEUs) for participating in the Annual Meeting program offerings. For a complete list of each ACPE UAN and activity type allocated for pharmacy-certified program offerings, please refer to pages 133–135.

ACPE Credit Requests

DIA is required by the ACPE to report pharmacy requested credit into the CPE Monitor. All ACPE credit requests need to be submitted through DIA's My Transcript within 45-days post activity. Please make sure that your DIA Profile has your correct degree prior to requesting ACPE credit. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted in time. If you previously submitted your NABP e-Profile ID and date of birth to DIA, this data is stored in your DIA Profile. If you need to obtain your NABP e-Profile ID, please visit www.cpemonitor.net. ACPE credit requests made after the 45-days post activity (Thursday, July 31, 2014) may not be accepted by ACPE through the CPE Monitor. It is the pharmacist responsibility to request ACPE credit within the required time.

American Nurses Credentialing Center (ANCC)

This educational activity for 18 contact hours is provided by PIM.

PIM is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

California Board of Registered Nursing

PIM is approved by the California Board of Registered Nursing, Provider Number 13485 for 18 contact hours.

Project Management Institute (PMI)

The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). PMI#: 2166-000160

Participants may receive up to 15 professional development units (PDUs) for attending the Annual Meeting program offerings.

The PMI Registered Education Provider logo is a registered mark of the Project Management Institute, Inc.

International Association for Continuing Education and Training (IACET)

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 2.4 CEUs for this program.

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending DIA 2014 50th Annual Meeting, please complete your state's application for credit and submit accordingly.

If you require additional information to complete your application, please contact Karen Tenaglia at karen.tenaglia@diahome.org for assistance.

CONTINUING EDUCATION CREDIT ALLOCATION

MONDAY THROUGH THURSDAY, JUNE 16–19

All program offerings that are designated for credit and are ***1.5 hours in length,*** offer up to:

- 1.5 *AMA PRA Category 1 Credits™*
- 1.5 pharmacy contact hours or .15 CEUs
- 1.5 nursing contact hours
- 1.5 PMI PDUs
- .2 IACET CEUs

All program offerings that are designated for credit and are ***1 hour in length*** (*TURBO* offering), offer up to:

- *1 AMA PRA Category 1 Credit™*
- 1 pharmacy contact hour or .1 CEU
- 1 nursing contact hour
- 1 PMI PDU
- .1 IACET CEU

DIA CERTIFICATE PROGRAMS

Individuals enrolled in DIA Certificate Programs may receive elective units for the designated programs noted below:

- Clinical Research Certificate Program: 12 Elective Units
- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
- Project Management Certificate Program: 8 Elective Units
- Regulatory Affairs Certificate Program: 12 Elective Units

Visit **diahome.org/certificateprograms** for more information on DIA's Certicate Programs.

STATEMENT OF CREDIT

Participants who would like to receive continuing education credits for the DIA 2014 50th Annual Meeting must scan their DIA name badge at each program offering to record their attendance and complete each program offering evaluation form.

Participants must scan their badges within 45 minutes after the start of each 1.5 hours program offering and within 30 minutes after the start time for the 1 hour *TURBO* offering. Attendees who do not scan their badges within the allotted time will not be eligible to request the available continuing education credits for that program offering. If a participant attends multiple program offerings within the same timeframe, only the last scanned entry within the time frame listed above will be recorded.

To request a statement of credit, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" for each program offering. *My Transcript will open on Tuesday, June 24, 2014.*

Reminder — All ACPE credit requests must be submitted by Thursday, July 31.

If you experience any difficulties, please contact DIA at mytranscript@diahome.org

DISCLOSURE OF CONFLICTS OF INTEREST

The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations. PIM and DIA are committed to providing its learners with high quality CME activities and related materials that promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.

The faculty members, planners and managers financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interest related to the content of this continuing education activity are noted on pages 125–131.

DISCLOSURE OF UNLABELED USE

This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA. PIM and DIA do not recommend the use of any agent outside of the labeled indications.

The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of PIM or DIA. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

EVALUATION

Access to DIA 2014 50th Annual Meeting online evaluations are found at **www.diahome.org/DIA2014evals**. At the end of each day, all participant scanned data will be uploaded and only the offerings you attended will appear.

Complete your scanned offerings evaluations and be entered to win great prizes! DIA will randomly select three winners who have completed all scanned offerings evaluations for each day of the Annual Meeting to win one of the following prizes:

- Free registration for the DIA 2015 51st Annual Meeting, Washington D.C.
- Microsoft Surface
- Apple iPad Mini

During the week of July 21, the three drawings will take place and the winners will be notified by email.

MEETING SCHEDULE BY DAY AND TIME

DIA 2014 50TH ANNUAL MEETING TRACKS AND INTEREST AREAS

Track #	Track Title	Interest Area
Track 01	Clinical Operations	Clinical Research (CR), Clinical Supplies (CS), Research and Development (RD), Investigative Sites (IS), Manufacturing (MF)
Track 02	Project/Portfolio Management and Strategic Planning	Project Management (PM), Financing (FI), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Nonclinical and Translational Development/Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Regulation of Product Advertising and Marketing in an Ever-changing World	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Communication, Medical Writing, and Medical Science Liaison	Medical Writing (MW), Medical Communications (MC), Medical Science Liaison (MSL)
Track 07	Processes and Technologies for Clinical Research	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Study EndPoints (SE), Document Management (DM), Validation (VA)
Track 08	Regulatory Affairs and Submissions	Regulatory Affairs (RA), Submissions (SUBS)
Track 09	Medical Devices, In Vitro Diagnostics, and Combination Products	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/Health Care Compliance/Law	Public Policy, Law, Corporate Compliance (PPLCC)
Track 11	Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice	Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC)
Track 13	Comparative Effectiveness Research/Global Health Outcomes and Economics	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistics (ST)
Track 16	Professional Development	Professional Education, Training, and Development (PETD)
Track 17	Rare/Orphan Diseases	Rare, Orphan Diseases (ROD)
Track 18	Global Regulatory	ALL
Track 19	Executive Program	ALL
Track 20	Late-breaking Topics	ALL
Track 21	Innovation Theater	ALL

CONTENT LEVEL GUIDE

The difficulty level of each offering has been determined by the program offering Chairperson and is indicated by one of the following symbols. This provides a guide for registrants in their selection of program offerings to attend.

● **Basic Level Content:**
Appropriate for individuals new to the topic/subject area.

■ **Primarily Intermediate Level Content:**
Appropriate for individuals who already have a basic understanding of the topic/subject area.

◆ **Primarily Advanced Level Content:**
Appropriate for individuals with an in-depth knowledge of the topic/subject area.

DIFFERENT FORMAT FOR DIFFERENT LEARNERS

FORUM
A 60-minute (called TURBO Offering) or 90-minute blended presentation and panel discussion.

SESSION
A 60-minute (called TURBO Offering) or 90-minute presentation delivered lecture-style from the podium.

SYMPOSIUM
A blend of three 20-minute presentations.

WORKSHOP
A 90-minute conceptual presentation delivered in an interactive/simulation or role playing format.

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
MONDAY, JUNE 16 8:30–10:00 AM							
#101	Global Clinical Trials Symposium: Opportunities and Challenges	1B	SYMPOSIUM	Level: ■	CR, AHC/IS	Track 01A	CME, IACET, RN
#102	Bringing the Patient Voice to Clinical Development	3	FORUM	Level: ●	RD, CR, PT	Track 01B	ACPE, CME, IACET, RN
#103	Does One Size Fit All? Understanding the Impact of Cultural Differences Across the Globe	16A	WORKSHOP	Level: ■	CR, PETD, PT	Track 01C	ACPE, CME, IACET, RN
#104	Stage Gate Decision-Making Workshop (Part 1 of 2)	16B	WORKSHOP	Level: ●	SP, RD, CR	Track 02A	CME, IACET, RN
#105	Making Better Go/No-Go Decisions: Improving Success Rates and Reducing Costs	5A	SESSION	Level: ◆	FI, PR, RD	Track 02B	CME, IACET, RN
#106	Beyond Operational Excellence: A Survey on Sponsor Expectations of Preferred Business Partners	4	FORUM	Level: ■	PR, CR	Track 03	CME, IACET, RN
#107	Pioneering Regenerative Medicine: Trends in Regulations for New Therapy	7B	SESSION	Level: ■	BT, RA, NC	Track 04	CME, IACET, RN
#108	Delivering Value Through Medical Content to Health Care Providers	31AB	SESSION	Level: ■	MC, MSL, AP	Track 06	ACPE, CME, IACET, RN
#109	Central Statistical Monitoring Revealed: How to Enhance Data Quality and 'De-Risk' Studies Through Enhanced Risk-Based Monitoring	32AB	SESSION	Level: ■	ST, CDM	Track 07A	ACPE, CME, IACET, RN
#110	Data Warehousing and Integration: Current Status, Key Success Ingredients and Alternative Approaches for Maximizing the Value of Your Data	33AB	SYMPOSIUM	Level: ■	CDM, CR	Track 07B	ACPE, CME, IACET, RN
#111	Global Pediatric Development: We Are Making Progress	30AB	SESSION	Level: ■	CR, RA	Track 08	CME, IACET, RN
#112	One Paddle for Two Boats? Policy Alternatives to Buoy Adoption of Precision Therapies and Their Companion Diagnostics	11A	FORUM	Level: ■	CmbP, RA	Track 09	CME, IACET, RN
#113	Formal Dispute Resolution at CDER: When, Why, and How	11B	SESSION	Level: ■	RA, HT	Track 10	CME, IACET, RN
#114	Protocol Deviations: Finding the Yellow Brick Road (Part 1 of 2)	17A	WORKSHOP	Level: ■	GCP, CR, RA	Track 11	CME, IACET, RN
#115	Implementation of Quality by Design: Progress Update	7A	SESSION	Level: ■	MF, RA	Track 12	CME, IACET, RN
#116	A Common Decision Framework for Health Technology Assessment and Regulatory Agencies: Is This of Benefit to Stakeholders?	9	SESSION	Level: ■	RA, PR	Track 13	CME, IACET, RN
#117	Risk Management in the US, EU, and Asia: Where Are We Now?	6D	SESSION	Level: ■	RA, CP	Track 14	CME, IACET, RN
#118	Design and Sample Size Planning for Multiregional Clinical Trials	5B	SESSION	Level: ■	CR, RD	Track 15	CME, IACET, RN
#119	The Twitter Value Proposition for Life Science Professionals	30CD	WORKSHOP	Level: ●	CR, RA, CP	Track 16A	ACPE, CME, IACET, RN
#120	DIA 2014 Student Forum: Maintaining Your Career—Continuing Education and Changing Your Track	1A	FORUM	Level: ●	ALL	Track 16B	CME, IACET, RN
#121	New Approaches to International Collaboration Between Regulators (Part 1 of 2)	6F	FORUM	Level: ■	RA, CR, CP	Track 18	CME, IACET, RN
MONDAY, JUNE 16 11:00 AM–12:30 PM							
#122	Adaptive Monitoring: One Company's Experience with Practical Implementation	1B	SESSION	Level: ■	CR, IT, QA/QC	Track 01A	ACPE, CME, IACET, RN
#123	Engaging Patients through Digital and Social Media Communities	2	FORUM	Level: ■	CR, RD, PT	Track 01B	ACPE, CME, IACET, RN
#124	Stage Gate Decision-Making Workshop (Part 2 of 2)	16B	WORKSHOP	Level: ●	SP, RD, CR	Track 02A	CME, IACET, RN
#125	Improving Returns on Invested Capital in the Pharmaceutical and Biotechnology Industry	5A	SESSION	Level: ◆	FI, RD	Track 02B	CME, IACET, RN
#126	R&D and Technology Outsourcing Today: An Industry Update	4	SESSION	Level: ◆	RD, OS	Track 03A	CME, IACET, PMI, RN
#127	Risk Sharing or Risk Transfer? Striking the Perfect Balance in Strategic Partnerships	3	FORUM	Level: ■	OS, SP	Track 03B	CME, IACET, RN

**Due to their interactive format, workshops will not be recorded.*

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
#128	Proarrhythmic Risk Assessment WITHOUT the Thorough QT: FDA and Pharmaceutical Company Perspectives	7B	FORUM	Level: ■	RD, CP, HT	Track 04	CME, IACET, RN
#129	Regulatory Submissions: Better, Faster, and Cheaper	31AB	SYMPOSIUM	Level: ■	ESUBS, DM, MW	Track 06	CME, IACET, RN
#130	Electronic Clinical Outcome Assessments: Coming to a Device Near You!	32AB	FORUM	Level: ■	SE, CR	Track 07A	CME, IACET, RN
#131	Why Waste Time and Money? Data Standards from the Beginning: Working Together for Good Science and Good Submissions	33AB	SESSION	Level: ■	CDM, RA, ESUBS	Track 07B	ACPE, CME, IACET, RN
#132	Driving Toward Standardization: Overcoming Barriers—eDM, eTMF, and CTMS	30CD	SYMPOSIUM	Level: ■	DM, ESUBS	Track 07C	CME, IACET, RN
#133	Pediatric Drug Development: Lessons Learned During FDASIA Implementation	10	SESSION	Level: ■	RA, PPLC, RD	Track 08A	ACPE, CME, IACET, RN
#134	Fact or Fiction: Patient Engagement in the Drug Development Process	30AB	SESSION	Level: ■	RA, PT, RD	Track 08B	ACPE, CME, IACET, RN
#135	FDA Regulation of Therapeutic Products Derived from Human Stem Cells: Successfully Navigating the Regulatory Hurdles	11B	FORUM	Level: ■	RA, HT, NC	Track 10	CME, IACET, RN
#136	Defining, Measuring, and Assessing "Fit for Purpose" Quality in a Risk-Based Monitoring Model: Industry and Agency Perspectives	5B	SESSION	Level: ■	GCP, CR	Track 11A	CME, IACET, RN
#137	Protocol Deviations: Finding the Yellow Brick Road (Part 2 of 2)	17A	WORKSHOP	Level: ■	GCP, CP	Track 11B	CME, IACET, RN
#138	Observational Studies of Comparative Effectiveness: How to Recognize Good Practice	9	FORUM	Level: ●	CP, CR, PR	Track 13	ACPE, CME, IACET, RN
#139	Assessment of Impact and Effectiveness of Risk Management and Minimization in the EU and US	6D	SYMPOSIUM	Level: ■	RA, CR	Track 14A	ACPE, CME, IACET, RN
#140	Effective Communication Model Between Drug Safety, Regulatory Affairs, and Clinical Development	6E	SESSION	Level: ■	RA, CR	Track 14B	CME, IACET, RN
#141	Strategic Quantitative Thinking: Designing a Roadmap for Innovation	8	SESSION	Level: ●	HT, RA	Track 15	ACPE, CME, IACET, RN
#142	Narrative Medicine: How to Tap into the Inherent Power of Words and Stories in the Clinical Trial Process	16A	WORKSHOP	Level: ●	ROD, CR, PT	Track 16	ACPE, CME, IACET, RN
#143	Pricing, Economics, Reimbursement, Market Share (PERMS) Strategy: An Interactive Holistic Approach in Rare Diseases	1A	SESSION	Level: ●	PR, PT, CEHTAEbM	Track 17	CME, IACET, RN
#144	New Approaches to International Collaboration Between Regulators (Part 2 of 2)	6F	FORUM	Level: ■	RA, CR, CP	Track 18	CME, IACET, RN

MONDAY, JUNE 16 1:00–2:00 PM

#145	**1:00–2:00 PM** INC Research Innovation Theater: "Organizing for Change"... Lessons Learned in Preparing a Global Organization for Innovation	Exhibit Hall	SPECIAL SESSION	Level: ■	FI, CR, PETD	Track 21	n/a

MONDAY, JUNE 16 2:30–4:00 PM

PLENARY SESSION & KEYNOTE ADDRESS • BALLROOM 20

Welcome Remarks, Awards, and Keynote Speaker Presentations

All registrants are encouraged to attend.

Keynote Speaker

Jamie Heywood

Co-Founder and Chairman, PatientsLikeMe

Founding Director, ALS Therapy Development Institute (ALS TDI)

MONDAY, JUNE 16 4:00–6:00 PM

OPENING RECEPTION AND DIA'S 50TH ANNIVERSARY CELEBRATION

EXHIBIT HALL

**Due to their interactive format, workshops will not be recorded.*

TUESDAY, JUNE 17 8:00–9:30 AM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
#201	Updated Strategies for Effective Recruitment of Patients in Clinical Trials	1B	FORUM	Level: ■	CR, IT, PT	Track 01A	CME, IACET, RN
#202	Collaboration in R&D: What's New for TransCelerate BioPharma?	2	FORUM	Level: ■	CR, SP, RD	Track 01B	ACPE, CME, IACET, RN
#203	Monitor Training: Building Essential Skills for Implementing Risk-Based Monitoring - Data Interpretation, Quality by Design	16A	WORKSHOP	Level: ■	AHC/IS, CR, PETD	Track 01C	ACPE, CME, IACET, RN
#204	Drug Development and the Virtual Company	5A	FORUM	Level: ◆	PR, OS, RD	Track 02A	CME, IACET, PMI, RN
#205	Effective Leadership in Hybrid Team Between West and East Asia in New Drug Development	1A	FORUM	Level: ●	RD, PETD, SP	Track 02B	CME, IACET, RN
#206	Big Data, Big Impact: New Levels of Strategic Partnerships Between Sponsors-CROs	3	FORUM	Level: ■	SP, RD	Track 03	CME, IACET, RN
#207	Nanotechnology: Application to Medical Products	7B	SESSION	Level: ●	BT, RD, HT	Track 04	ACPE, CME, IACET, RN
#208	Prescription Drug Marketing Regulatory Primer	7A	WORKSHOP	Level: ●	AP, RA, MA	Track 05	ACPE, CME, IACET, RN
#209	Communicating Clinical Trial Results: Targeting the Patient Audience	31AB	SESSION	Level: ■	MW, PT, MC	Track 06	ACPE, CME, IACET, RN
#210	Electronic Source Data in Clinical Investigations (Part 1 of 2): Regulatory Considerations	30CD	FORUM	Level: ■	EC, RA, CR	Track 07A	ACPE, CME, IACET, RN
#211	Clinical Outcomes Assessment and Patient Engagement Symposium	32AB	SYMPOSIUM	Level: ■	SE, PT	Track 07B	ACPE, CME, IACET, RN
#212	Bioinformatics and Translational Medicine	33AB	SESSION	Level: ■	IT, NC, CR	Track 07C	ACPE, CME, IACET, RN
#213	PDUFA V New Molecular Entity Program: History, Implementation and Future of the Program	8	SESSION	Level: ■	PT, RA	Track 08A	CME, IACET, RN
#214	Regulated Product Submissions and eCTD 4: The Path to Progress	30AB	SESSION	Level: ■	ESUBS, RA	Track 08B	CME, IACET, RN
#215	The Regulatory Intelligence Function: Evolution Over the Past Decade in an Expanded Global Marketplace △	31C	SESSION	Level: ■	RA, SP	Track 08C	CME, IACET, RN
#216	CDRH Town Hall	11A	FORUM	Level: ●	RA, MDD	Track 09	CME, IACET, RN
#217	Regulatory and GCP Quality Trends in Emerging Markets	6E	SESSION	Level: ■	GCP, RA, CR	Track 11A	CME, IACET, RN
#218	Quality and Risk Management in an Increasingly Complex Clinical Research Environment: State of the Industry and Leading Practices	6C	FORUM	Level: ■	GCP, CR, RA	Track 11B	CME, IACET, RN
#219	CMC Development of Breakthrough Therapies	4	SESSION	Level: ■	CMC/GMP, RA	Track 12	CME, IACET, RN
#220	Using Comparative Effectiveness Research to Make Health Care Decisions: Exploring the Environment, Opportunities, and Challenges Through Real-World Examples △	9	SESSION	Level: ●	PR, RD	Track 13	ACPE, CME, IACET, RN
#221	Benefit-Risk Throughout the Product Life Cycle: How Should Benefit-Risk Be Evaluated and Communicated from Development through Marketing as New Information Emerges?	6D	SYMPOSIUM	Level: ■	RA, PT	Track 14	CME, IACET, RN
#222	Mitigating Missing Data in Clinical Trials: Moving Toward Global Behavioral Change Impacts Efficacy, Safety, and Quality	5B	SESSION	Level: ■	CR, RA, CDM	Track 15	ACPE, CME, IACET, RN
#223	Capital Efficient Drug Development with Revolutionary Technologies: Calculated Risks	11B	SESSION	Level: ■	FI, IT, RD	Track 16	CME, IACET, PMI, RN
#224	Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall	6F	FORUM	Level: ■	RA, CR, CP	Track 18	CME, IACET, RN
#225	The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances, and Precision Medicine (Part 1 of 2)	10	FORUM	Level: ■	RD, SP, OS	Track 19	CME, IACET, RN
#226	Covering Industry Trends in the Biomedical Industry	16B	FORUM	Level: ●	ALL	Track 20	IACET

Due to their interactive format, workshops will not be recorded.

TUESDAY, JUNE 17 10:30 AM–12:00 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
#227	Risk-Based Monitoring: From Concept to Practice	2	FORUM	Level: ■	CR, PM, OS	Track 01A	ACPE, CME, IACET, RN
#228	Improving the Informed Consent Process	1B	SYMPOSIUM	Level: ■	CR, AHC/IS, PT	Track 01B	ACPE, CME, IACET, RN
#229	Social Listening as a Tool to Inform Study Teams on Social Media Strategy for Recruitment and Building Patient-Centric Trials △	3	FORUM	Level: ●	CR, SP	Track 01C	ACPE, CME, IACET, RN
#230	Leaping the Valley of Death: Keys to Successfully Going from the Lab to the Clinic for Pharmaceutical Products	5A	SESSION	Level: ■	RD, PM	Track 02A	CME, IACET, RN
#231	National Strategy to Bridge the Gap Between Academic Innovation and Commercialization in Asia	1A	FORUM	Level: ■	FI, RD	Track 02B	CME, IACET, RN
#232	The State of Clinical Outsourcing: Do Outsourcing Partnerships Promote or Impede Progress Toward Clinical Trial Optimization?	6C	FORUM	Level: ■	CR, OS	Track 03	CME, IACET, PMI, RN
#233	Juvenile Animal Studies and Pediatric Nonclinical Development △	7B	SESSION	Level: ■	RD, NC	Track 04	CME, IACET, RN
#234	Understanding Corporate Integrity Agreements/Trends: What Can We Expect and Why Is It Important?	7A	SESSION	Level: ■	AP, RA, PPLC	Track 05	CME, IACET, RN
#235	Preparing for a Successful Product Launch	31AB	SESSION	Level: ■	MC, RA, MSL	Track 06A	ACPE, CME, IACET, RN
#236	Update on Postmarketing Safety Reporting	30AB	SESSION	Level: ■	MW, CP, DM	Track 06B	ACPE, CME, IACET, RN
#237	Improving Communication in the Informed Consent Process: The Advantages of eConsent	16A	WORKSHOP	Level: ■	EC, CR	Track 07A	ACPE, CME, IACET, RN
#238	Electronic Source Data in Clinical Investigations (Part 2 of 2): Practical Implementation	30CD	FORUM	Level: ■	EC, RA, CR	Track 07B	ACPE, CME, IACET, RN
#239	FDA Programs to Encourage Innovation: Maximizing the Opportunities and Confronting the Challenges of New Product Development	11B	FORUM	Level: ■	RA, CR, HT	Track 08A	ACPE, CME, IACET, RN
#240	Efficient Distribution of Information Across Documents to Support Product's Benefit-Risk Ratio for Patients Worldwide	16B	WORKSHOP	Level: ◆	ESUBS, RA, MW	Track 08B	CME, IACET, RN
#241	Device and Diagnostic Innovation	11A	SESSION	Level: ■	MDD, RA	Track 09	CME, IACET, RN
#242	Health Care's Revolutionary Printing Press? 3D Printing—Blue Sky and Regulatory Path	6E	FORUM	Level: ■	HT, IT, RA	Track 10	ACPE, CME, IACET, RN
#243	GCP Inspection Findings: A Roundtable Discussion	8	FORUM	Level: ■	GCP, RA, CP	Track 11	CME, IACET, RN
#244	Manufacturing Challenges for Breakthrough Products	4	SESSION	Level: ■	CMC/GMP, RA, MF	Track 12	CME, IACET, RN
#245	Drug Development with Reimbursement in Mind: Obtaining the Input of Payers to Inform Clinical Trial Design	9	FORUM	Level: ■	PR, CR, HT	Track 13	CME, IACET, RN
#246	EMA-FDA Collaboration in Pharmacovigilance: Common Objectives and Common Challenges	6D	SESSION	Level: ■	CR, RA	Track 14	CME, IACET, RN
#247	Impact of Bayesian Methods in Drug Development with a Focus on Comparative Effectiveness Research	5B	FORUM	Level: ■	CEHTAEbM, RA, CR	Track 15	ACPE, CME, IACET, RN
#248	Networking: It's Not What You Know, But Who You Know!	17A	WORKSHOP	Level: ●	CR, RA, CP	Track 16	ACPE, CME, IACET, RN
#249	Industry Trends, Successes, and Failures in Orphan and Rare Disease Therapeutics △	32AB	FORUM	Level: ■	CR, RA, HT	Track 17	ACPE, CME, IACET, RN
#250	Development of an Integrated Orphan Drug Framework in Canada	33AB	SESSION	Level: ■	ROD, RA, CR	Track 18A	CME, IACET, RN
#251	Europe Town Hall	6F	FORUM	Level: ■	RA, CR, CP	Track 18B	CME, IACET, RN
#252	The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances, and Precision Medicine (Part 2 of 2)	10	FORUM	Level: ■	RD, SP, OS	Track 19	CME, IACET, RN

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
TUESDAY, JUNE 17 11:45 AM–1:15 PM							
#253	**11:45 AM–12:30 PM** Covance Innovation Theater: Risk-Based Monitoring—Seeing the Forest for the Trees When Designing and Deploying an Enterprise Process	Exhibit Hall	SPECIAL SESSION	Level: ■	CR, GCP, IT	Track 21A	n/a
#254	**12:45 PM–1:15 PM** Veeva Innovation Theater: Industry's Largest eTMF Survey: Benchmarks and Insights	Exhibit Hall	SPECIAL SESSION	Level: ■	MW, IT, DM	Track 21B	n/a
TUESDAY, JUNE 17 1:30–3:00 PM							
#255	Improving Investigative Site Selection Practices	3	SYMPOSIUM	Level: ●	AHC/IS, ST	Track 01A	CME, IACET, RN
#256	Optimization of and Enhancements to Interactive Response Technology to Ensure Efficient Investigational Product and Study Material Management △	1B	SYMPOSIUM	Level: ■	CS, CM, CR	Track 01B	ACPE, CME, IACET, RN
#257	Virtual Teams in Clinical Development	5A	SYMPOSIUM	Level: ●	PM, CR	Track 02A	CME, IACET, PMI, RN
#258	Challenges and Strategic Approaches to Development of a Novel Biologic Versus a Biosimilar	1A	SESSION	Level: ◆	SP, BT, RD	Track 02B	CME, IACET, RN
#259	Collaborating to Streamline Drug Development: Case Studies of What Works (and What Doesn't)	2	FORUM	Level: ■	RD, CR, RA	Track 03	CME, IACET, RN
#260	Organs on a Chip: The Future of Efficacy and Safety Testing	7B	SESSION	Level: ■	BT, HT, RD	Track 04	CME, IACET, RN
#261	FDA Enforcement Update: Advertising and Promotion	7A	FORUM	Level: ■	AP, RA	Track 05	ACPE, CME, IACET, RN
#262	Promotional Material Management: From Review to Submission—Contemporary Ideas	31AB	SESSION	Level: ■	MC, AP, RA	Track 06A	ACPE, CME, IACET, RN
#263	In-Sourcing, Out-Sourcing: Where Do We Go from Here?	32AB	SESSION	Level: ■	MW, ST	Track 06B	CME, IACET, RN
#264	Computer System Validation in the Cloud: Cloud Is Here Today and Here to Stay	31C	SESSION	Level: ■	VA, RA, IT	Track 07A	CME, IACET, RN
#265	Embracing Change: The New Face of Clinical Data Management	33AB	SYMPOSIUM	Level: ■	CDM, CR	Track 07B	ACPE, CME, IACET, RN
#266	Enabling Participants' Access to the Electronic Clinical Trial Data: The Blue Button Project	30CD	SESSION	Level: ■	CR, PT, IT	Track 07C	ACPE, CME, IACET, RN
#267	Breakthrough Therapy Designation: One Year After	6F	SESSION	Level: ■	RA, ROD	Track 08A	CME, IACET, RN
#268	How to Make a Successful Electronic Registration and Listing Submission: NDC, Regulatory Compliance, and Technical Requirements	10	SESSION	Level: ■	ESUBS, RA	Track 08B	ACPE, CME, IACET, RN
#269	Dare to Be Different: Comparing Biosensor Data to Patient-Reported Outcomes Data—Learnings from Asthma △	11A	SESSION	Level: ■	SE, MDD	Track 09	CME, IACET, RN
#270	Digital Health: Mobile Medical Apps and the Future of Health Care Delivery	6E	FORUM	Level: ■	PPLC, RA, PR	Track 10	ACPE, CME, IACET, RN
#271	Adapting GCPs to Evolving Drug Development Paradigm (Part 1 of 2)	8	SESSION	Level: ■	GCP, RA, QC	Track 11A	CME, IACET, RN
#272	EMA-FDA GCP Initiative: Current Status and Future Perspectives	11B	SESSION	Level: ■	GCP, CR, RA	Track 11B	CME, IACET, RN
#273	Introducing CDER's Office of Pharmaceutical Quality	6C	SESSION	Level: ●	RA, HT, CP	Track 12	CME, IACET, PMI, RN
#274	Unraveling Evidence-Based Medicine: A Scientific, Ethical, and Socio-Political Analysis	9	FORUM	Level: ●	PR, RA, CR	Track 13	ACPE, CME, IACET, RN
#275	Who's Moving the PV Cheese? Three Game Changing Topics—Impact of Emerging New Requirements for E2B (R3), ICSR Quality Standards, and Benefit-Risk Management	6D	SYMPOSIUM	Level: ■	CP, ESUBS	Track 14A	CME, IACET, RN
#276	How Do We Keep Kids Safe? Pediatric Safety Monitoring From Beginning to End	4	SYMPOSIUM	Level: ●	RA, CR	Track 14B	ACPE, CME, IACET, RN
#277	Predictive Enrichment: Design, Development Strategies, and Methodological Issues	5B	SESSION	Level: ■	RD, SP	Track 15	CME, IACET, RN
#278	Yes and … Applying Improvisational Skills to Improve Innovation	16A	WORKSHOP	Level: ●	PM, CR, RA	Track 16	ACPE, CME, IACET, RN
#279A	Asia Town Hall	30AB	FORUM	Level: ■	RA, CR, CP	Track 18	CME, IACET, RN

**Due to their interactive format, workshops will not be recorded.*

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
TUESDAY, JUNE 17 2:45–3:15 PM							
#279B	BBK Innovation Theater: Reaching the Tipping Point of Innovation	Exhibit Hall	SPECIAL SESSION	Level: ■	RD, CR, PETD	Track 21	n/a
TUESDAY, JUNE 17 3:30–5:00 PM							
#280	Building a Site Budget from the Ground Floor	16A	WORKSHOP	Level: ■	FI, RA, AHC/IS	Track 01A	CME, IACET, RN
#281	Perfecting the Protocol: Designing Studies for Success	1B	SYMPOSIUM	Level: ●	CR, SE, FI	Track 01B	ACPE, CME, IACET, RN
#282	Patient Registries: Designing, Implementing, and Leveraging to Accelerate Clinical Trials	3	SESSION	Level: ■	RD, PT	Track 01C	ACPE, CME, IACET, RN
#283	Development of Central Nervous System Drugs with Abuse Potential	1A	SESSION	Level: ◆	RD, CR	Track 02	ACPE, CME, IACET, RN
#284	How a New Collaboration Between a Biopharmaceutical Company and a CRO Is Improving the Quality, Speed, and Efficiency of Drug Development △	2	FORUM	Level: ■	CR, RD	Track 03	ACPE, CME, IACET, RN
#285	Gene Therapy Symposium	7B	SYMPOSIUM	Level: ■	BT, CP, CR	Track 04	CME, IACET, RN
#286	International Regulatory Advertising and Promotion Considerations	7A	SESSION	Level: ■	AP, RA	Track 05	CME, IACET, RN
#287	Our First Year Under Sunshine: Impact on Medical and Scientific Communications	31AB	SESSION	Level: ■	MC, MW, PPLC	Track 06A	ACPE, CME, IACET, RN
#288	The Regulatory Writing Game Show	16B	WORKSHOP	Level: ■	MW, RA	Track 06B	CME, IACET, RN
#289	Electronic Standardized Study Data: Regulatory Considerations	30CD	FORUM	Level: ■	CDM, RA	Track 07A	ACPE, CME, IACET, RN
#290	Transforming Culture and Mindsets to Deliver a Higher Quality eTMF	33AB	SESSION	Level: ■	DM, CR	Track 07B	ACPE, CME, IACET, RN
#291	Prequalification of Medicines for Neglected Tropical Diseases	30AB	SESSION	Level: ●	RA, ROD, HT	Track 08A	ACPE, CME, IACET, RN
#292	Using a Hub and Spoke Model to Drive Efficiency and Cost-Effectiveness in the Global Regulatory Process	10	SESSION	Level: ■	ESUBS, FI, RA	Track 08B	CME, IACET, RN
#293	Utilizing 505(b)(2) to Accelerate Drug Development Plans △	6D	SESSION	Level: ■	RA, CMC/GMP, CR	Track 08C	CME, IACET, RN
#294	Biomedical Product Development and Public Policy: Hear from Leaders of PhRMA, BIO, AdvaMed, and ACRO	6E	FORUM	Level: ●	PPLC, CR, RA	Track 10	CME, IACET, RN
#295	Adapting GCPs to Evolving Drug Development Paradigm (Part 2 of 2)	8	SESSION	Level: ■	GCP, RA, PT	Track 11A	ACPE, CME, IACET, RN
#296	Misconduct and Management of Serious or Continued Noncompliance: Differences, Similarities, and Building a World-Class Program	11B	SESSION	Level: ■	GCP, CR, ST	Track 11B	CME, IACET, RN
#297	Lessons Learned in the Development and Registration of Fixed-Dose Combination Products: CMC Focus △	5A	FORUM	Level: ■	CmbP, CMC/GMP	Track 12	CME, IACET, RN
#298	Assessing Comparative Effectiveness Research Feasibility and Interpretability A Priori	9	SESSION	Level: ■	PR, CR	Track 13	ACPE, CME, IACET, RN
#299A	Evaluating Potential Contribution of Social Media to Postmarketing Medication Safety Surveillance	6C	SESSION	Level: ■	CDM, CR	Track 14A	ACPE, CME, IACET, RN
#299B	The Pharmacovigilance System Master File: Business as Usual? Can This File Help Industry?	4	SESSION	Level: ■	DM, RA, IT	Track 14B	CME, IACET, RN
#299C	Key Subgroup Analysis Issues in Clinical Trials	5B	SESSION	Level: ■	CR, RD	Track 15	ACPE, CME, IACET, RN
#299D	Managing Innovation: Challenges and Opportunities Today and for the Future	17A	WORKSHOP	Level: ■	HT, RA, PR	Track 16	CME, IACET, RN
#299E	Orphan Drugs and Treatment of Rare Diseases in Asia	32AB	SYMPOSIUM	Level: ■	RA, CR, CP	Track 17	ACPE, CME, IACET, RN
#299F	FDA—Health Canada Regulatory Cooperation Council (RCC) Town Hall	11A	FORUM	Level: ■	RA, ESUBS, CMC/GMP	Track 18	CME, IACET, RN
#299G	Power Up! Give Your Brain a Vacation	31C	SESSION	Level: ●	ALL	Track 20	n/a

**Due to their interactive format, workshops will not be recorded.*

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
WEDNESDAY, JUNE 18 8:00–9:30 AM							
#301	Metrics Benchmarking, Predictive Analytics, and Virtual Population Simulation: New Tools to Contextualize and Forecast Trial Performance	1B	SYMPOSIUM	Level: ■	CR, SE, IT	Track 01A	CME, IACET, RN
#302	The Sites Have Spoken: Implementing Paperless Trials and Risk-Based Monitoring from a Site's Perspective	3	SESSION	Level: ●	IT, AHC/IS	Track 01B	CME, IACET, RN
#303	Life Cycle Management of Biopharmaceuticals: An Approach and Lessons Learned for an Imperative Business Practice △	1A	SESSION	Level: ■	SP, BT, FI	Track 02A	CME, IACET, RN
#304	Why Does Drug Development Need Project Management? △	5A	SESSION	Level: ◆	PM, CR, RA	Track 02B	CME, IACET, RN
#305	Achieving Success in a Mega-Trial Sponsor/ARO/CRO Collaboration: Approaches to Overcome Challenges and Optimize Results	2	FORUM	Level: ■	CR, PM	Track 03A	CME, IACET, PMI, RN
#306	Optimizing Outsourcing Relationships: Data-Driven Strategies to Support Vendor Selection, Negotiation, and Management	4	SYMPOSIUM	Level: ●	OS, PR	Track 03B	CME, IACET, PMI, RN
#307	Designing Smarter and More Cost-Effective Phase 1 Protocols	7B	SESSION	Level: ■	NC, CR, PR	Track 04	CME, IACET, RN
#308	Professional Career Development Within Medical Affairs: A Perspective from Medical Communications, Medical Science Liaisons, and Medical Writers △	31AB	SESSION	Level: ●	MW, MSL, MC	Track 06	CME, IACET, RN
#309	CDISC BRIDG Implementation: A Model for System Interoperability and as a Data Base Model	30CD	SESSION	Level: ◆	CDM, CR	Track 07A	ACPE, CME, IACET, RN
#310	Clinical Trials Technology Implementation: Bringing Together Patient- and Site-Centric Approaches	33AB	SESSION	Level: ■	EC, CR, PT	Track 07B	ACPE, CME, IACET, RN
#311	Proprietary Name Review: International Perspectives from the FDA, Health Canada, and EMA	6D	SESSION	Level: ■	RA, CP	Track 08A	CME, IACET, RN
#312	Regulatory Strategic Plan: Don't Start Development Without One	16A	WORKSHOP	Level: ■	RA, SP	Track 08B	CME, IACET, RN
#313	Changing Global Regulatory Climates: Effects on Companion Diagnostics and Combination Products	11A	SESSION	Level: ■	RA, CmbP, MDD	Track 09	CME, IACET, RN
#314	The Legal, Ethical, and Commercial Issues Impacting the Development and Accessibility of Pediatric Medicines	6E	FORUM	Level: ■	RA, CR	Track 10	CME, IACET, RN
#315	Research Site Quality Compliance Programs: Review of Industry Gold Standards	16B	WORKSHOP	Level: ■	GCP, AHC/IS, CP	Track 11	CME, IACET, RN
#316	Balancing Manufacturing Quality Improvements and Drug Shortage	11B	SESSION	Level: ■	MF, CR, RA	Track 12A	ACPE, CME, IACET, RN
#317	ICH Update: Emerging Guidelines	10	SESSION	Level: ■	RA, CMC/GMP	Track 12B	CME, IACET, RN
#318	Leveraging Electronic Health Record Data to Understand Clinical Nuance in Complex Real-World Populations: A Case Study △	9	FORUM	Level: ■	IT, RD, CDM	Track 13	ACPE, CME, IACET, RN
#319	Signal Detection: Challenges and Strategic Aspects	30AB	FORUM	Level: ■	ST, PT	Track 14A	ACPE, CME, IACET, RN
#320	The Challenges of High Quality Risk Management with Single Shared System REMS and Physician Knowledge Surveys	8	SESSION	Level: ■	RA, IT	Track 14B	CME, IACET, RN
#321	Your Future Success as a Master's Level Statistician: Learn from the Past of These Industry Masters	5B	FORUM	Level: ●	PETD	Track 15A	IACET
#322	Seeing Is Believing! Good Graphic Design Principles for Medical Research	7A	SESSION	Level: ●	MW	Track 15B	ACPE, CME, IACET, RN
#323	Innovative Engagement Strategies to Inspire Higher Level Commitment and Performance	17A	WORKSHOP	Level: ●	CR, RA, CP	Track 16	CME, IACET, RN
#324	International Cooperation in Rare Disease Research	32AB	FORUM	Level: ■	FI, CR	Track 17	ACPE, CME, IACET, RN
#325	Transforming ICH Toward Greater Global Harmonization	31C	SESSION	Level: ●	RA, CR, CP	Track 18	CME, IACET, RN

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WEDNESDAY, JUNE 18 10:30 AM–12:00 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
#326	Risk-Based Monitoring Symposium	2	SYMPOSIUM	Level: ■	CR, IT, FI	Track 01A	ACPE, CME, IACET, RN
#327	Site Selection and Feasibility Symposium	1B	SYMPOSIUM	Level: ■	AHC/IS, CR, IT	Track 01B	CME, IACET, RN
#328	Clinical Supply Symposium	1A	SYMPOSIUM	Level: ●	CS, AHC/IS, CR	Track 01C	ACPE, CME, IACET, RN
#329	Project Management Basics: Creating a High-Level Project Plan	16A	WORKSHOP	Level: ●	PM, PETD, CR	Track 02A	CME, IACET, PMI, RN
#330	Career Planning and Limitations for Mid- to Upper-Level Project Managers	5A	FORUM	Level: ◆	PETD, RD	Track 02B	CME, IACET, RN
#331	The Present and Future of Pharmaceutical Development Outsourcing: Where Are We Today and Where Are We Going?	4	FORUM	Level: ■	OS, RD, SP	Track 03A	CME, IACET, PMI, RN
#332	Vendor Selection for a Small Company △	5B	FORUM	Level: ■	GCP, OS	Track 03B	CME, IACET, RN
#333	Site Certification of Early Phase Research Units: An International Perspective	7B	SESSION	Level: ■	AHC/IS, NC, PC	Track 04	CME, IACET, RN
#334	Field-Based Medical Communications on a Global Scale △	31AB	SESSION	Level: ■	MSL, MC	Track 06	ACPE, CME, IACET, RN
#335	Maximizing the Potential of Your EDC System	30CD	SYMPOSIUM	Level: ■	CDM, CR	Track 07A	CME, IACET, RN
#336	Emerging Technologies in Regulatory Science	6F	FORUM	Level: ■	RA, CR, EC	Track 07B	ACPE, CME, IACET, RN
#337	Implementation of GDUFA: Progress and Expectations	3	SESSION	Level: ■	RA, HT, PPLC	Track 08A	CME, IACET, RN
#338	From the Protocol to the Patient: Clinical Trial Data Disclosure	6D	SESSION	Level: ■	PPLC, PT, CR	Track 08B	ACPE, CME, IACET, RN
#339	Combination Products: An Overview of Clinical Benefits, Regulatory Issues, and Manufacturing Challenges	16B	WORKSHOP	Level: ■	CmbP, RA, MF	Track 09	CME, IACET, RN
#340	Approaches to Decrease the Time Gap Between FDA Approval and the Ability to Market a DEA Scheduled Drug	6E	SESSION	Level: ■	RA, MA	Track 10A	ACPE, CME, IACET, RN
#341	Strengthening Public Policy for Sustainable Clinical Research Enterprise in Africa, Asia, and South America: Progress and Prospects	11A	SESSION	Level: ■	CR, RA	Track 10B	CME, IACET, RN
#342	GCP Audits in a Risk-Based Environment	8	FORUM	Level: ■	GCP, QA/QC, CP	Track 11	CME, IACET, RN
#343	Update from the FDA-EMA Parallel Assessment Pilot	10	SESSION	Level: ■	RA, CMC/GMP	Track 12	CME, IACET, PMI, RN
#344	Public-Private Partnerships: An Innovative Strategy for Patient Registries	17A	WORKSHOP	Level: ■	SP	Track 13	ACPE, CME, IACET, RN
#345	Prediction of Safety: An Evolving Field for Selecting Low-Risk Compounds Towards an Effective Life Cycle of a Product	11B	SESSION	Level: ■	BT, PC, NC	Track 14A	CME, IACET, RN
#346	Expanding the Scope: Empowering the Public in Pharmacovigilance	30AB	SYMPOSIUM	Level: ■	CR, PT, CP	Track 14B	ACPE, CME, IACET, RN
#347	Separating Perceptions from Reality in the Acceptance of Adaptive Trials by Regulatory Agencies	7A	SESSION	Level: ■	CR, RA	Track 15	CME, IACET, RN
#348	Be a Change Agent: Leveraging Communication and Training Tools to Help Promote Project and Career Transformation	31C	FORUM	Level: ■	PM	Track 16	ACPE, CME, IACET, PMI, RN
#349	An International Approach to Benefit-Risk Assessment of Medicines: An Evaluation by a Consortium of Established Agencies	33AB	SESSION	Level: ■	RA, CR, CP	Track 18	CME, IACET, RN
#350	The Patient Point-of-View: Unrehearsed but Revealing Conversation to Rectify Patient Enrollment	9	FORUM	Level: ■	CR, PT	Track 20	ACPE, CME, IACET, RN

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
WEDNESDAY, JUNE 18 11:45 AM–1:15 PM							
#351	**11:45 AM–12:15 PM** SAS/JMP Innovation Theater: Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP Clinical	Exhibit Hall	SPECIAL SESSION	Level: ■	CP, CR	Track 21A	n/a
#352	**12:30–1:15 PM** SAS Innovation Theater: Data Transparency and Sharing: Research Benefits, Risks and the Future	Exhibit Hall	SPECIAL SESSION	Level: ■	CDM, IT, CEHTAEbM	Track 21B	n/a
WEDNESDAY, JUNE 18 1:30–3:00 PM							
#353	Hot Topics in Patient Recruitment: Global Demographics, Underrepresented Populations, and the Science Behind Patient Communications	3	SYMPOSIUM	Level: ■	CR, PT, CEHTAEbM	Track 01A	ACPE, CME, IACET, RN
#354	Social Media in Patient Recruitment: How to Best Leverage the Digital Ecosystem	2	SYMPOSIUM	Level: ■	PT, CR, AHC/IS	Track 01B	ACPE, CME, IACET, RN
#355	Complex Drug Projects: Complex Project Management	1A	FORUM	Level: ◆	PM, RD	Track 02	CME, IACET, PMI, RN
#356	Functional Service Provider Relationships: Critical Factors to Ensuring Long-Term Success	4	FORUM	Level: ■	SP, OS	Track 03A	CME, IACET, RN
#357	Costing Strategies for Sustainable Drug Development	5A	SYMPOSIUM	Level: ●	RD, PR, OS	Track 03B	CME, IACET, RN
#358	Phase 1 Studies in Renal and Hepatic Subjects: Considerations and Best Practices in Design and Conduct	7B	FORUM	Level: ■	CR, CP	Track 04	CME, IACET, RN
#359	Broadening Health Care Communications: Learnings from Health Authority Initiatives	31AB	SYMPOSIUM	Level: ■	MC, RA, PT	Track 06	ACPE, CME, IACET, RN
#360	Innovative Direct-to-Patient Study Model to Capture PRO Instrument Validation Data for Submission to a Regulatory Authority	30CD	SESSION	Level: ■	SE, CR, PT	Track 07A	ACPE, CME, IACET, RN
#361	A Cloud-Based Approach to Evaluating and Maintaining Global Regulatory Content Alignment	33AB	SESSION	Level: ●	IT, RA	Track 07B	CME, IACET, RN
#362	Adaptive, Progressive or Risk-Based Licensing Models: What Approaches Could Be Considered by Mature and Emerging Markets?	5B	SESSION	Level: ■	RA, RD, CEHTAEbM	Track 08A	CME, IACET, RN
#363	Benefit-Risk Assessments of Medicines: Framework Development and Use in Marketing Applications	6D	FORUM	Level: ■	RA, CP	Track 08B	ACPE, CME, IACET, RN
#364	Medical Device Update: Unique Device Identification Rule, Medical Device Reporting Draft Guidance, and Postmarketing Clinical Research Reporting Requirements	11A	SYMPOSIUM	Level: ■	MDD, RD, CP	Track 09	CME, IACET, RN
#365	EU Clinical Trial Data Transparency Debate: Where Are We?	6E	FORUM	Level: ■	RA, CR	Track 10A	CME, IACET, RN
#366	Making Comments Count: Best Practices in Developing Comments for a Global Audience	16A	WORKSHOP	Level: ■	PPLC, RA	Track 10B	CME, IACET, RN
#367	Clinical Study Risk Management: What Does It Really Mean and How Do You Do It? (Part 1 of 2)	16B	WORKSHOP	Level: ■	GCP, CP, CR	Track 11	CME, IACET, RN
#368	Recent Advancement of the Pharmaceutical Inspection Cooperation Scheme and Good Manufacturing Practices in the Asia Pacific Region	10	SESSION	Level: ■	QA/QC, RA	Track 12	CME, IACET, RN
#369	Nesting Studies Within Patient Registries to Support Comparative Effectiveness Research	17A	WORKSHOP	Level: ■	ST, CR	Track 13	ACPE, CME, IACET, RN
#370	Natalizumab and Progressive Multifocal Leukoencephalopathy: A Risk Management Case Study	8	SESSION	Level: ■	RA, CR	Track 14A	ACPE, CME, IACET, RN
#371	The Role of Intelligent Signaling in Digital Disease Detection and Proactive Pharmacovigilance △	30AB	SESSION	Level: ■	CDM, IT	Track 14B	ACPE, CME, IACET, RN
#372	Exploring Bayesian Approaches Applied to New Treatments for Rare Diseases	7A	SESSION	Level: ■	ROD, CR	Track 15	CME, IACET, RN
#373	Managing Global Teams: Navigating Through Cultural, Lingual, and Geographic Challenges △	1B	SESSION	Level: ●	PM	Track 16A	CME, IACET, PMI, RN
#374	Abstract and Article Publication Opportunities with DIA	31C	WORKSHOP	Level: ■	PETD, CR, RA	Track 16B	IACET

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
#375	Optimizing Orphan Drug Development and Using Appropriate Methodology: Key Tips for Success	32AB	SYMPOSIUM	Level: ■	CR, RA	Track 17	ACPE, CME, IACET, RN
#376	Challenges and Opportunities Facing FDA's International Posts	11B	SESSION	Level: ◆	RA, MF	Track 18	CME, IACET, RN

WEDNESDAY, JUNE 18 3:30–5:00 PM

#377	Filling the Gaps and Speeding Up Results: What an Educated, Sophisticated Patient Population Can Do for You	3	FORUM	Level: ●	CR, RD, PT	Track 01A	ACPE, CME, IACET, RN
#378	Optimize Protocol Design: A Path to Efficient, Lower Cost Trial Execution	2	SYMPOSIUM	Level: ■	CR, PR, CP	Track 01B	ACPE, CME, IACET, RN
#379	Project Management Plays Critical Roles in the New Challenging Environment	1A	FORUM	Level: ◆	PM, BT, CR	Track 02	CME, IACET, PMI, RN
#380	The Sponsor-Vendor-Vendor Relationship: A Fine Balance	5A	SESSION	Level: ■	OS, CR	Track 03A	CME, IACET, RN
#381	Effective Strategic Partnering Between Small Pharmaceutical Companies and CROs: Discussion and Case Study	4	FORUM	Level: ■	PM, SP	Track 03B	CME, IACET, RN
#382	Predicting Drug Off-Target Protein Binding to Hypothesize Mechanisms for Safety Issues	7B	SESSION	Level: ■	CP, BT	Track 04	CME, IACET, RN
#383	Powering Up Communications: Improving the Information Exchange Between Patients and Industry	31AB	SESSION	Level: ■	MC, PT, MSL	Track 06A	ACPE, CME, IACET, RN
#384	Transforming Organizational Knowledge into Product Information: Can Structured Authoring Save the Day?	31C	SESSION	Level: ■	MW, DM, RA	Track 06B	CME, IACET, RN
#385	Sustainable Solutions for Global Clinical Research Site Documentation	30CD	SYMPOSIUM	Level: ◆	DM, CR	Track 07A	CME, IACET, RN
#386	End-to-End Data and Metadata in Today's Clinical Trials	33AB	SYMPOSIUM	Level: ■	IT, SE, CR	Track 07B	CME, IACET, RN
#387	Why, When, and How Should Patients Be Involved in the Benefit-Risk Assessment of Medicines?	6D	SESSION	Level: ■	RA, CP, PT	Track 08A	ACPE, CME, IACET, RN
#388	Health Authority Meeting Preparation: There Are No Do-Overs	5B	SESSION	Level: ■	RA, SP	Track 08B	CME, IACET, RN
#389	The Realities of Late Life Cycle Management for Very Old Legacy Brands	1B	FORUM	Level: ■	RA, SP	Track 08C	ACPE, CME, IACET, RN
#390	Regulatory Perspectives in the Execution of Clinical Studies and Medical Product Commercialization in Asia Pacific	11A	SYMPOSIUM	Level: ■	RA, MDD	Track 09	CME, IACET, RN
#391	Industry in the Sunshine: How the "Sunshine" Provisions of the Affordable Care Act Will Change Industry Policy and Practice	6E	SESSION	Level: ■	AP, RA, HT	Track 10A	ACPE, CME, IACET, RN
#392	Patient Voice in Decision Making: How Are Regulators Making This Work?	9	FORUM	Level: ■	PT, RA	Track 10B	CME, IACET, RN
#393	Clinical Study Risk Management: What Does It Really Mean and How Do You Do It? (Part 2 of 2)	16B	WORKSHOP	Level: ■	GCP, CR, ST	Track 11	CME, IACET, RN
#394	CMC Regulatory Pathways in the Emerging Markets: Focus on Asia Pacific	10	SESSION	Level: ■	RA, CMC/GMP	Track 12	CME, IACET, RN
#395	Compliance, Potential Financial Implications, and Impact of New Safety Measures	8	SESSION	Level: ■	GCP, FI	Track 14A	ACPE, CME, IACET, RN
#396	Product Crisis Management: Crisis, What Crisis?	30AB	SESSION	Level: ■	MC, HT	Track 14B	ACPE, CME, IACET, RN
#397	Benefit-Risk Evaluation in Drug Development	7A	SESSION	Level: ■	CR, RA	Track 15A	CME, IACET, RN
#398	Pediatric Trials: Improvements through Bayesian Methods, Adaptive Designs, and Modeling/Simulation	11B	SESSION	Level: ◆	CR, RA	Track 15B	ACPE, CME, IACET, RN
#399A	Women as Transformational Leaders	17A	WORKSHOP	Level: ●	CR, RA	Track 16	CME, IACET, RN
#399B	Regulatory Challenges for Orphan Medicines	32AB	SYMPOSIUM	Level: ■	CR, RA	Track 17	ACPE, CME, IACET, RN
#399C	Informed Medication Use in Pregnancy: A Collaborative Approach to Address Needs for Data, Communication, and Engagement	16A	FORUM	Level: ■	CR, PT, PPLC	Track 20	ACPE, CME, IACET, RN

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Interest Area(s)	Track Number	Continuing Education Credits
THURSDAY, JUNE 19 9:00–10:30 AM							
#401	Accelerating Research in a Large Health Care System: Streamlining Research Review and Study Initiation	16A	WORKSHOP	Level: ■	CR, AHC/IS	Track 01	CME, IACET, RN
#402	Exploring Responder-Patient Clinical Study Design Approaches	3	SESSION	Level: ◆	PT, SP, PM	Track 02	ACPE, CME, IACET, RN
#403	Keeping It Together: Syncing CRO Data and Metrics	4	SESSION	Level: ■	CR, OS	Track 03	CME, IACET, RN
#404	Today's Dynamic Medical Science Liaison Environment	7A	SESSION	Level: ●	MSL, RA	Track 06	CME, IACET, RN
#405	Qualifying a Software Vendor in a Regulated Industry △	10	SESSION	Level: ●	VA, RA, IT	Track 07	ACPE, CME, IACET, RN
#406	Hot Topics in Medical Devices Labeling: US and Global	2	FORUM	Level: ●	RA, MDD, CR	Track 08	CME, IACET, RN
#407	FDA Drug Claims Substantiation after IMS and Caronia: Will Court Scrutiny Based on the First Amendment Lead to Change in Current Policy and Practice?	9	FORUM	Level: ■	AP, RA	Track 10	ACPE, CME, IACET, RN
#408	GCP Quality Agreements	8	SESSION	Level: ■	GCP, CR	Track 11	CME, IACET, RN
#409	Question-Based Review (QbR): A Risk-Based, Standardized Pharmaceutical Quality Assessment Tool	5A	SESSION	Level: ■	RA, CMC/GMP, CP	Track 12	CME, IACET, PMI, RN
#410	Universal Health Coverage and Health Technology Assessment in Emerging Asia Pacific Countries	7B	SESSION	Level: ■	CR, PR	Track 13	CME, IACET, RN
#411	Safety in Special Situations: Stem Cells, Vaccines, and Combination Products	1B	SYMPOSIUM	Level: ■	HT, CmbP, CR	Track 14	ACPE, CME, IACET, RN
#412	Moving Beyond the Traditional Psychometric Validation of New Phase 3 Clinical Outcome Assessments	5B	FORUM	Level: ■	SE, CR, RA	Track 15	CME, IACET, RN
#413	Independent Consultant or Permanent Role: Get the Position You Want (Tips from Insiders)	11A	FORUM	Level: ●	CR, RA, OS	Track 16	CME, IACET, RN
#414	CDER Town Hall (Part 1 of 2)	6B	FORUM	Level: ●	RA, CR, CP	Track 18	ACPE, CME, IACET, RN
THURSDAY, JUNE 19 10:45 AM–12:15 PM							
#415	Parents as Partners: Overcoming Unique Challenges to Pediatric Recruitment and Retention	9	SESSION	Level: ■	AHC/IS, CR, PT	Track 01	CME, IACET, RN
#416	A Hitchhiker's Guide to Working with Management Consultants	16A	WORKSHOP	Level: ■	PM, OS, SP	Track 02	CME, IACET, PMI, RN
#417	The Evolution of Strategic Partnerships and the Four P's of International Relationship Building	5B	FORUM	Level: ■	SP, CR	Track 03	CME, IACET, PMI, RN
#418	Risk-Based Monitoring: Where We Are and Where We Are Headed	10	SYMPOSIUM	Level: ◆	CDM, EC, CR	Track 07	ACPE, CME, IACET, RN
#419	Ethnic Difference in Clinical Trial Data: A 15-Year History of an Investigation by Regulatory Agencies and Industry	4	SESSION	Level: ■	RA, CR, CDM	Track 08A	ACPE, CME, IACET, RN
#420	Trends in Biosimilars Regulation Within Developed and Emerging Markets	3	SESSION	Level: ■	RA, BT	Track 08B	CME, IACET, RN
#421	Bringing Quality to Quality Metrics	8	SESSION	Level: ■	GCP, SP, OS	Track 11	CME, IACET, RN
#422	How Can Studies that Inform Relative Effectiveness Best Be Incorporated into Global Drug Development Plans?	7B	FORUM	Level: ■	RD, CR, PR	Track 13	CME, IACET, RN
#423	Changing the Mindset Towards Case Quality, Audits, and Inspections: A Practical Approach	5A	SYMPOSIUM	Level: ■	QA/QC, RA, IT	Track 14	CME, IACET, RN
#424	Walking the Tightrope of Talent Acquisition and Retention: The Balancing Act for Maintaining Productivity, Efficiency, and Quality	11A	SYMPOSIUM	Level: ■	OS, CR, RA	Track 16	CME, IACET, PMI, RN
#425	Innovative Patient Recruitment Solutions for Rare Disease Clinical Trials	7A	SYMPOSIUM	Level: ■	CR, PT, RA	Track 17	ACPE, CME, IACET, RN
#426	CDER Town Hall (Part 2 of 2)	6B	FORUM	Level: ●	RA, CR, CP	Track 18	ACPE, CME, IACET, RN

**Due to their interactive format, workshops will not be recorded.*

NOTES

Call for Papers

tirs.sagepub.com

Therapeutic Innovation & Regulatory Science

Editor-in-Chief
Stephen P. Spielberg, M.D., Ph.D.

Therapeutic Innovation & Regulatory Science (TIRS), is the official journal of DIA, publishing bi-monthly. ***TIRS*** publishes peer-reviewed original articles and commentaries across all phases of medical product discovery, development, regulation, and use. At a time of rapid change in medical science innovation, ***TIRS*** encourages international, cross-disciplinary, translational contributions that will help inform and drive innovation and regulatory science. Cutting edge articles on new science issues dedicated to fostering health and wellness worldwide will be included in each issue and feature hot topics such as CER, HTA, companion diagnostics, personalized medicine and more. Finally, commentaries on emerging healthcare issues will continue to engage readers in the ongoing conversation between industry, academia, regulators and patients.

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Your journey begins with an array of beautifully complex molecules, which, when bonded together in just the right way, have a chance of curing a disease, treating a condition and perhaps changing the world.

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SATURDAY, JUNE 14 — MONDAY, JUNE 16

The information that was made available to DIA as of April 24 is included in the following agenda.
Visit www.diahome.org/dia2014 for the most up-to-date information.

SATURDAY JUNE 14

Registration Hours:

9:00 AM–5:00 PM Exhibitor Registration

SUNDAY, JUNE 15

Registration Hours:

8:00–9:00 AM Registration for Full Day, Morning Preconference Tutorials*
8:00 AM–6:00 PM Exhibitor Registration
12:30–1:00 PM Registration for Afternoon Preconference Tutorials*
3:00–6:00 PM Attendee and Speaker Registration

Schedule:

8:30 AM–12:00 PM Half Day Preconference Tutorials*
9:00 AM–5:00 PM Full Day Preconference Tutorials*
1:00–4:30 PM Half Day Afternoon Preconference Tutorials*
4:00–5:00 PM DIA 2014 50th Annual Meeting Orientation and Networking

**Space is limited for Preconference Tutorials, therefore preregistration is strongly recommended. Availability for onsite registration is not guaranteed.*

MONDAY, JUNE 16

Registration Hours:

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

Schedule:

7:30–8:20 AM DIA 2014 50th Annual Meeting Orientation/Networking and Coffee
7:45–8:30 AM Coffee and Breakfast Breads
7:45 AM–2:30 PM Student Poster Session (Sails Pavilion Lobby)
8:30–10:00 AM Educational Opportunities
90-minute Offerings (8:30–10:00 AM)
8:30–10:00 AM Student Forum
9:30 AM–6:00 PM Exhibit Hall Open
10:00–11:00 AM Coffee Break
11:00 AM–12:30 PM Educational Opportunities
90-minute Offerings (11:00 AM–12:30 PM)
12:30–2:30 PM Lunch & Exhibit Hall Innovation Theater Presentations
2:30–4:00 PM Plenary Session & Keynote Address

Keynote Speaker

Jamie Heywood
Co-Founder and Chairman, PatientsLikeMe
Founding Director, ALS Therapy Development Institute (ALS TDI)

4:00–6:00 PM Opening Reception and DIA's 50th Anniversary Celebration
4:30 PM Student Poster Award Ceremony (DIA Booth #1531)

#101 Track 01A – Clinical Operations

Related Interest Area(s): CR, AHC/IS

8:30–10:00 AM | Level: ■ | Format: SYMPOSIUM
Room 1B | *CME and Nursing*

Global Clinical Trials Symposium: Opportunities and Challenges

CHAIRPERSON
JeanMarie Markham
Chief Executive Officer, Clinlogix

This symposium will include presentations addressing the opportunities and challenges in conducting clinical trials around the world, specifically Russia, Latin America, and the Asia Pacific region.

Clinical Trials in Mexico, Central America, and the Caribbean: Challenges and Opportunities
Jose Luis Viramontes, MD
Director, Clinical Management, Mexico, Central America and the Carribean, PPD, Mexico

Best Practices for Appropriate Site Selection in Multicentric Clinical Trials in the Asia Pacific Regions
Charu Gautam, MD
Director, Global Clinical Operations, Cliantha Research Ltd, India

Harmonizing Laboratory Test Results for Clinical Trials in Russia: Managing Variability in Multiple Central Laboratories
Tomasz Anyszek, DrMed
Director, Synevo Central Lab, Poland

#102 Track 01B – Clinical Operations

Related Interest Area(s): RD, CR, PT

8:30–10:00 AM | Level: ● | Format: FORUM
Room 3 | *CME, Pharmacy, and Nursing*

Bringing the Patient Voice to Clinical Development

CHAIRPERSON
Mary Stober Murray, MBA
Associate Director, Advocacy, Bristol-Myers Squibb Company

Patient advocacy groups have an important role to play in the clinical development of potential new treatments. They not only advise pharmaceutical developers on protocol design, site selection, and other key aspects of clinical development, but also educate patients and help them find appropriate studies that may be important options in their treatment journey. This forum features representatives from industry, advocacy, and patient groups sharing collaborative models that integrate patient needs into clinical operations.

Patients Powering Progress in Research
Bonnie J. Addario
Founder and President, Addario Lung Cancer Foundation

Saving the Hearts of a Diverse America: Why Ensuring Clinical Trial Participation Is Key
Representative Invited
Chairman of the Board, Association of Black Cardiologists, Sharp Rees Stealy Medical Center

Incorporating Patient Perspectives in Clinical Trials: Models of Collaboration
Mary Stober Murray, MBA
Associate Director, Advocacy, Bristol-Myers Squibb Company

#103 Track 01C – Clinical Operations

Related Interest Area(s): CR, PETD, PT

8:30–10:00 AM | Level: ■ | Format: WORKSHOP
Room 16A | *CME, Pharmacy, and Nursing*

Does One Size Fit All? Understanding the Impact of Cultural Differences Across the Globe

CHAIRPERSON
Lisa Palladino Kim, MS
Global Trial Optimization Specialist, inVentiv Health Clinical

This workshop will increase research professionals' multicultural awareness. Speakers will emphasize how to address cultural barriers during the development and execution of recruitment strategies, site communications, and patient interactions.

This workshop has been developed by the DIA Patient Engagement, Clinical Research, Investigator and Investigative Sites, and Professional Education, Training and Development Communities.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Susan K. Nunchuck, PhD, MSN
Senior Clinical Research Associate, Actelion Clinical Research

Fernando Martinez
Vice President, Business Development, InVentiv Health Clinical, Spain

#104 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, RD, CR

8:30–10:00 AM | Level: ● | Format: WORKSHOP
Room 16B | *CME and Nursing*

Stage Gate Decision-Making Workshop (Part 1 of 2)

CHAIRPERSON
Courtland R. LaVallee, Jr.
Director, Project Management, Theravance, Inc.

This interactive two-part workshop will help attendees who may be primarily involved in tactical activities understand how a company makes strategic decisions for moving a product forward. After a review of a new drug product, attendees will work in teams to discuss their product's information and make recommendations for whether and how their product should be advanced through the development pipeline.

Workshop content is based on DIA's New Drug Product Development and Life Cycle Management training course. Part 1 of this workshop will focus on processes and decisions in phase 2, while Part 2 will focus on phase 3 and the decision to file.

Preregistration is required, and attendees are strongly encouraged to attend both Part 1 and Part 2.

Part 2 will take place on Monday at 11:00 AM (Session #124).

To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Stage Gate Decision-Making Workshop.

***Due to workshop format, seating will be limited. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.*

#105 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): FI, PR, RD

8:30–10:00 AM | Level: ◆ | Format: SESSION
Room 5A | *CME and Nursing*

Making Better Go/No-Go Decisions: Improving Success Rates and Reducing Costs

CHAIRPERSON
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts Center for the Study of Drug Development

This session will examine trends in success rates and recently developed methods which establish a set of factors that can be scored and combined to improve the predictability of approval for compounds that have undergone mid-stage clinical testing.

APGAR Begets ANDI: What Drug Developers Can Learn from Orchestra Auditions and Crying Newborns
Wayne Rackoff, MD, MA
Vice President, Clinical Oncology, Janssen Research & Development, LLC

Improving Phase 2 Go/No-Go Decision-Making with a Simple Scoring Algorithm
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts Center for the Study of Drug Development

Looking at Cost/Time/Risk/Value Scenarios to Improve Clinical Program Decision-Making
Rick Sax, DrMed, FACP
Senior Vice President, Clinical Design and Reporting Services, Quintiles Transnational Corporation

#106 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): PR, CR

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 4 | *CME and Nursing*

Beyond Operational Excellence: A Survey on Sponsor Expectations of Preferred Business Partners

CHAIRPERSON
Rikki Hansen Bouchard, MPA
President and Chief Executive Officer, RH Bouchard & Associates Inc.

This forum will present survey results on nonoperational, business-focused activities that could create a "Partner of Choice" for clinical trial sponsors. It will include an interactive discussion with expert CRO and sponsor panelists.

Panelists
John Potthoff, PhD
President and Chief Executive Officer, Theorem Clinical Research

Mary Kachinsky
Senior Director, Strategic Sourcing, Cubist Pharmaceuticals, Inc.

#107 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, RA, NC

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Pioneering Regenerative Medicine: Trends in Regulations for New Therapy

CHAIRPERSON
Shinji Miyake, PhD
Professor, Center for Clinical Research, Keio University School of Medicine, Japan

This session will introduce the first clinical research of induced pluripotent stem (iPS) cell products in Japan. We will review the most updated regulatory status and governmental efforts surrounding regenerative medicine.

Application of iPS Cells to Retinal Diseases
Masayo Takahashi, PhD
Project Leader, Laboratory for Retinal Regeneration, Riken Center for Developmental Biology, Japan

PMDA Perspective
Daisaku Sato
Director, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

EMA Perspective
Representative Invited
Member, EMA Committee on Advanced Therapies, Medical University of Poland, Poland

#108 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MSL, MC, AP

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Delivering Value Through Medical Content to Health Care Providers

CHAIRPERSON
Robin L. Winter-Sperry, MD
President and Chief Executive Officer, Scientific Advantage LLC

Pharmaceutical companies have an obligation to provide medical content, while maintaining a balance that protects patients. This medical content is regularly provided reactively and often contains information outside of the approved label to respond to questions received from health care providers. This off-label communication is a part of the product life cycle, and guidance for providing this content is currently provided by FDA draft guidance. This session will discuss the delivery of medical communications, both on-label and off-label, to a variety of health care audiences. Several aspects of creating content and differing delivery formats will be addressed.

The Art of Medical Communication: Setting the Stage
Robin L. Winter-Sperry, MD
President and Chief Executive Officer, Scientific Advantage LLC

Defining the Role of the MIS and MSL
Dannis Y. Chang, PharmD
Medical Communications Scientist, Genentech, A Member of the Roche Group

Current US Legal Healthcare Industry Environment
Representative Invited
Chief Regulatory Counsel, Hospira

Going Global: One Step at a Time
Bethany L. Drimalla, PharmD, MS
Manager, Global Oncology Medical Information, Novartis Pharmaceuticals Corporation

#109 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, ST

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 32AB | *CME, Pharmacy, and Nursing*

Central Statistical Monitoring Revealed: How to Enhance Data Quality and 'De-Risk' Studies Through Enhanced Risk-Based Monitoring

CHAIRPERSON
Francois Torche, MBA
Chief Executive Officer, CluePoints, Belgium

The session explores the role of central statistical monitoring in risk-based monitoring (RBM) strategies. The presentations will help sponsors improve data quality by identifying anomalies earlier and addressing issues as they are uncovered to de-risk studies and decrease cost/resource inefficiencies.

Risk-Based Monitoring Revealed: How an Independent and Objective Assessment of Data Quality Will De-Risk Your Study
Francois Torche, MBA
Chief Executive Officer, CluePoints, Belgium

Beyond RBM: Using a Central Monitoring Application as an Oversight Tool in a Cardiovascular Mega-Trial
Eric Genevois-Marlin, MSc
Vice President, Biostatistics and Programming, Sanofi Aventis R&D, France

Realizing the Value of CSM: Showcasing How a Measured Implementation of Central Statistical Monitoring Can Benefit an Organization
Brian J. Nugent, BSN, RN
Associate Director, Clinical Operations, Gilead Sciences, Inc.

#110 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, CR

8:30–10:00 AM | Level: ■ | Format: SYMPOSIUM
Room 33AB | *CME, Pharmacy, and Nursing*

Data Warehousing and Integration: Current Status, Key Success Ingredients and Alternative Approaches for Maximizing the Value of Your Data

CHAIRPERSON
Jonathan Haddad, MPH, MT
Director, Clinical Statistics, Stiefel, A GSK Company

The importance of maximizing the value of precious clinical data is a topic on the minds of many organizations. This session will investigate current technologies, opportunities, challenges and operational processes associated with the optimal use of pooled clinical data. This symposium seeks to provide attendees with insights that will help them evaluate approaches that will best address the needs of their organizations.

Unifying Your Clinical Data Pool for Optimal Clinical Research
Jonathan Palmer
Senior Director, Product Strategy, Clinical Warehousing, Oracle Health Sciences, United Kingdom

The Importance of Clinical SOPs and Processes to Make a Clinical Data Warehouse Program Successful
Rajiv Prasad, MBA
Head, Life Sciences Business Services, HCL America, Inc.

Real-Time Alternatives to Data Warehouses
Rick Morrison
Founder and Chief Executive Officer, Comprehend Systems

#111 Track 08 – Regulatory Affairs and Submissions

Related Interest Area(s): CR, RA

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 30AB | *CME and Nursing*

Global Pediatric Development: We Are Making Progress

CHAIRPERSON
Chin Koerner, MS
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

Representatives from the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Pharmaceutical and Medical Device Agency (PMDA) will provide the latest regional policy developments, share examples of similar policies and agreements and share examples where the agencies differ.

Into the Future: Go Global Pediatric Development Forward for Children Worldwide — Beyond Current Regulations
Junko Sato, DrSc, PhD
Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

FDA Perspective
Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

EMA Perspective
Jordi Llinares, DrMed, MSc
Head of Product Development Scientific Support Department, European Medicines Agency, European Union

#112 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): CmbP, RA

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 11A | *CME and Nursing*

One Paddle for Two Boats? Policy Alternatives to Buoy Adoption of Precision Therapies and Their Companion Diagnostics

CHAIRPERSON
Jeffrey N. Stuart, PhD, RAC
Director, Regulatory Affairs, Novartis Pharmaceuticals Corporation

Precision drug development and adoption are spurred by numerous regulatory initiatives, yet formal mechanisms are lacking for its companion diagnostic. This forum explores policy alternatives to enhance development and proper use of these combinations.

Navigating the Regulatory Pathway for Drug/Companion Diagnostic Co-Development in Precision Medicine
Kenneth Butz
Manager, Medical Devices and Diagnostic Consulting, PPD

FDA Perspective
Christopher Leptak, MD, PhD
OND Biomarker and Companion Diagnostic Lead, CDER, FDA

Opportunities and Barriers to Clinical Implimentation of Genomics in Oncology
Eric Padron, MD
Assistant Member, Section Head, Genomics and Personalized Medicine, H. Lee Moffitt Cancer Center and Research Institute

#113 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, HT

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 11B | *CME and Nursing*

Formal Dispute Resolution at CDER: When, Why, and How

CHAIRPERSON
Kim M. Quaintance
Head, US Regulatory Policy, Bayer HealthCare Pharmaceuticals

Your company has received a decision from CDER on an important issue. Your team reviews the decision, and does not agree with CDER. What do

you do now? Is formal dispute resolution an option, and if it is, is it the best option? The speakers, all with first-hand experience with this process, will discuss the strategy for requesting formal dispute resolution with CDER. The presentations will provide information on when to undertake formal dispute resolution, and when to consider other pathways. Audience members will learn how to successfully navigate the process, including the critical nature of a well written request. Finally, the panelists will go beyond the granted or denied decision and discuss what constitutes a positive outcome. This session will include a case study of a disputed decision.

We Disagree: Is Formal Dispute Resolution an Option?
Kim M. Quaintance
Head, US Regulatory Policy, Bayer HealthCare Pharmaceuticals

Strategy for Discussing Formal Dispute Resolution
Josephine Torrente, JD, MS
Attorney, Hyman, Phelps & McNamara, P.C.

A Dispute Resolution Case Study
Heather Turner, JD
Senior Vice President, General Counsel and Secretary, Orexigen

#114 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR, RA

8:30–10:00 AM | Level: ■ | Format: WORKSHOP
Room 17A | *CME and Nursing*

Protocol Deviations: Finding the Yellow Brick Road (Part 1 of 2)

CHAIRPERSON
Yvonne P. McCracken, MPH
Director of Business Development, PMG Research, Inc

This two-part workshop addresses the lack of consistent terminology and methodology for managing and reporting protocol deviations. A hands-on experience will focus on developing a protocol deviation handling plan and classification of protocol deviations.

Part 1 will provide an overview of the DIA GCP/QA community position paper "Life Cycle and Management of a Protocol Deviation." This position paper represents the inputs of industry experts (including pharmaceutical companies, IRBs, regulatory agency, clinical sites, and others) and provides a common definition for protocol deviations and best practices for categorizing, managing, and reporting study deviations

Preregistration is strongly recommended, and attendees are expected to attend both Part 1 and Part 2.

Part 2 will take place on Monday at 11:00 AM (Session #137).

Workshop sessions will be interactive so attendees are asked to download all handouts to tablet or laptop and bring to both workshop sessions. To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Protocol Deviations Workshop.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Maryrose Petrizzo
Senior Consultant, Halloran Consulting Group, Inc.

Munish Mehra, PhD
Executive Director Business Development, Tigermed-Macrostat

#115 Track 12 – Pharmaceutical Quality

Related Interest Area(s): MF, RA

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 7A | *CME and Nursing*

Implementation of Quality by Design: Progress Update

CHAIRPERSON
Moheb M. Nasr, PhD, MS
Vice President, Regulatory CMC Strategy, GlaxoSmithKline

Leading industry and regulatory speakers will share their perspectives on quality by design (QbD) implementation progress. The session will outline specific implementation strategies and progress made so far, as well as remaining regulatory and technical challenges.

Progress and Remaining Challenges: Industry Perspective
John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

Progress and Remaining Challenges: FDA Perspective
Sarah C. Pope Miksinski, PhD
Acting Director, Division II, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

EMA Perspective
Evdokia Korakianiti, PhD, MSc
Head of Chemicals Section, Quality of Medicines, European Medicines Agency, European Union

#116 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): RA, PR

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 9 | *CME and Nursing*

A Common Decision Framework for Health Technology Assessment and Regulatory Agencies: Is This of Benefit to Stakeholders?

CHAIRPERSON
Neil McAuslane, PhD, MSc
Director, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

It is essential that there is a common framework for health technology assessment and regulatory agencies to enable efficient drug development. This session will present the rationale for why this is critical for stakeholders involved in the development and review of medicines.

EMA Perspective
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Health Canada Perspective
Barbara J. Sabourin, FACP
Director General, Health Products and Food Branch, Health Canada

Industry Perspective
Edward Reilly, PharmD, MSc
Vice President, Global Regulatory Affairs, GSK Vaccines, Belgium

#117 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CP

8:30–10:00 AM | Level: ■ | Format: SESSION

Room 6D | *CME and Nursing*

Risk Management in the US, EU, and Asia: Where Are We Now?

CHAIRPERSON

Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

This session will provide an overview of the current status of risk management in the US, EU, and Asia, with particular reference to new legislation and its implementation.

FDA Perspective
Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

EU Perspective
Peter Richard Arlett, MRCP
Head of Pharmacovigilance Department, European Medicines Agency, European Union

Japan Risk Management Plans (RMP): Experience in Its First Year
Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

#118 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RD

8:30–10:00 AM | Level: ■ | Format: SESSION

Room 5B | *CME and Nursing*

Design and Sample Size Planning for Multiregional Clinical Trials

CHAIRPERSON

Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

This session will address how to design a multiregional clinical trial depending on the availability of associated historical information, and will include regulatory and industry perspectives.

Statistical Considerations in Planning Sample Size for MRCT
H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Science, CDER, FDA

Optimal Designs for Multiregional Clinical Trials with an Additional Regional Requirement
Zhaoyang Teng, MA
PhD Candidate, Biostatistics, Boston University

Discussion from Industry Perspective
Gordon Lan (Kuang Kuo), PhD
Senior Scientific Director, Janssen R&D, LLC

#119 Track 16A – Professional Development

Related Interest Area(s): CR, RA, CP

8:30–10:00 AM | Level: ● | Format: WORKSHOP

Room 30CD | *CME, Pharmacy, and Nursing*

The Twitter Value Proposition for Life Science Professionals

CHAIRPERSON

Robin S. Whitsell
President, Whitsell Innovations, Inc.

This workshop will outline the value of Twitter to a life sciences professional. Initially, we will detail the basics of Twitter, how to get started, how to tweet professionally and compliantly, and how to jury decisions about whom to follow. We will outline the most relevant hashtags and how to follow and/or get involved in conversations based on those hashtags. As the life science industry is heavily regulated (and individuals may have corporate-regulated social media policies), we will discuss establishing personal ground rules associated with tweeting. Though the FDA has remained mostly silent on the topic of Twitter, this workshop will present guidance documents where social media is addressed as both a personal and corporate tool. The goal of this workshop is to allow attendees to more fully understand the value proposition of participating in the Twitter realm of social media. Attendees are encouraged to have Twitter on their mobile phone.

Please note, as a workshop with interactivity, this offering will not be recorded.

Facilitator
Tracy A. England, MBA
Vice President, Marketing, OpenQ

#120 Track 16B – Professional Development

Related Interest Area(s): ALL

8:30–10:00 AM | Level: ● | Format: FORUM

Room 1A | *CME and Nursing*

DIA 2014 Student Forum: Maintaining Your Career - Continuing Education and Changing Your Track

CHAIRPERSON

Danny A. Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

So you've launched your career and have a few years' experience. In the old days, this meant that you would find your final employer and settle in for your inhouse advancement and 25-year gold watch. This is not true today. Our degrees give us basic credentials, our experience is portable to many different fields in the industry, and our career tracks are flexible. This forum will give an overview of updating your education throughout your career and how one can leverage education and experience to change career tracks.

Opportunities for Pharmacists in Industry
Aaron W. Hambrick, PharmD
Manager, Global Medical Review, AbbVie Inc.

Post Graduate Education Needs from 2014 to 2025
Jeremy Whitty, MBA, MSc
Director School of Health Sciences, Hibernia College, Ireland

Maintaining Your Career: Continuing Your Education
Danny A. Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

#121 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 6F | *CME and Nursing*

New Approaches to International Collaboration Between Regulators (Part 1 of 2)

CHAIRPERSON

Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

Starting with the original ICH partners, this forum will explore how the model of regulatory collaboration is evolving from traditional harmonization and information sharing models to strategic coalitions and work-sharing initiatives. It will examine emerging efforts to avoid duplication and increase mutual reliance between regulators and their impact on industry.

Part 2 will take place on Monday at 11:00 AM (Session #144).

Panelists

Margaret A. Hamburg, MD
Commissioner, FDA

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

Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

10:00–11:00 AM COFFEE BREAK

#122 Track 01A – Clinical Operations

Related Interest Area(s): CR, IT, QA/QC

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 1B | *CME, Pharmacy, and Nursing*

Adaptive Monitoring: One Company's Experience with Practical Implementation

CHAIRPERSON

C. Grant Simmons, MSc
Director, Clinical Systems Innovation, Novartis Pharmaceuticals Corporation

This session will provide a large pharmaceutical company's experience over the prior year with an adaptive monitoring approach in a small number of pilot clinical trials, from the perspective of field and central clinical operations, quality assurance, and technology groups.

Adaptive Monitoring Implementation: Operational and Technology Aspects
C. Grant Simmons, MSc
Director, Clinical Systems Innovation, Novartis Pharmaceuticals Corporation

Adaptive Monitoring Implementation: Process and Compliance Aspects
Joanne Spallone
Global Head, Franchise QA Operations and Strategy, Novartis Pharmaceuticals Corporation

#123 Track 01B – Clinical Operations

Related Interest Area(s): CR, RD, PT

11:00 AM–12:30 PM | Level: ■ | Format: FORUM
Room 2 | *CME, Pharmacy, and Nursing*

Engaging Patients through Digital and Social Media Communities

CHAIRPERSON

Brian Loew
Chief Executive Officer, Inspire

Patients now have unprecedented access to medical information, creating new challenges and opportunities for researchers. In this forum, we will discuss strategies and tactics to leverage social and digital media in clinical research and review guidelines which ensure that research integrity is not compromised by social and digital media community members. The patient perspective on how social networks are used for research and support will also be addressed.

Strategies and Tactics to Leverage Social and Digital Media in Clinical Research
Brian Loew
Chief Executive Officer, Inspire

Preserving Patient Safety and Research Integrity
Kenneth A. Getz, MBA
Director of Sponsored Research; Chairman, CISCRP, Tufts Center for the Study of Drug Development

Engaging Patients Through Digital and Social Communities
Bonnie A. Brescia
Founding Principal, BBK Worldwide

#124 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, RD, CR

11:00 AM–12:30 PM | Level: ● | Format: WORKSHOP
Room 16B | *CME and Nursing*

Stage Gate Decision-Making Workshop (Part 2 of 2)

CHAIRPERSON

Courtland R. LaVallee, Jr.
Director, Project Management, Theravance, Inc.

This interactive two-part workshop will help attendees who may be primarily involved in tactical activities understand how a company makes strategic decisions for moving a product forward. After a review of a new drug product, attendees will work in teams to discuss their product's information and make recommendations for whether and how their product should be advanced through the development pipeline.

Workshop content is based on DIA's New Drug Product Development and Life Cycle Management training course. Part 1 of this workshop will focus on processes and decisions in phase 2, while Part 2 will focus on phase 3 and the decision to file.

Preregistration is required, and attendees are strongly encouraged to attend both Part 1 and Part 2.

Part 1 will take place on Monday at 8:30 AM (Session #104).

To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Stage Gate Decision-Making Workshop.

***Due to workshop format, seating will be limited. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.*

#125 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): FI, RD

11:00 AM–12:30 PM | Level: ◆ | Format: SESSION
Room 5A | *CME and Nursing*

Improving Returns on Invested Capital in the Pharmaceutical and Biotechnology Industry

CHAIRPERSON

Akhil Agrawal, PhD, PMP
Associate Director, Janssen Research & Development, LLC

This session will focus on sharing best practices when adapting to the changing health care environment and improving the value of R&D projects. Presentations including case studies will be provided followed by an open forum discussion.

Early Commercialization: It's More Than Just Early Input from Marketing
Michele Pontinen, MA, MBA
Senior Principal, Accenture LLC

Report of Findings on Key Cost Drivers of Clinical Trials in the US
Frank J. Cattie
Vice President, Trial Planning Solutions, Medidata Solutions Worldwide

Maximizing the Value of Licensed Drug: Blending Science with Commercial Assessment and Contemporary Funding Models
Richard N. Williams, JD, PhD
Senior Director Global Regulatory Strategy, Covance Inc.

#126 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RD, OS

11:00 AM–12:30 PM | Level: ◆ | Format: SESSION
Room 4 | *CME, Nursing, and PMI PDUs*

R&D and Technology Outsourcing Today: An Industry Update

CHAIRPERSON

Keith W. Wenzel
Senior Director, Global Alliances, PAREXEL International

This session will explore the current trends in outsourcing from large strategic to functional sourcing to technology partnerships, as well as identify new trends and hear perspectives about the future of outsourcing.

CRO Perspective
Heather Zigmund, PharmD
Senior Director, Clinical Vendor Management, PRA

CMO Perspective
Esther Sadler-Williams, MPharm, MSc
Global Director, Strategic Development and Innovation, Catalent Pharma Solutions, Inc., United Kingdom

Pharmaceutical Perspective on Outsourcing Trends
Keith E. Anderson, PhD
Vice President, Pharmaceutical Sciences, Seragon Pharmaceuticals

#127 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, SP

11:00 AM–12:30 PM | Level: ■ | Format: FORUM
Room 3 | *CME and Nursing*

Risk Sharing or Risk Transfer? Striking the Perfect Balance in Strategic Partnerships

CHAIRPERSON

Andrew Townshend
Vice President, Alliance Development, INC Research

Sponsors continue to pursue partnerships that transfer accountability to their CRO partners based on performance, while CROs seek a better balance between risk and reward. This forum explores risk-sharing arrangements, related benefits, and drawbacks.

Panelists
Mark L. Lacy
President and Chief Executive Officer, Benchmark Research

Mark A. Sanders, MBA
Senior Director, Clinical Development and Medical Sourcing Lead, Pfizer Inc

#128 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): RD, CP, HT

11:00 AM–12:30 PM | Level: ■ | Format: FORUM
Room 7B | *CME and Nursing*

Proarrhythmic Risk Assessment WITHOUT the Thorough QT: FDA and Pharmaceutical Company Perspectives

CHAIRPERSON

Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

In this forum, we will describe development of an assay for the proarrhythmic potential of drugs that is based on characterization of effects on the major human cardiac ion channels. The assay is largely intended to reduce false positives with the thorough QT study.

The Need for a New Paradigm to Assess Proarrhythmic Effects of Drugs
Philip T. Sager, MD, FACC
Consulting Professor of Medicine-Stanford; Chair, Scientific Programs Committee, Stanford University

Industry Perspective on Nonclinical Proarrhythmia Assessment
Gary Gintant, PhD, MA
Research Fellow, AbbVie Inc.

Implementation and Implications of Nonclinical Proarrhtyhmia Assessment
Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

Design of a Comprehensive In Vitro Proarrhythmia Assay
Royce A. Morrison, MD, MS
Principal Consultant, RMDinsight LLC

#129 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, ESUBS, DM

11:00 AM–12:30 PM | Level: ■ | Format: SYMPOSIUM
Room 31AB | *CME and Nursing*

Regulatory Submissions: Better, Faster, and Cheaper

CHAIRPERSON

Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

You can't have it all, we are told, so pick two. This symposium provides strategies that enable medical writers to author high-quality clinical documents for a new drug application (NDA) or biologics license application (BLA), submitted on time and within budget. This symposium will also include the results of a survey on extra hours spent on tasks associated with CSR writing.

Medical Writing Processes for New Drug Application Submissions: Real-World Case Studies
Anita Frijhoff, PhD
Senior Writer, Randstad Pharma

Festina Lente (Make Haste Slowly): Time- and Cost-Effective eCTD-Based Drug Applications
Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

Creating a More Effective Authoring Environment
Marijke H. Adams, PharmD, PhD
President and Principal Scientist, MH Adams & Associates, Inc.

#130 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): SE, CR

11:00 AM–12:30 PM | Level: ■ | Format: FORUM
Room 32AB | *CME and Nursing*

Electronic Clinical Outcome Assessments: Coming to a Device Near You!

CHAIRPERSON

J. Jason Lundy, PhD
Assistant Director, Patient-Reported Outcome Consortium, Critical Path Institute

This forum will describe site-based and field-based electronic data collection and discuss new trends (such as bring your own device studies) for deploying electronic clinical outcome assessment (eCOA) instruments in clinical studies. Opportunities for using electronic platforms in clinical practice and postmarket surveillance studies will also be discussed.

Panelists
Tim Davis
Chief Executive Officer, Exco InTouch, United Kingdom

Cindy Howry
Vice President, eCOA, ePRO Product Management; Vice-Director, ePRO Consortium, Y Prime

#131 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, RA, ESUBS

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 33AB | *CME, Pharmacy, and Nursing*

Why Waste Time and Money? Data Standards from the Beginning: Working Together for Good Science and Good Submissions

CHAIRPERSON

Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

PDUFA V has shined the light on data standards. Everyone recognizes that our trial and reporting processes need to be more effective and efficient. We need to use accepted data standards throughout the clinical data life cycle. With this new awareness and urgency, a number of players (eg, FDA, NCI, CDISC, the C-Path Institute, TransCelerate, and FDA) are working together to make it happen. What do we all want/need? What does this coordinated vision of collaborative standards development and effective application look like? Are we truly coordinating and collaborating across these organizations, so that we can put all of the many pieces together. This session will discuss standards development for this clinical data life cycle, discussing the goals, objectives, and progress of some of the many organizations engaged in this quest.

FDA Perspective
Benjamin Peter Vali, MS
Biostatistical Reviewer, Division of Biometrics III, Office of Translational Science, Office of Biostatistics, CDER, FDA

Protocol Standardization, Common Protocol Templates, and Data Standards: Streamlining Clinical Development
Robert A. Di Cicco, PharmD
Vice President, Clinical Pharmacology Sciences and Study Operations, GlaxoSmithKline

Realizing the Promise of End-to-End Standards through CFAST and CDISC SHARE
Wayne R. Kubick, MBA
Chief Technology Officer, CDISC

Panelist
Paula Brown Stafford, MPH
President, Clinical Development, Quintiles Inc.

#132 Track 07C – Processes and Technologies for Clinical Research

Related Interest Area(s): DM, ESUBS

11:00 AM–12:30 PM | Level: ■ | Format: SYMPOSIUM
Room 30CD | *CME and Nursing*

Driving Toward Standardization: Overcoming Barriers - eDM, eTMF, and CTMS

CHAIRPERSON

Nancie E. Celini, DrPH
Chief Health Technology Advisor and Educator, CAB Inc.

Significant resources (people, technology, funding) have been allocated by industry across several critical technologies required to support an overwhelming amount of data/document flows through today's modern biological/pharmaceutical/device industry. While the transition from paper to electronic systems remains a work in progress the need for standardization has never been greater. Well-formed, pragmatic standards for data transfer

and document management processes can drive efficiencies and encourage faster progress. This is especially pertinent in the current industry context where organizations fall in a matrix of just starting to implement electronic trial master file (eTMF), electronic document management system (EDMS), clinical trial management system (CTMS) to advanced implementations. This symposium, a critical starting point to three dialogues on EDM, eTMF, investigator portal and CTMS, provides an introduction and real-world critique of these systems.

eTMF/EDM/eCTD: The Whole Shebang
Adair Turner
Director, Regulatory and Clinical Operations, Mission3

The Complicated Life of a (TMF) eSubmission Document
Lisa D. Mulcahy
Owner and Principal Consultant, Mulcahy Consulting LLC

Integrating Across Pharmaceutical Company CTMS Systems to Generate a Uniform Data Structure
Graeme Benson, PhD
Chief Information Officer, Drugdev.org, United Kingdom

#133 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, PPLC, RD

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 10 | *CME, Pharmacy, and Nursing*

Pediatric Drug Development: Lessons Learned During FDASIA Implementation

CHAIRPERSON
Rosemary M. Addy
Supervisory Consumer Safety Officer, Office of New Drugs, CDER, FDA

Now that the pediatric study plan required under the Food and Drug Administration Safety and Information Act (FDASIA) has been implemented, this session will review lessons learned from both an FDA, discuss how to coordinate with European pediatric inverstigational plan (PIP) and include an industry perspective.

You Want Us to Withdraw our PSP? A PSP Case Study
Betsy J. Waldheim
Senior Director, Regulatory Affairs, Eisai Inc.

Pediatric Study Plans: Examples Across One Company's Pipeline
Lisa L. Mathis, MD
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

Early Experiences with Title V Post-FDASIA Across the Industry
Christina Bucci-Rechtweg, MD
Head, Pediatric and Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

#134 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, PT, RD

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 30AB | *CME, Pharmacy, and Nursing*

Fact or Fiction: Patient Engagement in the Drug Development Process

CHAIRPERSON
Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

This session will involve a discussion on experiences with patient engagement and the benefits and challenges faced by industry and regulators. The panel will include representatives from a patient advocacy group, industry and a regulatory authority.

This forum has been developed by the DIA Patient Engagement, Regulatory Affairs, and Clinical Trial Disclosure Communities.

Industry Perspective
Michael Maher
Executive Director, US Regulatory Policy and Global Intelligence, Pfizer Inc

Patient Perspective
Debra Madden
Cancer Research Advocate, Patient Representative, Ann's Place; National Breast Cancer Coalition (NBCC); Research Advocacy Network

FDA Perspective
John J. Whyte, MD, MPH
Director, Professional Affairs and Stakeholder Engagement, Office of the Center Director, CDER, FDA

#135 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): NC, RA, HT

11:00 AM–12:30 PM | Level: ■ | Format: FORUM
Room 11B | *CME and Nursing*

FDA Regulation of Therapeutic Products Derived from Human Stem Cells: Successfully Navigating the Regulatory Hurdles

CHAIRPERSON
Torrey Cope, JD
Partner, Sidley Austin LLP

FDA regulates many types of therapeutic products derived from human stem cells as biological drugs. This forum will address the basic regulatory requirements for these products, common hurdles that arise in research and development, and options for addressing those hurdles.

Panelists
Ellen G. Feigal, MD, MSc
Senior Vice President, Research and Development, California Institute for Regenerative Medicine (CIRM)

Linda Marban
Chief Executive Officer, Capricor Therapeutics

#136 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 5B | *CME and Nursing*

Defining, Measuring, and Assessing "Fit for Purpose" Quality in a Risk-Based Monitoring Model: Industry and Agency Perspectives

CHAIRPERSON
John Poland, PhD
Senior Director, Regulatory Policy and Compliance, Covance Clinical Development Services, United Kingdom

FDA and EMA guidance encourage a shift from 100% data verification to "fit for purpose" trial quality. Key concepts, metrics that allow trial oversight, and how trial quality can be reported and assessed will be addressed in this context.

EMA Perspective
Anabela Marcal
Head of Compliance and Inspections Department, European Medicines Agency, European Union

FDA Perspective
Jean Mulinde, MD
Acting Senior Advisor, Division of GCP Compliance, Office of Scientific Investigations, CDER, FDA

Industry Perspective
Mike Sobczyk, MSc
Senior Director, Regulatory Compliance, Gilead Sciences, Inc.

#137 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CP

11:00 AM–12:30 PM | Level: ■ | Format: WORKSHOP
Room 17A | *CME and Nursing*

Protocol Deviations: Finding the Yellow Brick Road (Part 2 of 2)

CHAIRPERSON
Yvonne P. McCracken, MPH
Director of Business Development, PMG Research, Inc

This two-part workshop addresses the lack of consistent terminology and methodology for managing and reporting protocol deviations. A hands-on experience will focus on developing a protocol deviation handling plan and classification of protocol deviations.

In Part 2, attendees will participate in a hands-on experience where a protocol deviation handling plan will be developed, potential protocol deviations will be prospectively identified and classified, and important protocol deviations will be identified for regulatory agency reporting. Tools will be provided to workshop attendees.

Preregistration is strongly recommended, and attendees are expected to attend both Part 1 and Part 2.

Part 1 will take place on Monday at 8:30 AM (Session #114).

Workshop sessions will be interactive so attendees are asked to download all handouts to tablet or laptop and bring to both workshop sessions. To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Protocol Deviations Workshop.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Maryrose Petrizzo
Senior Consultant, Halloran Consulting Group, Inc.

Munish Mehra, PhD
Executive Director Business Development, Tigermed-Macrostat

#138 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CP, CR, PR

11:00 AM–12:30 PM | Level: ● | Format: FORUM
Room 9 | *CME, Pharmacy, and Nursing*

Observational Studies of Comparative Effectiveness: How to Recognize Good Practice

CHAIRPERSON
Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

Understanding that a randomized clinical trial can only be used to answer a tiny fraction of questions, this forum addresses how real-world data are used from the perspective of industry, government, and payers, and how quality observational research can be identified.

Best Evidence to Support Regulatory Decision Making
Jordi Llinares, DrMed, MSc
Head of Product Development Scientific Support Department, European Medicines Agency, European Union

The Practice of Observational Research in Risk Management
J. Michael Sprafka, II, PhD, MPH
Executive Director, General Medicine, Inflammation & Bone TA Lead, Amgen Inc.

Using the GRACE Checklist for Quality in Observational Research
Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

#139 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

11:00 AM–12:30 PM | Level: ■ | Format: SYMPOSIUM
Room 6D | *CME, Pharmacy, and Nursing*

Assessment of Impact and Effectiveness of Risk Management and Minimization in the EU and US

CHAIRPERSON
Saad A.W. Shakir, MD, FFPM, FISPE, FRCP
Director, Drug Safety Research Unit (DSRU), United Kingdom

This symposium will provide insights, information about tools used, and approaches to assess and measure the effectiveness and impact of risk management and minimization methods in the EU and US.

Evaluating Risk Evaluation and Mitigation Strategies Effectiveness Using Existing Tools
Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, UBC: An Express Scripts Company

Impacts of Safety Warning and Risk Evaluation and Mitigation Strategies on Drug Utilization and Clinical Outcome
Jason C. Hsu
Assistant Professor, Institute of Clinical Pharmacy and Pharmaceutical Sciences, National Cheng Kung University, Taiwan

Monitoring and Studying the Effectiveness of Risk Management and Minimization in the EU
Saad A.W. Shakir, MD, FFPM, FISPE, FRCP
Director, Drug Safety Research Unit (DSRU), United Kingdom

#140 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

11:00 AM–12:30 PM | Level: ■ | Format: SESSION

Room 6E | *CME and Nursing*

Effective Communication Model Between Drug Safety, Regulatory Affairs, and Clinical Development

CHAIRPERSON

Thomas Felix, MD
Director, Research and Development Policy, Amgen Inc.

This session reviews ideal interactions between regulatory affairs, safety, and clinical development in order to avoid noncompliance. Effective communication between safety, regulatory affairs, and clinical is key to address issues arising during development and postapproval.

Data Transparency
Representative Invited
Vice President and Head, Global Regulatory Affairs and Patient Safety, AstraZeneca

The Evolution of Pharmacovigilance in the EU: A Look at Member States' Experiences a Year After the Directive
Thomas Felix, MD
Director, Research and Development Policy, Amgen Inc.

Compasssionate Use
Representative Invited
Partner, EU Life Sciences, Arnold & Porter LLP, United Kingdom

#141 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): HT, RA

11:00 AM–12:30 PM | Level: ● | Format: SESSION

Room 8 | *CME, Pharmacy, and Nursing*

Strategic Quantitative Thinking: Designing a Roadmap for Innovation

CHAIRPERSON

Stephen E. Wilson, DrPH
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Science, CDER, FDA

Making effective regulatory decisions through the use of strategic quantitative thinking—PDUFA V, PROs, Benefit-risk, rare diseases, safety, missing data, subgroup analysis, multiregional trials, meta-analysis, Big Data, antibacterial trial design and analysis, sensitivity analysis, data quality, improving trials, data standards, SMART Trials, enrichment designs, Bayesian designs, strategic planning, precompetitive collaborations, leadership, communication. This will be a far-ranging, open-microphone Q&A session that will examine priorities, prospects and next steps—an opportunity to think about innovative systems and approaches to the design and analysis of the quantitative evidence that we need to make decisions regarding the safety and effectiveness of medical products.

Panelists

H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Science, CDER, FDA

Rima Izem, PhD
Lead Mathematical Statistician, Office of Translational Science, CDER, FDA

Lisa M. LaVange, PhD
Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Karen Lynn Price, PhD, MA
Research Advisor, Eli Lilly and Company

Ram Tiwari, PhD
Associate Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Lilly Yue, PhD
Deputy Director, Division of Biostatistics, CDRH, FDA

#142 Track 16 – Professional Development

Related Interest Area(s): ROD, CR, PT

11:00 AM–12:30 PM | Level: ● | Format: WORKSHOP

Room 16A | *CME, Pharmacy, and Nursing*

Narrative Medicine: How to Tap into the Inherent Power of Words and Stories in the Clinical Trial Process

CHAIRPERSON

Jesus Rivera, MSc
Senior Learning Manager, Bristol-Myers Squibb Company

Narrative medicine helps doctors, nurses, social workers, and therapists improve the effectiveness of care by developing the capacity for attention, reflection, representation, and affiliation with patients and colleagues. This workshop will introduce the concept of narrative medicine and the skills and habits of reflective writing and listening to better recognize, receive, absorb, interpret, and honor stories of illness towards the goal of achieving narrative competence.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

#143 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): PR, PT, CEHTAEbM

11:00 AM–12:30 PM | Level: ● | Format: SESSION

Room 1A | *CME and Nursing*

Pricing, Economics, Reimbursement, Market Share (PERMS) Strategy: An Interactive Holistic Approach in Rare Diseases

CHAIRPERSON

Peter J. Mallow, PhD
Director of Economic Evaluations, S2 Statistical Solutions

Many countries incentivize orphan drug development; however, reimbursement is not assured at a viable level. This session presents a strategy to assess orphan drug development that accounts for pricing, economics, reimbursement, and market size.

Rare Disease Aspects of Pricing, Economics, Reimbursement, Market Share (PERMS) Strategy
William Irish
Vice President, Health Outcomes Research and Biostatistics, CTI Clinical Trial and Consulting Services

Real-World Experience with Reimbursement for Orphan Drugs
Representative Invited
Executive Director, NPS Pharmaceuticals

Economic Aspects of Pricing, Health Economics, Reimbursement, Market Share (PHERMS) Strategy
John Rizzo
Professor, Economics and Preventative Medicine, Stony Brook University

#144 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

11:00 AM–12:30 PM Level: ■ Format: FORUM
Room 6F *CME and Nursing*

New Approaches to International Collaboration Between Regulators (Part 2 of 2)

CHAIRPERSON
Murray M. Lumpkin, MD, MSc
Deputy Director, Regulatory Affairs, Global Health and Integrated Development, Bill and Melinda Gates Foundation

Building on Part 1, that explored how the model of regulatory collaboration has evolved from traditional harmonization and information sharing models to strategic coalitions and work-sharing initiatives, this part 2 forum will discuss regulatory collaboration efforts in a wider international context and with a wider group of regulators. The specific role of WHO and non- governmental organizations will also be addressed.

Part 1 will take place on Monday at 8:30 AM (Session #121).

Panelists
Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

John Skerritt, PhD
National Manager, Therapeutic Goods Administration (TGA), Australia

Representative Invited
Vice Minister, China Food and Drug Adminsitration (CFDA), China

Lembit Rago, MD, PhD
Head, Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

Dirceu Brás Aparecido Barbano
Director-President, Agência Nacional de Vigilância Sanitária (ANVISA), Brazil

12:30–2:30 PM

Lunch & Exhibit Hall Innovation Theater Presentations

#145 Track 21 - Innovation Theater

Related Interest Area(s): FI, CR, PETD

1:00–2:00 PM Level: ■ Format: SPECIAL SESSION
Exhibit Hall

INC Research Innovation Theater: "Organizing for Change"... Lessons Learned in Preparing a Global Organization for Innovation

Our industry is facing pressure to reduce development costs and ensure better outcomes from clinical trials. These pressures can be translated into opportunities if we identify the necessary strategic innovation and successfully drive the technological and organizational change to realize it. Change is hard for any company. INC will share the critical partnership between Project and Change Management and highlight key elements in delivering innovation through successful organizational change.

Opening Plenary – Keynote Address

2:30–4:00 PM Level: ●
Room Ballroom 20

Plenary Session & Keynote Address

Join us as DIA kicks off the celebration for its 50th Annual Meeting, "celebrating the past" as we reflect on the many advancements in therapeutic innovation and regulatory science over the past 50 years, and being a part of "inventing the future" in health care worldwide.

Welcome Remarks

Minnie Baylor-Henry, JD, RPh
Worldwide Vice President, Regulatory Affairs, Johnson & Johnson Medical Devices & Diagnostics
DIA President and Chair, Board of Directors

Opening Remarks

Rear Adm. (ret.) Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA
Program Co-Chair

Freda C. Lewis-Hall, MD, FAPA
Executive Vice President and Chief Medical Officer;
PCORI Board of Governors, Pfizer Inc
Program Co-Chair

Keynote Address

Jamie Heywood
Co-Founder and Chairman, PatientsLikeMe
Founding Director, ALS Therapy Development Institute (ALS TDI)

4:00–6:00 PM

Opening Reception and DIA's 50th Anniversary Celebration

Exhibit Hall

NOTES

JOIN A DIA COMMUNITY!

This exclusive member benefit helps DIA members stay connected even after the meeting ends! DIA Communities allow members to exchange information, explore industry hot topics and grow their professional network.

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- ✓ Keep up-to-date on hot topics and community-generated content and programming
- ✓ Share best practices, knowledge resources, articles and more

To join or see a full listing of DIA's Communities, please visit
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To become a DIA member, please visit the registration desk or go to
diahome.org/Membership

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TUESDAY

Drug Safety eLearning Program

Buy all Six Modules and Save $600!

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Introductory Offer!*

Drug safety affects everyone involved in the pharmaceutical product life cycle. Every organization would benefit by requiring their employees to enroll in the Drug Safety eLearning Program.

This eLearning program includes six self-paced modules accessible anytime, anywhere, and provides a broad overview of safety regulations, requirements, and activities throughout the product life cycle from clinical trials, approval, to postmarketing activities.

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Module 1: Introduction to Drug Safety
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Available Today!

Module 3: Premarketing Clinical Trial Safety
Launch Date: July 2014

Module 4: Postmarketing Safety Management
Launch Date: August 2014

Module 5: Basics of Signal Detection and Pharmacoepidemiology
Launch Date: September 2014

Module 6: Safety Audits and Inspections
Launch Date: October 2014

Introductory Package: $1800 | Package after August 31, 2014: $2400 | Individual Module: $400

Enroll today at diahome.org/safetyelearning

*Purchase all six modules in one transaction before August 31, 2014, and receive 25% off the purchase price.

TUESDAY, JUNE 17

Registration Hours:

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

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
7:15 AM–4:00 PM	Professional Poster Session #1 (Sails Pavilion)
8:00–9:30 AM	Educational Opportunities: 60-minute TURBO Offerings △ (8:00–9:00 AM) 90-minute Offerings (8:00–9:30 AM)
9:00 AM–5:00 PM	Exhibit Hall Open
9:30–10:30 AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30 AM–12:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (10:30–11:30 AM) 90-minute Offerings (10:30 AM–12:00 PM)
11:30 AM–1:30 PM	Lunch & Exhibit Hall Innovation Theater Presentations
1:30–3:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (1:30–2:30 PM) 90-minute Offerings (1:30–3:00 PM)
1:30–3:30 PM	Exhibit Guest Passes
2:30–3:30 PM	Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30–5:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (3:30–4:30 PM) 90-minute Offerings (3:30–5:00 PM)

#201 Track 01A – Clinical Operations

Related Interest Area(s): CR, IT, PT

8:00–9:30 AM | Level: ■ | Format: FORUM

Room 1B | *CME and Nursing*

Updated Strategies for Effective Recruitment of Patients in Clinical Trials

CHAIRPERSON

Elizabeth Mahon, JD
Associate Director, TCSM-US, Janssen Research & Development, LLC

Data confirm the inability of trials to meet recruitment goals.This forum responds with discussion of new and emerging communications channels, processes, and technologies with potential to improve recruitment rates.

Clinical Trial Recruitment Challenges: Patient Advocacy Perspectives
Representative Invited
Executive Director, Education Network to Advance Cancer Clinical Trials (ENACCT)

Are Patients Like Mine in the Clinical Trials?: Regulatory Challenges and Realities
Jonca C. Bull, MD
Director, Office of Minority Health, Office of the Commissioner, FDA

Recruitment Methods: Old and New
Elizabeth Mahon, JD
Associate Director, TCSM-US, Janssen Research & Development, LLC

#202 Track 01B – Clinical Operations

Related Interest Area(s): CR, SP, RD

8:00–9:30 AM | Level: ■ | Format: FORUM

Room 2 | *CME, Pharmacy, and Nursing*

Collaboration in R&D: What's New for TransCelerate BioPharma?

CHAIRPERSON

Susan Cantrell
Senior Vice President and Managing Director, DIA Americas, DIA

This forum will provide highlights and accomplishments from the original five TransCelerate initiatives – development of a standardized approach for risk-based site monitoring, mutual recognition of clinical trial site qualification and training, development of clinical data standards, establishment of a comparator drug network and development of a shared investigator site portal, as well as discuss current progress of new initiatives and line extensions in 2014, including creation of common clinical trial protocol templates, development of a special populations (pediatric and minority) clinical trial network and establishment of a shared investigator registry. There will also be Q&A with the panel, which will include members of TransCelerate's Board of Directors and Operations Committee.

Panelists
Dalvir Gill, PhD
Chief Executive Officer, TransCelerate Biopharma Inc

Annalisa Jenkins, MRCP
Chairwoman, Board of Directors, TransCelerate Biopharma Inc.; Former Executive Vice President, Head of Global Research and Development, Merck Serono, Germany

Representative Invited
Senior Vice President and Worldwide Head of Development Operations, Pfizer Inc

Lynn G. Marks, MD
Senior Vice President, Projects, Clinical Platforms and Sciences, GlaxoSmithKline

#203 Track 01C – Clinical Operations

Related Interest Area(s): AHC/IS, CR, PETD

8:00–9:30 AM | Level: ■ | Format: WORKSHOP

Room 16A | *CME, Pharmacy, and Nursing*

Monitor Training: Building Essential Skills for Implementing Risk-Based Monitoring - Data Interpretation, Quality by Design

CHAIRPERSON

Penelope K. Manasco, MD, MS
Chief Executive Officer, MANA Consulting

This workshop provides monitors with the skills to evaluate data, develop intervention plans for sites and to remotely follow up on the outcome of the interventions. We will teach methods for data review and interpretation and translating to practice.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Christine Riley-Wagenmann
Manager, NextGen CDS

Libby Cerullo, MSc
President, Pivotal Consulting LLC

#204 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PR, OS, RD

8:00–9:30 AM | Level: ◆ | Format: FORUM
Room 5A | *CME, Nursing, and PMI PDUs*

Drug Development and the Virtual Company

CHAIRPERSON

Carrie Nodgaard Helland, MBA, PMP
Vice President, Project Management and Manufacturing, CytRx Corporation

This forum will explore drug development at the virtual biotechnology company through cash planning, management, and control for development programs; the role of the project manager; and partnering and outsourcing.

Drug Development and the Virtual Company: Cash Management
Carrie Nodgaard Helland, MBA, PMP
Vice President, Project Management and Manufacturing, CytRx Corporation

Drug Development and the Virtual Company: Outsourcing
Anca Maria Copaescu, MBA, MSc
Senior Director, Clinical Outsourcing and Analytics, BioMarin Pharmaceutical Inc.

Drug Development and the Virtual Company: Project Management
Haley Laken, PhD
Director, Tesaro

#205 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RD, PETD, SP

8:00–9:30 AM | Level: ● | Format: FORUM
Room 1A | *CME and Nursing*

Effective Leadership in Hybrid Team Between West and East Asia in New Drug Development

CHAIRPERSON

Atsushi Tsukamoto, PhD, MSc, PMP
Senior Director, Global Project Management, Daiichi Sankyo Company, Ltd., Japan

In this forum, we will discuss key success factors and common gaps in a West and East Asian hybrid team in drug development. Participants will learn practical tips that can be used immediately for successful hybrid team leadership and management.

Panelists
Robert A. Hilke, MA
Chief Executive Officer, Hilke Communications Corporation, Japan

Gareth Julian Monteath, MBA, MS
Program Director, Link Global Solution Inc., Japan

Atsushi Tsukamoto, PhD, MSc, PMP
Senior Director, Global Project Management, Daiichi Sankyo Company, Ltd., Japan

#206 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP, RD

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 3 | *CME and Nursing*

Big Data, Big Impact: New Levels of Strategic Partnerships Between Sponsors-CROs

CHAIRPERSON

MaryAnne Rizk, PhD, MS, PMP
Global Head, CRO Business Partnerships, Oracle Health Sciences

The big data transformation within life sciences has revolutionized collaborations and how strategic partnerships between CROs and sponsors are formed. This forum will show how to leverage the wealth of new data and improved analytics to enhance future innovation partnerships that will feed the drug development pipeline. Panelists will include speakers from both CROs and their sponsor partners addressing leading techniques to improve their productivity and efficiency in order to better demonstrate clinical benefit and health outcomes.

Panelists
Brendan M. Buckley, MD, PhD
Chief Medical Officer, ICON plc, Ireland

Gary J. Thompson, MS
Senior Director, Data Sciences and Solutions, Eli Lilly and Company

MaryAnne Rizk, PhD, MS, PMP
Global Head, CRO Business Partnerships, Oracle Health Sciences

#207 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, RD, HT

8:00–9:30 AM | Level: ● | Format: SESSION
Room 7B | *CME, Pharmacy, and Nursing*

Nanotechnology: Application to Medical Products

CHAIRPERSON

Suzanne Sensabaugh
President and Principal Consultant, Hartmann Willner LLC

This session will address the topic of nanotechnology with a focus on its use for drugs and biologics. It will define the term; provide a basic overview of the technology and uses; and address development, scientific, and regulatory challenges.

Biomedical Nanotechnology: The Smaller the Thing, the Bigger the Challenge
Michael Drues, PhD
Founder and President, Vascular Sciences

Nanomaterials in Drug Products: A Regulatory Update
Celia N. Cruz, PhD
Senior Product Quality Reviewer, Office of Pharmaceutical Science, CDER, FDA

Industry Perspectives of Nanomedicines: It's a Small World After All
Frank J. Malinoski, MD, PhD
Chief Medical Officer, Liquidia Technologies

#208 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): AP, RA, MA

8:00–9:30 AM | Level: ● | Format: WORKSHOP
Room 7A | *CME, Pharmacy, and Nursing*

Prescription Drug Marketing Regulatory Primer

CHAIRPERSON

Janet "Lucy" Rose, MBA
President, Lucy Rose and Associates, LLC

This interactive workshop will provide a basic introduction to the regulation of prescription drug advertising and promotion. It will cover such important information as fair balance, required claim support, comparative claims, preapproval activities, and medical conventions.

Please note, as a workshop with interactivity, this offering will not be recorded.

Facilitator
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

#209 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, PT, MC

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Communicating Clinical Trial Results: Targeting the Patient Audience

CHAIRPERSON

David B. Clemow, PhD
Senior Clinical Research Scientist, Lilly USA, LLC

This session will describe current venues where drug development organizations communicate clinical trial results to patients, how to best communicate, and the importance of meeting patients' needs for them and the drug development organization.

This session has been developed by the DIA Medical Writing, Patient Engagement, Medical Communications, and Clinical Trial Disclosure Communities.

Patient Perspective on Communication
Colleen Zak, BSN
Founder/President, ARPKD/CHF Alliance

Communicating Through Clinical Trial Disclosures
Barbara Godlew, RN
President, The FAIRE Company, LLC

Communicating Medical Information
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Communicating Through Advertising/Promotion
David B. Clemow, PhD
Senior Clinical Research Scientist, Lilly USA, LLC

#210 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, RA, CR

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 30CD | *CME, Pharmacy, and Nursing*

Electronic Source Data in Clinical Investigations (Part 1 of 2): Regulatory Considerations

CHAIRPERSON

Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

This two-part forum's panel will focus on the regulatory and practical considerations with respect to the FDA Guidance on Electronic Source Data in Clinical Investigations (eSource).

Part 2 will take place on Tuesday at 10:30 AM (Session #238).

Electronic Source Data in Clinical Investigations
Mitra Rocca, MS
Senior Medical Informatician, Office of Translational Science, CDER, FDA

Panelists
Leonard Sacks, MD
Associate Director of Clinical Methodology, Office of Medical Policy, CDER, FDA

Sean Y. Kassim, PhD
Acting Office Director, Office of Scientific Investigations, Office of Communications, CDER, FDA

#211 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): SE, PT

8:00–9:30 AM | Level: ■ | Format: SYMPOSIUM
Room 32AB | *CME, Pharmacy, and Nursing*

Clinical Outcomes Assessment and Patient Engagement Symposium

CHAIRPERSON

Keith W. Wenzel
Senior Director, Global Alliances, PAREXEL International

Engaging patients, collecting study endpoints data, and interpreting patient-reported data is important and nuanced work. This symposium brings together experts in patient reminders, study endpoints data collection, and interpretation of patient-reported outcome (PRO) treatment effects to provide the most recent trends in clinical outcomes assessments and patient engagement.

Interpreting Treatment Effects From Patient-Reported Outcome (PRO) Endpoints: Patient Global Ratings of Concept versus Change
Cicely Kerr, PhD, MSc
Lead Outcomes Researcher, Patient Reported Outcomes, ICON plc, United Kingdom

Patient Survey Data Results: Reminder Preferences in Patient-Reported Outcomes Studies
Mark Wade
Director, Patient Focused Solutions, Almac

The Mobile Platform for Infant Flu Vaccine Surveillance
Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

#212 Track 07C – Processes and Technologies for Clinical Research

Related Interest Area(s): IT, NC, CR

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 33AB | *CME, Pharmacy, and Nursing*

Bioinformatics and Translational Medicine

CHAIRPERSON

Julia Zhang, PhD
Associate Director, Sanofi US

This session will focus on how informatics can glue together big data and translational medicine, therefore enabling the translational medicine. Semantic web technology and big data will be discussed for the enabling.

Informatics Glues Big Data and Translational Medicine
Julia Zhang, PhD
Associate Director, Sanofi US

Semantic Web Technology and Big Data
Andreas Matern
Vice President, Disruptive Innovation, Thomson Reuters IP & Science

eagle-i Network: A National Consortium for Sharing Biomedical Resources to Speed up Translational Science Research
Bhanu Bahl, PhD, MA, PMP
Director, Harvard Clinical and Translational Science Center, Harvard Medical School

#213 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): PT, RA

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 8 | *CME and Nursing*

PDUFA V New Molecular Entity Program: History, Implementation and Future of the Program

CHAIRPERSON

Brian Michael Mayhew, MBA
Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

The key component of PDUFA V is the New Molecular Entity Review Program (the Program). This session will provide a background on the Program, including key elements, how it came to be, and why. This session will also provide an implementation update from FDA, including a discussion of milestones achieved thus far and those still to come. An industry representative will discuss their perspective on the implementation of the program via a business case. Lastly, the panel and the audience will engage in a discussion of what could be included in subsequent PDUFA reauthorizations.

Status Update: An FDA Perspective
Beth Duvall
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

Industry Perspective
Deepika Jalota, PharmD
Director, Global Regulatory Strategy, Ophthalmology/Dermatology, Bayer HealthCare

Panelist
Kate Rawson
Senior Editor, The RPM Report: Regulation Policy and Market Success

#214 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): ESUBS, RA

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 30AB | *CME and Nursing*

Regulated Product Submissions and eCTD 4: The Path to Progress

CHAIRPERSON

Joel Finkle
Senior Strategist, Regulatory Informatics, CSC Life Sciences

With HL7 standard approval, regulated product submissions (RPS) now move to International Organization for Standardization (ISO) approval prior to ICH Step 4 adoption as electronic common technical document (eCTD) 4.0. Listen to vendor, agency, and sponsor viewpoints on the impact of this long-awaited submission standard.

FDA Perspective on RPS/eCTD 4
Mark A. Gray
Director, Division of Data Management Services and Solutions, Office of Business Informatics, CDER, FDA

Industry Perspective on RPS/eCTD 4
Representative Invited
Associate Director, Global Submissions Management (US), Eisai Co., Inc.

Vendor Perspective on RPS/eCTD 4
Joel Finkle
Senior Strategist, Regulatory Informatics, CSC Life Sciences

#215 Track 08C – Regulatory Affairs and Submissions

Related Interest Area(s): RA, SP

8:00–9:00 AM △ | Level: ■ | Format: SESSION
Room 31C | *CME and Nursing*

The Regulatory Intelligence Function: Evolution Over the Past Decade in an Expanded Global Marketplace

CHAIRPERSON

Emily Huddle
Regulatory Intelligence Executive, GlaxoSmithKline

This session will examine the current characteristics of the regulatory intelligence function across industry and compare the evolution of the function utilizing metrics collected from surveys conducted in previous years. The session will also explore sources of global regulatory intelligence and an approach to triaging this business critical information in a company of any size.

Regulatory Intelligence Benchmarking Survey: 2002 — Present
Emily Huddle
Regulatory Intelligence Executive, GlaxoSmithKline

Gathering and Triaging Global Regulatory Intelligence
Kimberly Belsky, MS
Executive Director, Advertising, Labeling and Policy, Valeant Pharmaceuticals

#216 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): RA, MDD

8:00–9:30 AM | Level: ● | Format: FORUM

Room 11A | *CME and Nursing*

CDRH Town Hall

CHAIRPERSON

Janet Jenkins-Showalter
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

This forum will provide a unique opportunity to hear from the director of the Center for Devices and Radiological Health (CDRH) who will report on the state of CDRH and its vision for the future. Topics to be addressed include: FDASIA accomplishments and activities; the view toward 2017 MDUFA Reauthorization; companion diagnostics and personalized medicine; investigational device exemptions for in vitro diagnostic products (including companion diagnostic products); FDA's Unique Device Identification (UDI) program; regulation of mobile and web software applications; CDRH's Case-for-Quality Initiative—promoting device quality in the global marketplace; and public-private partnerships, ie, Medical Devices Innovation Consortium (MDIC) and other CDRH innovative programs.

Please come prepared with your questions for the CDRH panel. You may submit questions and topics of interest in advance to annualmeetingprogram@diahome.org, and include "CDRH Panel" in the subject line.

Panelists
Jeffrey Shuren, JD, MD
Director, CDRH, FDA

Alberto Gutierrez, PhD
Director, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

Representative Invited
Director, Office of Device Evaluation, CDRH, FDA

Kirsten H. Paulson, MS, RAC
Senior Officer, Medical Device Initiative, The Pew Charitable Trusts

#217 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, RA, CR

8:00–9:30 AM | Level: ■ | Format: SESSION

Room 6E | *CME and Nursing*

Regulatory and GCP Quality Trends in Emerging Markets

CHAIRPERSON

Fred Feldstein, JD
Head of Primary and Consumer Healthcare BU Quality Assurance, Pfizer Inc

This session presents an understanding of the regulatory environment and challenges that may exist, the trends identified through GCP audits and inspections, and harnessing the opportunities of conducting trials in emerging countries.

IRBs and Sites Quality Cerifications in Latin America: Do We Really Have a Trend Regarding This Matter in the Region?
Charles Schmidt, MD
Head Scientific Medical Advisory Board, Prof., Santa Casa Medical School, Esterm Medical CRO, Brazil

CRO Perspective
Deborah Wade
Vice President, Process Quality Management, PAREXEL International

#218 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR, RA

8:00–9:30 AM | Level: ■ | Format: FORUM

Room 6C | *CME and Nursing*

Quality and Risk Management in an Increasingly Complex Clinical Research Environment: State of the Industry and Leading Practices

CHAIRPERSON

Steven B. Whittaker
Executive Director, The Avoca Group

Data from a recent quality consortium assessment, a collaboration focused on proactive quality management, will serve as a catalyst for interactive audience discussion. The focus will be on managing quality, decision making, and mitigating risk.

EU Regulatory Perspective
Anabela Marcal
Head of Compliance and Inspections Department, European Medicines Agency, European Union

US Regulatory and Sponsor Perspective
Ann Meeker-O'Connell, MS
Senior Director, QA Clinical Strategy Team Lead, Janssen Pharmaceuticals, Inc.

Large Sponsor Perspective
Coleen M. Glessner
Vice President, Clinical Trial Process and Quality, Pfizer Inc

How Can Decision Analytic Techniques Be Used Within Clinical Trial Settings?
Brian Hagen
Managing Director, Decision Empowerment Institute

#219 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC/GMP, RA

8:00–9:30 AM | Level: ■ | Format: SESSION

Room 4 | *CME and Nursing*

CMC Development of Breakthrough Therapies

CHAIRPERSON

Sarah C. Pope Miksinski, PhD
Acting Director, Division II, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

This session will focus on regulatory considerations regarding drug development of breakthrough therapies, with an emphasis on the relationship of CMC development data to overall patient benefit-risk as well as innovative approaches to consider for submission of CMC information in breakthrough (or otherwise expedited) submissions.

Quality and Benefit Risk Management for Breakthrough Therapies
G.K. Raju, PhD, MS
Chairman and Chief Executive Officer, Light Pharma Inc.

Impact of Accelerated Launch in the Development Pathway for Large Molecules
Brian Kelley, PhD
Vice President, Bioprocess Development, Genentech, A Member of the Roche Group

Quality Considerations for Breakthrough Drugs: FDA Perspective
Ramesh K. Sood, PhD
Supervisory Chemist, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

Panelist
Angelica Dorantes, PhD, MSc
Biopharmaceutics Team Leader, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

#220 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): PR, RD

8:00–9:00 AM △ Level: ● Format: SESSION
Room 9 *CME, Pharmacy, and Nursing*

Using Comparative Effectiveness Research to Make Health Care Decisions: Exploring the Environment, Opportunities, and Challenges Through Real-World Examples

CHAIRPERSON
Kimberly Westrich, MA
Director, Health Services Research, National Pharmaceutical Council

This session will illustrate efforts to track the environment for comparative effectiveness research (CER), as recent health care surveys have gauged the importance of CER to stakeholders, assessed the perceived current and future impact of CER, and tracked perceptions about agencies or groups considered influential in developing, conducting, and disseminating research. We will examine processes for evaluating when CER is sufficient for making decisions by utilizing the GRACE checklist. We will also present real-world CER examples for translating, disseminating, and implementing CER.

Recognizing Non-Interventional Research Good Enough for Purpose
Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

CER Dissemination, Implementation and Impact: Challenges and Strategies in Integrated Delivery Systems
Brian Mittman, PhD
Kaiser Permanente Dept of Research and Evaluation, VA Center for Implementation Practice and Research Support

#221 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, PT

8:00–9:30 AM Level: ■ Format: SYMPOSIUM
Room 6D *CME and Nursing*

Benefit-Risk Throughout the Product Life Cycle: How Should Benefit-Risk Be Evaluated and Communicated from Development through Marketing as New Information Emerges?

CHAIRPERSON
Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

The benefit-risk balance of a drug must be positive in order to gain and maintain product approval. Yet there are no formal or generally agreed upon approaches to characterization and evaluation of the benefit-risk profile. This symposium will also consider the current sources for new benefit information in the ICH territories as well as current practices by cross-functional teams for assessing and reporting the information and using it in benefit-risk evaluations. A framework for assessing the benefit-risk balance early in the drug's development life cycle can be a potential means of driving and adapting the benefit-risk messaging as new data continue to emerge. Speakers will represent each of the ICH regions, and an active discussion will be encouraged to consider the issues surrounding the generation and evaluation of new benefit information and what approaches should be used for regional documents such as risk management profiles (RMPs) and common technical documents (CTDs) or global documents such as the periodic safety update report (PSUR/PBRER).

New Benefit Information for Approved Drugs That Is Meaningful to Patients
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Harmonizing Benefit-Risk Messages in Documents During Development at Initial Submission and in Postapproval Stages
Rebecca Nyquist, PhD
Senior Expert Medical Writer, Novartis Pharma AG, Switzerland

New Benefit Information and its Evaluation
Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

#222 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): RA, CDM, CR

8:00–9:30 AM Level: ■ Format: SESSION
Room 5B *CME, Pharmacy, and Nursing*

Mitigating Missing Data in Clinical Trials: Moving Toward Global Behavioral Change Impacts Efficacy, Safety, and Quality

CHAIRPERSON
Carol Robertson-Plouch
Clinical Research Advisor, Eli Lilly and Company

Missing data concerns have been illustrated recently by emerging safety and efficacy concerns with approved and unapproved medication. The bar is being raised regarding acceptability of clinical data with large amounts of missing data. What is this about? What mitigation strategies can be taken? This session will broaden your understanding of what missing data is, where it comes from, and the historical events leading to current scrutiny.

Pharmaceutical Company Sponsor Perspective
Carol Robertson-Plouch
Clinical Research Advisor, Eli Lilly and Company

A Regulatory Perspective
Representative Invited
Director, Division of Biometrics II, Office of Biostatistics, Office of Translational Science, CDER, FDA

A Statistician's Perspective
Representative Invited
Director of Statistics, Quintiles Inc.

#223 Track 16 – Professional Development

Related Interest Area(s): FI, IT, RD

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 11B | *CME, Nursing, and PMI PDUs*

Capital Efficient Drug Development with Revolutionary Technologies: Calculated Risks

CHAIRPERSON
Robert Wright, MBA
Chief Editor, Life Science Connect

Being willing to take risks is essential to innovation. Calculated risk involves considerable analysis and market understanding but also requires passion, guts, perseverance, and constant reassessment and willingness to change course. This session will address how life science leaders must focus on practical translation of the science while being mindful of the convergence of multiple disciplines like ethics, information technology, and economics.

Build It and They Will Come, Won't They?
Leslie J. Williams
Director, Founder, President and Chief Executive Officer, ImmusanT

Tale of Two Pharmas
Thomas Hughes, PhD
President and Chief Executive Officer, Zafgen, Inc.

Plans, People and Process
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group, Inc.

#224 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 6F | *CME and Nursing*

Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall

CHAIRPERSON
Nobumasa Nakashima, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representatives from the Pharmaceuticals and Medical Devices Agency (PMDA) will explain its current services and the Japanese drug regulation, and answer your questions on PMDA's future initiatives/challenges for faster review and better life cycle management of drugs.

Future Plan of PMDA for the Next Five Years
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA's Efforts in the Medical Area
Tetsuo Nagano, PhD
Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Safety Measures: The Risk Management Plan in Japan
Hiroshi Yamamoto, MS
Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Introduction of the Third 5-Year Mid-Term Plan of PMDA
Masaru Hiraiwa
Director, Office of Planning and Coordination, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#225 Track 19 – Executive Program

Related Interest Area(s): RD, SP, OS

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 10 | *CME and Nursing*

The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances, and Precision Medicine (Part 1 of 2)

CHAIRPERSON
Kenneth A. Getz, MBA
Director of Sponsored Research; Chairman, CISCRP, Tufts Center for the Study of Drug Development

The landscape for pharmaceutical R&D is shifting dramatically: From large pharmaceutical companies to small and specialty pharmaceutical companies, from vertically integrated companies to collaborative partnerships and innovation networks, and from high volume markets to targeted and precision medicines. This two-part forum will explore the impact of these changes on the R&D landscape.

This first forum will focus on the small and specialty pharmaceutical company sector as the new engine of bioinnovation, and will look at the role of innovative collaborative partnerships and strategic alliances in the discovery, development, and commercialization of new medical products.

Part 2 will take place on Tuesday at 10:30 AM (Session #252).

Panelists
Kenneth I. Kaitin, PhD
Professor and Director, Center for the Study of Drug Development, Tufts University School of Medicine

Ellen G. Feigal, MD, MSc
Senior Vice President, Research and Development, California Institute for Regenerative Medicine (CIRM)

David G. Shoemaker, PhD
Senior Vice President, R&D, Rho, Inc.

Bruce M. Wagman, MBA, RN, RAC
Vice President, Regulatory Affairs and Quality Assurance, Prometheus, Inc.

#226 Track 20 – Late-breaking Topics

Related Interest Area(s): ALL

8:00–9:30 AM Level: ● Format: FORUM
Room 16B

Covering Industry Trends in the Biomedical Industry

CHAIRPERSON

Representative Invited
Senior Editor at Pharmaceutical Executive

Journalists who cover the biomedical industry will discuss their areas of coverage and recent stories and offer insight into what they see as industry trends. Reporters and editors will take questions from the audience following the panel discussion.

9:30–10:30 AM

Coffee Break & Exhibit Hall Innovation Theater Presentations

#227 Track 01A – Clinical Operations

Related Interest Area(s): CR, PM, OS

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 2 *CME, Pharmacy, and Nursing*

Risk-Based Monitoring: From Concept to Practice

CHAIRPERSON

Nicholas Alp, MD, PhD, FRCP
Vice President, Drug Development Services, ICON Clinical Research, United Kingdom

This forum will explore risk-based monitoring, including adapting internal processes and working with third-party providers. Pharmaceutical and CRO experts, with direct experience of working together on these initiatives, will present and lead an interactive discussion.

Successful Messaging for Stakeholders and Decision Makers
Thomas R. Provencher
Senior Director, Clinical Trial Support and Compliance, Pfizer Inc

Models, Processes and Sourcing for Risk-Based Monitoring
Nicole Ratliffe Sheetz, PharmD
Advisor, Clinical Development Innovation, Eli Lilly and Company

Driving Change Management in Risk-Based Monitoring
Brett Wilson
Associate Director, Business Operations, Bristol-Myers Squibb Canada, Canada

#228 Track 01B – Clinical Operations

Related Interest Area(s): CR, AHC/IS, PT

10:30 AM–12:00 PM Level: ■ Format: SYMPOSIUM
Room 1B *CME, Pharmacy, and Nursing*

Improving the Informed Consent Process

CHAIRPERSON

Kathleen Findlen
Head of Clinical Operations and Project Management, Piramal Life Sciences

In this symposium, we will describe and discuss needed guidelines, address concrete ways to obtain effective consent in acute settings while respecting the potential participant, study design and enrollment numbers, and examine data-informed solutions to address the most effective key strategies to improving comprehension of the informed consent.

Research Consent in Acute Settings: What Works?
Mitchell E. Parrish, JD, RAC
Regulatory Attorney, Quorum Review, Inc.

Can Subjects Who Cannot Sign Informed Consent Be Enrolled in My Trial?
Ricardo Nunez, DrMed
Director, Medical. Central Nervous System., Quintiles Inc.

Strategies to Improve the Informed Consent Process to Enhance Comprehension and Recruitment of Ethnically Diverse Populations
Brenda Jamerson, PharmD
Adjunct Associate Professor, Campbell University College of Pharmacy and Health Sciences

#229 Track 01C – Clinical Operations

Related Interest Area(s): CR, SP

10:30–11:30 AM △ Level: ● Format: FORUM
Room 3 *CME, Pharmacy, and Nursing*

Social Listening as a Tool to Inform Study Teams on Social Media Strategy for Recruitment and Building Patient-Centric Trials

CHAIRPERSON

Melissa Jean Mottolo
Patient Strategist Associate, Genentech, A Member of the Roche Group

Social (web) listening is a way to monitor and analyze social media by extracting data from blogs, social networks, message boards, wikis, Twitter, and news sources. With over two billion people online, and one in four people in the world using social media, social listening has quickly become an essential customer intelligence tool. In this forum, we will examine how by listening to the patient and caregiver, one can start to understand the patient's voice, which in turn can have a positive impact on the trial design and recruitment strategy. We are in business to serve patient's needs, so why not listen to them?

Panelists
Melissa Jean Mottolo
Patient Strategist Associate, Genentech, A Member of the Roche Group

Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

#230 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RD, PM

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 5A *CME and Nursing*

Leaping the Valley of Death: Keys to Successfully Going from the Lab to the Clinic for Pharmaceutical Products

CHAIRPERSON

Michael A. Swit, Esq, JD
Special Counsel, Duane Morris, LLP

Going from the lab to the clinic is the first huge leap in drug development. In this session, we will examine that process and explore how to ensure the jump over the "valley of death" avoids the sponsor falling into an abyss of bad decisions and poor results.

That Valley Is a Big One! Who/What Will Help Me Cross?
Gerald J. Yakatan, PhD
Chairman, Chief Executive Officer, and Founder, IriSys, Inc.

Indiana Jones' Regulatory Toolbox: Crossing the Valley in Today's World
Michele Yelmene
Head of Biotech Division, Pharmalink Consulting Inc.

#231 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): FI, RD

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 1A | *CME and Nursing*

National Strategy to Bridge the Gap Between Academic Innovation and Commercialization in Asia

CHAIRPERSON
Herng-Der Chern, MD, PhD
Chief Medical Officer, Supra Integrated and Incubation Center, Taiwan

There are major funding and drug development know-how gaps in commercialization for translational research in academia. This forum will use three venture capital-like national strategies in Singapore, Korea, and Taiwan to bridge these gaps.

The Stanford SPARK Model
Representative Invited
Professor, Co-Director of SPARK, Stanford University

Singapore's D3 Model
Representative Invited
Head of Business Development and Licensing, D3, A*STAR, Singapore

#232 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, OS

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 6C | *CME, Nursing, and PMI PDUs*

The State of Clinical Outsourcing: Do Outsourcing Partnerships Promote or Impede Progress Toward Clinical Trial Optimization?

CHAIRPERSON
Denise A. Calaprice-Whitty, PhD, MS
Consultant, The Avoca Group

This forum will explore best practices for using outsourcing relationships to promote intelligent (data-driven) approaches in clinical trial design and management. Experts will provide perspectives on data from an industry survey, sharing thoughts on areas of opportunity.

Perspectives and Reflection on Data from Industry Survey
Representative Invited
Vice President, Alliance Management, PPD

Perspectives and Reflection on Data from Industry Survey
Adrian Otte
Vice President, Global Development Operations, Amgen Inc.

Perspectives and Reflection on Data from Industry Survey
Kathleen Ford, BSN, RN
Senior Vice President, Head of Global Clinical Operations, Merck KGaA, Germany

#233 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): RD, NC

10:30–11:30 AM △ | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Juvenile Animal Studies and Pediatric Nonclinical Development

CHAIRPERSON
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

The need for early consideration of pediatric populations in the investigational development of medicines, to support an indication in pediatric populations, has led to an increased focus on the strategy in relation to nonclinical aspects of the pediatric development and the relevance of nonclinical studies in juvenile animals. General considerations for determining whether juvenile toxicity studies are necessary to support pediatric drug development are in EU and US Guidelines (juvenile animal guidance). This session will explore the importance of nonclinical juvenile animal guidance in pediatric drug development, share real world experience from available historical data on juvenile animal studies, and examine if juvenile animal studies in nonclinical support for pediatric drug development has significantly changed.

Juvenile Animal Studies and Pediatric Nonclinical Development: EU Perspective
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Juvenile Animal Studies and Pediatric Nonclinical Development: Industry Perspective
Mark E. Hurtt, PhD
Executive Director and Global Head, DSRD Centers of Emphasis, Pfizer Inc

#234 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): AP, RA, PPLC

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 7A | *CME and Nursing*

Understanding Corporate Integrity Agreements/ Trends: What Can We Expect and Why Is It Important?

CHAIRPERSON
Philomena McArthur, JD
Senior Director, Regulatory Compliance, Johnson & Johnson International

In the past few years the scope of Corporate Integrity Agreements (CIAs) has evolved and broadened, affecting a greater variety of company activities, including both "promotional" and "non-promotional" areas, such as R&D and medical affairs activities. This increase in scope raises significant questions for companies, including understanding the impact on the broader organization. The CIAs that will be discussed may be US based, but the issues they cover are global. Whether you are US or globally focused, from regulatory affairs, medical, clinical, compliance or legal, this session is relevant to you and will help you understand the key CIA trends, their impact, and considerations in how to proactively address them.

Industry Perspectives
Philomena McArthur, JD
Senior Director, Regulatory Compliance, Johnson & Johnson International

Representative Invited
Senior Vice President and Deputy General Counsel, Bristol-Myers Squibb Company

Bhavana Desai, MBA
Senior Director, Business Compliance, GSM, Medical Affairs, and R&D, Allergan, Inc.

#235 Track 06A – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MC, RA, MSL

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Preparing for a Successful Product Launch

CHAIRPERSON
Dannis Y. Chang, PharmD
Medical Communications Scientist, Genentech, A Member of the Roche Group

With new technological and research advancement throughout the past decade, many companies in the biopharmaceuticals, companion diagnostics, and medical devices arena are gearing up respective programs and internal strategies in anticipation for a potential launch. While awaiting for FDA approval, not only does the commercial team need to strategize plans from a sales and marketing perspective; other areas of a company such as medical affairs play an integral part to ensure a successful product launch. This session will review what key requirements are needed for a successful product launch from multiple functions of medical affairs such as medical science liaisons and medical information across various industries. We will also cover several key activities that require planning and execution such as early access program (EAP) initiatives, medical response documents and call center preparations, trainings for internal and field colleagues (both US and ex-US stakeholders), and post-launch considerations. In addition, we will discuss situations in which prescription products are switched to over-the-counter and how medical information plays a role in the transition process.

New Product Launch: Recent Learnings from a Medical Information Perspective
Elbert Chang, PharmD, MSc
Manager, I&I Medical Information, Celgene Corporation

The Role of a Medical Science Liaison During a Product Launch
Dipam Doshi, PharmD
Senior Medical Science Liaison, Daiichi Sankyo, Inc

So the Prescription Product I Support Is Going Over-the-counter: Now What?
Tamar S. Yarkoni, PharmD, RPh
Senior Manager, Medical Information Services, Sanofi US

#236 Track 06B – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, CP, DM

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 30AB | *CME, Pharmacy, and Nursing*

Update on Postmarketing Safety Reporting

CHAIRPERSON
Leonardo Ebeling, DrMed, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

This session will outline periodic Benefit-risk evaluation reports (PBRER) requirements, how they are prepared and why, review the requirements and setup of a PBRER report, describe a simple and effective solution to the review of clinical and regulatory documents, and discuss the benefits and efficiencies that can be gained by outsourcing this service.

Continuous Benefit-Risk Analysis
Leonardo Ebeling, DrMed, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

Understanding Periodic Benefit-Risk Evaluation Reports
Representative Invited
Executive Director, Medical Writing, INC Research

Document-Specific, Role-Based Review Matrix
Gurparkash Singh, PhD
Principal Medical Writing Scientist, Janssen Pharmaceuticals, Inc.

#237 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, CR

10:30 AM–12:00 PM | Level: ■ | Format: WORKSHOP
Room 16A | *CME, Pharmacy, and Nursing*

Improving Communication in the Informed Consent Process: The Advantages of eConsent

CHAIRPERSON
Lindsay McNair, MD, MPH, MS
Chief Clinical Research Officer, WIRB-Copernicus Group

Informed consent is an ethical cornerstone of clinical research. This workshop will look at eConsent and how it can improve communication of information during the informed consent process.

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eConsent: An Advance in Communication and Ethics
Nicholas H. Steneck, PhD
Director, Research Ethics Program, Institute for Clinical and Health Research, University of Michigan

The Sponsor's Experience: Managing an eConsent Pilot Study
Representative Invited
Clinical Trial Lead, Janssen Scientific Affairs LLC

#238 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, RA, CR

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 30CD *CME, Pharmacy, and Nursing*

Electronic Source Data in Clinical Investigations (Part 2 of 2): Practical Implementation

CHAIRPERSON

Linda King, MT
Director, Data Sciences and Solutions, Eli Lilly and Company

This two-part forum's FDA-industry panel will focus on the regulatory and practical considerations with respect to the FDA Guidance on Electronic Source Data in Clinical Investigations (eSource).

Part 1 will take place on Tuesday at 8:00 AM (Session #210).

Sponsor-Provided eSource Solutions and Challenges to Implementation
Andrew Roberts, MS
Clinical Business Strategy Expert, Novartis Institutes for BioMedical Research, Switzerland

EHRs for Clinical Research: Pivotal Progress Toward Global Data Standards
Bron Witt Kisler
Vice President, Strategic Initiatives, CDISC

Direct Transmission of Data from the EHR to the eCRF: Insights from a Real-World Implementation
Jane Griffin, RPh
Director, Cerner Research, Cerner Corporation

#239 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CR, HT

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 11B *CME, Pharmacy, and Nursing*

FDA Programs to Encourage Innovation: Maximizing the Opportunities and Confronting the Challenges of New Product Development

CHAIRPERSON

Coleen Klasmeier, JD
Global Coordinator, Food, Drug and Medical Device Regulatory Practice, Sidley Austin LLP

This forum will address FDA initiatives to foster innovation in the areas of regulatory science, breakthrough therapies, biomarker qualification, and increased efficiency of clinical trials.

Drivers, Antecedents, and Limitations of FDA's Expedited Programs for Serious Conditions
Carl C. Peck, MD
Adjunct Professor, Dept of Bioengineering and Sciences; Chairman, NDA Partners, University of California San Francisco

Panelists
Representative Invited
Resident Fellow, American Enterprise Institute

Frank J. Sasinowski, JD, MPH, MS
Director, Hyman Phelps & McNamara, P.C.

#240 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): ESUBS, RA, MW

10:30 AM–12:00 PM Level: ◆ Format: WORKSHOP
Room 16B *CME and Nursing*

Efficient Distribution of Information Across Documents to Support Product's Benefit-Risk Ratio for Patients Worldwide

CHAIRPERSON

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist, eCTDconsultancy B.V., Netherlands

Can you work with Microsoft Word®? Likely you will say "Yes." But how many text processor features beyond that of type writing machine do you use? Likely, lots of post-finalization publishing of the resulting PDF files is needed to get your document eCTD ready. Concerning the content, do you know how to convey your message using supportive and circumstantial information, using many references or even repetition of information out of courtesy for the reader, confirming your statements? These documents contain the requested content but in the context of the objective of that particular time.

Regulatory documentation includes information to support the particular purpose at the time of writing and beyond! Documents have to support products now, and in the future, at the FDA, EMA, and other agencies; for INDs and NDAs; where possible for Product A and Product B; drug substance A and drug substance B, etc. Documents can be written once and reused more often. This requires that documents are written as lean stand-alone documents. Specific details that can be deduced from the inclusion of the document in a specific dossier must neither become part of the content, the header nor the naming. Attendees will learn how the 80-20 rule can make them more efficient in using MS-Word beyond the features of a typewriter. Moreover, they will be sensitized for redundant contextual words that block the reusability of documents for other purposes.

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#241 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): MDD, RA

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 11A *CME and Nursing*

Device and Diagnostic Innovation

CHAIRPERSON

Janet Jenkins-Showalter
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

US patients and physicians must sometimes wait years for promising new technologies to reach the market. In an effort to shorten development time, the Center for Devices and Radiological Health (CDRH) has initiated a number of innovative programs to ensure that the necessary regulatory pathways are established to maintain pace with scientific advances, such as the Innovation Pathway (similar to CDER's breakthrough therapy designation), the Medical Device Innovation Consortium (MDIC), Entrepreneurs-in-Residence, and the Pediatric Device Consortia. Additionally, CDRH is considering the possibility of shifting some of the premarket effectiveness data requirements to the postmarketing setting as a potential way to accelerate patient access to innovative devices.

In this session, we will discuss a program instituted by PEW Charitable Trusts to use registry data to support device preapproval and clearance. This program uses a variety of approaches to utilize the information contained in registries; for example, in cardiovascular devices the data has recently been used as a control group to support PMA approval and reimbursement. Additionally, the possibility of using a risk-based approach for approval of in vitro companion diagnostics associated with therapies that have breakthrough designation will be discussed. New technologies that are on the horizon and could stretch the limits of CDRH's current approval pathways also will be considered. We will also review the activities of the MDIC, which includes CDRH participants, and is focusing on accelerating the development, assessment and review of new medical devices.

Regulating Diagnostics for Breakthrough Therapies
Mya Thomae, RAC
Founder and Chief Executive Officer, Myraqa

Panelists
Kirsten H. Paulson, MS, RAC
Senior Officer, Medical Device Initiative, The Pew Charitable Trusts

Representative Invited
Associate Director for Sciences, CDRH, FDA

#242 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): IT, RA, HT

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 6E | *CME, Pharmacy, and Nursing*

Health Care's Revolutionary Printing Press? 3D Printing - Blue Sky and Regulatory Path

CHAIRPERSON
Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

Disruptive technology and health care are not usually used in the same sentence. We don't hear "Let's print out a new drug" or "How about a new ear" every day either. While news articles have only speculated about how 3D printing could revolutionize drug discovery and tissue regeneration, the technology is already being used in certain areas of health care—for example, to create customized joint replacements. Come hear experts from the 3D printing world, regulatory officials, and industry leaders discuss the potential impact of 3D printing on drug discovery and health delivery, and the regulatory challenges the technology may face as it continues its advance into health care.

Scientific Policy on 3D Printers
Representative Invited
Director, Office of Science and Engineering Labs, CDRH, FDA

Industry Perspective
Eric M. David, JD, MD
Co-Founder and Chief Strategy Officer, Organovo

#243 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, RA, CP

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 8 | *CME and Nursing*

GCP Inspection Findings: A Roundtable Discussion

CHAIRPERSON
Deborah Driscoll
Vice President, Quality Assurance, Medical Division, Pfizer Inc

During the forum of GCP inspections, some important themes are identified by the inspectors as being common to multiple inspections. In a similar way, GCP auditors working for industry identify key issues of concern. This forum provides an opportunity to identify and discuss some of these key findings with a panel of GCP inspection experts from regulatory authorities. Attendees will be asked to submit questions related to GCP inspections and audits in advance and at the session for the panel to address.

Panelists
Jean Mulinde, MD
Acting Senior Advisor, Division of GCP Compliance, Office of Scientific Investigations, CDER, FDA

Anabela Marcal
Head of Compliance and Inspections Department, European Medicines Agency, European Union

Tomonori Tateishi, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#244 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, MF, CMC/GMP

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 4 | *CME and Nursing*

Manufacturing Challenges for Breakthrough Products

CHAIRPERSON
Patricia N. Hurter, PhD, MS
Senior Vice President, Global Pharmaceutical Development and Regulatory Affairs, Vertex Pharmaceuticals

This session will focus on considerations regarding manufacturing development for breakthrough therapies and will highlight related challenges and opportunities for breakthrough drugs.

Continuous Manufacturing: An Innovative and Collaborative Approach to Bring High Quality Breakthrough Therapies to Market
Hayden Thomas, PhD
Vice President, Formulation Development, Vertex Pharmaceuticals

FDA Perspective
Mahesh R. Ramanadham, PharmD, MBA
Team Leader, Office of Compliance, CDER, FDA

Industry Perspective
John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

#245 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): PR, CR, HT

10:30 AM–12:00 PM | Level: ■ | Format: FORUM

Room 9 | *CME and Nursing*

Drug Development with Reimbursement in Mind: Obtaining the Input of Payers to Inform Clinical Trial Design

CHAIRPERSON

Charles A. Stevens, JD, MBA
Vice President and General Manager, PAREXEL Consulting

Regulatory approval does not lead to commercial success unless sponsors understand the evidence requirements of payers. Sponsors can minimize the risks of reimbursement denial by incorporating payer input into preregistration studies. This session will explore practical ways in which sponsors can seek and obtain actionable payer input during drug development.

Panelists

Andrew Bate, PhD, MA
Senior Director, Analytics Team Lead, WSR Epidemiology, Pfizer Inc, United Kingdom

Brandon T. Suehs, PharmD, PhD
Principal Researcher, Comprehensive Health Insights, a Humana Company

#246 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR, RA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION

Room 6D | *CME and Nursing*

EMA-FDA Collaboration in Pharmacovigilance: Common Objectives and Common Challenges

CHAIRPERSON

Peter Richard Arlett, MRCP
Head of Pharmacovigilance Department, European Medicines Agency, European Union

This session will cover the current collaboration between EMA and FDA on drug-specific evaluations, collaborative efforts on their development, effective implementation of new pharmacovigilance tools, and how the two organizations address common challenges.

FDA Perspective
Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

Industry Perspective
Representative Invited
EU QPPV, Executive, Global Patient Safety, Eli Lilly and Company Ltd, United Kingdom

#247 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CEHTAEbM, RA, CR

10:30 AM–12:00 PM | Level: ■ | Format: FORUM

Room 5B | *CME, Pharmacy, and Nursing*

Impact of Bayesian Methods in Drug Development with a Focus on Comparative Effectiveness Research

CHAIRPERSON

Karen Lynn Price, PhD, MA
Research Advisor, Eli Lilly and Company

This forum will provide an overview of how Bayesian methods are used in practice, with particular emphasis on applications in comparative effectiveness research. We will focus on how such approaches can improve efficiency and provide clear quantitative development decisions.

This forum has been developed by the DIA Bayesian Scientific Working Group.

Bayesian Evidence Synthesis and Network Meta-Analysis in Context of CER
Bradley P. Carlin, PhD, MS
Professor and Head of Biostatistics, University of Minnesota

FDA Perspective
Ram Tiwari, PhD
Associate Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Panelist
Matthew D. Rotelli, PhD
Director, Global PK/PD and Pharmacometrics, Bio-Medicines, Eli Lilly and Company

#248 Track 16 – Professional Development

Related Interest Area(s): CR, RA, CP

10:30 AM–12:00 PM | Level: ● | Format: WORKSHOP

Room 17A | *CME, Pharmacy, and Nursing*

Networking: It's Not What You Know, But Who You Know!

CHAIRPERSON

Bob Muzerall
Vice President, Sales and Sales Training, ForeignExchange Translations

This workshop will assist in gaining the skills to reduce the fear of approaching strangers and learn to be comfortable in a wide range of situations. You will interact with other attendees, learning and practicing networking strategies.

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Experience the Power of Networking
Christopher Matheus, MBA
Director, Business Development, Y Prime

#249 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): HT, CR, RA

10:30–11:30 AM △ Level: ■ Format: FORUM
Room 32AB *CME, Pharmacy, and Nursing*

Industry Trends, Successes, and Failures in Orphan and Rare Disease Therapeutics

CHAIRPERSON
Christine Blazynski, PhD
Chief Science Officer and Senior Vice President, Citeline

This forum will overview orphan and rare disease drug development from the patient and affected community perspective to the industry's response over the past 30 years until today. The activist community will be contrasted with how industry has approached the needs of the few.

When Your Company Adopts an Orphan Drug
Robin L. Winter-Sperry, MD
President and Chief Executive Officer, Scientific Advantage LLC

Industry Trends, Successes and Failures in Orphan and Rare Disease Therapeutics
Christine Blazynski, PhD
Chief Science Officer and Senior Vice President, Citeline

#250 Track 18A – Global Regulatory

Related Interest Area(s): ROD, RA, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 33AB *CME and Nursing*

Development of an Integrated Orphan Drug Framework in Canada

CHAIRPERSON
Agnes V. Klein, DrPH, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Health Canada is developing regulations, guidance and operational supports simultaneously for an integrated orphan drug framework that represents a significant departure from current practice. The session will offer insights into the management of a range of complex issues in developing an adaptive licensing framework for the full life cycle of a class of products, from predesignation to postmarket. Attendees will also learn how a full framework can be designed to reflect the national legislative context, and also to promote international alignment in implementation, to get drugs for rare diseases from brainwave (concept) to bench to bedside.

From Regulation to Implementation: Operationalizing a New Framework for Orphan Drugs
Cathy A. Parker
Acting Senior Executive Director, BGTD; Chair, Orphan Drugs Working Group, Health Canada

Setting the Stage: The Development of Comprehensive Regulations for Orphan Drugs
Lynn Mainland, MA
Associate Director, Office of Legislative and Regulatory Modernization, HPFB, Health Canada

#251 Track 18B – Global Regulatory

Related Interest Area(s): RA, CR, CP

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 6F *CME and Nursing*

Europe Town Hall

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

The European Union regulatory network, including the European Medicines Agency, national agencies in the Member States and European Commission, has developed a range of initiatives and entry points to facilitate regulatory procedures and scientific dialogue from early development to postmarketing authorization stages. In addition to discussing some of the scientific and regulatory challenges facing regulators and industry in Europe, the forum will showcase what is being done to support biopharmaceutical R&D, in particular through the Innovative Medicines Initiative (IMI), benefiting both industry and public health. This forum offers the opportunity to interact directly with senior leadership from the European Medicines Agency, national medicines agencies, and the IMI regarding recent initiatives.

Panelists
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Michel Goldman, MD, PhD
Executive Director, Innovative Medicines Initiative (IMI), Belgium

Representative Invited
Head, Institute Marketing Authorisation and Lifecycle Management, Austrian Medicines and Medical Devices Agency (AGES), Austria

#252 Track 19 – Executive Program

Related Interest Area(s): RD, SP, OS

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 10 *CME and Nursing*

The Changing Landscape for Bioinnovation: The Emergence of Small Pharma, Strategic Alliances, and Precision Medicine (Part 2 of 2)

CHAIRPERSON
Kenneth I. Kaitin, PhD
Professor and Director, Center for the Study of Drug Development, Tufts University School of Medicine

The landscape for pharmaceutical R&D is shifting dramatically: from large pharmaceutical companies to small and specialty pharmaceutical companies, from vertically integrated companies to collaborative partnerships and innovation networks, and from high volume markets to targeted and precision medicines. This two-part forum will explore the impact of these changes on the R&D landscape.

This second forum will examine the ramifications of industry's shift to targeted and precision medicines, and the impact smaller patient populations and smaller market opportunities are having on portfolio and R&D investment decisions.

Part 1 will take place on Tuesday at 8:00 AM (Session #225).

Panelists
Kenneth A. Getz, MBA
Director of Sponsored Research; Chairman, CISCRP, Tufts Center for the Study of Drug Development

Annalisa Jenkins, MRCP
Chairwoman, Board of Directors, TransCelerate Biopharma Inc.; Former Executive Vice President, Head of Global Research and Development, Merck Serono, Germany

Representative Invited
Executive Vice President, R&D, Allergan, Inc.

Representative Invited
Chief Medical Officer and Vice President, Verizon Enterprise Solutions

11:30 AM–1:30 PM

Lunch & Exhibit Hall Innovation Theater Presentations

#253 Track 21A – Innovation Theater

Related Interest Area(s): CR, GCP, IT

11:45 AM–12:30 PM | Level: ■ | Format: SPECIAL SESSION
Exhibit Hall

Covance Innovation Theater: Risk-Based Monitoring - Seeing the Forest for the Trees When Designing and Deploying an Enterprise Process

This theater presentation will share key experience gathered during a five-year, cross-functional journey to design and implement an enterprise risk-based monitoring process. The presentation shares real life data from the full process life cycle, with a focus on Quality by Design and RBM benefits, such as:

- Increased early identification of issues at highest risk sites;
- Ability to provide qualitative assessment of site compliance;
- Increased efficiency and reduced study delivery costs;
- Improved data flow cycle times with reduced data cleaning resources required.

#254 Track 21B – Innovation Theater

Related Interest Area(s): MW, IT, DM

12:45–1:15 PM | Level: ■ | Format: SPECIAL SESSION
Exhibit Hall

Veeva Innovation Theater: Industry's Largest eTMF Survey: Benchmarks and Insights

Hear results from the industry's largest eTMF survey to date. This 2014 survey represents the experience and opinions of over 250 TMF owners, identifying the barriers, business drivers, and benefits in moving to fully paperless trial master files. The data shows where organizations are on the spectrum of paper to paperless TMFs and how they've gone electronic – see how you compare. Lastly, learn what benefits they've experienced and why some benefit more than others.

#255 Track 01A – Clinical Operations

Related Interest Area(s): AHC/IS, ST

1:30–3:00 PM | Level: ● | Format: SYMPOSIUM
Room 3 | *CME and Nursing*

Improving Investigative Site Selection Practices

CHAIRPERSON
Kenneth A. Getz, MBA
Director of Sponsored Research; Chairman, CISCRP, Tufts Center for the Study of Drug Development

This symposium provides an overview of the changing global investigative site landscape and discusses new tools and approaches to improve and optimize site selection practices. Highlighted new approaches will include an assessment and discussion of metrics that are better able to predict successful investigative site performance and a detailed review of the characteristics and expected utility of a new investigator databank of more than 120,000 investigators worldwide.

Anticipating Trends and Changes in the Fragmented Global Investigative Site Landscape
Kenneth A. Getz, MBA
Director of Sponsored Research; Chairman, CISCRP, Tufts Center for the Study of Drug Development

Advancing a Data-Driven Foundation for Investigative Site and Country Selection Strategies
Shawn Phillip Tedman, MBA
Global Feasibility Manager, Quintiles Inc.

Investigator Databank Collaboration: A Global Platform for Precompetitive Sharing
Elisa F. Cascade, MBA
Vice President, Drugdev.org

#256 Track 01B – Clinical Operations

Related Interest Area(s): CS, CM, CR

1:30–2:30 PM △ | Level: ■ | Format: SYMPOSIUM
Room 1B | *CME, Pharmacy, and Nursing*

Optimization of and Enhancements to Interactive Response Technology to Ensure Efficient Investigational Product and Study Material Management

CHAIRPERSON
Larry A. Blankstein, PhD
Senior Director, Clinical Research, Genzyme Corporation, A Sanofi Company

This symposium will describe how interactive response technology (IRT) can be implemented and enhanced to provide global full supply chain visibility, ensure timely investigational product (IP) and other study material expiration management, accurate drug accountability at the site and efficient drug reconciliation at study completion, as well as drug and material ordering. Case studies will be presented to highlight successful implementation of IRT for IP management.

Clinical Supplies Accountability: Using Technology to Transform Your Paper-based Accountability Process
Christine Oliver
Account Director, Endpoint Clinical, Inc.

Electronic Tools for Trial Material Supplies Management: Closing the Gaps to Ensure Full Control, Traceability, and Visibility
Andrey Gurachevsky
Senior Technical Logistics Coordinator, PAREXEL International, Germany

#257 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, CR

1:30–3:00 PM | Level: ● | Format: SYMPOSIUM
Room 5A | *CME, Nursing, and PMI PDUs*

Virtual Teams in Clinical Development

CHAIRPERSON

Kristen Snipes
Project Director, Rho, Inc.

Project meetings and communication, internal or with all stakeholders, happen routinely throughout a study. Often they fail to engage project team members in a way that helps them retain key information. This symposium will focus on specific tips for conducting effective meetings and communication in the virtual environment to ensure that project team members walk away prepared to successfully execute the study.

Tips and Tricks for Conducting an Effective Kickoff Meeting
Kristen Snipes
Project Director, Rho, Inc.

Moving Investigator Meetings into the 21st Century: The Impact
Leslie (Mi Ok) Chong, MA
Senior Clinical Program Leader, Genentech, A Member of the Roche Group

Effective Communication Pathways for Global Virtual Teams
Donna Sattler
Technical Project Manager, Maxisit Inc.

#258 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, BT, RD

1:30–3:00 PM | Level: ◆ | Format: SESSION
Room 1A | *CME and Nursing*

Challenges and Strategic Approaches to Development of a Novel Biologic Versus a Biosimilar

CHAIRPERSON

Jayanthi Reddy, MBA, MS, PMP
Director and Biologics Pipeline Leader, Global Project Management, Merck & Co., Inc.

Through a case study approach, this session will address the strategic approaches adopted by companies to deal with the unique challenges faced in the development of a novel biologic versus a biosimilar.

Introduction and Overview of Challenges in Development of a Novel Biologic Versus a Biosimilar
Jayanthi Reddy, MBA, MS, PMP
Director and Biologics Pipeline Leader, Global Project Management, Merck & Co., Inc.

Biologics CMC Development: Strategies for Biosimilars, Novels, and Breakthrough Therapies
Steve Farrand, PhD, MSc
Vice President BioProcess Development, Merck Research Laboratories

Challenges for Attaining Biosimilar Success in the Regulated Markets
Andrew Rankin, PhD
Executive Vice President, Operations, Qforma

#259 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RD, CR, RA

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 2 | *CME and Nursing*

Collaborating to Streamline Drug Development: Case Studies of What Works (and What Doesn't)

CHAIRPERSON

Douglas J. Peddicord, PhD
Executive Director, Association of Clinical Research Organizations

This forum will examine case studies of innovative projects to streamline specific product development projects undertaken over the past year. The panelists will discuss the positive, negative, and equivocal results.

Panelists
Dalvir Gill, PhD
Chief Executive Officer, TransCelerate Biopharma Inc

Christine K. Pierre, RN
President, Society for Clinical Research Sites

Pamela Tenaerts, MD, MBA
Executive Director, Clinical Trial Transformation Initiative

Ann Meeker-O'Connell, MS
Senior Director, QA Clinical Strategy Team Lead, Janssen Pharmaceuticals, Inc.

#260 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, HT, RD

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Organs on a Chip: The Future of Efficacy and Safety Testing

CHAIRPERSON

Barry Mangum, MD
Director, Clinical Pharmacology, Duke University Medical Center

Preclinical studies for proof of concept and drug safety are often performed in animal models. Our desire to reduce animal use in drug development and to make more accurate predictions of safety and efficacy has led to large investments in the development of models of human organs arranged serially on microchips. The goal is to be able to introduce candidate drug substances and monitor pharmacological and toxicological effects in each organ. Significant progress is being made with models of human liver, lung, intestine, and breast. Despite this encouraging progress, significant challenges remain. These include source of human tissues: Normal primary cells usually taken postmortem or induced pluripotent stem cells. Differentiated cells in culture require unique cell culture media in order to maintain their differentiated state; however, multiple organs on a chip will need to be bathed in a common medium. Finally, translating the information collected from the chips to responses in humans will be a challenge. How will this information be used to determine if a candidate pharmaceutical causes pain, nausea, or increases the risk for cancer or birth defects? While progress in the area is encouraging and may be useful in selecting among early drug candidates, it seems clear that utility in the regulatory arena is still years away.

#261 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): AP, RA

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 7A | *CME, Pharmacy, and Nursing*

FDA Enforcement Update: Advertising and Promotion

CHAIRPERSON

Janet "Lucy" Rose, MBA
President, Lucy Rose and Associates, LLC

FDA enforcement actions and policy guidances need to be understood by every company because they reflect FDA's priorities and concerns in regulating advertising and promotion. In this forum, an FDA professional and a representative from industry will examine the latest agency enforcement actions and policies and what they mean.

CDER Perspective
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

CBER Perspective
Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, CBER, FDA

#262 Track 06A – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MC, AP, RA

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Promotional Material Management: From Review to Submission – Contemporary Ideas

CHAIRPERSON

Julia Petses, PharmD
Director, Medical Information Services Oncology/Hematology, Sanofi US

A risk-based approach for the review of commercial materials to ensure they are truthful, accurate, and balanced, and not false or misleading will be discussed. A global perspective and the challenges of performing a global versus a country-specific review will be explored. Additionally, regulatory requirements in the US and around the world are impacting the traditional separation of promotional review and regulatory operations. Evaluating how this new paradigm will change the promotional review process is necessary to ensure efficiency, quality, and accuracy.

Optimization of the Promotional Review Process
Robert K. Morris, PharmD
Director, Medical Information, HIV and Dermatology, GlaxoSmithKline

The Benefits and Risks with Global Promotional Review
Victoria Dlensi
Associate Director, Neuroscience, Shire AG, Switzerland

Marketing Globally Means Complying Regionally: How Promotional Review and Regulatory Affairs are Becoming More Integrated to Support Regional and Global Requirements
Dirk Karston Beth
Managing Director, Mission3

#263 Track 06B – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, ST

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 32AB | *CME and Nursing*

In-Sourcing, Out-Sourcing: Where Do We Go from Here?

CHAIRPERSON

Helle-Mai Gawrylewski, MA
Senior Director, Medical Affairs and Alliance Management in Medical Writing, Janssen Research & Development, LLC

Outsourcing of medical writing and medical information activities has been increasingly common as large and small pharmaceutical companies look to conserve internal resources, secure additional expertise, and lower overall cost. Establishing successful external relationships comes with new challenges as resourcing models evolve. It's a myth that any project can simply be passed off to any external service provider, no matter the location, without maintaining oversight, training, and support of many types. This session will update on long term success factors like partner selection, relationship type, and quality monitoring. First, asking the right questions and getting the right answers are key. Once the partner is in place, what kind of relationship works well? Some ideas about a model that leverages successful practices and communication strategies will be covered. Equally important is maintaining quality in the project deliverables. What aspects need to be in place, such as measuring quality to maintain quality, compliance, accuracy, and the customer experience?

Crafting the Right Questions to Get Useful Answers From Prospective Medical Writing Supplier Partners
Lauren Sobocinski
Associate Director, Business Development, Synchrogenix Information Strategies Inc.

Co-Sourcing: An Outsourcing Paradigm Poised for Growth
Gurparkash Singh, PhD
Principal Medical Writing Scientist, Janssen Pharmaceuticals, Inc.

Quality in Outsourced Medical Information
Richard T. Lippincott, RPh
Executive Director, PPD

#264 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): VA, IT, RA

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 31C | *CME and Nursing*

Computer System Validation in the Cloud: Cloud Is Here Today and Here to Stay

CHAIRPERSON

Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

Organizations developing and using computerized systems are benefiting from novel approaches to the development, validation, and deployment of such systems in a regulated environment. This session will provide real examples of how practices such as Agile software development, Software/Platform/Infrastructure as a Service, and cloud deployment are being used today to great effect. The session will also address what these practices mean to suppliers, sponsors and CROs, and regulators.

Computerized System Validation in the Cloud
Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

Industry Perspective
Representative Invited
Head of Applications, ICON plc, Ireland

FDA Perspective
Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

#265 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, CR

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 33AB | *CME, Pharmacy, and Nursing*

Embracing Change: The New Face of Clinical Data Management

CHAIRPERSON
Maryanne C. Nicosia, MS
Director, Clinical Data Management, Neurocrine Biosciences Inc.

As clinical research changes, so must the role of the clinical data manager (CDM), who is being asked to do more than ever to ensure data quality. This symposium will provide ideas on how to leverage a clinical data repository to create efficiencies in the discrepancy management and serious adverse event (SAE) reconciliation processes. Attendees will also learn through case studies how to leverage existing data management processes on eSource studies in order to ensure an efficient study start-up, decreased data review time, and high quality data. This symposium will also focus on identifying the expanded skill set required of the CDM and how those currently in the CDM role can ensure that they have the skills needed to be successful in the changing clinical development environment.

Leveraging a Clinical Warehouse for Discrepancy Management and Adverse Event Reconciliation
Subra Subramanian, MBA
Director, Product Strategy, Oracle Health Sciences

Data Quality Custodian: The New Role for Clinical Data Managers
Vadim Tantsyura, DrPH, MA, MS
Director, Data Management, Cincinnati Children's Hospital Medical Center

eSource: Clinical Data Manager's Tale of Three Studies
Maura Bearden
Clinical Data Manager I, DATATRAK International

#266 Track 07C – Processes and Technologies for Clinical Research

Related Interest Area(s): CR, PT, IT

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 30CD | *CME, Pharmacy, and Nursing*

Enabling Participants' Access to the Electronic Clinical Trial Data: The Blue Button Project

CHAIRPERSON
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Historically, patients participating in clinical trials do not have an easy way to receive or use the clinical data generated during a trial to improve their personal health and wellness. This session will discuss how a large pharmaceutical company, in December 2013, launched the Blue Button Project, an innovative project enabling patients who have participated in specified clinical trials the opportunity to download their individual clinical data. Using the Blue Button standard launched by the White House, patients are empowered to use their individual electronic clinical data to improve their overall health and wellness, from sharing data with health care providers to powering clinical risk assessment tools.

Deploying the Blue Button to Advance Clinical Research: The Blue Button Project
Representative Invited
Senior Director, Data Management and Reporting, Pfizer Inc

Impact of Access to Data for Study Participants: The Patient Perspective
Regina Holliday
Patient Activist and Mural Artist

Introduction to the Blue Button: Empowering Patients With Health Data
Thomas A. Krohn, MBA, RPh
Advisor, Clinical Open Innovation, Eli Lilly and Company

#267 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, ROD

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 6F | *CME and Nursing*

Breakthrough Therapy Designation: One Year After

CHAIRPERSON
Martine Zimmermann, PharmD
Vice President, Global Regulatory Affairs, Alexion Pharma International Sàrl, Switzerland

This session will discuss the impact of breakthrough therapy designation on the development of new medicines for serious conditions. An industry representative will present a real case study, and a regulatory agency view will also be shared.

The Forecast for Breakthrough Therapy Designations and Lessons Learned from Oncology
Karen Jones
Vice President, Global Head Oncology Regulatory, Genentech, A Member of the Roche Group

FDA Perspective
Representative Invited
Deputy Center Director for Science Operations, CDER, FDA

Sovaldi for HCV: Case Study on Breakthrough Therapy
Paul Tomkins, PhD
Senior Director, HIV and Liver Disease Regulatory Affairs, Gilead Sciences, Inc.

#268 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): ESUBS, RA

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 10 | *CME, Pharmacy, and Nursing*

How to Make a Successful Electronic Registration and Listing Submission: NDC, Regulatory Compliance, and Technical Requirements

CHAIRPERSON

Leyla Rahjou-Esfandiary, PharmD
Pharmacist, Office of Compliance, CDER, FDA

This session focuses on all disclosable information related to drug establishment registration and drug listing requirements from the legal and technical perspective. It also discusses the FDA's current position on National Drug Code (NDC), its assignment to CDER-regulated products, and its use inside and ouside of FDA.

Complying with Registration and Listing Requirements: CDER Perspective
Soo Jin Park, PharmD
Regulatory Officer, Office of Compliance, CDER, FDA

SPL Data Standard Perspective: Electronic Registration and Listing
Lonnie D. Smith
Policy Analyst, Office of Operations, Office of Information Management, Office of Communications, FDA

Industry Perspective
Thomas R. Bizzaro, RPh
Vice President, Health Policy and Industry Relations, FDB (first Databank, Inc.)

#269 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): SE, MDD

1:30–2:30 PM △ | Level: ■ | Format: SESSION
Room 11A | *CME and Nursing*

Dare to Be Different: Comparing Biosensor Data to Patient-Reported Outcomes Data - Learnings from Asthma

CHAIRPERSON

Alison Greene, MPH
Senior PRO Scientist, Genentech, A Member of the Roche Group

A study of asthma patients compared data collected by wearable-device and "usual" self-reported diary format. Session topics include: Lessons learned, implications for clinical trial design, and wider landscape of biosensors in clinical studies.

Rethinking Outcomes Assessments: Where Do Biosensors Fit in Drug Development?
Alison Greene, MPH
Senior PRO Scientist, Genentech, A Member of the Roche Group

Implementing New Technology in Clinical Trials: An Interesting Adventure
John Reites
Senior Director, Offer and Product Development, Quintiles Inc.

#270 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PPLC, RA, PR

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 6E | *CME, Pharmacy, and Nursing*

Digital Health: Mobile Medical Apps and the Future of Health Care Delivery

CHAIRPERSON

Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

This forum will explore opportunities created by the rapidly evolving field of digital health, its potential impact on health care delivery, and the regulatory, reimbursement and technical challenges associated with it.

Panelists
George Savage, MD
Co-founder and Chief Medical Officer, Proteus Digital Health

Representative Invited
Policy Advisor, Office of the Center Director, CDRH, FDA

#271 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, RA, QC

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 8 | *CME and Nursing*

Adapting GCPs to Evolving Drug Development Paradigm (Part 1 of 2)

CHAIRPERSON

Shaghig Palanjian, MBA
Head of Clinical and Medical QA and Compliance, Shire Pharmaceuticals

The session will focus on the changing product development paradigm and considerations for quality systems, QA audits, and GCP compliance considerations, as we see the shift in industry to personalized medicine, increased focus on rare diseases, and the new technologies. We will review the point of view from sponsor, service provider (CRO) and QMS design perspectives, and how it impacts GCP compliance when we work with smaller patient populations, limited number of investigators within disease areas, limited data and data sources etc., as we see shifts in the development paradigm and regulatory framework.

Part 2 will take place on Tuesday at 3:30 PM (Session #295).

Changing Drug Development Paradigms and Considerations for Quality Systems
Kirsten Ledwith Morasco
Vice President, Clinical and Quality Compliance, Compliance Implementation Services (CIS)

Patient Perspective
Debra Madden
Cancer Research Advocate, Patient Representative, Ann's Place; National Breast Cancer Coalition (NBCC); Research Advocacy Network

Panelists
Mike Sobczyk, MSc
Senior Director, Regulatory Compliance, Gilead Sciences, Inc.

Representative Invited
Senior Vice President, Global Quality and Compliance, PPD

#272 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR, RA

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 11B | *CME and Nursing*

EMA-FDA GCP Initiative: Current Status and Future Perspectives

CHAIRPERSON

Anabela Marcal
Head of Compliance and Inspections Department, European Medicines Agency, European Union

The session will cover the current status of the EMA-FDA collaboration on inspections involving clinical research and discuss the achievements, such as a mutual understanding of inspection procedures, and challenges of such an initiative. The most recent and future areas of collaboration will be addressed.

EMA Perspective
Anabela Marcal
Head of Compliance and Inspections Department, European Medicines Agency, European Union

FDA Perspective
Kassa Ayalew
Medical Officer, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#273 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, HT, CP

1:30–3:00 PM | Level: ● | Format: SESSION
Room 6C | *CME, Nursing, and PMI PDUs*

Introducing CDER's Office of Pharmaceutical Quality

CHAIRPERSON

Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

This session will describe the mission and function of CDER's proposed Office of Pharmaceutical Quality with a focus on risk-based regulatory decision making. CDER is proposing a reorganization of quality related functions into a single Office of Pharmaceutical Quality (OPQ), based on the following principles: Risk-based resource management and decision making, maximal development and utilization of staff expertise, proactive view of product quality through quality surveillance; and enhanced integration of review and inspectional functions.

FDA Perspective
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Quality Metrics in the Office of Pharmaceutical Quality
Russell Wesdyk, MBA
OPS Scientific Coordinator, Office of Strategic Programs, CDER, FDA

#274 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): PR, RA, CR

1:30–3:00 PM | Level: ● | Format: FORUM
Room 9 | *CME, Pharmacy, and Nursing*

Unraveling Evidence-Based Medicine: A Scientific, Ethical, and Socio-Political Analysis

CHAIRPERSON

Nancie E. Celini, DrPH
Chief Health Technology Advisor and Educator, CAB Inc.

There is concern worldwide about rising health costs and shrinking health budgets, and it is now broadly accepted that we must all apply the best alternatives in medical treatment. But disagreement persists as to what methods are acceptable for comparing treatments, and whether they are ethically, politically, and commercially sound. Some of the scientific and ethical questions will be addressed in this important cross-discipline community dialogue.

This forum has been developed by the DIA Evidence Based Medicine Community, the DIA Ethics and the Medicines Lifecycle Community, and the Comparative Effectiveness Scientific Working Group.

Panelists
Wendy Louise Lipworth, MD, PhD
Senior Research Fellow, Centre for Values, Ethics and the Law in Medicine, University of Sydney, Australia

Kitty Rajagopalan, PhD, MS
Vice President, Health Economics and Outcomes Research, Sunovion Pharmaceuticals Inc.

Lisa M. Hess, PhD
Principal Research Scientist, US Health Outcomes, Eli Lilly and Company

#275 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP, ESUBS

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 6D | *CME and Nursing*

Who's Moving the PV Cheese? Three Game Changing Topics – Impact of Emerging New Requirements for E2B (R3), ICSR Quality Standards, and Benefit-Risk Management

CHAIRPERSON

Elizabeth E. Garrard, PharmD, RPh
Senior Director, Safety Risk Management, United Therapeutics Corporation

This session will focus on three new emerging requirements and game changing trends in pharmacovigilance. Expectations for life science companies from regulators is clear, ICSR quality needs improvement. We will explore existing ICSR approaches and discuss innovative and scientific approaches to optimize the quality of ICSR case processing. Regulatory agencies are preparing for the new ICH E2B (R3) standard. We will discuss how the new standards will impact life science organizations and provide insights into how to prepare for the change. As risk management shifts from largely a reactive and issue driven activity to a proactive life cycle management activity, we will explore how companies are developing life cycle approaches including measurements on effectiveness.

Embracing the ICH E2B (R3) Standard for Individual Case Summary Report (ICSR) Submissions
Will C. Gordon
Senior Product Strategist, Oracle Health Sciences

Top Five Pharmacovigilance Trends on Quality and How They Will Affect You
Representative Invited
Director, Pharsafer Associates, United Kingdom

Emerging Trends of Risk Management in Medical Safety
Yun-Yi He, Esq, MS
Director, Risk Management Strategic Operational Leader, Janssen Research & Development, LLC

#276 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

1:30–3:00 PM | Level: ● | Format: SYMPOSIUM
Room 4 | *CME, Pharmacy, and Nursing*

How Do We Keep Kids Safe? Pediatric Safety Monitoring From Beginning to End

CHAIRPERSON
Judith Ulett Cope, MD, MPH
Medical Officer, Office of Pediatric Therapeutics, Office of Communications, FDA

This symposium will provide a background of federal legislation for FDA pediatric-focused safety reporting to FDA's Pediatric Advisory Committee (PAC). It will review why postmarketing safety assessments are crucial, how the FDA tracks and plans which products are reviewed, provides examples of why FDA would contact sponsors before PAC meetings and provide a summary of the past decade of reporting. The roles of IRBs and DSMBs will be examined and how they help ensure the safety of children in trials. Industry perspective is provided. The importance of long-term surveillance and registries will be reviewed.

Pediatric Safety Monitoring: Role of IRBs and DSMBs
Kathryn Elaine Bohannon
Principal Strategist, Pediatrics, INC Research

Global Rare Diseases Patient Registry Data Repository: A Model for Pediatric Registries
Yaffa Rubinstein, PhD
Director, Patient Resources for Clinical and Translational Research, National Institutes of Health (NIH)

Pediatric Safety Monitoring: Industry Perspective
Christina Bucci-Rechtweg, MD
Head, Pediatric and Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Panelist
Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

#277 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): RD, SP

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 5B | *CME and Nursing*

Predictive Enrichment: Design, Development Strategies, and Methodological Issues

CHAIRPERSON
Zoran Antonijevic, MSc
Senior Director, Strategic Consulting, Cytel, Inc.

This session will analyze implications of predictive enrichment on drug approvability and labeling, and illustrate situations when it is most beneficial. It will also address uncertainty about the prognostic value of the predictive biomarker.

Strategic and Methodological Considerations for Predictive Enrichment in Drug Development
Zoran Antonijevic, MSc
Senior Director, Strategic Consulting, Cytel, Inc.

Integration of Predictive Biomarkers and Classifiers into Oncology Clinical Development Programs
Robert A. Beckman, MD
Executive Director, Clinical Development Oncology, Daiichi-Sankyo, Inc.

FDA Perspective
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design & Pharmacogenomics, Office of Biostatistics, Office of Translational Science, CDER, FDA

#278 Track 16 – Professional Development

Related Interest Area(s): PM, CR, RA

1:30–3:00 PM | Level: ● | Format: WORKSHOP
Room 16A | *CME, Pharmacy, and Nursing*

Yes and ... Applying Improvisational Skills to Improve Innovation

CHAIRPERSON
Lauren Edelstein Henry
Senior Principal Operational Specialist, Janssen Pharmaceutical Companies of Johnson & Johnson

Improvisational theatre is suggestion-fueled theatre that is unscripted and where all scenes are created spontaneously. At the heart of improvisational theatre is the phrase "yes and ... ," which facilitates engagement of all voices in a group. Playfulness is a useful tool which catalyzes innovation by enabling people to connect with others, have the courage to share, and freely explore new approaches. For this workshop, we have applied the tools of improvisational theatre and playfulness together. The attendee will take away new skills and tools to bring back to the office, such as enhancing the ability to accept suggestions of others, adapting more successfully to people and situations, thinking more effectively on one's feet, and, most importantly, having fun AND being productive at the same time.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitator
Akshay Sateesh, MS
Founder and Facilitator, Ziksana Consulting

#279A Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 30AB | *CME and Nursing*

Asia Town Hall

CHAIRPERSON

Nobumasa Nakashima, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representatives from Asian regulatory agencies will explain the current status of pharmaceutical regulations in each country and the direction of international collaboration.

PMDA Point of View
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

India Perspective
Representative Invited
Joint Secretary, Ministry of Health and Family Welfare, India

Recent Trend of Pharmaceutical Regulations in Taiwan
Ming-kung Yeh, PhD
Director-General, Taiwan Food and Drug Administration (TFDA), Taiwan

2:30–3:30 PM

Refreshment Break & Exhibit Hall Innovation Theater Presentations

#279B Track 21 - Innovation Theater

Related Interest Area(s): RD, CR, PETD

2:45–3:15 PM | Level: ■ | Format: SPECIAL SESSION
Exhibit Hall

BBK Innovation Theater: Reaching the Tipping Point of Innovation

Sometimes innovation can be intimidating. In fact, for some, it may feel like an impossible feat. But the truth is, innovation doesn't have to be hard to be good. Drawing on Malcolm Gladwell's "The Tipping Point," this interactive presentation will suggest how, when it comes to the clinical R&D industry, little changes can make a big difference. Whether your organization is an innovation leader, laggard, or something in between, this presentation will help you reach your next tipping point of innovation.

#280 Track 01A – Clinical Operations

Related Interest Area(s): FI, RA, AHC/IS

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 16A | *CME and Nursing*

Building a Site Budget from the Ground Floor

CHAIRPERSON

Lindsey Sarno
Client Relations Specialist, Medidata Solutions Worldwide

Site budgets are an increasingly complex and important part of the overall clinical budget. This workshop will discuss the components of a site budget and share best practices for ensuring regulatory compliance and achieving quicker site startup.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

#281 Track 01B – Clinical Operations

Related Interest Area(s): CR, SE, FI

3:30–5:00 PM | Level: ● | Format: SYMPOSIUM
Room 1B | *CME, Pharmacy, and Nursing*

Perfecting the Protocol: Designing Studies for Success

CHAIRPERSON

JeanMarie Markham
Chief Executive Officer, Clinlogix

This symposium will help you understand if the inclusion/exclusion criteria for your company's protocol are too restrictive, discuss recent trends in study endpoints and clinical outcome measures, and also discuss what data and experience CROs can use to help you assess the best balance between speed and cost.

How CROs Can Better Support Sponsor Protocol Development
Jeffery Fairbairn, MBA
Senior Director, Partnership Office, PAREXEL International

Hunting a Needle in the Haystack? But It's All Straw! Are There ANY Subjects that Match the Inclusion/Exclusion Criteria?
John E. Humphreys, MS
Senior Product Manager, Clinical Trial Optimization Solutions, IMS Health

Designing for Success? Recent Trends in Study Endpoints and Clinical Outcome Measures in Autoimmune and Inflammatory Diseases
Sylvia Marecki, PhD
Senior Director, Product Management & Strategy, Citeline

#282 Track 01C – Clinical Operations

Related Interest Area(s): RD, PT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 3 | *CME, Pharmacy, and Nursing*

Patient Registries: Designing, Implementing, and Leveraging to Accelerate Clinical Trials

CHAIRPERSON

Lisa Palladino Kim, MS
Global Trial Optimization Specialist, inVentiv Health Clinical

This session will examine how the biopharmaceutical industry, academic organizations, and patient advocacy groups value and utilize patient registries in clinical trials. We will discuss areas of controversy and best practices.

Beyond the RFP: Driving Value Through Effective Registry Strategy, Design, and Operations
Leanne Larson
Vice President and Global Head, Observational Research, PAREXEL International

Incorporating Patient Voice to Speed Development Using Rare Disease Registries
Patti Engel
President and Chief Executive Officer, Engage Health Inc.

Bridging Patient Registries to Clinical Research: A Win-Win Opportunity
Thomas A. Krohn, MBA, RPh
Advisor, Clinical Open Innovation, Eli Lilly and Company

#283 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RD, CR

3:30–5:00 PM | Level: ◆ | Format: SESSION
Room 1A | *CME, Pharmacy, and Nursing*

Development of Central Nervous System Drugs with Abuse Potential

CHAIRPERSON
Anne Tomalin, RAC
President, Therapeutic Products Inc, Canada

This session will explore the FDA/Drug Enforcement Administration's process for defining and managing controlled drugs, the conduct of clinical trials of drugs with abuse potential, and current state of the art regarding abuse-resistant formulations and associated labeling claims. The development of products with abuse potential is a quickly evolving area within our industry, and rules governing what can and cannot be done are quickly changing. This session will provide newcomers with an overview of the current status of such development and will provide those who have been involved in the area for some time with a recent update.

Assessment of Abuse Liability in Drug Development for Central Nervous System Active Compounds
Eva Finney, PhD, PMP
Director, Global Project Management, Merck & Co., Inc.

Development of Abuse Resistant/Deterrant Formulations and Associated Label Claims
Damon Smith
Chief Executive Officer, Altus Formulation Inc., Canada

Conducting Clinical Trials with Drugs Having Abuse Potential
Ann Marie Hake, MD
Medical Advisor, Medical Division, Neurosciences, Lilly USA, LLC

#284 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, RD

3:30–4:30 PM △ | Level: ■ | Format: FORUM
Room 2 | *CME, Pharmacy, and Nursing*

How a New Collaboration Between a Biopharmaceutical Company and a CRO Is Improving the Quality, Speed, and Efficiency of Drug Development

CHAIRPERSON
Smita Desai, RPh
Senior Vice President, Clinical Development, Quintiles Transnational Corporation, United Kingdom

This forum will explore how a novel collaboration between a biopharmaceutical company and service provider is optimizing productivity in the design and execution of studies with a focus on improving quality, speed, and efficiency.

Getting to Yes: Putting a Strategic Collaboration Between a Biopharmaceutical Company and a CRO into Action
Kathrin Schoenborn-Sobolewski
Global Head Clinical Trial Management, Merck KGAA, Germany

#285 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, CP, CR

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM
Room 7B | *CME and Nursing*

Gene Therapy Symposium

CHAIRPERSON
Barry Mangum, MD
Director, Clinical Pharmacology, Duke University Medical Center

This symposium will include presentations that address the concept of biosafety with respect to gene therapy and application to clinical trials, discuss the potential pitfalls that could affect the development and approval of advanced therapies which are by nature complex, and examine how the various stakeholders can achieve benefit-risk assessments that satisfy their responsibilities for diligence.

How to Achieve Regulatory Approval of Cell and Gene Therapies
Gopalan Narayanan, MD, MRCP, FFPM, FRCP
Biotech and ATMP Expert, NDA Group, United Kingdom

Human Gene Therapy: Biosafety to Bedside
Chris Jenkins, PhD, MPH
Senior Director of IBC Services and Biosafety Consulting, WCG Clinical

Stakeholder Challenges in Early-Phase Studies of Potentially High-Risk Products
Royce A. Morrison, MD, MS
Principal Consultant, RMDinsight LLC

#286 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): AP, RA

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 7A | *CME and Nursing*

International Regulatory Advertising and Promotion Considerations

CHAIRPERSON
Thomas M. Casola, MBA
Vice President, Global Regulatory Affairs, Advertising, Promotion, and Labeling, Shire Specialty Pharmaceuticals

Requirements for disclosure of payments to health care professionals are changing the nature of relationships between pharmaceutical manufacturers and health care practitioners. The impact of the Sunshine Act is already being seen in the US market and new transparency requirements are now being rolled out in International markets. This session will review transparency requirements, what companies should be thinking about to prepare for new disclosure rules in International markets, and how these requirements will affect both commercial and drug development activities.

Industry Perspectives
Representative Invited
Regulatory Affairs Specialist, BMI System Inc., France

Representative Invited
Partner, Pharmaceutical and Life Sciences Advisory, PricewaterhouseCoopers LLP

#287 Track 06A – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MC, MW, PPLC

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Our First Year Under Sunshine: Impact on Medical and Scientific Communications

CHAIRPERSON

Monica A. Kwarcinski, PharmD
Executive Director, Medical Services, Purdue Pharma L.P.

Having passed the one-year milestone of the Physician Payments Sunshine Act, industry continues to evaluate and tweak internal processes on collecting the required data and anxiously awaits the publishing of these data on a publicly available website. This session will describe the obligations, challenges, and impact the Sunshine Act has had on industry medical information departments, medical science liaisons, and medical writers as well as industry sponsored publications. This will be an interactive session with opportunity for discussion and questions from the audience.

The Sunshine Act and Medical Communications
Monica A. Kwarcinski, PharmD
Executive Director, Medical Services, Purdue Pharma L.P.

The Sunshine Act and The Medical Science Liaison
Kathleen M. Guindon, MS, RN
Senior Medical Science Liaison, Genentech, A Member of the Roche Group

#288 Track 06B – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, RA

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 16B | *CME and Nursing*

The Regulatory Writing Game Show

CHAIRPERSON

Jennifer Vande Weghe
Regulatory Writing Senior Manager, Amgen Inc.

It's time to play THE REGULATORY WRITING GAME SHOW! Test your knowledge of regulatory documents, from the mundane to the exotic. This workshop will emphasize group participation and sharing of experience.

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Facilitators
Michael Kelley, PhD
Regulatory Writing Senior Manager, Amgen Inc.

Karin L. Beloussow
Regulatory Writing, Senior Manager, Amgen Inc.

Judges
Becky Norquist
Consultant, Norquist Consulting

Sandra J. Hecker, RAC
US Agent; Regulatory Strategist for Clinical Trial and Marketing Applications, Hecker & Associates, LLC

#289 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, RA

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 30CD | *CME, Pharmacy, and Nursing*

Electronic Standardized Study Data: Regulatory Considerations

CHAIRPERSON

Mary Ann Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

This forum will provide an update on the standardized study data guidance and the regulatory impact of the Food and Drug Administration Safety and Innovation Act (FDASIA) on the requirement to submit study data in conformance with standards.

New Regulatory Guidance on Standardized Study Data
Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

FDA Perspective
Stephen E. Wilson, DrPH
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Science, CDER, FDA

#290 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): DM, CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 33AB | *CME, Pharmacy, and Nursing*

Transforming Culture and Mindsets to Deliver a Higher Quality eTMF

CHAIRPERSON

Bryan Ennis
Director, R&D Customer Success, Veeva Systems

This session will provide best practices that can be used to leverage technology and drive cultural and mindset changes to increase the quality and value of the electronic trial master file (eTMF). Cutting-edge survey results will be presented on industry drivers and barriers to a paperless eTMF, lined up with proven best practices, and demonstrated by a sponsor case study.

What Is Keeping Us From a Paperless TMF: Survey Results
Bryan Ennis
Director, R&D Customer Success, Veeva Systems

Five Factors to Consider to Maximize External Use of an eTMF System
Michael Agard, MS
Principal Consultant, Paragon Solutions

Transforming Clinical Processes to Make the Most of the eTMF: Case Study
Renee Fate
Senior Manager, Document Management, Kythera Biopharmaceuticals, Inc.

#291 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, ROD, HT

3:30–5:00 PM | Level: ● | Format: SESSION
Room 30AB | *CME, Pharmacy, and Nursing*

Prequalification of Medicines for Neglected Tropical Diseases

CHAIRPERSON

Jacqueline M. Kline, PhD
Senior Director Global Regulatory Affairs, Eisai Inc.

More than one billion people in developing countries suffer from neglected tropical diseases (NTDs) that cause immense human suffering and death. Safe and effective treatments and control methods are available to fight some NTDs, however, delivering the interventions to poor and hard-to-reach communities in developing countries where people have little access to healthcare is a formidable challenge. In this session, efforts on the part of the World Health Organization (WHO) and the Bill and Melinda Gates Foundation to control, eliminate, or even eradicate NTDs will be discussed. In addition, the successful prequalification of diethylcarbamazine (DEC) for use in the elimination of lymphatic filariasis through the WHO Prequalification of Medicines Programme will be described.

WHO Perspective
Lembit Rago, MD, PhD
Head, Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

Challenges in Registering Products in Low- and Middle-Income Countries and What We Are Trying to Do With Various Partners
Murray M. Lumpkin, MD, MSc
Deputy Director, Regulatory Affairs, Global Health and Integrated Development, Bill and Melinda Gates Foundation

WHO Prequalification of Diethylcarbamazine for Elimination of Lymphatic Filariasis
Jacqueline M. Kline, PhD
Senior Director Global Regulatory Affairs, Eisai Inc.

#292 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): ESUBS, RA, FI

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 10 | *CME and Nursing*

Using a Hub and Spoke Model to Drive Efficiency and Cost-Effectiveness in the Global Regulatory Process

CHAIRPERSON

Peter Lassoff
Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

As the high cost of drug development persists and regional regulations continue to be increasingly nuanced and complex, many biopharmaceutical companies are exploring innovative models that offer a smarter approach to bringing compounds to market. This session will examine a Hub and Spoke model, which has proven effective in driving a more efficient and cost-effective use of resources for regulatory activities on a global scale. This program is focused on medium to large companies.

Using a Hub and Spoke Model to Drive Efficiency and Cost-Effectiveness
Peter Lassoff
Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

Effective Regulatory Information Management Leveraging a Hub and Spoke Model: An Industry Case
Susanne Andreae, PhD
Senior Director, Head of Regulatory Informatics and Submission Management, EMD Serono, Inc.

Developing an Effective Model for Global Registration Management
Representative Invited
Director, Regulatory Affairs, Allergan, Inc.

#293 Track 08C – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CMC/GMP, CR

3:30–4:30 PM △ | Level: ■ | Format: SESSION
Room 6D | *CME and Nursing*

Utilizing 505(b)(2) to Accelerate Drug Development Plans

CHAIRPERSON

Kenneth Phelps
President and Chief Executive Officer, Camargo Pharmaceutical Services, LLC

This session will discuss how the application of the 505(b)(2) development strategy has been embraced by a wide range of drug development companies as a means of shortening the development timeline and reducing development costs when compared with development under the traditional 505(b)(1) process. Because 505(b)(2) allows the use of existing literature and data from approved drugs in support of the application, it may mean that some clinical trials can be completely eliminated in some development programs, while others will require only clinical bridging studies to establish a connection to the approved drug. The result can be a streamlined development program that may still provide significant marketing exclusivity for successful products.

Utilizing 505(b)(2) in Clinical Bridging Studies
Kenneth Phelps
President and Chief Executive Officer, Camargo Pharmaceutical Services, LLC

Taking Full Advantage of the 505(b)(2) NDA Pathway
Jeff Antos
Vice President, The Weinberg Group Inc.

#294 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PPLC, CR, RA

3:30–5:00 PM | Level: ● | Format: FORUM
Room 6E | *CME and Nursing*

Biomedical Product Development and Public Policy: Hear from Leaders of PhRMA, BIO, AdvaMed, and ACRO

CHAIRPERSON

Ciaran Murray
Chief Executive Officer, ICON plc, Ireland

This is a unique opportunity to hear from elected leadership from four major trade organizations representing the biopharmaceutical, device and clinical research sectors who will discuss global policy and regulatory priorities for their industries.

Panelist
Bert Liang, MD, PhD, MBA
Chief Executive Officer, Pfenex, Inc.

#295 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, RA, PT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 8 | *CME, Pharmacy, and Nursing*

Adapting GCPs to Evolving Drug Development Paradigm (Part 2 of 2)

CHAIRPERSON

Ann Meeker-O'Connell, MS
Senior Director, QA Clinical Strategy Team Lead, Janssen Pharmaceuticals, Inc.

Emerging technologies have the potential to dramatically increase the efficiency and quality of clinical trials. Significant attention has been given to technology that may benefit both sponsor and investigator sites, such as electronic data capture (EDC) systems and eSource systems; these are technologies that may streamline data collection at the site-level, change data quality control paradigms, and provide sponsors with real-time insight into the accumulating data about an investigational product. This session will turn the focus to emerging technologies that may facilitate patient participation in clinical trials, such as electronic informed consent forms (eICF) and electronic patient reported outcome (ePRO) tools. FDA, industry, and patient advocate speakers will discuss the potential benefits of adopting patient-centric technology, the potential challenges in implementation, as well as compliance considerations in meeting applicable laws and regulations.

Part 1 will take place on Tuesday at 1:30 PM (Session #271).

Regulatory Perspective
Sean Y. Kassim, PhD
Acting Office Director, Office of Scientific Investigations, Office of Communications, CDER, FDA

Patient Perspective
Debra Madden
Cancer Research Advocate, Patient Representative, Ann's Place; National Breast Cancer Coalition (NBCC); Research Advocacy Network

Industry Perspective
Coleen M. Glessner
Vice President, Clinical Trial Process and Quality, Pfizer Inc

#296 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR, ST

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 11B | *CME and Nursing*

Misconduct and Management of Serious or Continued Noncompliance: Differences, Similarities, and Building a World-Class Program

CHAIRPERSON

Deborah A. Waltz, MS
Vice President, Global Compound Support, Quality Assurance, Takeda Pharmaceuticals International, Inc.

This session will provide regulatory perspective on new enforcement directives which place greater emphasis on accountability for compliance for all parties involved in the research enterprise.

Risk-Based Monitoring and Fraud Detection in Clinical Trials
Richard C. Zink, PhD
Principal Research Statistician Developer, SAS Institute, Inc.

FDA Perspective
Faranak Jamali, MD
Medical Officer, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#297 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CmbP, CMC/GMP

3:30–4:30 PM △ | Level: ■ | Format: FORUM
Room 5A | *CME and Nursing*

Lessons Learned in the Development and Registration of Fixed-Dose Combination Products: CMC Focus

CHAIRPERSON

Chandra Vemavarapu, PhD
Associate Director, Bristol-Myers Squibb Company

Hear from industry and regulatory experts on best practices for development and registration of combination products in this forum.

FDA Perspective
George Lunn, PhD
Chemist, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

#298 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): PR, CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 9 | *CME, Pharmacy, and Nursing*

Assessing Comparative Effectiveness Research Feasibility and Interpretability A Priori

CHAIRPERSON

Matthew D. Rotelli, PhD
Director, Global PK/PD and Pharmacometrics, Bio-Medicines, Eli Lilly and Company

Observational studies and comparative effectiveness research (CER) in settings outside of randomized clinical trials have an important role in informing health care decisions about alternative therapies, but are not without their challenges. CER design and analytic features can influence results. Researchers should understand the feasibility of adequately controlling for bias and confounding prior to launching a study. We recommend steps to be conducted in advance of CER to assess feasibility in light of inherent bias and confounding. Researchers must understand their data source and whether outcomes, exposures and confounding factors are captured sufficiently in the database to address the research question. Taking such steps will help ensure that such studies yield results that are interpretable and valid. Recommended a priori analyses include assessments of confounding by indication, robustness to unmeasured confounding, and construction of empirical null distributions based on negative controls.

This session has been developed by the DIA Comparative Effectiveness Scientific Working Group in association with the Evidence Based Medicine Community and the DIA Ethics and the Medicines Lifecycle Community.

Feasibility of Comparative Effectiveness Research: Unmeasured Confounding and Operational Characteristics
Douglas E. Faries, PhD
Research Fellow, Eli Lilly and Company

Additional Steps for Feasibility and Pre-Indentifying Sensitivity Analyses Prior to Launching CER
Cynthia J. Girman, DrPH
Executive Director, Comparative and Outcomes Evidence, Merck Research Laboratories

Discussant
Robert T. O'Neill, PhD
Senior Statistical Advisor, Office of Translational Sciences, CDER, FDA

#299A Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CDM, CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 6C | *CME, Pharmacy, and Nursing*

Evaluating Potential Contribution of Social Media to Postmarketing Medication Safety Surveillance

CHAIRPERSON
Preciosa M. Coloma, MD, PhD, MSc, RPh
Assistant Professor/Senior Researcher, Erasmus MC University Medical Center, Netherlands

Social media is a phenomenon that is increasingly becoming influential in health care. In this session, we will give an overview and evaluation of the potential contribution of social media data sources for postmarketing drug safety surveillance.

Social Media and Pharmacovigilance
Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

Reinventing Safety: What Will It Take to Realize the Promise of Digital Pharmacovigilance and Social Media?
Michael A. Ibara, PharmD
Head of Business Development Coordination & Innovation, WW Safety & Regulatory, Pfizer Inc

Evaluating Medication Safety and Effectiveness Using Patient-Generated Data
Sally Okun, RN
Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe Inc.

#299B Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): DM, RA, IT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 4 | *CME and Nursing*

The Pharmacovigilance System Master File: Business as Usual? Can This File Help Industry?

CHAIRPERSON
Niels Gronning, MSc
Management Consultant, NNIT, Denmark

Since the effective date of Module II of the Guidelines on Good Pharmacovigilance Practices (GVP) (July 2012), Marketing Authorization Holders (MAH) have struggled to ensure compliance with the new legislative measures for the EU. This session will review the comprehensiveness of the Pharmacovigilance System Master File (PSMF); in particular the requirements for organizational process and data oversight which continuously challenges MAH's, and will provide insight into the industry/regulatory perspective of the PSMF and the inherent challenges associated with the implementation and enforcement of the legislation.

The ABCs of the PSMF (Pharmacovigilance System Master File)
Doreen Lechner, PhD
Vice President, Telerx

Implementation of the PSMF: IT and Organizational Considerations
Niels Gronning, MSc
Management Consultant, NNIT, Denmark

Industry/Regulator Perspective on PSMF
Shelley Gandhi
Director, NDA Group, United Kingdom

#299C Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RD

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 5B | *CME, Pharmacy, and Nursing*

Key Subgroup Analysis Issues in Clinical Trials

CHAIRPERSON
Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants LLC

This session will discuss key subgroup analysis issues arising in late-phase clinical trials, including statistical methods commonly used in exploratory and confirmatory subgroup analysis and applicable regulatory requirements.

The New CHMP Guideline on Subgroup Analysis: What's New?
David Ohlssen, PhD
Senior Expert Methodologist, Novartis Pharmaceuticals Corporation

FDA Perspective
Lilly Yue, PhD
Deputy Director, Division of Biostatistics, CDRH, FDA

Key Statistical Considerations in Subgroup Analysis
Representative Invited
Senior Director, Center for Statistics in Drug Development, Innovation, Quintiles Inc.

#299D Track 16 – Professional Development

Related Interest Area(s): HT, RA, PR

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 17A | *CME and Nursing*

Managing Innovation: Challenges and Opportunities Today and for the Future

CHAIRPERSON
Michael Drues, PhD
Founder and President, Vascular Sciences

Life science companies have created disincentives to making innovative changes to products and processes. Innovation in a regulated environment is challenging. Successful innovation in any organization depends on inspired and planful change agents. This workshop will analyze the role of the

organizational change agent, and participants will complete a change agent assessment based on the personality traits of a successful change agent.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitator
Susan Morris, MEd
Director, Merit Systems

#299E Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RA, CR, CP

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM
Room 32AB | *CME, Pharmacy, and Nursing*

Orphan Drugs and Treatment of Rare Diseases in Asia

CHAIRPERSON
Noriaki Murao, MS
Representative, NM Consulting, Japan

This symposium will focus on activities related to orphan drugs and rare diseases in Asia, examining some of the efforts from academic societies, patient organizations, and pharmaceutical companies in facilitating the diagnosis and treatment for rare diseases in Asia, along with an overview of recent regulatory measures in Japan. The symposium also includes the information on epidemiology of rare diseases in Asia.

Government Challenges and Initiatives on Rare Diseases in Asia
Hiroshi Mizushima
Chief Senior Researcher, Center for Public Health Informatics, National Institute of Public Health, Japan

Developing Treatments of Rare Diseases in Asia
Wuh-Liang Hwu, MD, PhD
Professor in Pediatrics, National Taiwan University, Taiwan

Japanese Regulation on Orphan Medicines and Drug Development in Rare Diseases
Harumasa Nakamura, MD
Deputy Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#299F Track 18 – Global Regulatory

Related Interest Area(s): RA, ESUBS, CMC/GMP

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 11A | *CME and Nursing*

FDA - Health Canada Regulatory Cooperation Council (RCC) Town Hall

CHAIRPERSON
Leslie Ball, MD
Assistant Commissioner and Deputy Director, OIP, Office of Communications, FDA

At the request of stakeholders, FDA and Health Canada will highlight their work and lessons learned under the four Regulatory Cooperation Council (RCC) initiatives on the electronic submission gateway, common monographs for over-the-counter drugs, good manufacturing practices and veterinary drugs. Presentations will be followed by a question and answer period on next steps in the RCC process. Stakeholders are encouraged to express their views and innovative ideas as regulators discuss the future of RCC.

Panelists
Louise Déry
Director, Policy, Planning and International Affairs Directorate, Health Canada

Sema D. Hashemi
Office of International Programs, Office of the Commissioner, FDA

#299G Track 20 – Late-breaking Topics

Related Interest Area(s): ALL

3:30–5:00 PM | Level: ● | Format: SESSION
Room 31C

Power Up! Give Your Brain a Vacation

CHAIRPERSON
Julie Ho
Senior Manager, Annual Meeting Content Development, DIA

Join us in this inaugural Power Up! session that breaks the mold of the traditional DIA Annual Meeting Program Offering. Give your brain a break from all the scientific stuff and come and enjoy this fun opportunity to laugh and be inspired by none other than your colleagues. A series of 5-minute presentations will be delivered by Annual Meeting attendees who will share unique stories.

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WEDNESDAY, JUNE 18

Registration Hours:

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

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
7:15 AM–4:00 PM	Professional Poster Session #2 (Sails Pavilion)
8:00–9:30 AM	Educational Opportunities 60-minute TURBO Offerings △ (8:00–9:00 AM) 90-minute Offerings (8:00–9:30 AM)
9:00 AM–4:00 PM	Exhibit Hall Open
9:30–10:30 AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30 AM–12:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (10:30–11:30 AM) 90-minute Offerings (10:30 AM–12:00 PM)
11:30 AM–1:30 PM	Lunch & Exhibit Hall Innovation Theater Presentations
1:30–3:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (1:30–2:30 PM) 90-minute Offerings (1:30–3:00 PM)
1:30–3:30 PM	Exhibit Guest Passes
2:30–3:30 PM	Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30–5:00 PM	Educational Opportunities 60-minute TURBO Offerings △ (3:30–4:30 PM) 90-minute Offerings (3:30–5:00 PM)

#301 Track 01A – Clinical Operations

Related Interest Area(s): CR, SE, IT

8:00–9:30 AM | Level: ■ | Format: SYMPOSIUM

Room 1B | *CME and Nursing*

Metrics Benchmarking, Predictive Analytics, and Virtual Population Simulation: New Tools to Contextualize and Forecast Trial Performance

CHAIRPERSON

Badri Rengarajan, MD

Vice President, Medical Affairs and Senior Principal Consultant, Evidera

Given the significant cost, time, and risk of conducting clinical trials, it behooves clinical development professionals to avail themselves of tools that help better plan clinical studies, monitor their progress, and take corrective action as needed to stay under budget, on time, and within expectations (and aspirations). In this symposium, we will describe three novel tools and share case studies demonstrating their application: • Using a novel R&D benchmarking database to examine operational performance of clinical trials for sponsors, CROs and service providers • Employing predictive analytics to forecast operational outcomes of clinical studies • Forecasting clinical outcomes of a study as it is enrolling by simulating a virtual population reflecting the enrolled population.

Using Virtual Population Simulation to Forecast Likely Study Outcomes as a Trial Is Enrolling
Badri Rengarajan, MD
Vice President, Medical Affairs and Senior Principal Consultant, Evidera

Predictive Analytics for Dummies: How Anyone Can Use Analytics to Forecast Clinical Study Operational Outcomes
Representative Invited
Senior Director, Life Sciences Product Strategy, Oracle Health Sciences

A Benchmarking Database for Comparing Industry R&D Performance
David S. Zuckerman, MS
Chief Executive Officer, Metrics Champion Consortium LLC

#302 Track 01B – Clinical Operations

Related Interest Area(s): IT, AHC/IS

8:00–9:30 AM | Level: ● | Format: SESSION

Room 3 | *CME and Nursing*

The Sites Have Spoken: Implementing Paperless Trials and Risk-Based Monitoring from a Site's Perspective

CHAIRPERSON

Penelope K. Manasco, MD, MS

Chief Executive Officer, MANA Consulting

This session brings sites that have adopted paperless trials together to provide their opinions and insights into this new approach to clinical trial conduct.

Site Satisfaction with a P3 Paperless Clinical Trial
Mary R. Flack
Vice President, Clinical and Medical Affairs, NanoBio Corporation

A Site's Experience with Implementing Electronic Source
Emily W. Galdes, JD
Vice President and Chief Operating Officer, Diablo Clinical Research

Implementing eSource for Home Visits by Home Health Nurses
Teresa Suek
President, Research 3, Inc.

#303 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, BT, FI

8:00–9:00 AM △ | Level: ■ | Format: SESSION

Room 1A | *CME and Nursing*

Life Cycle Management of Biopharmaceuticals: An Approach and Lessons Learned for an Imperative Business Practice

CHAIRPERSON

Keith Ruark, MBA

Vice President, AVOS Consulting, INC Research

This session will provide insights on strategic and financial objectives and goal-setting for key functions that are typically critical to life cycle management (LCM) planning success, on the role and value of a consistent and codified process at the enterprise level to evaluate evidence generation options, and on common pitfalls and challenges of LCM strategy development and implementation.

LCM Approach and Lessons Learned
Keith Ruark, MBA
Vice President, AVOS Consulting, INC Research

Bridget Martell
Managing Director, BAM Consultants

#304 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, CR, RA

8:00–9:00 AM △ Level: ◆ Format: SESSION
Room 5A *CME and Nursing*

Why Does Drug Development Need Project Management?

CHAIRPERSON

Timothy M. Phelan, PhD
Executive Director, Merck & Co., Inc.

Bringing a new medicine to patients is one of the truest examples of project management, yet the business results for large pharmaceuticals suggest we have not fully realized the business benefit of applying project management theory and practice. This session will discuss how maximizing the project management infrastructure already installed in drug development organizations will improve their business results.

Panelists

Vanessa Graham, MBA
Executive Director, Global Program Management, Amgen Inc.

Jim L. Vandergriff, II
Pharmaceutical Project Management, Eli Lilly and Company

#305 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, PM

8:00–9:30 AM Level: ■ Format: FORUM
Room 2 *CME, Nursing, and PMI PDUs*

Achieving Success in a Mega-Trial Sponsor/ARO/CRO Collaboration: Approaches to Overcome Challenges and Optimize Results

CHAIRPERSON

Jay A. Turpen
Advisor, Clinical Project Management, Eli Lilly and Company

This forum focuses on how a sponsor, an academic research organization, and a contract research organization collaborated to form a united, highly successful global project team focused on one common goal. Specific examples that can be applied to clinical trial management will be provided.

Panelists

Jay A. Turpen
Advisor, Clinical Project Management, Eli Lilly and Company

Ellen McErlean, MSN, RN
Senior Project Manager, Coordinating Centre for Clinical Research, Cleveland Clinic

Penny Piper, PhD, PMP
Project Director, Covance Clinical & Periapproval Services Ltd, United Kingdom

#306 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, PR

8:00–9:30 AM Level: ● Format: SYMPOSIUM
Room 4 *CME, Nursing, and PMI PDUs*

Optimizing Outsourcing Relationships: Data-Driven Strategies to Support Vendor Selection, Negotiation, and Management

CHAIRPERSON

Margaret S. Richards, PhD, MPH
Executive Director, Epidemiology and Health Outcomes, PPD

Armed with data (both qualitative and quantitative) — and taking a strategic rather than a tactical approach in selecting, negotiating with, and managing vendors — selection teams can save their companies time and money. This symposium will speak to each phase of the outsourcing relationship and provide helpful information, tips, and tools to those who serve on the critically important vendor selection teams. Negotiation strategies will be shared along with the results of a national survey of outsourcing models (single, preferred, integrated alliance) employed by top biopharmaceutical companies. Best practices that have been implemented to improve the effectiveness of the outsourcing relationship will be at the heart of this symposium.

RFIs with Soul: Asking the Right Questions to Find the Best Answers
Margaret S. Richards, PhD, MPH
Executive Director, Epidemiology and Health Outcomes, PPD

Strategies for Clinical Vendor Negotiations: Implementing a Data-Driven Process to Optimize Vendor Performance and Cost
Kent Mahoney, MBA
Managing Director, Soltex Consulting LLP

Optimizing Outsourcing Relationships
Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

#307 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): NC, CR, PR

8:00–9:30 AM Level: ■ Format: SESSION
Room 7B *CME and Nursing*

Designing Smarter and More Cost-Effective Phase 1 Protocols

CHAIRPERSON

Gary L. Steinman, MS
President, Medexetech

In this session, experienced phase 1 clinical and preclinical investigators will present realistic protocols, identify and evaluate the impact of unnecessary, costly and time-consuming requirements that can drive up conduct costs and/or impede timely study completion, offer protocol design recommendations that can improve study conduct efficiency and, by incorporating translational methodologies, more effectively discern the viability of drug candidates in early clinical development.

Jazz, Tetris and CPUs: An Introduction
Gary L. Steinman, MS
President, Medexetech

Designing and Executing Efficient Phase 1 Protocols: Clinical Aspects
William B. Smith, MD
President, New Orleans Center For Clinical Research and Volunteer Research Group

Designing and Executing Efficient Phase 1 Protocols: Operations Aspects
Mary L. Westrick, PhD
Vice President, US Phase I, Quintiles Inc.

#308 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, MSL, MC

8:00–9:00 AM △ Level: ● Format: SESSION
Room 31AB *CME and Nursing*

Professional Career Development Within Medical Affairs: A Perspective from Medical Communications, Medical Science Liaisons, and Medical Writers

CHAIRPERSON
Rebecca A. Vermeulen, RPh
Senior Director, BioOncology Medical Science Liaisons, Genentech, A Member of the Roche Group

How does an individual build a career within the medical affairs function of the pharmaceutical industry? What options are available and what are the skillsets needed for success within these careers? Join this session to learn more about career paths for the medical communications, medical science liaisons, and medical writing roles. Individuals will share their experiences and career paths to offer guidance to both new and experienced attendees.

Transitional Moves in Medical Writing
Frances Pu, PhD
Principal Service Provider, Renaissance Writing Services, LLC

Experience and Commitment to Developing People Within Medical Affairs
Jenny Colombo, PharmD
Vice President, Scientific Strategies and Communications, US Medical Affairs, Takeda Pharmaceuticals International, Inc.

#309 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, CR

8:00–9:30 AM Level: ◆ Format: SESSION
Room 30CD *CME, Pharmacy, and Nursing*

CDISC BRIDG Implementation: A Model for System Interoperability and as a Data Base Model

CHAIRPERSON
Terry D. Hardin
Director, Information Management, Perceptive Informatics

This session will discuss the impact that the Biomedical Research Integrated Domain Group (BRIDG) is having on data as an asset, from study set-up to analysis and reporting. We will examine moving from BRIDG as a concept to generation of physical artifacts, and how this industry initiative is changing the structure of data stored in clinical data repositories. Case studies will be presented examining the pros and cons of BRIDG implementations, from a basis for messaging structures to data base models, and consumption of BRIDG-based data in analysis and reporting.

A Case Study in CDISC BRIDG Implementation: BRIDG as a Canonical Data Model
Terry D. Hardin
Director, Information Management, Perceptive Informatics

A Case Study in BRIDG Implementation: Leveraging BRIDG as a Database Model for Clinical Trials
Smita Hastak, MS
Chief Executive Officer, Samvit Solutions, LLC

Crossing the BRIDG: Some Reviewer Thoughts and Perspectives
Stephen E. Wilson, DrPH
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Science, CDER, FDA

#310 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, CR, PT

8:00–9:30 AM Level: ■ Format: SESSION
Room 33AB *CME, Pharmacy, and Nursing*

Clinical Trials Technology Implementation: Bringing Together Patient- and Site-Centric Approaches

CHAIRPERSON
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, United Kingdom

This session will review current technology advances that are aimed at key external stakeholder satisfaction - the site and the patient. We will explore site feedback on these developments and look at the integration of both approaches.

Site-centric Approaches to Clinical Trial Technology Application
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, United Kingdom

The Use of Mobile Technology to Place Patients at the Center of Clinical Trials
Tim Davis
Chief Executive Officer and Co-founder, Exco InTouch, United Kingdom

Leveraging Mobile Technology to Deploy Clinical Trial Materials and Enhance Site Communications
Angela Kaiser
Global Project Lead, Duke Clinical Research Institute

#311 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CP

8:00–9:30 AM Level: ■ Format: SESSION
Room 6D *CME and Nursing*

Proprietary Name Review: International Perspectives from the FDA, Health Canada, and EMA

CHAIRPERSON
Lina Aljuburi, PharmD, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

A trademark that minimizes the risk for medication errors is important to all stakeholders. Learning the role of trademarks and review is critical to the success of the process. An international panel of regulators will discuss the approach they take.

FDA Perspective
Representative Invited
Acting Director, Division of Medication Error Prevention and Analysis, CDER, FDA

EMA Perspective
Isabelle Moulon, MD
Head of Medical Information, European Medicines Agency, European Union

#312 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, SP

8:00–9:30 AM | Level: ■ | Format: WORKSHOP
Room 16A | *CME and Nursing*

Regulatory Strategic Plan: Don't Start Development Without One

CHAIRPERSON
Mark A. Ammann, PharmD
President, Catalyst Regulatory Services, LLC

This interactive, hands-on workshop will provide instruction on how to prepare a regulatory strategic plan. Participants will be divided into teams and given a template. With the help of instructors, each team will prepare key components.

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Facilitator
James T. Rawls, PharmD
Vice President, Regulatory Affairs, Sunovion Pharmaceuticals Inc.

#313 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): RA, CmbP, MDD

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 11A | *CME and Nursing*

Changing Global Regulatory Climates: Effects on Companion Diagnostics and Combination Products

CHAIRPERSON
Shayesteh Fuerst-Ladani, MBA, MS
Director, SFL Regulatory Affairs & Scientific Communication, Switzerland

This session will focus on EU and US FDA developments in the regulation of drug/device combination products and companion diagnostics with an emphasis on clinical considerations. The session will provide an overview of the revision of the EU medtech legislation and summarize the main changes of the latest development of the proposed medical devices and in vitro diagnostic regulations. This will include an assessment on the impact of these changes on the regulatory framework for combination products and companion diagnostics. How these amendments will affect clinical study design of drugs and companion diagnostics will be highlighted. The session will also include discussion of FDA current and future guidance, including human factor considerations in developing combination products.

Revision of EU Medtech Law: Impact on Regulatory Framework of Companion Diagnostics and Combination Products
Shayesteh Fuerst-Ladani, MBA, MS
Director, SFL Regulatory Affairs & Scientific Communication, Switzerland

Global Clinical Trial Design Considerations When Incorporating a Companion Diagnostic
Sabah Malek
Associate Director, Global Regulatory Affairs, Eisai Inc.

US FDA Regulation of Combination Products: Clinical and Technical Considerations
Jill Hartzler Warner
Associate Commissioner for Special Medical Programs, FDA

#314 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, CR

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 6E | *CME and Nursing*

The Legal, Ethical, and Commercial Issues Impacting the Development and Accessibility of Pediatric Medicines

CHAIRPERSON
Marie Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

This forum will assess the European Commission's five-year report on the performance of the pediatric regulation and identify from a legal and ethical dimension the strengths and weaknesses in the operational structure.

This forum has been developed by the DIA Legal Affairs and Ethics and the Medicines Lifecycle Communities.

What Have Been the Benefits and Lessons Learned After Five Years of the Pediatric Regulation?
Marie Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

Impact Of The EU Pediatric Regulation
Klaus Rose, MD, MS
Chief Executive Officer, klausrose Consulting, Switzerland

The EU Pediatric Regulation: The Regulator's Perspective
Karl-Heinz Huemer, MD, PhD
Clinical Assessment Safety and Efficacy, Austrian Medicines and Medical Devices Agency (AGES), Austria

#315 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, AHC/IS, CP

8:00–9:30 AM | Level: ■ | Format: WORKSHOP
Room 16B | *CME and Nursing*

Research Site Quality Compliance Programs: Review of Industry Gold Standards

CHAIRPERSON
Liz Wool, BSN, RN
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

This workshop provides a review with examples of site quality compliance frameworks and programs. Additionally, this workshop reviews the risk management strategies for sites to use when launching or augmenting their quality compliance framework.

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Core Elements: Site Quality Compliance Framework
Christine K. Pierre, RN
President, Society for Clinical Research Sites

Building Quality by Design (QbD) and Quality Risk Management (QRM) Systems into Clinical Site Operations
Marina Malikova
Executive Director, Surgical Translational Research Operations and Compliance, Boston University School of Medicine

#316 Track 12A – Pharmaceutical Quality

Related Interest Area(s): MF, CR, RA

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 11B | *CME, Pharmacy, and Nursing*

Balancing Manufacturing Quality Improvements and Drug Shortage

CHAIRPERSON
Jeannie C. David, MS
Senior Program Management Officer, CDER Drug Shortage Staff, FDA

Drug shortages are a significant public health threat that can delay, and in some cases even deny, critical care for patients. Critical drug shortages that involve issues with drug manufacturing tend to be persistent. This session will discuss key considerations to promoting and sustaining high quality drug manufacturing while ensuring a reliable supply of critical medicines. Purchase of new equipment, renovation of facilities, or implementation of new manufacturing processes and technologies are effective long-term solutions to shortages. However, it remains critical to patients when no alternative medicines are available, for manufacturers to be able to implement these changes while avoiding disruptions in ongoing supply. How does one improve manufacturing and quality systems to ensure a reliable supply of critical medicines in the long term while maintaining supply in the short term? This session will focus on case studies of sterile injectables, a dosage form with challenging considerations and timelines, to learn what has contributed to successful implementation and the limitations to overcome. We will cover manufacturing changes, communications with the FDA, management of production and supply, and submitting changes to the FDA. The audience will gain an overview of industry efforts to improve manufacturing facilities and products while avoiding shortages and the FDA's role. The session will also describe publicly available drug shortage related information, and early notification as a critical tool to mitigate and prevent shortages.

Industry Perspective
Janet Stevens, MBA
Vice President, Quality International Pharma and Biologics, Hospira, Inc.

Quality Aspects of Drug Shortages
Frances M. Zipp
President, Lachman Consultants

FDA Perspective
Jeannie C. David, MS
Senior Program Management Officer, CDER Drug Shortage Staff, FDA

#317 Track 12B – Pharmaceutical Quality

Related Interest Area(s): RA, CMC/GMP

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 10 | *CME and Nursing*

ICH Update: Emerging Guidelines

CHAIRPERSON
Stephen Miller, PhD
CMC Lead, Office of New Drug Quality Assessment, CDER, FDA

This session will provide an update on the current thinking for safety assessment and control of elemental impurities and mutagenic impurities in pharmaceuticals.

ICH Q3D Update: Looking Ahead to a Globally Harmonized Approach to Elemental Impurities
Mark G. Schweitzer
Global Head, Analytical Science and Technology, Novartis Pharmaceuticals Corporation

Health Canada Perspective
Alisa Vespa, PhD
Assessment Officer, Metabolic and Musculoskeletal Drugs Division, Health Canada

ICH M7: Mutagenic Impurities - Chemistry, Manufacturing, and Controls Aspects
Stephen Miller, PhD
CMC Lead, Office of New Drug Quality Assessment, CDER, FDA

#318 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): IT, RD, CDM

8:00–9:00 AM △ | Level: ■ | Format: FORUM
Room 9 | *CME, Pharmacy, and Nursing*

Leveraging Electronic Health Record Data to Understand Clinical Nuance in Complex Real-World Populations: A Case Study

CHAIRPERSON
Brett Jason Davis
Principal and General Manager, Convergehealth By Deloitte

Real-world evidence is becoming important in life sciences decision-making as a result of value-based reimbursement, personalized medicine, and safety pressures. Explore how electronic health record (EHR) data can be used to understand outcomes in real-world populations.

Panelists
Brett Jason Davis
Principal and General Manager, Convergehealth By Deloitte

Nicole Kay Hobbs, PhD
Director of Operations, Intermountain Healthcare

#319 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): ST, PT

8:00–9:30 AM Level: ■ Format: FORUM
Room 30AB *CME, Pharmacy, and Nursing*

Signal Detection: Challenges and Strategic Aspects

CHAIRPERSON

Alan M. Hochberg
Process Development Leader, F. Hoffmann-La Roche Ltd., Switzerland

This forum will consider three aspects of signal detection which are not frequently emphasized, but which have a significant influence on the overall quality of pharmacovigilance for a product — the role of proper identification and assessment of premarketing signals in maintaining a favorable benefit-risk profile throughout a product's life cycle, the optimization of practices and systems in ambulatory and institutional settings for reporting and tracking drug-related adverse events, and the consequences for patient benefit-risk optimization of the analysis and publication of pharmacovigilance data and safety signals by a broad array of stakeholders including academic institutions, insurers, nonprofits, and web businesses, in addition to industry and regulators.

Premarketing Signaling: The What's, Why's and How's
Michael J. Klepper, MD
President and Founder, Drug Safety Navigator

Optimizing Product Specific Safety Monitoring
Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

Who Should Do Safety Signal Detection and Why (or Why Not)?
Alan M. Hochberg
Process Development Leader, F. Hoffmann-La Roche Ltd., Switzerland

#320 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, IT

8:00–9:30 AM Level: ■ Format: SESSION
Room 8 *CME and Nursing*

The Challenges of High Quality Risk Management with Single Shared System REMS and Physician Knowledge Surveys

CHAIRPERSON

Albin Karimattam, JD, PharmD
Associate Director, US Safety Risk Management, Novartis Pharmaceuticals Corporation

Single shared system risk evaluation and mitigation strategies (REMS) are increasing in frequency with varying degrees of complexity. This session presents different perspectives to investigate its benefits & challenges to the different stakeholders. Physician knowledge surveys (EU) are increasingly requested of drug manufacturers. The session will focus on how best to design surveys to reliably measure physician awareness of safety.

Establishing and Managing Single Shared REMS Programs: A PMO Perspective on Challenges and Best Practices
Jemma Contreras, PhD
Director, Medical Affairs, Campbell Alliance

Single Shared System REMS: FDA Perspective
Gary H. Slatko, MD
Director, Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology, CDER, FDA

Physician Knowledge Surveys as Part of Risk Minimization Plans and Pharmacovigilance
Alexander Liede, PhD, MSc
Observational Research Director, Amgen Inc.

#321 Track 15A – Statistical Science and Quantitative Thinking

Related Interest Area(s): PETD

8:00–9:30 AM Level: ● Format: FORUM
Room 5B

Your Future Success as a Master's Level Statistician: Learn from the Past of These Industry Masters

CHAIRPERSON

Aileen M. Murphy, MPH
Senior Director, Biometrics, Seattle Genetics Inc.

The speakers will present examples of successful master's level career paths. Learn from the past of these industry veterans to create your future career as a master's level statistician in industry.

Beyond the Master's Degree: My Path into Bayesian Trial Design
Kristine Broglio, MS
Statistical Scientist, Berry Consultants LLC

Mastering the Interim Analysis: Perspectives from a Master's-level IDMC Reporting Statistician
Matthew Downs, MPH
Statistical Scientist, Statistics Collaborative, Inc.

So You Want a Career in Biostatistics
Luke Hickey, MSc
Executive Director, Biostatistics, INC Research

Panelist
Barbara Day
Group Director, Permanent Division and Biostatistics Recruitment, inVentiv Health Clinical

#322 Track 15B – Statistical Science and Quantitative Thinking

Related Interest Area(s): MW

8:00–9:30 AM Level: ● Format: SESSION
Room 7A *CME, Pharmacy, and Nursing*

Seeing Is Believing! Good Graphic Design Principles for Medical Research

CHAIRPERSON

Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Have you noticed when browsing an article how your eye is drawn to figures more than words? The visual impact of statistical graphs can be powerfully used to communicate key points. This session highlights ways to optimally use graphs.

Motivators for Use of Graphs in Medical Research
Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Not Every Graph Is a Good One: Examples of Improvements to Commonly Used Graphs
Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences, Eli Lilly and Company

Spaghetti, Lasagna, and Cooking Up Graphs from Scratch
Richard Forshee, PhD
Associate Director for Research, Office of Biostatistics and Epidemiology, CBER, FDA

#323 Track 16 – Professional Development

Related Interest Area(s): CR, RA, CP

8:00–9:30 AM | Level: ● | Format: WORKSHOP
Room 17A | *CME and Nursing*

Innovative Engagement Strategies to Inspire Higher Level Commitment and Performance

CHAIRPERSON
Lynn King, MHA
Senior Director, Clinical Operations, TKL Research

This workshop will provide an interactive environment for learning about employee engagement and discovering successful methods for inspiring commitment. Attendees will explore the definition and impact of engagement and discuss innovative strategies and tools for engaging yourself and others in your workplace. The intricate relationship between engagement, commitment, and performance will be discussed, and attendees will develop an action plan for direct application in their workplace.

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Manager as Chief Engagement Officer: Inspiring Higher Levels of Commitment and Performance from Your Employees and Teams
Gary M. Bufferd
Lead Clinical Research Associate, United BioSource Corporation

Employee Engagement: How to Motivate Peak Performance in Your Organization
Donny Chen, MBA
Associate Director, Project Management, PPD

#324 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): FI, CR

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 32AB | *CME, Pharmacy, and Nursing*

International Cooperation in Rare Disease Research

CHAIRPERSON
Paul Lasko, PhD
Chair, Executive Committee, International Rare Diseases Research Consortium, Canada

This forum will address the role of the International Rare Diseases Research Consortium (IRDiRC) in fostering international collaboration in rare disease research and discuss recent progress toward identifying rare disease genes and developing new therapeutics. We will also examine a proposed cooperation network in Asia Pacific in orphan drug clinical trials.

Panelist
Paul Lasko, PhD
Chair, Executive Committee, International Rare Diseases Research Consortium, Canada

EMA Perspective
Jordi Llinares, DrMed, MSc
Head of Product Development Scientific Support Department, European Medicines Agency, European Union

Facilitate the Accessibility via Asia-Pacific Collaboration Network of Clinical Trials for Orphan Drugs
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

#325 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

8:00–9:30 AM | Level: ● | Format: SESSION
Room 31C | *CME and Nursing*

Transforming ICH Toward Greater Global Harmonization

CHAIRPERSON
Justina A. Molzon, JD, MSc
Associate Director for International Programs, Office of Strategic Program CDER, FDA

ICH is defining new governance procedures to enable wider participation by participants beyond US, Europe, and Japan. This session will discuss the proposed structural and procedural changes to ICH toward increasing global regulatory harmonization.

Panelists
Petra Doerr, PharmD
Head of Communication and Networking, Deputy Director, Swissmedic, Swiss Agency For Therapeutic Products, Switzerland

Louise Déry
Director, Policy, Planning and International Affairs Directorate, Health Canada

9:30–10:30 AM

Coffee Break & Exhibit Hall Innovation Theater Presentations

#326 Track 01A – Clinical Operations

Related Interest Area(s): CR, IT, FI

10:30 AM–12:00 PM | Level: ■ | Format: SYMPOSIUM
Room 2 | *CME, Pharmacy, and Nursing*

Risk-Based Monitoring Symposium

CHAIRPERSON
Marcus Thornton
Senior Director, CTMS, Medidata Solutions Worldwide, United Kingdom

Life science organizations are actively implementing and executing risk-based monitoring programs, but what will this mean for current onsite monitoring practices and how will this shape the role of a clinical research associate (CRA)? This symposium will examine practical approaches to

building a site management and monitoring team that supports a risk-based program and discuss how today's functional monitoring role might evolve.

The Role of the Monitor: Considerations to Adopting a Risk-Based and Adaptive Monitoring Program
Marcus Thornton
Senior Director, CTMS, Medidata Solutions Worldwide, United Kingdom

Occupying the White Space Between the Clinical Data Manager and the Clinical Research Associate
Dermot Kenny
Senior Vice President, Global Data Management, ICON plc, Ireland

De-Risking Your Risk-Based Monitoring (RBM) Plan: Practical Considerations in Implementing RBM at the CRA Level
Rita Purvis
Vice President, Clinical Operations, inVentiv Health Clinical

#327 Track 01B – Clinical Operations

Related Interest Area(s): AHC/IS, CR, IT

10:30 AM–12:00 PM | Level: ■ | Format: SYMPOSIUM
Room 1B | *CME and Nursing*

Site Selection and Feasibility Symposium

CHAIRPERSON
Ira Charles Spector, PhD, MBA
(former) Senior Vice President, Global Development Operations, Allergan, Inc.

This symposium will cover the use of data analytic tools to identify the best clinical research sites for use in clinical studies. Traditional approaches to site selection often result in a number of sites not enrolling. This symposium will address the use of performance metric tools to enrich the probability of selecting sites that enroll well and retain patients during clinical trials.

Predicting Clinical Research Site Performance
Ira Charles Spector, PhD, MBA
(former) Senior Vice President, Global Development Operations, Allergan, Inc.

Mining the Mother Lode: Harnessing the Right Data and Metrics to Find the Best Sites for Your Study
Suresh Kannan, MBA
Vice President, Product Development, Clinical Trial Optimization Solutions, IMS Health

Using a Data-Driven Approach at the Site Level During the Feasibility Process to Help Ensure a More Accurate Trial Outcome
Rebecca Little
Associate Director, Business Development, Rx Trials

Site Perspective
Daniel M. Ulrey, MBA
President and Chief Executive Officer, Midwest Clinical Support, Inc.

#328 Track 01C – Clinical Operations

Related Interest Area(s): CS, AHC/IS, CR

10:30 AM–12:00 PM | Level: ● | Format: SYMPOSIUM
Room 1A | *CME, Pharmacy, and Nursing*

Clinical Supply Symposium

CHAIRPERSON
Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

This clinical supply symposium will examine some of the challenges in managing drug supply including strategies to address drug shortages, various approaches to clinical supply planning, and those areas that investigative sites report can cause delays in clinical trials. Results of a global survey as well as real-life examples will be presented and discussed.

A Study of Global Clinical Supply Practices among Investigative Sites
Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

Drug Shortages in Clinical Trials
Amy Rupp
Manager, IRT Project Manager, BioClinica, Inc.

Optimal Planning for Global Clinical Trial Supply
Vladimir Shnaydman, PhD
President, ORBee Consulting

#329 Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, PETD, CR

10:30 AM–12:00 PM | Level: ● | Format: WORKSHOP
Room 16A | *CME, Nursing, and PMI PDUs*

Project Management Basics: Creating a High-Level Project Plan

CHAIRPERSON
Karla Childers, MS
Director, Strategic Projects, Johnson & Johnson

This workshop will assist attendees in the development of a high-level project plan. A work breakdown structure will be the basis for identification of key activities, durations, resources and risks. Tools and methodology will be shared.

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#330 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PETD, RD

10:30 AM–12:00 PM | Level: ◆ | Format: FORUM
Room 5A | *CME and Nursing*

Career Planning and Limitations for Mid- to Upper-Level Project Managers

CHAIRPERSON

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

If you have been managing R&D drug development projects for several years, what options do you have for further advancement or to continue to develop depth and expertise? If you feel that you have reached a limit or have plateaued, this forum will provide a variety of perspectives to consider as you evaluate what is next in your career.

Panelists

Michele C. Livesey, MBA
Drug Development Strategy and Execution Consultant, Livesey Consulting

Tina Rarick, MBA
President, Angus Bio Consulting, LLC

Nita Ichhpurani, PMP
Senior Director, External Study Management, Drug Development, Celerion, Canada

#331 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, RD, SP

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 4 | *CME, Nursing, and PMI PDUs*

The Present and Future of Pharmaceutical Development Outsourcing: Where Are We Today and Where Are We Going?

CHAIRPERSON

Jon Meyer, MBA, MSc
Co-founder and Managing Member, Life Science Strategy Group, LLC

Over the past decade, the pharmaceutical industry has increasingly turned to the use of outsourced service providers (CROs) for drug development as a strategy to cut internal costs, accelerate project timelines, and increase overall R&D efficiencies. During these last 10+ years, pharmaceutical sponsors have employed various strategies in working with CROs/outsourced partners, including the use of CROs in functional roles, use of a limited number of preferred partners, and even forming strategic partnerships over longer periods of time. This forum will present novel, proprietary data collected from a quantitative global sample of outsourcing professionals at biopharmaceutical companies to understand the frequency of use of various outsourcing models/strategies, sponsor satisfaction with the approaches and also explore how outsourcing methods/strategies are expected to evolve over the next five years. A diverse panel will provide commentary on the results of the research as the data are presented.

The CRO-Sponsor Relationship – Then and Now: A Look at Past Outsourcing Models and Their Impact on Future Relationships
Andrew Townshend
Vice President, Alliance Development, INC Research

Panelist
Mitchell A. Katz, PhD
Executive Director, Medical Research Operations, Purdue Pharma L.P.

#332 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): GCP, OS

10:30–11:30 AM △ | Level: ■ | Format: FORUM
Room 5B | *CME and Nursing*

Vendor Selection for a Small Company

CHAIRPERSON

Katie Walsh McCarthy
Principal Consultant, Halloran Consulting Group, Inc.

This session will discuss challenges that small companies face when working with CROs and vendors, and offer solutions for successful selection and collaboration along with examples of successful strategic collaborations including learnings from audits.

Panelists

Alicia B. Savage
Director and Project Leader, Neuroscience iMed, AstraZeneca Neuroscience Innovative Medicines (imed)

Kathryn Stiede
Senior Director, Clinical Operations, Lantheus Medical Imaging, Inc.

#333 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): AHC/IS, NC, PC

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Site Certification of Early Phase Research Units: An International Perspective

CHAIRPERSON

Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

The Medicine and Healthcare Products Regulatory Agency (MHRA) has implemented a site certification process. An industry association has established guidelines for the operation of phase 1 units. This session will explore the impact of this on the industry.

Certification: A US Early Phase Perspective
Royce A. Morrison, MD, MS
Principal Consultant, RMDinsight LLC

Implementation of Site Certification
Elizabeth Allen, PhD
Vice President Phase 1, Quintiles Drug Research Unit At Guy's Hospital, Quintiles Limited, United Kingdom

MHRA Perspective on Site Certification
Representative Invited
Regulatory Agency Europe, Switzerland

#334 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MSL, MC

10:30–11:30 AM △ Level: ■ Format: SESSION
Room 31AB *CME, Pharmacy, and Nursing*

Field-Based Medical Communications on a Global Scale

CHAIRPERSON

J. Lynn Bass, PharmD, RPh
Director, Medical Affairs Operations, Jazz Pharmaceuticals

The pharmaceutical industry is challenged with communicating and providing education to both local and global constituents on the risks and benefits of its products. In the field, this communication is often provided by Medical Science Liaisons (MSLs) to a variety of health care providers. Since the inaugural team of MSLs was deployed, the role and function of individual MSL has evolved and pivoted in numerous directions. This evolution has expanded and now includes education on a global basis to a broader base of customers. In this session, we will explore the proper assessment to determine when a global MSL team is essential, evaluate how a MSL team is developed to support global needs with regional implementation considerations, and discuss the challenges of assessing outcomes for these teams.

Medical Affairs and Their Significant Others
Robin L. Winter-Sperry, MD
President and Chief Executive Officer, Scientific Advantage LLC

MSLs: From Global to Regional Implementation
Geoff Brockway
Director, Global MSL Excellence, AstraZeneca, Canada

#335 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, CR

10:30 AM–12:00 PM Level: ■ Format: SYMPOSIUM
Room 30CD *CME and Nursing*

Maximizing the Potential of Your EDC System

CHAIRPERSON

Maryanne C. Nicosia, MS
Director, Clinical Data Management, Neurocrine Biosciences Inc.

Electronic data capture (EDC) is not a new technology, but many organizations are not realizing the expected efficiencies and full potential of their chosen EDC system. This symposium will provide ideas on how organizations can enhance efficiency and reduce overhead through a unique approach to electronic case report form (eCRF) creation. Attendees will also learn how an EDC workflow that uses a continuous review and lock process can help enable study go/no-go decisions to be made before unnecessary time and money have been spent collecting and cleaning data. Attendees will hear how to effectively handle rescue studies and EDC data from multiple EDC systems so that final datasets are consistent no matter where or how the data was collected.

Enhancing Efficiency, Reducing Overheard Through a New Approach to eCRF Creation
Gill Hallett, MS
Director of Project Consultancy, Datatrial, United Kingdom

Achieving the Full Potential of EDC Through Efficient Workflows
Simon Wilson
Subject Matter Expert, Clinical, ArisGlobal, United Kingdom

EDC Rescue Studies: Combining Multiple Datasets to Meet Reporting Requirements
Carmen Weese
Senior Vice President, Data Operations, INC Research

#336 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, RA, CR

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 6F *CME, Pharmacy, and Nursing*

Emerging Technologies in Regulatory Science

CHAIRPERSON

Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

This forum will discuss the regulatory and implementation challenges and opportunities with current and emerging technologies such as mobile devices, smartphone apps and social media. Audience participants will be invited to interactively offer their insights after hearing the perspectives of industry, academia and FDA CDER in three dialogues concerning the vision, the challenges and importantly, the opportunities before us all to leverage a fully electronic landscape.

Regulatory Perspective
Leonard Sacks, MD
Associate Director of Clinical Methodology, Office of Medical Policy, CDER, FDA

Industry Perspective
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Academic Perspective
Nancie E. Celini, DrPH
Chief Health Technology Advisor and Educator, CAB Inc.

#337 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, PPLC, HT

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 3 *CME and Nursing*

Implementation of GDUFA: Progress and Expectations

CHAIRPERSON

Kathleen Uhl, MD
Director (Acting), Office of Generic Drugs, Office of Pharmaceutical Science, CDER, FDA

With the implementation of The Generic Drug User Fee Amendments (GDUFA) on October 1, 2012, new processes and expectations for both the generic industry and the FDA were also implemented. This session will discuss the progress in implementation of GDUFA.

Overview of Significant GDUFA-Related Policy Changes
Keith J. Flanagan
Regulatory Counsel, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, FDA

GDUFA Regulatory Science: Implementation Update
Robert A. Lionberger
Acting Deputy Director for Science, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, FDA

Overview of GDUFA: Changes and Progress
Kathleen Uhl, MD
Director (Acting), Office of Generic Drugs, Office of Pharmaceutical Science, CDER, FDA

#338 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): PPLC, PT, CR

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 6D | *CME, Pharmacy, and Nursing*

From the Protocol to the Patient: Clinical Trial Data Disclosure

CHAIRPERSON
Barbara Godlew, RN
President, The FAIRE Company, LLC

This session focuses on US and EU clinical trial disclosure requirements, including results reporting and patient-level data disclosure. This session applies to regulatory, clinical operations, medical writing, patient advocacy, and other areas.

US Update of Clinical Trial Disclosure
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH

Clinical Trial Data Open for All?: An Update on the Current International Debate on Data Sharing
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Preparing Disclosures for Patient Populations
Stephen Mikita, JD
Patient Advocate, Spinal Muscular Atrophy Foundation

#339 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): CmbP, RA, MF

10:30 AM–12:00 PM | Level: ■ | Format: WORKSHOP
Room 16B | *CME and Nursing*

Combination Products: An Overview of Clinical Benefits, Regulatory Issues, and Manufacturing Challenges

CHAIRPERSON
Michael Drues, PhD
Founder and President, Vascular Sciences

Combination products are the future of medicine and pose many challenges to regulatory professionals. Using case study examples, this workshop will provide a unique learning opportunity for participants to understand this dynamic and challenging arena.

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Best Practices When Considering Device Development for Combination Products
Lilli Zakarija, MBA
President, EdgeOne Medical Inc

#340 Track 10A – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, MA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 6E | *CME, Pharmacy, and Nursing*

Approaches to Decrease the Time Gap Between FDA Approval and the Ability to Market a DEA Scheduled Drug

CHAIRPERSON
Virginia Beakes-Read, BSN, JD
Executive Director, Global Regulatory Policy and Intelligence, Eisai Inc.

When FDA approves a drug with abuse potential that needs to be scheduled by the Drug Enforcement Administration (DEA), sponsors may not market the drug until DEA scheduling is complete, which can take a year. FDA, DEA, and others must find a way to ensure patient access to new therapies. This session will explore ways for sponsors to work with FDA and DEA to facilitate the scheduling process, including changes that could be made to the process, regulations, or legislation.

Industry Perspective
Lynn W. Mehler, JD
Partner, HoganLovells

A Former Regulators Perspective on Controlled Substance Scheduling
Alan G. Santos
Vice President, Pharmaceutical Compliance and Related Services, Pyramid Healthcare Solutions

The Science of Abuse Liability Assessment: History and Future Challenges
Lawrence Carter, PhD,
Director, Clinical Development, JazzPharmaceuticals

#341 Track 10B – Public Policy/Health Care Compliance/Law

Related Interest Area(s): CR, RA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 11A | *CME and Nursing*

Strengthening Public Policy for Sustainable Clinical Research Enterprise in Africa, Asia, and South America: Progress and Prospects

CHAIRPERSON
Ekopimo O. Ibia, MD, MPH, FRCP
Director Global Regulatory Policy, Merck & Co., Inc.; FDA Alumni Association International Network

This session examines evolving significant policies and initiatives about clinical research in Africa, Asia, and South America. The session will also provide information on potential linkages to regulatory pathways and initiatives in the US/EU that could assist product development and registration.

Clinical Research in Latin America: Regulatory Environment
Maria Joao Queiroz, DrMed
Global Chief Executive Officer, Eurotrials, Portugal

APEC Regulatory Harmonization Steering Committee and Its Impact on Clinical Trials
Florence Houn, MD, MPH, FACP
Vice President, Regulatory Affairs; Co-chair, Celgene Corporation; FDA Alumni Association International Network

Clinical Trial Environment in Africa
Thomas Nyirenda, MD, MS
Manager, Networking and Capacity Development, European & Developing Countries Clinical Trials Partnership (EDCTP), South Africa

#342 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, QA/QC, CP

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 8 | *CME and Nursing*

GCP Audits in a Risk-Based Environment

CHAIRPERSON
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

This forum will look at how a robust Corrective and Preventative Actions (CAPA) process is an essential component of a company's quality system. Included in these CAPA elements is the requirement of a mechanism to verify that the actions taken to correct and prevent the nonconformance were effective.

Using a Risk-Based Approach to CAPAs
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Responding to FDA 483s and Audit Observations: Implementing CAPA and Applying Root Cause Analysis
Gloria Katherine Miller, RAC
Senior Auditor, Premier Research

Responding to FDA 483s and Audit Observations: Implementing CAPA and Applying Root Cause Analysis
Debra P. Farrow, RN
Senior Compliance Auditor, Bristol-Myers Squibb Company

#343 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, CMC/GMP

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 10 | *CME, Nursing, and PMI PDUs*

Update from the FDA-EMA Parallel Assessment Pilot

CHAIRPERSON
Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

In 2011, FDA and EMA established a pilot program for parallel assessment and consultative advice for applications containing quality by design (QbD) elements. Based on the joint experiences and learning from these applications, several Question and Answer documents have been published, addressing topics such as Criticality, Design Space Verification, and Level of Detail in Applications. This session will provide an update on the EMA-FDA pilot for QbD and a discussion of the resulting Q&A documents. Regulatory authorities from the US and Europe will provide an overview of lessons learned and continued efforts toward harmonization. Additionally, the PMDA will give their views of the published Q&A documents.

EMA Perspective
Evdokia Korakianiti, PhD, MSc
Head of Chemicals Section, Quality of Medicines, European Medicines Agency, European Union

PMDA Perspective
Yoshihiro Matsuda, PhD
Deputy Director, Office of Standards and Guidelines Developoment, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#344 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): SP

10:30 AM–12:00 PM | Level: ■ | Format: WORKSHOP
Room 17A | *CME, Pharmacy, and Nursing*

Public-Private Partnerships: An Innovative Strategy for Patient Registries

CHAIRPERSON
Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

Public-private partnerships (PPPs) can offer an innovative, efficient approach to using registries for comparative effectiveness research (CER). This workshop will examine developing registries through PPPs and present examples of PPPs that support registries for effectiveness research.

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Results of the ADVANCE Survey on Models of Partnerships for Observational Studies
Peter Richard Arlett, MRCP
Head of Pharmacovigilance Department, European Medicines Agency, European Union

Facilitator
Michael Schatz, MD, MS
Department of Allergy, Kaiser Permanente Medical Center

#345 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): BT, PC, NC

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 11B | *CME and Nursing*

Prediction of Safety: An Evolving Field for Selecting Low-Risk Compounds Towards an Effective Life Cycle of a Product

CHAIRPERSON
Pradip Paul, MD, MS
Strategic Pharmacovigilance and Risk Management, Consultant

Chemical structure, molecular modeling, PK-PD, ADME studies, and genomics early in drug development, may predict possible safety abnormalities in the life cycle of a product. This session will focus on the latest developments to utilize such concepts and techniques in their own setup.

Using Virtual Population Simulation to Generate Insights on Drug Performance in Special Populations
Badri Rengarajan, MD
Vice President, Medical Affairs and Senior Principal Consultant, Evidera

Stevens Johnson Syndrome: Mechanistic Insights
Keith K. Burkhart, DrMed
Senior Advisor, Medical Toxicology, OCP, CDER, FDA

Prediction of Drug Induced Liver Injury (DILI)
Mark Avigan, MD
Associate Director, Office of Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, CDER, FDA

#346 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR, PT, CP

10:30 AM–12:00 PM | Level: ■ | Format: SYMPOSIUM
Room 30AB | *CME, Pharmacy, and Nursing*

Expanding the Scope: Empowering the Public in Pharmacovigilance

CHAIRPERSON
Magnus Wallberg, MSc
Product Manager Technical Solutions, Uppsala Monitoring Centre, Sweden

This session will discuss various tools currently being used to track adverse events reporting and data. We will discuss the VigiBase data resource which is the largest and most comprehensive source of spontaneous reports and is updated with incoming ICSRs on a continuous basis and the FDA will discuss MedWatchLearn, a web-based learning tool designed to educate health professionals and consumers/patients about reporting in a way that provides the best information for FDA reviewers to further investigate medical product problems.

Opening the WHO ICSR Database for Public Access
Magnus Wallberg, MSc
Product Manager Technical Solutions, Uppsala Monitoring Centre, Sweden

New FDA Tools for Adverse Event Reporting: MedWatchLearn, Mobile Technology, and Consumer/Patient MedWatch Form 3500B
Anna M. Fine, PharmD, MS
Director, Health Professional Liaison Program, Office of the Commissioner, FDA

EMA Perspective
Sabine Brosch, PharmD, PhD
Principal Scientific Administrator, Monitoring and Incident Management Services, Pharmacovigilance Department, European Medicines Agency, European Union

#347 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 7A | *CME and Nursing*

Separating Perceptions from Reality in the Acceptance of Adaptive Trials by Regulatory Agencies

CHAIRPERSON
David Ohlssen, PhD
Senior Expert Methodologist, Novartis Pharmaceuticals Corporation

A high level of uncertainty still persists within industry over the acceptance of innovative trials by regulatory agencies. With the FDA guidance document on adaptive trials near final, and the recent EMA qualification for statistical methodology combining proof of concept (PoC) and dose finding, this session aims to separate perceptions from reality, and demonstrate that agencies are more accepting of new methods than perhaps industry realizes. Although the draft FDA guidance document on adaptive clinical trials was issued in 2010 and the European Reflection Paper in 2007, a high level of uncertainty persists and, in some cases, disagreement relating to what is perceived as actually acceptable and what is not, from a regulatory point of view. As a consequence, often a more conservative position is taken within companies. This session looks at the barriers within industry and presents an opportunity to remove uncertainty and provide education and clarity regarding the acceptance of adaptive trials by regulatory agencies. One particular example further demonstrating the acceptance of innovative methods in drug development is given by EMA's CHMP favorable opinion on MCP-Mod as an efficient statistical methodology for model-based design and analysis of dose finding studies. The session will provide a case study of the MCP-Mod approach, which is an adaptive analysis method for combining PoC and model-based dose-finding.

FDA Viewpoint
Lisa M. LaVange, PhD
Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Innovative Dose-Finding Using Novel Adaptive Design and Analysis Approaches
Silke Jörgens, PhD
Senior Statistical Consultant, Aptiv Solutions, Germany

Adaptive Designs: An Exercise in Change Management
Michael Krams
Vice President, Quantitative Sciences, Janssen Pharmaceuticals, Inc.

#348 Track 16 – Professional Development

Related Interest Area(s): PM

10:30 AM–12:00 PM | Level: ■ | Format: FORUM
Room 31C | *CME, Pharmacy, Nursing, and PMI PDUs*

Be a Change Agent: Leveraging Communication and Training Tools to Help Promote Project and Career Transformation

CHAIRPERSON
Diane Cooney, MBA
Principal, Perceive Strategic Solutions LLC

Everyone can leverage organizational change management (OCM) principles in their work, particularly through communication and training tactics. This forum will briefly recap case studies where OCM techniques were applied to contribute to a successful outcome, and situations where OCM was not leveraged enough. OCM methodologies are flexible and can be used by employees at all levels to facilitate transformation. The panel will provide examples of how to apply OCM methodologies and engage leadership in order to provide participants unique insights and lessons learned. Applying change management principles to professional career change allows for individuals to approach change in a positive manner and achieve a successful outcome.

Adapting Change Management Methodologies to Company Culture and Leadership
Sarah Plush, MBA
Manager, Change Enablement and Communications, Shire Pharmaceuticals

Change Management: A Career Perspective
Crystal Donnelly, BSN, MBA, MSN
Associate Director, Quality and Compliance, Pfizer Inc

Solve Challenges and Get Results with Organizational Change Management
Diane Cooney, MBA
Principal, Perceive Strategic Solutions LLC

#349 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

10:30 AM–12:00 PM | Level: ■ | Format: SESSION

Room 33AB | *CME and Nursing*

An International Approach to Benefit-Risk Assessment of Medicines: An Evaluation by a Consortium of Established Agencies

CHAIRPERSON

Stuart Walker, PhD
Founder, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

Four regulatory agencies, Therapeutic Goods Administration (TGA), Health Canada, SwissMedic and Health Science Authority (HSA), formed a consortium for the purpose of shared and joint review and identified a need for an aligned approach for benefit-risk assessment. This session will focus on the Heads of Agencies Consortium, which consists of the TGA, Health Canada, and the HSA to review the challenges and opportunities for developing a systematic structured approach to the Benefit-risk assessment of medicines and the outcome of their studies.

TGA Perspective
John Skerritt, PhD
National Manager, Therapeutic Goods Administration (TGA), Australia

Health Canada Perspective
Barbara J. Sabourin, FACP
Director General, Health Products and Food Branch, Health Canada

SwissMedic Perspective
Petra Doerr, PharmD
Head of Communication and Networking, Deputy Director, Swissmedic, Swiss Agency For Therapeutic Products, Switzerland

HSA Perspective
Raymond S.B. Chua, MD, MBA, MPH, FRCP
Group Director, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore

#350 Track 20 – Late-breaking Topics

Related Interest Area(s): CR, PT

10:30 AM–12:00 PM | Level: ■ | Format: FORUM

Room 9 | *CME, Pharmacy, and Nursing*

The Patient Point-of-View: An Unrehearsed but Revealing Conversation to Rectify Patient Enrollment

CHAIRPERSON

Christine K. Pierre, RN
President, Society for Clinical Research Sites

Within the medical research enterprise, clinical trial patients are often the unsung heroes. They give of their time and energy to participate in studies that advance medicine and enable new therapies to become available for those who need them. Yet the industry continues to struggle with recruiting sufficient numbers of such heroes. Poor enrollment is this single most significant factor affecting the 72% of trials finishing at least a month beyond their targeted deadlines. There are numerous opportunities throughout the clinical trials process to improve the patient experience; the clinical research and medical practice communities can each benefit greatly by understanding clinical trial participation issues from the patient viewpoint. This panel discussion focuses on the patient's experience through their perspective. Join a diverse panel of clinical trial patients, who will provide personal accounts of their clinical trial experiences, including hurdles and obstacles they have encountered. Most importantly, this forum will provide recommendations for what industry must address immediately to rectify enrollment disappointments.

Panelists
T.J. Sharpe
Cancer Blog Author, www.Philly.com

Christopher J. Hoyle, MBA
Executive Director, Elite Research Network

11:30 AM–1:30 PM

Lunch & Exhibit Hall Innovation Theater Presentations

#351 Track 21A – Innovation Theater

Related Interest Area(s): CR, CP

11:45 AM–12:15 PM | Level: ■ | Format: SPECIAL SESSION

Exhibit Hall

SAS/JMP Innovation Theater: Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP Clinical

International guidelines suggest that clinical trial data should be actively monitored to ensure data quality. Traditional on-site review is time consuming, expensive, and as is true for any manual effort, limited in scope and prone to error. In contrast, risk-based monitoring (RBM) employs centralized review of trial data to determine if sites should receive more extensive review. We demonstrate the RBM and fraud detection capabilities of JMP Clinical to assess clinical trial data quality.

#352 Track 21B – Innovation Theater

Related Interest Area(s): CDM, IT, CEHTAEbM

12:30–1:15 PM | Level: ■ | Format: SPECIAL SESSION

Exhibit Hall

SAS Innovation Theater: Data Transparency and Sharing: Research Benefits, Risks and the Future

Whether called data transparency or data sharing, there's a movement to give more researchers greater access to patient-level clinical trial data. The goal is to create an environment for innovation in clinical research. Join this presentation to discuss what's being done, including exploring the value to the overall health care system of creating a multi-sponsor environment that gives researchers access to larger pools of data.

#353 Track 01A – Clinical Operations

Related Interest Area(s): CR, PT, CEHTAEbM

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM

Room 3 | *CME, Pharmacy, and Nursing*

Hot Topics in Patient Recruitment: Global Demographics, Underrepresented Populations, and the Science Behind Patient Communications

CHAIRPERSON

Christopher J. Hoyle, MBA
Executive Director, Elite Research Network

Patient recruitment remains one of the biggest challenges for clinical teams and research sites. To address this challenge, this symposium will blend

three presentations, the first of which will provide an update on demographic trends affecting patient recruitment both in the US and globally. To address recruitment of underrepresented minorities and increasing community trust of the clinical trials process, a community engaged research approach to reach ethnically diverse populations for participation in clinical trials will be shared. Finally, a patient-centric presentation will explore how understanding the patient journey is the foundation to driving engagement, ensuring successful recruitment and retention. Insights gained from the patient journey are translated into actionable recommendations using an evidence-based behavioral model.

Utilizing Community Engagement Approaches to Reach Ethnically Diverse Populations for Participation in Clinical Trials
Angela Burroughs
President and Chief Executive Officer, EthosExcel, Inc.

Update on Global Demographic Trends Affecting Patient Enrollment
Rebecca Lynn Budd
Managing Director, Navita Clinical Strategy

The Science Behind Recruitment and Retention: Patient Insight Generation and Communication Science
James P. Kremidas
Senior Vice President, inVentiv Clinical Trial Recruitment Solutions

#354 Track 01B – Clinical Operations

Related Interest Area(s): PT, CR, AHC/IS

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 2 | *CME, Pharmacy, and Nursing*

Social Media in Patient Recruitment: How to Best Leverage the Digital Ecosystem

CHAIRPERSON
JeanMarie Markham
Chief Executive Officer, Clinlogix

This symposium will examine the use of social media in patient recruitment, evaluate different social media platforms, review what is and is not working in partnerships between patient social networks and pharmaceutical companies and CROs, and discuss key elements of a social media community dedicated to aiding patient recruitment.

Social Media in Patient Recruitment
Tracy A. England, MBA
Vice President, Marketing, OpenQ

Using Social Networks to Transform Patient Recruitment for Clinical Trials: Clinical Study Partnerships
Eric J. Peacock, MBA
Cofounder and Chief Executive Officer, MyHealthTeams

Using Social Networks to Transform Patient Recruitment for Clinical Trials: Lessons Learned
Javier Zambrano, MD
Director, Medical US Avonex/Plegridy, Biogen Idec Inc.

Fueling Clinical Trial Recruitment through an Analysis of the Digital Ecosystem
Ritesh Patel
Global Head of Digital and Innovation, inVentiv Health Clinical

#355 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, RD

1:30–3:00 PM | Level: ◆ | Format: FORUM
Room 1A | *CME, Nursing, and PMI PDUs*

Complex Drug Projects: Complex Project Management

CHAIRPERSON
Peter Harpum, PhD, MSc
Client Director, Mannaz A/S, United Kingdom

Project management in the biopharmaceutical industry significantly lags behind other sectors. This forum will share emerging insights related to complexity from academicians in the field of project management and real-world drug project communities.

Panelists
Peter Harpum, PhD, MSc
Client Director, Mannaz A/S, United Kingdom

Brian Birchler
Vice President, Development Operations, Isis Pharmaceuticals, Inc.

#356 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP, OS

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 4 | *CME and Nursing*

Functional Service Provider Relationships: Critical Factors to Ensuring Long-Term Success

CHAIRPERSON
Andrew Townshend
Vice President, Alliance Development, INC Research

Functional service provider (FSP) partnerships are interpreted differently across the industry. This forum brings together experts to offer varying views on how to develop and implement an FSP model and its relative success in driving price reductions, speed, and innovation.

Panelists
Rose Kidd
Vice President, Clinical Operations, ICON plc, Ireland

Benjamin Thurmond, JD
FSP Alliance Manager, Global Pharma Procurement, Genentech, A Member of the Roche Group

Representative Invited
Executive Director, Global Head, Global Contracts and Outsourcing, Astellas Pharma Global Development

#357 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RD, PR, OS

1:30–3:00 PM | Level: ● | Format: SYMPOSIUM
Room 5A | *CME and Nursing*

Costing Strategies for Sustainable Drug Development

CHAIRPERSON

Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

As the cost of drug development continues to rise and drug development cycles are shortening, pharmaceutical and biotechnology companies are now under greater pressure to achieve high levels of efficiency and operating speed. There is a growing premium placed on capturing performance costs to determine return on investment. This symposium will open with a discussion on forecasting and planning metrics to identify best practices and strategies that contribute to process improvements. It will segue to a presentation of an analytical cost-benefit analysis of different CRO-Site partnership networks and models. It will close with discussion on a holistic analysis and view of all outsourcing costs incurred by both sponsors and CROs in sourcing clinical trials, thus providing a directional benchmark for enabling more mutually beneficial partnering discussions and potential cost savings.

Benchmarking the Clinical Budget and Outsourcing Processes
Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

Under Which Network Conditions Does Outsourcing to a CRO Reduce Clinical Trial Costs?
Erika Buonansegna, MSc
PhD Student, Technical University of Denmark, Denmark

Identifying Key Cost Drivers Involved with Outsourcing Clinical Trials: Perspectives from a CRO and Its Sponsor Partners
Gabriela St. Amant
Associate Director, Enterprise Solutions Development, Quintiles Transnational Corporation

#358 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): CR, CP

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 7B | *CME and Nursing*

Phase 1 Studies in Renal and Hepatic Subjects: Considerations and Best Practices in Design and Conduct

CHAIRPERSON

Nita Ichhpurani, PMP
Senior Director, External Study Management, Drug Development, Celerion, Canada

This forum will present the collective experience of two specialized phase 1 sites and a contract research organization (CRO) which have collaborated in the conduct of special population studies in renal and hepatic subjects. Due to the complex nature of renal and hepatic diseases, there are special design and safety issues that include classification of subjects into severity categories, common complications of the underlying disease, and concomitant medications encountered. Inclusion and exclusion criteria need to be tailored to the unique aspects of these special populations. There have been recent regulatory documents that impact study design and conduct. Proper interpretation of these documents is crucial to the successful design and conduct of a regulatory-compliant trial. Best practices to operationalize these challenges will be reviewed from the perspective of the CRO and by the panel of North American primary investigator experts.

Pathophysiological and Safety Issues in Special Populations Phase 1 Research
Richard A. Preston, MD, MBA, MS
Professor, Clinical Medicine; Director, Clinical Pharmacology Research, University of Miami

Special Considerations in Renal and Hepatic Clinical Trials
Thomas C. Marbury, MD
President, Orlando Clinical Research Center

FDA Perspective
Nancy Xu, MD
Medical Officer, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

#359 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MC, RA, PT

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 31AB | *CME, Pharmacy, and Nursing*

Broadening Health Care Communications: Learnings from Health Authority Initiatives

CHAIRPERSON

Stacey M. Fung, PharmD
Associate Director, Medical Communications, Genentech, A Member of the Roche Group

This session will include presentations reviewing FDA collaborations to broaden the reach of health messages to the public and the pharmaceutical industry, learnings from the EMA and how patients shape product information, and available information on expanded access trials with ways to best communicate on these topics.

The FDA and Innovative Collaborations to Broaden the Reach of Health Care Messages to the Public
Anna M. Fine, PharmD, MS
Director, Health Professional Liaison Program, Office of the Commissioner, FDA

Industry Perspective
Julia Petses, PharmD
Director, Medical Information Services Oncology/Hematology, Sanofi US

EMA Perspective on Communicating Health Care Messages to the Public
Martin Harvey-Allchurch, Esq., LLM
Head of Communication, European Medicines Agency, European Union

#360 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): SE, CR, PT

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 30CD | *CME, Pharmacy, and Nursing*

Innovative Direct-to-Patient Study Model to Capture PRO Instrument Validation Data for Submission to a Regulatory Authority

CHAIRPERSON

April N. Naegeli, DrPH, MPH
Senior Research Scientist, Global Patient Outcomes and Real World Evidence, Eli Lilly and Company

This session will discuss benefits and limitations associated with using a direct-to-patient model for observational research. In addition, we will present learnings from our experience using a direct-to-patient model for patient-reported outcome (PRO) instrument validation.

Strategic Approach to Using an Innovative Research Model for Validating a Patient-Reported Outcome Measure
April N. Naegeli, DrPH, MPH
Senior Research Scientist, Global Patient Outcomes and Real World Evidence, Eli Lilly and Company

Benefits and Limitations Associated With Implementing a Novel Direct-to-Patient Approach to Conducting a Validation Study
John Reites
Senior Director, Offer and Product Development, Quintiles Inc.

Advantages of Integrating Multiple Technologies and Rapidly Implementing Lessons Learned to Maintain Patient Engagement
Brandon M. Wojtowicz
Project Manager, eResearch Technology, ERT

#361 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): IT, RA

1:30–3:00 PM | Level: ● | Format: SESSION
Room 33AB | *CME and Nursing*

A Cloud-Based Approach to Evaluating and Maintaining Global Regulatory Content Alignment

CHAIRPERSON

Mauricha F. Marcussen, MBA
Chief Executive Officer, Auditgraph

This session will also cover the choice to use a SaaS-based deployment model and the business rationale behind this decision. Through the sharing of a case study, the audience will learn how the formation of an integrated technology approach is key to the success of these projects. Finally, the technology solutions will be tied back to the critical business needs and the successful progression towards the company's global compliance objectives.

Industry Trends for Successful Global Label Alignment
Tracy D. Rockney, JD
Vice President, Regulatory Affairs, Global Labeling, Advertising and Promotion, AbbVie Inc.

Global Label Harmonization and Compliance: A Case Study
Mauricha F. Marcussen, MBA
Chief Executive Officer, Auditgraph

Cloud Technology, Analytics, and Reporting for Global Labeling Compliance
Representative Invited
Chief Technology Officer, TVG

#362 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, RD, CEHTAEbM

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 5B | *CME and Nursing*

Adaptive, Progressive or Risk-Based Licensing Models: What Approaches Could Be Considered by Mature and Emerging Markets?

CHAIRPERSON

Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

This session will evaluate approval approaches to see how these could best be harnessed across agencies to provide new pathways for accelerated patient access to medicines. It will also provide an overview of approval pathways and perspectives on the global opportunities and hurdles.

Adaptive Licensing: An Update on International Developments
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Towards An Adaptively Learning Regulatory System: Current Challenges From a Regulatory Science Perspective
Pieter Stolk, PharmD, PhD
Project Manager, The Escher Project, Netherlands

Novel Development and Licensing Models: The Implications for HTAs and Payers
Representative Invited
Executive Director, Center for Drug Evaluation, Taiwan

#363 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CP

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 6D | *CME, Pharmacy, and Nursing*

Benefit-Risk Assessments of Medicines: Framework Development and Use in Marketing Applications

CHAIRPERSON

Nancy P. Smerkanich, MSc
Educational Liaison/Regulatory Science Doctoral Student, University of Southern California

This forum will focus on the overarching benefit-risk frameworks that regulators and industry are using to make decisions concerning drug approvals. The role of how a common framework could meet the challenges of future drug development will also be discussed.

Benefit-Risk Assessment of Medicines: Past, Present and Future
Stuart Walker, PhD
Founder, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

A Regulator's Perspective of Benefit-Risk Frameworks
James Leong, MPharm
Senior Regulatory Specialist, Health Sciences Authority (HSA), Singapore

An Industry Representative's Perspective of Implementation of Benefit-Risk Frameworks
Marilyn A. Metcalf, PhD
Senior Director, Benefit-Risk Evaluation, GlaxoSmithKline

#364 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): MDD, RD, CP

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 11A | *CME and Nursing*

Medical Device Update: Unique Device Identification Rule, Medical Device Reporting Draft Guidance, and Postmarketing Clinical Research Reporting Requirements

CHAIRPERSON

M.W. (Andy) Anderson, PhD, RAC
Senior Principal Advisor, RCRI, Inc.

Join three medical device experts for information critical to manufacturers: Unique Device Identification - Global Rules and Transformation for Practical Compliance; Draft 2013 FDA Guidance on Medical Device Reporting for Manufacturers: Assessment Against 1997 Guidance and Outcomes of International Medical Device Regulators Forum; and Safety Reporting Requirements and Clinical Trial Response in Medical Device Postmarketing Clinical Research.

Unique Device Identification: Global Rules and Transformation for Practical Compliance
M.W. (Andy) Anderson, PhD, RAC
Senior Principal Advisor, RCRI, Inc.

Draft 2013 FDA Guidance on Medical Device Reporting for Manufacturers: Assessment Against 1997 Guidance and Outcomes of International Medical Device Regulators Forum
Roshana Ahmed, MA, RAC
Senior Manager, Regulatory Affairs, Optum, Canada

Safety Reporting Requirements and Clinical Trial Response in Medical Device Postmarketing Clinical Research
Linda Zillman
Director Medical Device Business Unit, Theorem Clinical Research

#365 Track 10A – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, CR

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 6E | *CME and Nursing*

EU Clinical Trial Data Transparency Debate: Where Are We?

CHAIRPERSON

Marie Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

This forum will assess the European legal, political, and policy developments regarding enhanced transparency; the competing arguments for and against enhanced disclosure; and whether increased transparency is in the interests of the European public.

This forum has been developed by the DIA Legal Affairs and Clinical Trial Disclosure Communities.

EU Legal Issues With Respect to the Enhanced Disclosure of Clinical Trial Data
Marie Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

Current and Future Challenges Facing the Pharmaceutical Industry With Respect to the Enhanced Disclosure of Clinical Trial Data
Hanns-Georg Leimer, PhD
Head of Transparency, Disclosure, and Application Governance within Medical, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

#366 Track 10B – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PPLC, RA

1:30–3:00 PM | Level: ■ | Format: WORKSHOP
Room 16A | *CME and Nursing*

Making Comments Count: Best Practices in Developing Comments for a Global Audience

CHAIRPERSON

Linda F. Bowen, MS, RAC
Head, US Regulatory Policy and Intelligence, Sanofi US

In this workshop, we will share best practices in the development of comments, which gives industry an opportunity to influence regulatory authority thinking during an open consultation period.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Kimberly Belsky, MS
Executive Director, Advertising, Labeling and Policy, Valeant Pharmaceuticals

Amy N. Grant, MS
Director, HBG Memorial Fund

#367 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CP, CR

1:30–3:00 PM | Level: ■ | Format: WORKSHOP
Room 16B | *CME and Nursing*

Clinical Study Risk Management: What Does It Really Mean and How Do You Do It? (Part 1 of 2)

CHAIRPERSON

Liz Wool, BSN, RN
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

Part 1 of this two-part workshop will provide an overview of the proactive risk management approach described in ISO 31000 (Risk Management – Principles and Guidelines) as referenced by the FDA in their 2013 guidance Oversight of Clinical Investigations – a Risk-based Approach to Monitoring. The ISO 31000 principles and methods will be reviewed and include topics such as prospective study quality planning with the inclusion of risk monitoring activities. Relevant case studies will be shared that demonstrate the successful and flawed applications of these risk management components.

This workshop has been developed by the DIA Data Management, Good Clinical Practice/ Quality Assurance, Quality Risk Management, and Statistics Communities.

Preregistration is strongly recommended, and attendees are expected to attend both Part 1 and Part 2.

Part 2 will take place on Wednesday at 3:30 PM (Session #393).

To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Clinical Study Risk Management Workshop.

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Facilitators
Beat E. Widler, PhD
Managing Partner, Widler & Schiemann AG, Switzerland

Representative Invited
Consulting Associate Director, Good Clinical Practice Services, Falcon Consulting Group, LLC

#368 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, QA/QC

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 10 | *CME and Nursing*

Recent Advancement of the Pharmaceutical Inspection Cooperation Scheme and Good Manufacturing Practices in the Asia Pacific Region

CHAIRPERSON
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Asia Pacific nations such as China, Japan, and Taiwan invest heavily in good manufacturing practices (GMP). Taiwan has recently joined the Pharmaceutical Inspection Cooperation Scheme (PIC/S) for GMP. China has a new version of GMP regulations. The session will discuss the advancement of GMP in Asia and the impacts on industry.

TFDA Point of View
Ming-kung Yeh, PhD
Director-General, Taiwan Food and Drug Administration (TFDA), Taiwan

PMDA Point of View
Takashi Nagashima
GMP Expert, Office of GMP/QMS Inspection, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Industry Perspective
Representative Invited
Senior Director, Group Compliance and auditing, Novartis Pharma AG, Switzerland

#369 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): ST, CR

1:30–3:00 PM | Level: ■ | Format: WORKSHOP
Room 17A | *CME, Pharmacy, and Nursing*

Nesting Studies Within Patient Registries to Support Comparative Effectiveness Research

CHAIRPERSON
Nancy A. Dreyer, PhD, MPH, FISPE
Global Chief of Scientific Affairs, Real-World and Late Phase Research, Quintiles Outcome

Nesting studies within patient registries can be an efficient use of existing registry resources. This workshop will examine design and operational considerations for nested studies and present examples of nested studies used to support comparative effectiveness research.

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Facilitator
Stella C.F. Blackburn, MD, MA MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

#370 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 8 | *CME, Pharmacy, and Nursing*

Natalizumab and Progressive Multifocal Leukoencephalopathy: A Risk Management Case Study

CHAIRPERSON
Peter Richard Arlett, MRCP
Head of Pharmacovigilance Department, European Medicines Agency, European Union

Natalizumab is a treatment for multiple sclerosis. Cases of progressive multifocal leukoencephalopathy (PML) were reported in treated patients shortly after marketing. This real-life case study explores the issues facing regulators, physicians, and patients with a serious risk where knowledge is evolving.

Industry Perspective
Gary L. Bloomgren
Vice President, Drug Safety and Risk Management, Biogen Idec Inc.

Panelists
John Seeger, DrPH, PharmD
Assistant Professor, Harvard Medical School/Brigham & Women's Hospital

Patricia Saddier, MD, PhD
Executive Director, Epidemiology, Merck Research Laboratories

#371 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CDM, IT

1:30–2:30 PM △ | Level: ■ | Format: SESSION
Room 30AB | *CME, Pharmacy, and Nursing*

The Role of Intelligent Signaling in Digital Disease Detection and Proactive Pharmacovigilance

CHAIRPERSON
Representative Invited
Manager and Associate Professor, Boston Children's Hospital and Harvard Medical School

This session will focus on the potential use of intelligent signaling systems to analyze electronic health records/electronic medical records (EHR/EMR) and social media data in an effort to augment safety profiling and understand the potential use of these data streams for uncovering early signals. Presenters will examine how the use of intelligent signaling systems in conjunction with traditional adverse event (AE) data systems can offer an improved automated surveillance system that may assist or even eventually replace manual individual case study report (ICSR) case assessment. The use of social media sources such as Facebook, Twitter, web searches, news

reports, chat rooms, etc., to crowdsource data regarding disease outbreaks provides an opportunity to monitor, track and, ideally, forecast infectious disease outbreaks. These systems can make disease data publicly available earlier than traditional surveillance systems, therefore allowing us to limit their impact on communities. Collectively, these sources provide a view of global health that is fundamentally different from that yielded by the disease/AE reporting of the traditional public health infrastructure.

Automating Drug Safety Surveillance: Multisensory Signaling Using Health Care, Safety, and Social Media Data
Ambrish Mathur, MS
Vice President, Strategic Development, ArisGlobal

Industry Perspective
Representative Invited
President, Epidemico; Research Scientist, UNC at Chapel Hill

#372 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ROD, CR

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 7A | *CME and Nursing*

Exploring Bayesian Approaches Applied to New Treatments for Rare Diseases

CHAIRPERSON
Freda W. Cooner, PhD
Lead Mathematical Statistician, Div. of Biometrics III, Office of Biostatistics, Office of Translational Science, CDER, FDA

Drug trials for rare diseases often have small sample sizes, making it difficult to show statistically significant treatment differences. Bayesian approaches based on the "borrowing of strength" from other studies may potentially inform regulatory decisions. This session will discuss the potential of applying a Bayesian framework in rare disease drug development and assess anticipated difficulties in doing so. Some case studies will be used to illustrate the general concept.

Bayesian Methods in Related Diseases
John Troiani, MD, PhD
Acting Lead Medical Advisor, Office of Compliance-Immediate Office, CDER, FDA

Bayesian Design and Modeling for Rare Diseases
Scott M. Berry, PhD
President and Senior Statistical Scientist, Berry Consultants LLC

Adapting Design and Statistical Inference to Small Populations: Asterix
Kit B. Roes, PhD
Professor of Biostatistics; Director of Quality and Patient Safety, University Medical Center Utrecht, Netherlands

#373 Track 16A – Professional Development

Related Interest Area(s): PM

1:30–2:30 PM △ | Level: ● | Format: SESSION
Room 1B | *CME, Nursing, and PMI PDUs*

Managing Global Teams: Navigating Through Cultural, Lingual, and Geographic Challenges

CHAIRPERSON
Sukh Chugh, MBA
Director, R&D Informatics Services, Allergan, Inc.

Managing teams and individuals around the globe can be very difficult. Language, time zones, and cultural differences all serve as barriers to working effectively. This highly interactive session will be an opportunity to learn from one another the tips and techniques other leaders have employed to effectively manage global teams.

Navigating Through Cultural, Lingual, and Geographic Challenges
Sukh Chugh, MBA
Director, R&D Informatics Services, Allergan, Inc.

Out of Sight and Out of Mind? Engaging and Retaining Remotely-Based Employees
Gary M. Bufferd
Lead Clinical Research Associate, United BioSource Corporation

#374 Track 16B – Professional Development

Related Interest Area(s): PETD, CR, RA

1:30–3:00 PM | Level: ■ | Format: WORKSHOP
Room 31C

Abstract and Article Publication Opportunities with DIA

CHAIRPERSON
Julie Ho
Senior Manager, Annual Meeting Content Development, DIA

This workshop will provide you with information on how to share your articles and abstracts with DIA.

Add "published author" to your accomplishments! The Editor-in-Chief of DIA's official scientific, peer-review research journal *Therapeutic Innovation & Regulatory Science* (TIRS) will provide tips and answer your questions about submitting an article of original research for TIRS editorial peer review and publication. In addition, we will discuss additional publishing opportunities on the DIA website and our *Global Forum* industry and association newsmagazine.

Become a chairperson or speaker at the DIA 2015 51st Annual Meeting! This workshop will also provide tips and helpful hints in submitting an abstract for next year's DIA 2015 51st Annual Meeting that will be held June 14–18, 2015, in Washington, DC. Details will be shared regarding timelines for next year's abstract submission process.

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Panelists
Stephen Spielberg, MD, PhD
Editor-in-Chief, Therapeutic Innovation & Regulatory Science, DIA

Judy Connors
Associate Director, Editorial Services, DIA

#375 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, RA

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 32AB | *CME, Pharmacy, and Nursing*

Optimizing Orphan Drug Development and Using Appropriate Methodology: Key Tips for Success

CHAIRPERSON

Gopalan Narayanan, MD, MRCP, FFPM, FRCP
Biotech and ATMP Expert, NDA Group, United Kingdom

Around 7,000 diseases are considered rare/orphan diseases, and licensed medicines are available for only a fraction of these. The rarity of a disease makes novel drug development even more of a complex process. Navigating drug development for regulatory submissions requires special knowledge and expertise in order to make efficient use of resources, while at the same time maintaining a high standard of any new medical intervention. This symposium will cover key aspects of orphan drug development with tips on clinical development and regulatory strategy, using examples to illustrate the points. We will provide advice on how to overcome practical problems such as choosing the best CRO for the clinical trials, for example. It will also explore new methodologies in gathering relevant and required data to strengthen the evidence base, including use of registries and past research records.

Developing Products for Orphan Diseases: Perspectives of an Ex-Regulator
Gopalan Narayanan, MD, MRCP, FFPM, FRCP
Biotech and ATMP Expert, NDA Group, United Kingdom

Key Tips for Orphan Product Development
David G. Shoemaker, PhD
Senior Vice President, R&D, Rho, Inc.

Management of Rare Diseases: Orphan Drug Discovery Combining Evidence-Based Medicine and Genetic Information
Manish Khatri
Consultant, Life Sciences, Cognizant Technology Solutions Corporation

#376 Track 18 – Global Regulatory

Related Interest Area(s): RA, MF

1:30–3:00 PM | Level: ◆ | Format: SESSION
Room 11B | *CME and Nursing*

Challenges and Opportunities Facing FDA's International Posts

CHAIRPERSON

Leslie Ball, MD
Assistant Commissioner and Deputy Director, OIP, Office of Communications, FDA

The FDA has posts in eleven international locations that perform outreach to foreign regulators and industry, collect and share intelligence and information, and perform foreign facility inspections. This session will include directors of FDA's international offices in China, India, and Latin America, who will discuss the major activities of FDA's international posts, how the international offices align with other FDA Centers and Office of Regulatory Affairs, and the challenges they face in advancing the FDA mission internationally.

FDA in China
Christopher Jon Hickey, PhD
Country Director, China Office, OIP, Office of Communications, FDA, China

FDA in India
Altaf Ahmed Lal, PhD
Country Director, India, OIP, Office of Communications, FDA

FDA in Latin America
Representative Invited
Director, Latin America Regional Office, OIP, Office of Communications, FDA, Costa Rica

2:30–3:30 PM

Refreshment Break & Exhibit Hall Innovation Theater Presentations

#377 Track 01A – Clinical Operations

Related Interest Area(s): CR, RD, PT

3:30–5:00 PM | Level: ● | Format: FORUM
Room 3 | *CME, Pharmacy, and Nursing*

Filling the Gaps and Speeding Up Results: What an Educated, Sophisticated Patient Population Can Do for You

CHAIRPERSON

Kristin Nicole Voorhees, MA
Healthcare Relations Manager, National Foundation for Celiac Awareness

Educated and engaged patients can speed up clinical development and help to swiftly fill trials. This forum will feature perspectives of patient advocacy, biotechnology, and pharmaceutical industry leaders on how to effectively foster patient-industry relationships and will address realistic strategies for translating patient engagement into successful product development.

Panelists
Leslie J. Williams
Director, Founder, President and Chief Executive Officer, ImmusanT

Lona Vincent, MPH
Associate Director, Research Operations, Michael J. Fox Foundation For Parkinson's Research

Thomas Wallace, MPA
Senior Director, Global Advocacy and Professional Relations, Eli Lilly and Company

#378 Track 01B – Clinical Operations

Related Interest Area(s): CR, PR, CP

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM
Room 2 | *CME, Pharmacy, and Nursing*

Optimize Protocol Design: A Path to Efficient, Lower Cost Trial Execution

CHAIRPERSON

Larry A. Blankstein, PhD
Senior Director, Clinical Research, Genzyme Corporation, A Sanofi Company

This symposium will explore the challenges clinical teams face in developing protocols to ensure that the right patients are enrolled and that the right data are collected to demonstrate a drug is safe and efficacious, while at the same time managing study costs and study complexity. Each speaker will discuss the key factors to consider when developing protocols to minimize complexity while ensuring trial success.

Implementing a Protocol Design Process to Reduce Cost, Complexity, Risk, and Duration
Igor Gary Altman
Senior Product Manager, Medidata Solutions Worldwide

Quantifying the Magnitude and Cost of Gathering Nice to Have Data
Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

#379 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, BT, CR

3:30–5:00 PM | Level: ◆ | Format: FORUM
Room 1A | *CME, Nursing, and PMI PDUs*

Project Management Plays Critical Roles in the New Challenging Environment

CHAIRPERSON
John Z. Sun, PhD, MBA, PMP
Global Project Manager, IIS Primary Care, Novartis Pharmaceuticals Corporation

Many people narrowly define the project managers as those who set up deadlines and chase team members for deliverables. Not entirely true! This session will show what project management truly is and what the project managers can do.

This session has been developed by the DIA Project Management Community.

Panelists
Alberto Grignolo, PhD
Corporate Vice President, Global Strategy, PAREXEL Consulting

Leigh Shultz, PhD, PMP
Executive Director, Global Project Management, Merck & Co., Inc.

#380 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 5A | *CME and Nursing*

The Sponsor-Vendor-Vendor Relationship: A Fine Balance

CHAIRPERSON
Richard J. Mayewski
Associate Director, Clinical Trial Intelligence, Novartis Pharmaceuticals Corporation

This session examines the determinants of success or failure within the clinical research outsourcing environment, and offers the audience examples of ways to establish collaborative relationships in single vendor versus multi-vendor models.

The Vendor Perspective
Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

The Sponsor Perspective
Benton Schoen
Senior Clinical Scientist, Shire Pharmaceuticals

#381 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): PM, SP

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 4 | *CME and Nursing*

Effective Strategic Partnering Between Small Pharmaceutical Companies and CROs: Discussion and Case Study

CHAIRPERSON
Mitchell A. Katz, PhD
Executive Director, Medical Research Operations, Purdue Pharma L.P.

The forum will explore best practices for strategic partnering betweeen small to mid-sized pharmaceutical companies and CROs. Panelists with relevant experience will provide their perspectives and thoughts on areas of greatest opportunity.

Panelists
Alistair John MacDonald, MS
Chief Operating Officer, INC Research

Paul D. Spreen
Senior Vice President and Global Head, Customer Solutions Management Group, Quintiles Inc.

Denise A. Calaprice-Whitty, PhD, MS
Consultant, The Avoca Group

#382 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): CP, BT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Predicting Drug Off-Target Protein Binding to Hypothesize Mechanisms for Safety Issues

CHAIRPERSON
Keith K. Burkhart, DrMed
Senior Advisor, Medical Toxicology, OCP, CDER, FDA

A new technology predicts a drug's binding to protein ligands, potentially identifying off-target actions. Preclinical case studies and a postmarket analysis of drug-induced serotonin syndrome are presented.

Use of In Silico Approach for Safety Assessment of Clinical Candidates: Mitigation and Management for Clinical Drug Positioning
Laszlo A. Urban, DrSc, MD, PhD
Global Head, Preclinical Safety Profiling, Novartis Institutes for Biomedical Research

Predicting Secondary Pharmacology from Drug Off-Target Networks
Michael J. Keiser, PhD
Assistant Professor, UCSF; Founder, Seachange Pharmaceuticals Inc

Use of In Silico Protein Binding Predictions in Postmarket Safety Signal Analysis and Biological Plausibility
Keith K. Burkhart, DrMed
Senior Advisor, Medical Toxicology, Office of Clinical Pharmacology, CDER, FDA

#383 Track 06A – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MC, PT, MSL

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 31AB | *CME, Pharmacy, and Nursing*

Powering Up Communications: Improving the Information Exchange Between Patients and Industry

CHAIRPERSON

Rebecca A. Vermeulen, RPh
Senior Director, BioOncology Medical Science Liaisons, Genentech, A Member of the Roche Group

This session will educate providers in the pharmaceutical, biotechnology, and the device industries on how patients use information to make educated clinical treatment decisions. Attendees will learn how to improve information exchange between patients and industry.

This session has been developed by the DIA Medical Communications, Medical Science Liaison, and Patient Engagement Communities.

FDA: Empowering Patients with Trusted Resources
Anna M. Fine, PharmD, MS
Director, Health Professional Liaison Program, Office of the Commissioner, FDA

EMA Perspective
Representative Invited
EMA Liaison Official to the US FDA, European Medicines Agency, European Union

Patient Perspective
Stephen Mikita, JD
Patient Advocate, Spinal Muscular Atrophy Foundation

#384 Track 06B – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MW, DM, RA

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 31C | *CME and Nursing*

Transforming Organizational Knowledge into Product Information: Can Structured Authoring Save the Day?

CHAIRPERSON

Antoinette M. Azevedo
President and Chief Executive Officer, E-submissionssolutions.Com

We all do the same things when we author documents for submissions, technical and medical communication, and marketing and sales materials. We often author the same content to be used on a repeated basis with widely varying contexts but with legal, technical, regulatory, and practical impacts on the ability to use/reuse that content. At the same time, sponsors are concerned about the time and cost of medical writing and the impact to submission deadlines from last-minute changes and failure to agree on key messages. Can structured authoring impact this logjam? What is structured authoring? How can I implement it within my corporate culture and within the toolsets my authors are comfortable with?

Transforming Project Information to Organizational Knowledge: Interdisciplinary Collaboration and Knowledge Management
Joanna Hicks
Manager, Medical Writing, INC Research

#385 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): DM, CR

3:30–5:00 PM | Level: ◆ | Format: SYMPOSIUM
Room 30CD | *CME and Nursing*

Sustainable Solutions for Global Clinical Research Site Documentation

CHAIRPERSON

Betsy Fallen, RN
Site Ready Lead, Global Clinical Trial Operations, Merck & Co., Inc

In this age of cutting edge technology development, solutions have been developed to mitigate industry's challenges. This symposium will include valuable information on the management of documentation between sponsor, their agents, and clinical sites. Discussion will include investigator portal, digital signatures, and case studies.

Digital Signatures 2.0: Current Usage and Landscape in Clinical Operations
Rodd W. Schlerf
FDA and USDA Markets Manager, ARX Inc.

Building an Investigator Portal from the Ground Up: The Decisions, The Pitfalls, and The Lessons Learned
Sukh Chugh, MBA
Director, R&D Informatics Services, Allergan, Inc.

Using Technology and Processes to Effectively Manage Regulatory Documentation Requirements for Late-Phase Clinical Research
Kate Trainor
Vice President and Global Head, Late Phase Project Management and Technology, PAREXEL International

#386 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): IT, SE, CR

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM
Room 33AB | *CME and Nursing*

End-to-End Data and Metadata in Today's Clinical Trials

CHAIRPERSON

Keith W. Wenzel
Senior Director, Global Alliances, PAREXEL International

The sources of today's clinical trials data are ever expanding from classic electronic data capture (EDC) and electronic patient-reported outcome (ePRO) systems to progressive study endpoints data collection via physiologic devices (such physical activity monitors) to electronic health record (EHR) systems. At the same time, sponsors and CROs are desiring to leverage their substantial investments in case report form (CRF) designs across EDC system via metadata repositories. This innovative symposium will guide the audience in understanding the clinical trials equivalent of iTunes as well as provide real-world experiences from the first prospective study to utilize the CDISC standards for EHR integration.

Achieving the iTunes of Clinical Trials: Storing and Sharing of Content to Optimize the End-to-End Clinical Trial Process
Mark L. Wheeldon, PharmD
Chief Executive Officer, Formedix

The First Real-World Implementation of CDISC-based EHR Integration for a Prospective Clinical Trial
Jim Rogers
President and Chief Executive Officer, Nextrials

Delivering Real Efficiencies for Clinical Trials Using Electronic Healthcare Data: How CPRDs are Leading the Way
Representative Invited
Head of Research, The Clinical Practice Research Datalink Group (CPRD), United Kingdom

#387 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CP, PT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 6D | *CME, Pharmacy, and Nursing*

Why, When, and How Should Patients Be Involved in the Benefit-Risk Assessment of Medicines?

CHAIRPERSON
Stuart Walker, PhD
Founder, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

Patients' perspective on benefits and harms is critical to the development and review of medicines. The challenge for agencies, companies and patients is how and when this should occur. Possible solutions will be presented.

EMA Perspective
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

FDA Perspective
John J. Whyte, MD, MPH
Director, Professional Affairs and Stakeholder Engagement, Office of the Center Director, CDER, FDA

Patient Perspective
Durhane Wong-Rieger, PhD, MA
President and Chief Executive Officer, Canadian Organization For Rare Disorders (CORD), Canada

#388 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, SP

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 5B | *CME and Nursing*

Health Authority Meeting Preparation: There Are No Do-Overs

CHAIRPERSON
Mark A. Ammann, PharmD
President, Catalyst Regulatory Services, LLC

One measure of success for health authority interaction is having no surprises. There is no way to guarantee a positive outcome. However, if you thoroughly consider the potential challenges, you can diligently prepare and present your best case. This session will describe critical success factors to preparing for health authority meetings. Perspectives will be presented by a US Regulatory Affairs professional, a European Regulatory Affairs professional as well as a representative from the US FDA.

Getting it Right the First Time: Points to Consider in Preparing for Health Authority Meetings
Mark A. Ammann, PharmD
President, Catalyst Regulatory Services, LLC

Successful Meetings with CDER (FDA): Do's and Don'ts
Luz E. Rivera, PsyD, MEd, MS
Regulatory Health Project Manager, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

Meetings: Pathways to Success, a European Perspective
Robert T. Clay, MBA, MSc
Managing Director, Highbury Regulatory Science Limited, United Kingdom

#389 Track 08C – Regulatory Affairs and Submissions

Related Interest Area(s): RA, SP

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 1B | *CME, Pharmacy, and Nursing*

The Realities of Late Life Cycle Management for Very Old Legacy Brands

CHAIRPERSON
Bijal Pandhi, PharmD
Global Program Regulatory Manager, Novartis Pharmaceuticals Corporation

This forum will provide a recent case study that illustrates the challenges sponsors face when managing the life cycle of legacy brands. A panel of experts will provide their perspective and discuss ways to mitigate these challenges.

Industry Perspective
Paul Aftring, MD, PhD
Global Program Head, Established Medicines, Novartis Pharmaceuticals Corporation

FDA Perspective
Theresa Kehoe, MD
Clinical Team Leader, Division of Bone, Reproductive and Urologic Products, Office of New Drugs, CDER, FDA

Development of An Integrated Response
Steven M. Weisman, PhD
Head of Clinical and Regulatory Support, Innovative Science Solutions

#390 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): RA, MDD

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM
Room 11A | *CME and Nursing*

Regulatory Perspectives in the Execution of Clinical Studies and Medical Product Commercialization in Asia Pacific

CHAIRPERSON
Karen Jaffe
Consultant

Clinical studies are being executed in an increasingly global economy and harmonization. What strategic choices should be made when embarking on a device trial and what are the impacts to ultimate success? Japanese guidance on the drug companion diagnostics co-development was published by PMDA/MHLW in December 2013. Biomarker driven drug development will be reviewed using guidance or draft guidance from PMDA/MHLW, FDA and EMA. Current evolution/reformation of medical device regulatory agencies in Asia Pacific will be discussed in the post-global harmonization task force (GHTF) era under the International Medical Device Regulators Forum (IMDRF) and Asian Harmonization Working Party (AHWP). Experience from the Asia-Pacific Economic Cooperation (APEC) cooperation will be shared from industry and regulatory perspectives.

Lost in Translation: Conducting Device Trials in Asia
Karen Jaffe
Consultant

Regulatory Perspective on Co-Development of Drugs and Companion Diagnostics in Japan, US, and EU
Sumimasa Nagai, MD, PhD
Clinical Reviewer, Companion Diagnostics Project Team and Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Evolution and Recent Reformation of Regulatory Framework of Medical Devices in Asia Pacific
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

#391 Track 10A – Public Policy/Health Care Compliance/Law

Related Interest Area(s): AP, RA, HT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 6E | *CME, Pharmacy, and Nursing*

Industry in the Sunshine: How the "Sunshine" Provisions of the Affordable Care Act Will Change Industry Policy and Practice

CHAIRPERSON
John F. Kamp, JD, PhD
Attorney at Law; Executive Director, Wiley Rein LLP; Coalition for Healthcare Communication

This session will focus on changes in industry policy and practice in light of the Sunshine Act that created a national registry of gifts and payments to physicians beginning in late 2014. Panelists will focus on long- and short-term impact on industry research and marketing collaborations with research and clinical physicians; industry and government costs of implementation of the law; possible impact on peer review journal and textbook publishing; and possible long-term changes in the public image of the industry and organized medicine.

Physician Payment Sunshine: A Ray of Hope or a Deeply Flawed Law?
David M. Vulcano, MBA, MS, RAC
Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

Physician Payment Sunshine Act: Where Have We Gone and Where are We Going
Thomas Patrick Sullivan
President, Rockpointe Communication

The Sunshine Act's Impact on the Research Profession and Its Impact on Manufacturers That Sponsor Clinical Trials
Gary Shangold
Chief Executive Officer, InteguRx Therapeutics LLC

#392 Track 10B – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PT, RA

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 9 | *CME and Nursing*

Patient Voice in Decision Making: How Are Regulators Making This Work?

CHAIRPERSON
Eric Gascho
Director, Government Affairs, National Health Council

Bringing the patient's voice into decision making has allowed regulators to understand the real-life impact of regulatory decisions. It has also proven to enrich the quality of the scientific opinion while building trust in the regulatory process. This forum will discuss the main challenges the regulators are confronted with, which include the difficulty in identifying individuals with day-to-day experience of the disease and its therapeutic environment as well as the need to guarantee the independence of their views.

Patient's Voice in Decision Making: The EMA Model
Isabelle Moulon, MD
Head of Medical Information, European Medicines Agency, European Union

How to Build Up Capacity of Patient Experts, Advocates, and Health Interested Citizens? The EUPATI Project
Jytte Lyngvig, PhD
Director, DIA Europe, Switzerland

Patient's Voice in Decision Making: US Regulatory Perspective
James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, P.C.

#393 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR, ST

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 16B | *CME and Nursing*

Clinical Study Risk Management: What Does It Really Mean and How Do You Do It? (Part 2 of 2)

CHAIRPERSON
Liz Wool, BSN, RN
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

The lessons learned from Part 1 of this two-part workshop will provide the foundation for participants to apply the learned principles. Participants will have the opportunity to develop a study risk plan, identify and prioritize the risks, and determine a control plan (including tolerance levels). Participants will analyze factors critical to quality and successful study execution for the development of a risk management plan.

This workshop has been developed by the DIA Data Management, Good Clinical Practice/Quality Assurance, Quality Risk Management, and Statistics Communities.

Preregistration is strongly recommended, and attendees are expected to attend both Part 1 and Part 2.

Part 1 will take place on Wednesday at 1:30 PM (Session #367).

To secure a seat for this specific workshop, please email annualmeetingprogram@diahome.org, Subject line: Clinical Study Risk Management Workshop.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitators
Johann Proeve, PhD
Vice President, Global Strategy and Development Advisor, Bayer HealthCare, Germany

Kristin M. Neff, MS
Vice President, InVivo Therapeutics

Dale W. Usner, PhD
Vice President, Biostatistics and Data Management, Statistics and Data Corporation (SDC)

#394 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, CMC/GMP

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 10 | *CME and Nursing*

CMC Regulatory Pathways in the Emerging Markets: Focus on Asia Pacific

CHAIRPERSON
Thirunellai G. Venkateshwaran, PhD
Group Director, Pharma Technical Regulatory, Genentech, A Member of the Roche Group

This session will cover some of the CMC challenges observed during clinical trial authorization (CTA) and market application submission in Asia Pacific countries, provide the regulatory agency perspective on some of the reasons for the complexities, and provide an industry perspective from multinational corporations on ways to tackle some of the challenges observed in the process.

Regulatory Challenges for CMC Submissions in Singapore
Freddie Foo, MSc
Senior Regulatory Specialist, Therapeutic Products Branch, Health Sciences Authority (HSA), Singapore

Industry Perspective on Emerging Markets
Representative Invited
Director, CMC Advocacy, GlaxoSmithKline

Perspective from Taiwan
Representative Invited
Executive Director, Center for Drug Evaluation, Taiwan

#395 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): GCP, FI

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 8 | *CME, Pharmacy, and Nursing*

Compliance, Potential Financial Implications, and Impact of New Safety Measures

CHAIRPERSON
John Whitebrook
Director, Deloitte Consulting LLP

This session will discuss how industry has adapted and the real-world impacts of the legislation on pharmacovigilance organizations and processes. Adoption of new legislation, originating in all regulatory regions, requires significant investment from industry. However, the return on that investment is difficult to identify and/or quantify. The rising cost of drug safety is a concern to all stakeholders. Some new approaches, such as risk evaluation and mitigation strategies (REMS), are expected to show a return but also have limitations and are not always deemed to meet the needs of patients. This session will also consider how to address the inevitable increasing involvement of patients and mass media, without the costs of drug safety continuing to spiral.

Good Pharmacovigilance Practices (GVP): The Real Impacts and Consequences
John Whitebrook
Director, Deloitte Consulting LLP

Industry Perspective
Peter K. Honig, MD, MPH
Vice President and Head, Global Regulatory Affairs and Patient Safety, AstraZeneca

Financial Implications of Drug Safety Measures and a Potential Remedy
Tatsuo Kurokawa, PhD
Professor, Div. of Drug Development and Regulatory Sciences, Faculty of Pharmacy, Keio University, Japan

#396 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): MC, HT

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 30AB | *CME, Pharmacy, and Nursing*

Product Crisis Management: Crisis, What Crisis?

CHAIRPERSON
Mariette Boerstoel-Streefland, MD, MBA, MS
Consultant, MBS Drug Safety Consulting

What is a product crisis, and how can a pharmaceutical company best prepare and react? Principles for crisis management and communication will be discussed, with specific examples provided. Insight into crisis management in other industries will be given.

Pharmacovigilance: Planning for a Pandemic
Libbie Parker McKenzie, MD
Executive Director, Safety Knowledge and Reporting, Quintiles Inc.

Dousing the Flames: Audience-Directed Interventions for Crisis Communications
Gil Bashe
Executive Vice President, Health, Makovsky Health

Planning for the Unexpected: Product Crisis Management
Cesare Pinto
Deputy Director, Customer Care Services, Bayer HealthCare Pharmaceuticals

#397 Track 15A – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RA

3:30–5:00 PM | Level: ■ | Format: SESSION

Room 7A | *CME and Nursing*

Benefit-Risk Evaluation in Drug Development

CHAIRPERSON

Qi Jiang, PhD
Executive Director, Global Biostatistical Science, Amgen Inc.

This session will evaluate various potential systematic benefit-risk assessment approaches to cover the needs of global regulatory agencies and governance bodies, along with the application of the methods. This session was developed in conjunction with the Quantitative Sciences in Pharmaceutical Industry (QSPI) Benefit-Risk Working Group.

Panelists
George Quartey, PhD, MSc
Principal Statistical Scientist, Biostatistics, Genentech, A Member of the Roche Group

Andreas I. Sashegyi, PhD
Senior Research Advisor, Statistics, Eli Lilly and Company

Qi Jiang, PhD
Executive Director, Global Biostatistical Science, Amgen Inc.

#398 Track 15B – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RA

3:30–5:00 PM | Level: ◆ | Format: SESSION

Room 11B | *CME, Pharmacy, and Nursing*

Pediatric Trials: Improvements through Bayesian Methods, Adaptive Designs, and Modeling/Simulation

CHAIRPERSON

Gesine Bejeuhr, PharmD
Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany

This session provides practical examples of how Bayesian methods, adaptive designs and other statistical methods including modeling and simulation could contribute to pediatric trials and lead to better design and fewer children to be exposed. This session will stimulate a dialogue between technical experts in statistics/adaptive design and those who are involved in clinical trials, particularly examining pertinent questions: (1) What are the messages from statistics/adaptive design to be understood by those who are involved in pediatric development and then by those who are asked to consent to participate in clinical trials?, (2) What are the messages for key decision makers in pharmaceutical companies to agree to adaptive design/Bayesian or any other method?, and (3) What do authorities need?

This session has been developed by the DIA Pediatric Community and the Bayesian and Adaptive Design Scientific Working Groups.

Bayesian Statistics and Adaptive Design
Scott M. Berry, PhD
President and Senior Statistical Scientist, Berry Consultants LLC

Pediatric Studies and Bayesian Statistics: Challenges and Opportunities
Freda W. Cooner, PhD
Lead Mathematical Statistician, Div. of Biometrics III, Office of Biostatistics, Office of Translational Science, CDER, FDA

Industry Perspective
Representative Invited
Director, Clinical Pharmacology and Pharmacometrics, Bristol-Myers Squibb Company

#399A Track 16 – Professional Development

Related Interest Area(s): CR, RA

3:30–5:00 PM | Level: ● | Format: WORKSHOP

Room 17A | *CME and Nursing*

Women as Transformational Leaders

CHAIRPERSON

Susan Morris, MEd
Director, Merit Systems

Research shows that women are adept at building collaborations, are better emotional communicators, and are more inclined to develop their followers. These traits define transformational leaders, appropriate for complex organizations in turbulent markets. This workshop will examine how you can be a transformational leader.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

#399B Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, RA

3:30–5:00 PM | Level: ■ | Format: SYMPOSIUM

Room 32AB | *CME, Pharmacy, and Nursing*

Regulatory Challenges for Orphan Medicines

CHAIRPERSON

Martine Zimmermann, PharmD
Vice President, Global Regulatory Affairs, Alexion Pharma International Sàrl, Switzerland

This symposium will describe the regulatory environment and the current regulatory trends for orphan medicinal products around the world. It will also discuss how companies can use the orphan legislation in Europe and the US to support development of products for markets outside of these ICH regions.

Regulatory Challenges and Opportunities for Global Development of Orphan Medicinal Products: The Industry Perspective
Martine Zimmermann, PharmD
Vice President, Global Regulatory Affairs, Alexion Pharma International Sàrl, Switzerland

The Role of Orphan Drug Legislation in Emerging Markets
Isabel Zwart, PhD, MSc
Senior Regulatory Consultant, PAREXEL International, United Kingdom

Regulatory Challenges for Orphan Medicines
Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

#399C Track 20 – Late-breaking Topics

Related Interest Area(s): CR, PT, PPLC

3:30–5:00 PM | Level: ■ | Format: FORUM

Room 16A | *CME, Pharmacy, and Nursing*

Informed Medication Use in Pregnancy: A Collaborative Approach to Address Needs for Data, Communication, and Engagement

CHAIRPERSON

Lode Dewulf, MD, FFPM
Vice President and Chief Patient Affairs Officer, UCB, Belgium

This forum will explore factors leading to a lack of data-supported decision making on medication use in pregnancy and engage participants in discussing a multiple stakeholder approach to addressing these critical issues through collaboration.

Panelists

Lode Dewulf, MD, FFPM
Vice President and Chief Patient Affairs Officer, UCB, Belgium

Rear Adm. (ret.) Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

Jordi Llinares, DrMed, MSc
Head of Product Development Scientific Support Department, European Medicines Agency, European Union

See you in 2015

DIA Annual Meetings Around the World

27th Annual EuroMeeting 2015
April 13-15 | Paris, France

7th DIA CHINA Annual Meeting 2015
May | Beijing, China

DIA 2015 51st Annual Meeting
June 14-18 | Washington, DC

DETAILS COMING SOON

12th Latin American Conference of Clinical Research
September | TBA

DIA INDIA 2015 10th Annual Conference
October | TBA

DETAILS COMING SOON

DIA JAPAN 2015 12th Annual Meeting
November | TBA

DIA Mission

DIA fosters innovation to improve health and well being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services
- Delivering customized learning experiences
- Building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy

DIA Vision

DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well being worldwide.

THURSDAY

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DIA 2014

REGIONAL CALENDAR OF EVENTS

THURSDAY

DIA NORTH AMERICA

JUNE 26
Variations in the European Union: CMC/Quality Changes | Webinar

JULY 8
Seven-Part Series on Pediatric Drug Development - Part 4: Dosing in Children
Webinar

AUGUST 18-19
Clinical Project Management
Boston, MA

AUGUST 18-19
European Regulatory Affairs: Keeping Your Finger on the Pulse of Marketing Authorizations | Boston, MA

AUGUST 18-19
New Drug Product Development and Life Cycle Management | Boston, MA

AUGUST 18-20
Pragmatic Approaches to Drug Safety Across the Premarketing and Postmarketing Continuum | Boston, MA

AUGUST 18-21
Regulatory Affairs: The IND, NDA, and Postmarketing | Boston, MA

TUTORIALS: SEPTEMBER 21
MEETING: SEPTEMBER 22-24
EDM and ERS 2014
Washington, DC

COMING THIS FALL!
Pediatric Research Conference 2014

COMING THIS FALL!
DIA Biosimilars 2014

DIA LATIN AMERICA

JULY 10
Risk & Safety Management Training (Medium Level) | Mexico City, Mexico

SEPTEMBER 25-26
11th Annual Latin American Conference of Clinical Research (LACCR) 2014
Monterrey City, Nuevo Leon, Mexico

DIA EUROPE

SEPTEMBER 23-24
8th Annual European Medical Information and Communication Conference and Exhibition
London, United Kingdom

SEPTEMBER 23-24
Clinical Trials Workshop I – Translating the New Clinical Trials Regulation into Practice
London, United Kingdom

SEPTEMBER 24-25
Clinical Trials Workshop II – Translating the New Transparency Requirements into Practice London, United Kingdom

SEPTEMBER 24-25
Joint DIA/FIP European Workshop Biorelevant Performance Testing of Orally Administered Dosage Forms
Amsterdam, the Netherlands

SEPTEMBER 30-OCTOBER 1
EFGCP/DIA/EMA Annual Conference on Better Medicines for Children – Exploring ways to enhance collaboration between key players | EMA Headquarters, London, UK

OCTOBER 2-3
4th African Regulatory Conference and Exhibition | Dakar, Senegal

OCTOBER 9-10
Joint DIA/ICOS Conference on Cardiac Toxicity Resulting From Cancer Chemotherapy: Strategies for Early Detection, Risk Mitigation and Clinical Prevention and Exhibition | Prague, Czech Republic

END OCTOBER
Workshop on HTA and Access to Medicines Status and Future | TBA

NOVEMBER 6-7
ISPE/DIA Workshop on Computer Science Compliance "Maintain Data Integrity to Reduce Risk for the Patient"
Basel, Switzerland

NOVEMBER 10-11
Joint DIA/AEMPS Statistics Workshop
Barcelona, Spain

NOVEMBER
MAGHREB Regulatory Conference and Exhibition | Algiers, Algeria

DECEMBER 1-3
15th Conference on European Electronic Document Management (eDM) and Exhibition | Berlin, Germany

DECEMBER 2-3
Biosimilars Conference
Berlin, Germany

DIA JAPAN

JUNE 30
3rd CMC Forum
Tokyo

SEPTEMBER 10-11
3rd DIA Basic Statistical Concept Workshop for All Clinical Research Professionals | Tokyo

OCTOBER 23-24
5th DIA Cardiac Safety Workshop
Tokyo

OCTOBER 27-28
4th DIA Project Management Training Course Tokyo

NOVEMBER 16-18
DIA Japan 2014: 11th Annual Meeting
Tokyo

DECEMBER 8
2nd DIA Advanced Regulatory Affairs Training Course | Tokyo

DIA INDIA

JULY 4
Training Program on Clinical Data Management | Bangalore

AUGUST 1-2
Conference on Generics
Ahmedabad

OCTOBER 16-18
DIA India 2014 9th Annual Conference
Mumbai

DIA CHINA

JULY 7-9
Review a Global Quality Dossier (CTD) with Concepts of Quality By Design (QbD)
Shanghai

JULY 10-11
Drug Induced Liver Injury (DILI)
Shanghai

AUGUST
Individual Safety Case Report (ICSR) Medical Review | TBA

SEPTEMBER 4-6
Clinical Project Management (Part 1)
Shanghai

SEPTEMBER 15-16
Clinical Data Management in EDC Trials
Beijing

SEPTEMBER 25-26
Biostatistical Applications in Clinical Trials
Wuhan

OCTOBER
Quantitative Sciences Forum
Beijing

For the latest offerings and up-to-date information, visit **www.diahome.org.**

THURSDAY, JUNE 19

Registration Hours:

8:00–11:00 AM Attendee and Speaker Registration

Schedule:

8:15–9:00 AM Coffee and Breakfast Breads (Sails Pavilion)

9:00–10:30 AM Educational Opportunities
60-minute TURBO Offerings △ (9:00–10:00 AM)
90-minute Offerings (9:00–10:30 AM)

10:30–10:45 AM Coffee Break

10:45 AM–12:15 PM Educational Opportunities
90-minute Offerings (10:45 AM–12:15 PM)

#401 Track 01 – Clinical Operations

Related Interest Area(s): AHC/IS, CR

9:00–10:30 AM | Level: ■ | Format: WORKSHOP
Room 16A | *CME and Nursing*

Accelerating Research in a Large Health Care System: Streamlining Research Review and Study Initiation

CHAIRPERSON

Stuart Horowitz, PhD, MBA
President, Institutions and Institutional Services, WIRB-Copernicus Group

Large health care systems are challenged to start up clinical trials efficiently. Addressing these organizational challenges and adopting efficient processes are key to transforming institutions into more efficient and effective clinical research sites. This interactive workshop provides practical approaches to how to implement a more effective program.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The San Diego Convention Center has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this offering will not be recorded.*

Facilitator
Lori A. Nesbitt, PharmD, MBA
Chief Executive Officer, Compass Point Research

#402 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PT, SP, PM

9:00–10:30 AM | Level: ◆ | Format: SESSION
Room 3 | *CME, Pharmacy, and Nursing*

Exploring Responder-Patient Clinical Study Design Approaches

CHAIRPERSON

Joan M. Meyer, PhD, MS
Executive Director, Operational Strategy and Planning, Covance Inc.

Finding patients with a better chance of responding to a drug continues to evolve. This session will discuss how clinical trial design approaches can be employed, as well as how stakeholders can collaborate to accelerate advancements.

Industry Perspective
Joan M. Meyer, PhD, MS
Executive Director, Operational Strategy and Planning, Covance Inc.

FDA Perspective on Use of Biomarkers to Identify Treatment Responders
Christopher Leptak, MD, PhD
Office of New Drugs Biomarker and Companion Diagnostic Lead, CDER, FDA

#403 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, OS

9:00–10:30 AM | Level: ■ | Format: SESSION
Room 4 | *CME and Nursing*

Keeping It Together: Syncing CRO Data and Metrics

CHAIRPERSON

Eric Lake, MBA
Partner, Pharmica Consulting

When working with CROs, sponsor companies all face a common dilemma. What is the best way to get clinical trial management system-type data in-house and/or see status reports on all studies in one place, regardless of which CRO is involved? And what's the best way to use this information? Several options will be discussed in this session.

Best Practices for Exchanging Data in Clinical Trials
Representative Invited
Director, Clinical Data Sciences, Celerion

Peeking Over the Wall: Ensuring Study Quality Through Shared Metrics
Representative Invited
Manager, Senior Clinical Study, Allergan, Inc.

Sponsors and CROs: Are We Able to Use Information Together?
Lisa Zimmerman, MS
President, Axis Pharma

#404 Track 06 – Medical Communication, Medical Writing, and Medical Science Liaison

Related Interest Area(s): MSL, RA

9:00–10:30 AM | Level: ● | Format: SESSION
Room 7A | *CME and Nursing*

Today's Dynamic Medical Science Liaison Environment

CHAIRPERSON

Geoff Brockway
Director, Global MSL Excellence, AstraZeneca, Canada

Medical Science Liaison (MSL) organizations continue to expand and evolve secondary to the evolving needs within the pharmaceutical industry. A changing customer base, new and expanded regulations, and the growing complexity of therapeutic agents, offer new opportunities for the continued expansion and evolution of the MSL role. Currently, MLSs are engaged in clinical trial related activities, managed care and heath economics discussions, business development projects, and other activities. In this session, a diverse group of MSL representatives will share why these roles are critical and how they contribute to the overall medical affairs objectives.

Industry Perspectives
David A. Jencen, PhD
Principal, Jencen Field Medical Consulting LLC

Representative Invited
Senior Vice President, Medical Affairs, InVentiv Therapeutics Institute

#405 Track 07 – Processes and Technologies for Clinical Research

Related Interest Area(s): VA, RA, IT

9:00–10:00 AM △ Level: ● Format: SESSION
Room 10 *CME, Pharmacy, and Nursing*

Qualifying a Software Vendor in a Regulated Industry

CHAIRPERSON

Mark Willis, MS, PMP
Principal Business Analyst, Cubist Pharmaceuticals, Inc.

As technology continues to advance, so must the techniques surrounding the qualification of a software vendor for use in a regulated industry. This session describes the audit process, the financial aspect, and the evaluation of the associated risk.

Regulatory Requirements for Qualifying a Software Vendor
Mark Willis, MS, PMP
Principal Business Analyst, Cubist Pharmaceuticals, Inc.

Economics of Qualifying a Software Vendor
Representative Invited
Financial Systems Manager, Fresenius Medical Care North America

#406 Track 08 – Regulatory Affairs and Submissions

Related Interest Area(s): RA, MDD, CR

9:00–10:30 AM Level: ● Format: FORUM
Room 2 *CME and Nursing*

Hot Topics in Medical Devices Labeling: US and Global

CHAIRPERSON

Eileen S. Kahn, MEd, MS
Principal Labeling Associate, Sanofi US

In this forum, we will address the use of device labeling regulations, guidelines, standards, and other labeling for reference. We will discuss the use of corporate labeling to create harmonized device labeling, as well as the implementation of these corporate labeling documents in specific countries.

Universal Usability Principles in Drug Delivery Device Labeling
Anthony D. Andre, PhD
Founding Principal, Interface Analysis Associates

Challenges and Opportunities with Global UDI Implementation
Representative Invited
Vice President and UDI Practice Lead, USDM Life Sciences

Use of Social Media for Product Promotion: FDA and Company Coordination Issues to Consider
Alan G. Minsk, JD
Partner, Arnall Golden Gregory LLP

Panelist
Gerrit Nijveldt, MSc
Senior Director, Global Regulatory Affairs Labeling, Sanofi US

#407 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, AP

9:00–10:30 AM Level: ■ Format: FORUM
Room 9 *CME, Pharmacy, and Nursing*

FDA Drug Claims Substantiation after IMS and Caronia: Will Court Scrutiny Based on the First Amendment Lead to Change in Current Policy and Practice?

CHAIRPERSON

John F. Kamp, JD, PhD
Attorney at Law; Executive Director, Wiley Rein LLP; Coalition for Healthcare Communication

This forum will focus on the emerging law of claims substantiation in light of major court rulings affecting FDA regulation of marketing, particularly the Supreme Court decision in IMS v. Sorrell and the 2nd Circuit decision in US v. Caronia. Among other things, panelists will focus on Citizen Petitions before the FDA by PhRMA and the Information Working Group (IWG) of 13 major biopharmaceutical companies seeking clarity and reform of existing policies.

Panelists
Coleen Klasmeier, JD
Global Coordinator, Food, Drug and Medical Device Regulatory Practice, Sidley Austin LLP

Alan R. Bennett, JD
Senior Counsel, Ropes & Gray

#408 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, CR

9:00–10:30 AM Level: ■ Format: SESSION
Room 8 *CME and Nursing*

GCP Quality Agreements

CHAIRPERSON

Angelika Tillmann
Vice President Global Clinical Quality Assurance and Compliance, Theorem Clinical Research, Germany

This session will present and analyze the utilization of quality agreements in GCP from three different perspectives. These perspectives will include a CRO utilizing quality agreements with the CRO's vendors, a CRO having quality agreements with the sponsors, and from a sponsor organization having quality agreements with their CROs. All presentations will critically analyze the effectiveness of strategies in the utilization of quality agreements for the mutual benefit of all parties involved and their impact on quality for the conduct of clinical trials.

Quality Agreements from the Sponsor Perspective
Barney Horne, RPh
Senior Director, Quality Assurance, Daiichi Sankyo UK Ltd., United Kingdom

Quality Agreements: Help or Hindrance?
Angelika Tillmann
Vice President Global Clinical Quality Assurance and Compliance, Theorem Clinical Research, Germany

Vendor Quality Agreements: Complement to Quality Compliance
Kimberly Washburn
Senior Director, Quality Assurance, Quintiles Transnational Corporation

#409 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, CMC/GMP, CP

9:00–10:30 AM | Level: ■ | Format: SESSION
Room 5A | *CME, Nursing, and PMI PDUs*

Question-Based Review (QbR): A Risk-Based, Standardized Pharmaceutical Quality Assessment Tool

CHAIRPERSON

Jennifer A. Maguire, PhD
Acting Team Leader, Office of Pharmaceutical Science, FDA

This session will focus on the implementation of Question-Based Review (QbR) in the future Office of Pharmaceutical Quality. The speakers will provide an update on the current state of QbR revisions and will discuss the initiatives affecting both new and generic drug applicants.

Question-Based Review: A Vision
Ramesh K. Sood, PhD
Supervisory Chemist, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

Status Update on QbR for the Future Office Of Pharmaceutical Quality
Jennifer A. Maguire, PhD
Acting Team Leader, Office of Pharmaceutical Science, FDA

QbR for ANDA: Effective Tool For Development, Submission, and Review
Sivakumar R. Vaithiyalingam, PhD
Director, Regulatory Affairs, Teva Pharmaceuticals

PhRMA's Perspective on Risk-Based Regulatory Review
John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

#410 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CR, PR

9:00–10:30 AM | Level: ■ | Format: SESSION
Room 7B | *CME and Nursing*

Universal Health Coverage and Health Technology Assessment in Emerging Asia Pacific Countries

CHAIRPERSON

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Universal health coverage has been established in Taiwan since 1985. Its effectiveness and efficiency have taken off with health technology assessments since 2007. Various approaches of health coverage in Asia Pacific countries such as Japan, China, and Korea will be discussed.

Aligning the Scientific Requirements for Asia Pacific HTAs: Applied Learnings from Other Jurisdictions
Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

Trends in Emerging Asia Pacific: Health Financing and HTA
Abdulkadir Keskinaslan, MD, MBA, MPH
Head Market Access and External Affairs TR, Novartis Pharma AG, Switzerland

The Universal Coverage and the Experience Sharing from the National Health Authority's Perspective
Representative Invited
United States

#411 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): HT, CmbP, CR

9:00–10:30 AM | Level: ■ | Format: SYMPOSIUM
Room 1B | *CME, Pharmacy, and Nursing*

Safety in Special Situations: Stem Cells, Vaccines, and Combination Products

CHAIRPERSON

Anup Kalapur, MD
Medical Manager, Pharmacovigilance Operations, Novartis Pharmaceuticals Corporation, Switzerland

This symposium will provide insights and guidance for signal detection and analysis of vaccines along with the challenges of having disproportionally-based signal detection methodologies. It will also include some of the factors to consider for stem cells and regenerative medicine and combination products.

Safety Signal Detection and Evaluation in Vaccines: How Is It Different?
Anup Kalapur, MD
Medical Manager, Pharmacovigilance Operations, Novartis Pharmaceuticals Corporation, Switzerland

Requirements, Potential Approaches, and Challenges in Pharmacovigilance and Risk Management Practices for Combination Products
Ajay Keshava, MS
Managing Consultant, WCI Consulting

#412 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): SE, CR, RA

9:00–10:30 AM | Level: ■ | Format: FORUM
Room 5B | *CME and Nursing*

Moving Beyond the Traditional Psychometric Validation of New Phase 3 Clinical Outcome Assessments

CHAIRPERSON

Lisa A. Kammerman, PhD, MS
Senior Principal Scientist, AstraZeneca

Challenges faced by those who evaluate the results of randomized controlled trials that are designed to evaluate the performance of new clinical outcome assessments are discussed. Strategies beyond psychometric validation techniques are identified.

Panelists
Rima Izem, PhD
Lead Mathematical Statistician, Office of Translational Science, CDER, FDA

Cheryl Coon
Associate Director, Endpoint Development and Outcomes Assessment, Adelphi Values

Laura Lee Johnson, PhD
Statistician, National Center for Complementary & Alternative Medicine (NCCAM), National Institutes of Health

#413 Track 16 – Professional Development

Related Interest Area(s): CR, RA, OS

9:00–10:30 AM | Level: ● | Format: FORUM
Room 11A | *CME and Nursing*

Independent Consultant or Permanent Role: Get the Position You Want (Tips from Insiders)

CHAIRPERSON

Sameer Thapar, PharmD
Professor and Advisor, Biopharma Educational Initiative, Drug Safety and PV, Rutgers, The State University of New Jersey

This forum will present the options of industry employment versus independent consulting. Tips will be given on landing the first job in the pharmaceutical/biotech/research industry for new graduates as well as career changers, including key points when considering the independent consultant route. Viewpoints are provided from the perspective of a successful independent consultant who made the jump from being a company employee as well as tips gleaned from an academic with 15 years of pharma/CRO/consultancy experience as both a candidate and a hiring manager.

So You Think You Might Want to Be an Independent Consultant? Re-inventing Yourself So You Are Poised for Success
Lisa D. Mulcahy
Owner and Principal Consultant, Mulcahy Consulting LLC

Insider Tips on Breaking into the Industry
Sameer Thapar, PharmD
Professor and Advisor, Biopharma Educational Initiative, Drug Safety and PV, Rutgers, The State University of New Jersey

#414 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

9:00–10:30 AM | Level: ● | Format: FORUM
Room 6B | *CME, Pharmacy, and Nursing*

CDER Town Hall (Part 1 of 2)

CHAIRPERSON

Nancy D. Smith, PhD
Adjunct Professor, Temple University, FDA Alumni

This forum is a roundtable discussion with CDER leadership. It will include discussion and updates on regulatory changes; hot topics at CDER will be discussed, and the audience will be invited to submit questions of general interest.

Part 2 will take place on Thursday at 10:45 AM (Session #426).

Panelists

Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Rear Adm. (ret.) Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MSc
Associate Director for International Programs, Office of Strategic Program CDER, FDA

Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

10:30–10:45 AM

Coffee Break at Sails Pavilion

#415 Track 01 – Clinical Operations

Related Interest Area(s): AHC/IS, CR, PT

10:45 AM–12:15 PM | Level: ■ | Format: SESSION
Room 9 | *CME and Nursing*

Parents as Partners: Overcoming Unique Challenges to Pediatric Recruitment and Retention

CHAIRPERSON

Donald Sickler
Group Account Supervisor, CAHG

The number of pediatric drug trials is growing rapidly, but many of these trials have proven extremely difficult to enroll. This session presents lessons learned and best practices for engaging parents as partners in the trial process.

Parent Engagement: The Sponsor/CRO Perspective
Susan Tansey, MD, MRCP, FFPM
Medical Director, Paediatrics, Premier Research Group Ltd., United Kingdom

Pediatric Recruitment and Retention Pearls: A PI's Perspective
Lawrence Eichenfield, MD
Chief, Pediatric and Adolescent Dermatology, Rady Children's Hospital and University of California, San Diego

#416 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, OS, SP

10:45 AM–12:15 PM | Level: ■ | Format: WORKSHOP
Room 16A | *CME, Nursing, and PMI PDUs*

A Hitchhiker's Guide to Working with Management Consultants

CHAIRPERSON

Barbara Leishman, MA
External Business Alliance Leader, F. Hoffmann-La Roche Ltd., Switzerland

Professional or commercial organizations commonly engage external expertise from management consultants to help through times of change, but do we always derive the optimum benefit from such collaboration? From the perspective of both the consultant and the client, this workshop will address such topics as: (1) When do we need consultants? (2) What can consultants provide? (3) Consultancy models—does one size fit all? (4) Scoping the project and defining the consultancy model. (5) Getting the most out of the collaboration — do's and don'ts based on real-life experience. So long and thanks for all the slides — life after the consultants have gone.

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The Consultant's Perspective
Carolin Oelschlegel, MBA
Principal and European Lead of the Katzenbach Center, Booz & Company, United Kingdom

#417 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP, CR

10:45 AM–12:15 PM | Level: ■ | Format: FORUM
Room 5B | *CME, Nursing, and PMI PDUs*

The Evolution of Strategic Partnerships and the Four P's of International Relationship Building

CHAIRPERSON

Matthew Kibby, MBA
Principal, Technology and Innovation, BBK Worldwide

People, procedure, process, programming – this forum will introduce the communications mix required to build successful international relationships. Bringing together key industry stakeholders to present a multinational clinical trial case study as it relates to implementation in Japan, this forum will discuss how groups with competing interests can better work together to operate as a united force. Representing different silos and opinions, the presenters will share their experience operating as a team to enhance the overall study relationship. These relationships have and always will exist. The key to future clinical trial success is to leverage the trends and momentum of the industry, including technological innovations, engagement tactics, new and interactive media, and unique partnership models.

Panelists
Matthew Kibby, MBA
Principal, Technology and Innovation, BBK Worldwide

Christina Bodurow, PhD, MA
Senior Director, External Sourcing, Development Center of Excellence, Eli Lilly and Company

Kiyoshi Aoyagi
Director, Croee Inc., Japan

#418 Track 07 – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, EC, CR

10:45 AM–12:15 PM | Level: ◆ | Format: SYMPOSIUM
Room 10 | *CME, Pharmacy, and Nursing*

Risk-Based Monitoring: Where We Are and Where We Are Headed

CHAIRPERSON

Amita Malik, MS
Product Manager/Strategy, Oracle Health Sciences

The recent FDA guidance on risk-based monitoring (RBM) creates an opportunity for sponsors to leverage the advantages of reducing the amount of source document verification. This symposium will examine the current state of RBM, including how to implement a risk-based monitoring strategy, dealing with the challenges of RBM and how to overcome these challenges. In addition, speakers will provide practical guidelines for developing and deploying an effective RBM strategy.

Risk-Based Monitoring: Overview of the Current State and Guidelines on How to Design and Execute a Risk-Based Monitoring Plan
Amita Malik, MS
Product Manager/Strategy, Oracle Health Sciences

Addressing Key Aspects of the EMA Reflection Paper on Risk-Based Quality Monitoring: Quality Tolerance Limits and Quality Report
Andrew Lawton
Global Head, Clinical Data Management, Boehringer Ingelheim Ltd., United Kingdom

Experience Conducting Studies with Risk-Based Monitoring Strategies
Nancy Hammer
Vice President, Clinical Operations, ICON Clinical Research

#419 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CR, CDM

10:45 AM–12:15 PM | Level: ■ | Format: SESSION
Room 4 | *CME, Pharmacy, and Nursing*

Ethnic Difference in Clinical Trial Data: A 15-Year History of an Investigation by Regulatory Agencies and Industry

CHAIRPERSON

Akio Uemura, PhD
Director and Head, Regulatory Affairs, Allergan Japan K.K., Japan

Ethnic factors are very important in considering utilization of clinical data generated in population mixture. In this session, we will try to understand the current regulations of handling ethnic differences/similarities in clinical trial data by reflecting on ICH E5 utilization and explore future clinical trials aiming for global drug development with a particular focus on East Asian clinical trials.

Ethnic Similarities and Differences: Facts and Interpretations
Yoshiaki Uyama, PhD
Director, Analysis Division, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

New Drug Application in China: Value of Foreign Data
Chwen-Cheng Nathan Chen, MD, PhD
Clinical Site Head, Pfizer Inc

Utilization of Asian Clinical Trial Data for Drug Development in Korea: Investigator's Perspective
In-Jin Jang, MD, PhD
Professor and Director, Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Korea, Republic of

#420 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, BT

10:45 AM–12:15 PM | Level: ■ | Format: SESSION
Room 3 | *CME and Nursing*

Trends in Biosimilars Regulation Within Developed and Emerging Markets

CHAIRPERSON

Andrew S. Robertson, JD, PhD
Director, Global Regulatory Policy, Merck & Co., Inc.

This session will provide an in-depth assessment of current global debates and trends within biosimilars regulation. We will present a detailed comparative analysis of the biosimilars global regulatory landscape, identify areas of consistency, and outline areas where debate is ongoing. Panelists will further explore regional trends in biosimilars regulation, focusing on Latin America and the Asia Pacific region. Finally, we will present data that reflects current thinking on some key areas in biosimilars regulation, such as international naming conventions and regulatory standards for substitution and interchangeability. This discussion will provide insight into areas where there is large agreement in biosimilars regulation, and will help identify issues that would benefit from further global discussion.

Biosimilars: Evolving Trends in the Global Scenario: Emerging Role of the Asia Pacific Region
Sonica Sachdeva Batra
Director Clinical Development, Biologics, Dr. Reddy's Laboratories Ltd., India

Interdisciplinary Perspectives on Development of Naming Standards for Biosimilar Medicines
Richard O. Dolinar, MD
Chairman, Alliance for Safe Biologic Medicines

#421 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice

Related Interest Area(s): GCP, SP, OS

10:45 AM–12:15 PM | Level: ■ | Format: SESSION
Room 8 | *CME and Nursing*

Bringing Quality to Quality Metrics

CHAIRPERSON
Keith Dorricott
Senior Director, Quality Operations, Corporate Quality, INC Research, United Kingdom

The session will would provide an overview of recent developments in using metrics to deliver quality and how by using metrics for quality, a CRO can develop a better understanding of the needs of the sponsor.

Industry Developments in Definition and Use of Quality Metrics
Linda B. Sullivan, MBA
Chief Operating Officer, Metrics Champion Consortium LLC

Learnings From Use of Quality Metrics: Sponsor View
Christine R. Sahagian, MS
Director, Clinical Trial Oversight and Compliance, Cubist Pharmaceuticals, Inc.

Learnings From Use of Quality Metrics: CRO View
Keith Dorricott
Senior Director, Quality Operations, Corporate Quality, INC Research, United Kingdom

#422 Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): RD, CR, PR

10:45 AM–12:15 PM | Level: ■ | Format: FORUM
Room 7B | *CME and Nursing*

How Can Studies that Inform Relative Effectiveness Best Be Incorporated into Global Drug Development Plans?

CHAIRPERSON
Chris Chinn
Vice President, Real World Data, Value Evidence and Outcomes Group, R&D, GlaxoSmithKline UK Ltd., United Kingdom

GetReal, an EU Innovative Medicines Initiative (IMI) public-private partnership composed of pharmaceutical companies, academia, health technology assessment (HTA) agencies, and regulators, will host a discussion on ways of incorporating relative effectiveness objectives into pre-authorization development, and the implications for international HTA, regulatory, and drug development decision-making.

Panelists
Chris Chinn
Vice President, Real World Data, Value Evidence and Outcomes Group, R&D, GlaxoSmithKline UK Ltd., United Kingdom

Representative Invited
Executive in Residence and Visiting Scientist, Massachusetts Institute of Technology, Sloan School of Management

#423 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): QA/QC, RA, IT

10:45 AM–12:15 PM | Level: ■ | Format: SYMPOSIUM
Room 5A | *CME and Nursing*

Changing the Mindset Towards Case Quality, Audits, and Inspections: A Practical Approach

CHAIRPERSON
Maria C. Koster, PharmD
Senior Director International Relations, Vigilex, part of the Xendo Group, Netherlands

Companies' responsibilities to oversee their adherence to regulations, the quality of case reports across the globe and the benefit-risk profile of their products took on a new meaning in recent years. Now, in the wake of an increasing number of regulatory inspections, warning letters, and transparency, including sharing the results with the general public, many companies are refining the role of their corporate and regional audit functions and auditors will shoulder greater responsibility. This session will discuss the role of the auditing groups and how it is evolving in unprecedented ways.

Ensuring Standardized Case Quality in Safety and Pharmacovigilance Services through Web-Based Systems
Drew Kilpatrick, PhD
Vice President, Safety and Pharmacovigilance, INC Research, United Kingdom

Alternatives to Traditional Audit Methodologies: Effective Auditing While Risk-Based
Maria C. Koster, PharmD
Senior Director International Relations, Vigilex, part of the Xendo Group, Netherlands

Struggling with Three Inspectors From Different Worlds: Reality and Idealism
Teiki Iwaoka, PhD, MS
Executive Consultant, Director of Drug Safety Outsourcing Planning, CAC EXICARE Corporation, Japan

#424 Track 16 – Professional Development

Related Interest Area(s): OS, CR, RA

10:45 AM–12:15 PM | Level: ■ | Format: SYMPOSIUM
Room 11A | *CME, Nursing, and PMI PDUs*

Walking the Tightrope of Talent Acquisition and Retention: The Balancing Act for Maintaining Productivity, Efficiency, and Quality

CHAIRPERSON
Rebecca Padula
Clinical Operations Manager, Execupharm, Inc.

As outsourcing matures, more strategic, technical, and knowledge intensive activities like study design, trial management, data analytics, and medical writing are being outsourced versus more administrative or task-based

roles. Outsourcing companies/CROs are confronted with significant challenges in attracting high-performing staff. The race to acquire and maintain quality hires for clinical research requires adoption of a multidimensional strategy. The limited talent pool of trained and experienced staff is often bombarded with career transition opportunities. To remain competitive, CROs must be creative in devising programs aimed at not only attracting top talent but retaining them. Practical recruitment and retention strategies will position outsourcing companies/CROs for success in exceeding client expectations of quality. We will share the backdrop of why this is critical today with more specialized roles being outsourced. We will share some recruitment and retention strategies as well as experiences with a standardized training model that provides a steady stream of qualified and trained resources without compromising project deliverables. This model not only offers a career path and an excellent retention strategy for the company, but increases the overall talent pool in a country, making companies self-reliant as providers to industry and preventing a ratcheting up of salaries, squeezing margins, and making a particular country unviable.

How to Keep the Keepers: Recruiting and Retaining Operational Talent
Rebecca Padula
Clinical Operations Manager, Execupharm, Inc.

Institutionalizing Training for Capacity Expansion
Samyuktha Ajay, PhD
Director, Clinical Development, Sciformix, India

The Job Market Is Finally Looking Up...How the Heck Do We Keep Our Talent?
Matthew Pepe
Division Director, Workforce Integration

#425 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, PT, RA

10:45 AM–12:15 PM | Level: ■ | Format: SYMPOSIUM
Room 7A | *CME, Pharmacy, and Nursing*

Innovative Patient Recruitment Solutions for Rare Disease Clinical Trials

CHAIRPERSON
Neil Weisman
Executive Vice President and General Manager, Blue Chip Patient Recruitment

Patient recruitment for rare disease trials is challenging by nature due to small patient populations. Recent innovations have offered clinical development teams exciting new ways to accelerate patient recruitment efforts. This symposium will present three such innovations, including clinical trial simulations, in-home clinical trial visits, and activating patient advocacy and grassroots organizations to contribute to clinical trial enrollment. Case studies and best practices will be presented for each of these strategies.

Recruitment for Rare Diseases: Are You Maximizing Your Relationship with Your Patient Advocacy Group?
Neil Weisman
Executive Vice President and General Manager, Blue Chip Patient Recruitment

Bolstering Development Programs in Rare Diseases: Simulating Clinical Trials with a Virtual Patient Population
Badri Rengarajan, MD
Vice President, Medical Affairs and Senior Principal Consultant, Evidera

Helping the Rare Disease Patient Say Yes to Participation in Clinical Research
Nicki Norris, MBA
Chief Executive Officer, Symphony Clinical Research

#426 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR, CP

10:45 AM–12:15 PM | Level: ● | Format: FORUM
Room 6B | *CME, Pharmacy, and Nursing*

CDER Town Hall (Part 2 of 2)

CHAIRPERSON
Nancy D. Smith, PhD
Adjunct Professor, Temple University, FDA Alumni

This forum is a roundtable discussion with CDER leadership. It will include discussion and updates on regulatory changes; hot topics at CDER will be discussed, and the audience will be invited to submit questions of general interest.

Part 2 will take place on Thursday at 9:00 AM (Session #414).

Panelists
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Rear Adm. (ret.) Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MSc
Associate Director for International Programs, Office of Strategic Program CDER, FDA

Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

12:15 PM ANNUAL MEETING ADJOURNED

12:30–4:30 PM

MedDRA® User Group Meeting

Room 30AB

See you next year!

DIA 2015 51st Annual Meeting

June 14–18, 2015
Washington, DC

PRECONFERENCE TUTORIALS

Annual Meeting Preconference Tutorials are led by subject matter experts who provided in-depth instruction on some of today's hottest topics. DIA would like to take this opportunity to thank all of the preconference tutorial instructors who were involved in the Sunday, June 15 program.

TUTORIALS

TUT 20 Japan's Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Alberto Grignolo, PhD
Corporate Vice President, Global Strategy and Services
PAREXEL Consulting

Yoshiaki Uyama, PhD
Director, Analysis Division, Office of Safety I
Pharmaceuticals and Medical Devices Agency
(PMDA), Japan

TUT 21 The Sunshine Act: Understanding the Essentials of Compliance
Michael A. Swit, JD
Special Counsel
Duane Morris, LLP

TUT 22 Preparing for a US FDA Advisory Committee Meeting
Pete Taft
Founder and CEO
Taft and Partners/PharmApprove

TUT 23 Leadership: How to Organize and Lead People in Group Work
Michael Laddin, MBA, MS
CEO
LeaderPoint

TUT 24 Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions, and Regulatory Document Writing
Elaine B. Taylor
Director, Regulatory Strategy, Consulting, & Submissions
INC Research

Kathryn Wekselman, PhD, RN
Director, Regulatory and Scientific Affairs
CTI Clinical Trial and Consulting Services

TUT 30 Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation
Michael Laddin, MBA, MS
CEO
LeaderPoint

TUT 31 Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges, and Decision Criteria
Rick Lilley, PhD
Vice President, Global Regulatory Affairs
UCB, S.A., Belgium

TUT 32 Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development, and the Practice of Medicine
Michael Drues, PhD
Founder and President
Vascular Sciences

TUT 33 Bayesian Evidence Synthesis and Network Meta-analysis
Bradley P. Carlin, PhD, MS
Professor and Head of Biostatistics
University of Minnesota

Karen Price, PhD, MA
Research Advisor
Eli Lilly and Company

TUT 34 Preparation of Risk Evaluation and Mitigation Strategies Assessment Reports
Matthew A. Lee, PharmD
Director
Regulatory Affairs
Marathon Pharmaceuticals, LLC

Catherine Sigler, PhD, MPH
Senior Epidemiologist
United BioSource Corporation

Annette Stemhagen, DrPH, FISPE
Senior VP, Safety, Epidemiology, Registries & Risk Management
United BioSource Corporation

TUT 35 Understanding Translational Medicine: Benefits and Innovative Approaches
Aamir Shahzad, MD
President
European Society For Translational Medicine (EUSTM), Austria

TUT 40 Analysis of Safety Data from Clinical Trials
Joachim Vollmar, MSc
Executive Consultant
International Clinical Development Consultants, LLC

Jürgen Kübler, PhD
Global Head, Clinical Design, Analysis and Reporting
CSL Behring GmbH, Germany

TUT 41 Quality Oversight of CROs-Clinical Vendors
Liz Wool, BSN, RN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc.

Jennifer Poulakos, PhD
Director
Clinical Quality Assurance
Astellas

Jeffery Baldwin, BSN, RN
Senior Manager
Supplier Governance
Amgen Inc.

TUT 42 Regulatory Affairs for Biologics
Carol H. Danielson, DrPH, MS
President
Regulatory Advantage

TUT 43 Clinical Statistics for Nonstatisticians
Michael C. Mosier, PhD
Director, Biostatistics
EMB Statistical Solutions, LLC.

TUT 44 Quality by Design: From Theory to Practice
John H. Alexander, MD
Director, Cardiovascular Research
Vice Chief, Clinical Research, Cardiology
Duke Clinical Research Institute

Jean Mulinde, MD
Acting Senior Advisor
Division of GCP Compliance, Office of Scientific Investigations
CDER, FDA

Ann Meeker-O'Connell, MS
Senior Director
QA Clinical Strategy Team Lead
Janssen Pharmaceuticals, Inc.

TUT 45 Risk Management Plan
Nancy D. Smith, PhD
Adjunct Professor, Temple University;
FDA Alumni

TUT 46 The Good Pharmacovigilance Practices in the EU: Lessons Learned and Frequently Asked Implementation Questions
Sabine Brosch, PhD, PharmD
Principal Scientific Administrator
Monitoring and Incident Management Services, Pharmacovigilance Department
European Medicines Agency, European Union

Steve Jolley, MA
CEO
SJ Pharma Consulting, LLC

Saad A.W. Shakir, MD, FFPM, FISPE, FRCP
Director
Drug Safety Research Unit (DSRU), United Kingdom

Student Poster Session

Monday, June 16, 7:45 AM–2:30 PM
*Award Ceremony at 4:30 PM DIA Booth #1531

This year's Student Poster Program includes 18 students from various academic institutions from all over the world that will showcase their latest research in this year's program. Student Poster presenters will be judged for their poster and onsite presentation on Monday and recognized at the Student Poster Award Ceremony at 4:30 PM in the DIA Booth #1531. Posters will be displayed in the Sails Pavilion Lobby. Visit diahome.org/DIA2014 for abstract details.

M 01 **Use of Evidence-Based Medications in Treating Medicare Beneficiaries with Osteoporosis**
Feng-Hua Loh, MBA
University of Maryland School of Pharmacy

M 02 **The Effects of Levalbuterol versus Albuterol in Pediatric Patients with Asthma: A Cohort Study in a Low-income Population**
Jing Yuan
South Carolina College of Pharmacy

M 03 **Direct Observation in Correlation to Levels of Adherence in a Clinical Study**
Marguerite Monogue
University of Texas at Austin

M 04 **Globalization and Racial Composition of Pivotal Clinical Trials**
Todd Knepper
University of North Carolina of Chapel Hill

M 05 **Budget Impact Analysis of Tofacitinib for Treatment of Rheumatoid Arthritis**
Rituparna Bhattacharya, MS
West Virginia University

M 06 **Financial Crisis of Pharmaceutical Firms in China: Using Z-Score Model**
Xueyan Yang
University of Macau

M 07 **Anticholinergic Use and Risk of Pneumonia in Elderly Medicare Beneficiaries: A Nested Case-Control Study**
Satabdi Chatterjee, PhD, MS
University of Houston

M 08 **Improved Label and Liver Warning for Nonprescription Acetaminophen Products**
Tien Ho
University of California San Francisco

M 09 **Association of Prescription Opioid Use and Mortality in Community-Dwelling Medicare Beneficiaries with Non-Cancer Conditions**
Patience Moyo
University of Maryland Baltimore

M 10 **The Harmonization of Risk Management in the EU and the US: The Example of Vandetanib**
Agata Aleksandra Lazowska
University of Bonn, Germany

M 11 **A Cross Country Comparison of the Effect of Co-Payments for Prescriptions on Adherence to Medications**
Sarah-Jo Sinnott, PharmD, RPh
University College Cork, Ireland

M 12 **Unified Additional Requirement in Consideration of Regional Approval for Multiregional Clinical Trial**
Zhaoyang Teng, MA
Boston University

M 13 **Evaluating Factors Associated With Medication Reconciliation After Implementing an Electronic Medical Record (EMR) System**
Brittany Mani
Howard University School of Pharmacy

M 14 **Cost-Effectiveness Analysis of EGFR Mutation Testing and Gefitinib as First-Line Therapy for Non Small Cell Lung Cancer**
Yusuke Narita
Keio University, Japan

M 15 **Monitoring Medicines in Social Media, What are the Options? Example: Medicines Under Additional Monitoring in Europe**
Maartje Van Der Sar, MSc
Leiden University; Medicines Evaluation Board, Netherlands

M 16 **Health Canada's Request for Reconsideration Process: A Retrospective Analysis**
Lewis Lau
Humber College, Canada

M 17 **Who Benefits Most from Androgen Deprivation Therapy Among Newly Diagnosed Elderly Metastatic Prostate Cancer Patients?**
Abdalla Aly
University of Maryland

M 18 **Experimental Conditions of Creating a New Topical Remedy Containing Glucosamine and Ketroprofen**
Nataliia Davishnia, MS
National University of Pharmacy, Ukraine

Professional Posters

Selected Life Sciences Professionals from all fields related to the mission of DIA will participate in this year's Professional Poster Program. There are two Professional Poster Sessions in this year's program. Posters will be displayed in the Sails Pavilion. Visit diahome.org/DIA2014 for abstract details.

Professional Poster Session #1

T 01 **Development and Implementation of Product Safety Statistical Analysis Plans**
Barbara Hendrickson, MD
AbbVie Inc.

T 02 **Ensuring Patient Recruitment Success in Phase I Clinical Trials: The Important Role of Investigators**
Rachida Essalihi, PhD
Algorithme Pharma Inc, Canada

T 03 **Good Clinical Practice (GCP) Training: Identifying Key Elements and Strategies for Increasing Training Efficiency**
Jonathan Seltzer, MD, MA, MBA, FACC
Applied Clinical Intelligence, LLC

T 04 **Evaluation of Current and Future Medical Information Services Offered to Healthcare Providers by Pharmaceutical Companies**
Tracey Cannova
Rutgers, The State University of New Jersey

T 05 **Evaluation of Site Enrollment Estimates Pre- and Post-initiation to Actual Enrollment Performance: An Assessment of Accuracy**
Nicole Turner, MBA
Quintiles Inc.

T 06 **Country-Specific Clinical Data and Reporting Requirements in Support of Marketing Applications to Key Rest-of-World Countries**
Marianne Pedersen, PhD
Bristol-Myers Squibb Company

T 07 Effectiveness of REMS Patient Education: An Assessment of Patient Comprehension and Knowledge Retention
Paul Sheehan
Celgene Corporation

T 08 Development of an ELISA Method to Characterize C1q Binding Affinity
Kelly Colletti, PhD, MBA
Charles River Laboratories International, Inc.

T 09 Best Practices to Effectively Close a Complex, Global Study: Different Stakeholder Perspectives
Catherine Provosty
Covance Inc.

T 10 Using Gamification in the Life Science Industry
Niki Kutac
DATATRAK International, Inc.

T 11 Burden of Clinical Trial Operations and Value of Supporting Solutions: Results from a Global Investigator Survey
Elisa Cascade, MBA
DrugDev Inc.

T 12 The Role of Bioethics in the Pharmaceutical Industry: Informal Review of 5-Year Trends and One Company's Systematic Approach
Luann Van Campen, PhD, MA, MSc
Eli Lilly and Company

T 13 Out of the Box: A Survey of Boxed Warnings' Adverse Reactions in US Prescription Drug Labeling
Christine Cheng, PharmD
First Databank, Inc.

T 14 Processes and Responsibilities within Bioanalytical and Clinical Operations to Ensure PK Sample Management in Phase 1 Studies
Sandy Greene
Gilead Sciences, Inc.

T 15 Choosing Your Investment: What's the Right Data Quality Solution for You?
Nicole Zandy, PhD
Quintiles Transnational Corp.

T 16 Global Regulatory View of Nonprescription Medicines Classification
Dinah Duarte, PharmD, MSc
INFARMED, Portugal

T 17 Validation of Next Generation Sequencing Panels for Targetable Mutations in NSCLC and TNBC Using FFPEs and Liquid Biopsies
Rachel Skelton
Insight Genetics

T 18 A Regulatory Informatics Approach To Identifying Trends in Minimal Residual Disease for the Hematologic Malignancies
Elizabeth Rach
Janssen R&D, LLC

T 19 Characterizing Medical Information Requests from Payer Customers to Improve Database Planning for Respiratory Assets
Sarah White, PharmD
GlaxoSmithKline

T 20 Assessing Current Monitor Performance on Monitoring Competencies for Risk-Based Monitoring
Penelope Manasco, MD, MS
MANA Consulting

T 21 Utilization of Cross-Pollination Meeting Series: A Potential Catalyst for Innovation
Kelly Hageman, PharmD
MCPHS University School of Pharmacy

T 22 Evolution of Pharmacovigilance Regulations in the US and Europe
Dena Cosgrove, RPh
Quintiles Transnational Corp.

T 23 Validation of an Internal Communications Streamlining Initiative Utilizing an External Communications Benchmarking Study
Vinit Mehta, PharmD
Novo Nordisk

T 24 Electronic Investigator Site Files: The Hidden Gem that Completes Remote Risk Based Monitoring
Libby Cerullo, MSc
Pivotal Consulting LLC

T 25 Precision Laboratory Network (PLN): PBMC Processing and Nuclei Acid Isolation Suitability Study
Michael Waddington, MS
Precision Bioservices, Inc.

T 26 Use of Epidemiology Data to Inform Pediatric Clinical Trial Design and Execution and Its Impacts on MSL Support
Laura Wallace, MPH
Purdue Pharma L.P.

T 27 A Strategic Approach to Portfolio Benefit-Risk Assessments (BRAs)
Libbie McKenzie, MD
Quintiles Inc.

T 28 Avoid at Your Risk? The Potential for Naïve Sites to Rescue Failing Recruitment and Study Under-Performance
David Horsburgh
Quintiles East Asia Pte Ltd, Singapore

T 29 The Role of Medical Writers in Preparing Responses to Post-Submission Queries From FDA, PMDA, and EMA
Kai Yu Jen
Biogen Idec

T 30 The Evolution of an Enterprise Risk Based Monitoring Process
Ben Dudley
Covance Inc., United Kingdom

T 31 A Multi-Modalities Medical Imaging Investigative Network for Clinical Trials in Cardiovascular, Neurology and Oncology
Dominique Johnson
Montreal Health Innovations Coordinating Centre (MHICC), Canada

T 32 Analysis of Product Labeling Changes for Successful Prescription to Over-the-Counter Switches
Kim Le, PharmD
Rutgers Pharmaceutical Industry Fellowship Program

T 33 Utilizing the MSL Role to Characterize the Transition of Care of Patients with Attention Deficit Hyperactivity Disorder
Nicole Griswold
Shire Pharmaceuticals, Inc.

T 34 Descriptive Evaluation of REMS Knowledge in An Integrated Healthcare System
Nazia Rashid, PharmD, MS
Kaiser Permanente Southern California

T 35 International Comparison of Process and Procedures to Overcome Clinical Trial Applications Placed on Clinical Hold
Kenichi Otani, PhD
Sunovion Pharmaceiticals Inc.

T 36 Impact of FDA Advisory Committee Voting on FDA Approval Decisions for Drugs and Biologics
Regina Ballinger, BSN, MS, RN
Thomson Reuters

T 37 The Silver Lining of the PSMF: Flow Chart Displaying the Business and User Requirements
Zsuzsanna Csutor
B&C Consulting AG, Switzerland

T 38 Rock and a Hard Place: Mandated Multi-National Drug Utilization Studies in the Absence of Suitable Secondary Sources of Data
Krista Payne, MEd
United BioSource Corporation, Canada

T 39 **Medication Use Among Pregnant Women Enrolled in Medicaid**
Kristin Palmsten, Dr Sc
University of California San Diego

T 40 **eCTD Submission Capability to FDA for Academic Sponsor-Investigators: Process, Problems, and Possibilities**
E. Mitchell Seymour, PhD, RAC
University of Michigan Medical School

T 41 **Integrating ISO and Relevant Industry Standards to Improve Clinical Trial Project Management Processes**
Kathy Boardman, MS
VA Cooperative Studies Program

T 42 **Can Asia Help Expedite Cancer Drug Development? Analysis of Three North Asian Countries' Potential to Do More Clinical Trials**
NaRae Baek
Quintiles Transnational Korea Co., Ltd., Republic of Korea

T 43 **Electronic Data Capture in Oncology: A Review of Electronic Collection of Patient-Reported Outcomes**
Bhavini Srivastava
Novartis Pharmaceuticals Corporation

T 44 **Patient-Informed Clinical Trials: A Cross-Sectional Survey on a Patient Powered Research Network**
Sally Okun, MHS, RN
PatientsLikeMe

T 45 **Delivering Quality Systems Globally**
Craig Burnett
Hospira

Professional Poster Session #2

Wednesday, June 18, 7:15 AM–4:00 PM

W 01 **Evaluation of Operating Characteristics of MMRM Analysis Using All Available Longitudinal Data at Interim Compared to ANCOVA**
Weining Robieson, PhD
AbbVie Inc.

W 02 **Recent Developments in Scaled Average Bioequivalence**
Pascal Guibord, MSc
Algorithme Pharma Inc, Canada

W 03 **An Overview of Both Current Best Available and Next Generation of Drug Therapies for the Treatment of Depression**
Annette Williams, MBA, RPh
Quintiles Inc.

W 04 **Health Literacy Assessment, Usability Testing, and Revision of a European Union Risk Management Plan Public Summary**
Karen Lockwood
Eli Lilly and Company

W 05 **Coordination of a Multi-site Cell and Gene Therapy Study in an Academic Medical Center: A Success Story**
Bambi Grilley, RAC
Baylor College of Medicine

W 06 **An Innovative Way of Providing Timely Responses to Questions Related to Ingredients/Allergens**
Irene Sheng, PharmD
Bristol-Myers Squibb

W 07 **Evaluating and Supporting the Increasing Patient Need for Delivery of Clinical Trial Supplies Direct to Their Homes**
Esther Sadler-Williams, MPharm, MSc, RPh
Catalent Pharma Solutions, Inc., United Kingdom

W 08 **New Business Acumen Tool Guides Strategic Thinking: Learn How to Increase Your Value to the Company and to the Industry**
Ilyssa Levins
Center for Communication Compliance (CCC)

W 09 **Complexity in Protocol Design: Does it Lead to Better Clinical Trial Outcomes?**
Rebecca Hummel
CNS Healthcare

W 10 **Corporate Integrity Agreement and Its Impact on Industry**
Abhishek Harde
Cognizant Technology Solutions Corporation, India

W 11 **Giving Clinical Trial Start Up A Project Management Make-Over: Reducing Cycle Times Through Critical Path Focus**
Ben Quartley, PhD
Covance Inc., United Kingdom

W 12 **The Impact of Regulatory Reform in Mexico on Pharmaceutical Product Approval Rates**
Raul Vinueza
Data-Pharma LLC

W 13 **So How Do you implement eSource: Practical Tips for Enhancing Efficiency, Data Visibility, and Site Interactions**
Ed Seguine, MBA
Clinical Ink

W 14 **Duloxetine Feeding Tube Study: Medical Information Example of Collaboration with Laboratory Scientists to Deliver Answers**
Andrew Buchanan, RPh
Eli Lilly and Company

W 15 **Targeting the Best Sites with an Analytical Site Selection Model Using Multiple Metrics**
Elizabeth Nielsen
Quintiles Inc.

W 16 **Central Recruitment Methodologies in a Global Clinical Research Study of a Pediatric Autism Spectrum Disorder (ASD) Program**
Allan Spera
Forest Research Institute

W 17 **Evaluation of Shipping Systems to Maintain Sample Integrity in Clinical Research**
Mona Vimal, MSc
Gilead Sciences, Inc.

W 18 **A Comparison of MedDRA SMQs Relative to Individual Preferred Terms for Signal Detection on a Large Insurance Claims Database**
Christopher Bone
GlaxoSmithKline, United Kingdom

W 19 **Introducing and Conducting Traditional Chinese Medicine Trials in the US: Challenges, Obstacles, and Potential Solutions**
John Li, MD, MBA
ICON Clinical Research

W 20 **Coherence of Observed-to-Expected Disproportionality Methods Used for Pharmacovigilance at a Critical Threshold**
Geoffrey Gipson
Janssen Pharmaceuticals, Inc.

W 21 **Enhancing Project Management Tracking to Facilitate the Protocol Development Process**
Tracey Miller
Leidos Biomedical, Frederick National Labs

W 22 **Continued Tradition of Success: Critical Components of the Genzyme/Sanofi Oncology/MCPHS University Post-PharmD Fellowship**
Christina Gallagher, PharmD
MCPHS University

W 23 **Assessment of Violations Cited by OPDP in Untitled and Warning Letters Issued from 2004-2013**
Phil Reveal
Meda Pharmaceuticals, Inc

W 24 Accelerating Patient Recruitment Using In-Depth Market Research Insights: Collected via a 3rd Party - From Clinical Trial Site Staff
Jeff Jamer, MBA
Merck & Co., Inc

W 25 Implementing a Standard Report Set for Risk Based Monitoring Domains
Christine Riley-Wagenmann
NextGen CDS

W 26 Investigation of Association Between COPD Treatment and Cardiac Events With or Without Treatment for Co-Existing Disease
Ayako Takizawa, MS
Nippon Boehringer Ingelheim Co., Ltd, Japan

W 27 Reinventing the Study Build Process to Promote Consistency, Increase Build Efficiencies, and Reduce Overall Timelines
Caroline Lin, MA
Novella Clinical

W 28 Collaborative Development of an Open Source Repository for Standardized Analysis Using Cloud Services
Hanming Tu, MSc
Octagon Unit At Accenture

W 29 Quality of Japanese Clinical Trials and Proposed Strategy for the Trial Sites
Toshiyoshi Tominaga, PhD
Osaka City University, Japan

W 30 A Collaboration to Facilitate the Development of Antibacterial Agents for Unmet Need: Streamlining Clinical Trial Protocols
Charles Knirsch
Pfizer Inc

W 31 Global Regulatory Considerations for Biosimilar Approval
Holly Groelle, PhD
PPD

W 32 Impact of FDA Breakthrough Therapy Designation on the Regulatory Timelines of Chronic Lymphocytic Leukemia (CLL) Therapies
Alex Wei
Ernest Mario School of Pharmacy, Rutgers University

W 33 An Extension of Likelihood Ratio Test-Based Method for Signal Detection in a Drug Class with Application to FDA's AERS Database
Yueqin Zhao, PhD
FDA

W 34 Maintaining Effective Pharmacovigilance Oversight: The Role of Remote Auditing
Alun Tanner, PhD
Remedion Consulting LLC

W 35 Data Empowered Decision Making in a Pharmaceutical Company: Project Libraries and Workflows - Real Life Experience
Mikhail Samsonov
R-Pharm, Russian Federation

W 36 Sample Size Re-Estimation Can Be Very Inefficient
David Bristol, PhD
Statistical Consulting Services, Inc.

W 37 So You Hired a CRO...Now What? Advancing Clinical Research by Leveraging Government Sponsor Relationships with CROs
Jessica Kloda, PhD
Technical Resources International, Inc.

W 38 Office of Prescription Drug Promotion (OPDP) Enforcement Overview From 1997 to 2013
Cyril Carrere, MSc
Thomson Reuters (Scientific) Ltd., France

W 39 Enrollment of Pregnant Women in Medication Safety Research: MotherToBaby Pregnancy Studies
Jennifer Zellner, PhD
University of California San Diego

W 40 A Model for Centralized Monitoring: Reducing Costs While Ensuring Compliance, Risk Mitigation and Quality
Badhri Srinivasan, PhD, MS
Quintiles Inc.

W 41 Customer Satisfaction and Communication Methods Used in Conducting Large Multi-Center Clinical Trials
Barbara Del Curto
VA Cooperative Studies Program

W 42 Easy as A,B,C? Adapting Pediatric Protocol Designs from Existing Adult Data and Study Templates
Rona Grunspan
Premier Research Group

W 43 The Construction and Promotion of Medication-Used Safety Education for Traditional Chinese Medicine in Taiwan
Tsung-Ta Wu
Department of Chinese Medicine and Pharmacy, Taiwan

W 44 Patterns of Regulatory Approval for Targeted and Immunotherapeutic Compounds Indicated for the Treatment of Metastatic Melanoma in the US and EU
Jonathan Nguyen Diep
Rutgers, The State University of New Jersey

AWARD WINNERS

DIA Awards recognize significant individual or group accomplishments in the discovery, development or life cycle management of biopharmaceutical, device or related therapeutic health care products, and/or exceptional volunteer contributions to advancing DIA's Mission and Vision.

DIA PRESIDENT'S AWARD FOR OUTSTANDING ACHIEVEMENT IN WORLD HEALTH

This award recognizes the significant, innovative contributions of an individual, group of individuals, or organization to the improvement of world health.

PatientsLikeMe
Jamie Heywood
Co-Founder and Chairman
PatientsLikeMe;
Founding Director
ALS Therapy Development Institute (ALS TDI)
United States

FOUNDERS' SERVICE AWARD

The Founders' Service Award is named after the group of 30 professionals who founded the DIA in 1964 with a fundamental value that the Association is member driven and fueled by the pharmaceutical industry's need for a
neutral forum. It recognizes those individuals who have contributed to the advancement of the mission, vision and values of the DIA and fostered its growth and development through their dedicated and sustained volunteerism.

Klaus Olejniczak, DVM
Non-Clinical Regulatory Consultant
Germany

OUTSTANDING SERVICE AWARD

The DIA Outstanding Service Award is given to recognize those individuals who consistently, through their volunteer efforts, made contributions to the DIA mission and vision over the past several years. These individuals have exceeded expectations in their volunteer activities with DIA.

Mariette Boerstoel-Streefland, MD, MBA, MSc(epi)
MBS Drug Safety Consulting
United States

Nikos Dedes
Representative
European AIDS Treatment
Europe

Wanda Dobrzanski Nisiewicz, MD
Vice President, Clinical Operations Latin America & North America
inVentiv Health Clinical
Latin America

Shuting Li, MD
Director, GCP Center
The Cancer Hospital in Chinese Academy of Medical Sciences
China

Joanne Liu, MD, MBA
Director, Asia Pacific, Global Data Management & Standard
MSD R&D Co., Ltd.
China

Barry Mangum, PharmD, FCP
Director Clinical Pharmacology
Duke Clinical Research Unit
United States

Trine Moulvad
Vice President, Regulatory Affairs, Diabetes and Obesity Projects
Novo Nordisk A/S
Europe

Junichi Nishino, RPh, MSc
Head, Process Improvement & Excellence Group, Drug RA Department
Novartis Pharma K.K.
Japan

OUTSTANDING SERVICE AWARD, CONTINUED

Arturo Rodriguez Jacob, MBA
Director
Infinite Clinical Research
Latin America

Jorgen Seldrup, PhD
Owner
Jstatconsult
Europe

Hidetoshi Shuto
Corporate Executive, Vice President, Clinical Development Administration Department
Astellas Pharma Inc.
Japan

Stephen A. Sonstein, PhD
Director, Clinical Research Administration
Eastern Michigan University
United States

Atsushi Tsukamoto, PhD, MSc, PMP
Senior Director, Global Project Management
Daiichi Sankyo Co., Ltd
Japan

Wendy Yan, MD, PharmD, MBA
Global Regulatory Strategist, Global Regulatory Affairs, Asia, Global R&D Center
Bayer Healthcare Co. Ltd
China

COMMUNITY AWARD

The DIA Community Award is given to recognize a particular community that has demonstrated its ability to be instrumental in fostering the professional growth of their constituents while also advancing the mission, vision and overall goals of DIA. This commitment to professional excellence is shown through the variety of events and opportunities that the community has made available. The outcome of these activities increases a group or individual's professional development and global networking opportunities while working to achieve the DIA's mission and vision.

China Data Management Community

SPEAKER INDEX

No Relationship or Conflicts of Interest (Nothing to Disclose)

Thomas Abrams
Bonnie Addario
Rosemary Addy
Michael Agard
Akhil Agrawal
Roshana Ahmed
Samyuktha Ajay
Elizabeth Allen
Mark Ammann
Keith Anderson
M.W. (Andy) Anderson
Anthony Andre
Susanne Andreae
Tomasz Anyszek
Kiyoshi Aoyagi
Peter Arlett
Mark Avigan
Kassa Ayalew
Bhanu Bahl
Leslie Ball
Dirceu Barbano
Sonica Batra
Maura Bearden
Kimberly Belsky
Danny Benau
Graeme Benson
Dirk Beth
Brian Birchler
Thomas Bizzaro
Larry Blankstein
Christine Blazynski
Gary Bloomgren
Mariette Boerstoel-Streefland
Kathryn Bohannon
Geoff Brockway
Kristine Broglio
Sabine Brosch
Rebecca Budd
Gary Bufferd
Jonca Bull
Erika Buonansegna
Keith Burkhart
Angela Burroughs
Kenneth Butz
Susan Cantrell
Frank Cattie
Nancie Celini
Libby Cerullo
Dannis Chang
Elbert Chang
Donny Chen
Yeh-Fong Chen
Herng-Der Chern
Karla Childers
Leslie (Mi Ok) Chong
Leah Christl
Raymond Chua
Sukh Chugh
Preciosa Coloma
Jenny Colombo
Emer Cooke
Cheryl Coon
Freda Cooner
Diane Cooney
Anca Copaescu
Judith Cope
Torrey Cope
Celia Cruz
Gerald Dal Pan
Jeannie David
Brett Davis
Tim Davis
Barbara Day
Louise Déry
Bhavana Desai
Smita Desai
Lode Dewulf
Gretchen Dieck
Joseph DiMasi
Victoria Dlensi
Petra Doerr
Richard Dolinar
Crystal Donnelly
Angelica Dorantes
Donna Dorozinsky
Keith Dorricott
Dipam Doshi
Matthew Downs
Nancy Dreyer
Bethany Drimalla
Deborah Driscoll
Charles Drucker
Michael Drues
Dinah Duarte
Susan Duke
Beth Duvall
Leonardo Ebeling
Lauren Edelstein Henry
Lawrence Eichenfield
Hans-Georg Eichler
Patti Engel
Tracy England
Bryan Ennis
Jeffery Fairbairn
Betsy Fallen
Steve Farrand
Debra Farrow
Renee Fate
Ellen Feigal
Fred Feldstein
Kathleen Findlen
Anna Fine
Joel Finkle
Ron Fitzmartin
Mary Flack
Keith Flanagan
Michael Folkendt
Freddie Foo
Kathleen Ford
Richard Forshee
Anita Frijhoff
Shayesteh Fuerst-Ladani
Emily Galdes
Shelley Gandhi
Elizabeth Garrard
Eric Gascho
Charu Gautam
Eric Genevois-Marlin
Kenneth Getz
Dalvir Gill
Coleen Glessner
Barbara Godlew
Michel Goldman
Will Gordon
Amy Grant
Mark Gray
Jane Griffin
Niels Gronning
John Groskoph
Kathleen Guindon
Andrey Gurachevsky
Alberto Gutierrez
Brian Hagen
Susan Hagen
Gill Hallett
Laurie Halloran
Margaret Hamburg
Nancy Hammer
Michael Hamrell
Rikki Hansen Bouchard
Terry Hardin
Jill Hartzler Warner
Martin Harvey Allchurch
Sema Hashemi
Smita Hastak
Sandra Hecker
Christopher Hickey
Luke Hickey
Joanna Hicks
Robert Hilke
Masaru Hiraiwa
Julie Ho
Nicole Hobbs
Regina Holliday
Barney Horne
Stuart Horowitz
Cindy Howry
Christopher Hoyle
Emily Huddle
Karl-Heinz Huemer
Thomas Hughes
H. M. James Hung
Patricia Hurter
Mark Hurtt
Wuh-Liang Hwu
Nita Ichhpurani
William Irish
Teiki Iwaoka
Rima Izem
David Jacobson-Kram

No Relationship or Conflicts of Interest (Nothing to Disclose), *continued*

Karen Jaffe
Faranak Jamali
Brenda Jamerson
In-Jin Jang
David Jencen
Annalisa Jenkins
Chris Jenkins
John Jenkins
Qi Jiang
Laura Lee Johnson
Karen Jones
Mary Kachinsky
Eileen Kahn
Angela Kaiser
Kenneth Kaitin
Anup Kalapur
Lisa Kammerman
Suresh Kannan
Sean Kassim
Mitchell Katz
Nancy Katz
Theresa Kehoe
Brian Kelley
Dermot Kenny
Cicely Kerr
Ajay Keshava
Abdulkadir Keskinaslan
Manish Khatri
Matthew Kibby
Rose Kidd
Drew Kilpatrick
Lisa Kim
Linda King
Lynn King
Bron Kisler
Coleen Klasmeier
Agnes Klein
Michael Klepper
Jacqueline Kline
Chin Koerner
Tatsuya Kondo
Evdokia Korakianiti
Maria Koster
Michael Krams
James Kremidas
Thomas Krohn
Wayne Kubick
Tatsuo Kurokawa
Sandra Kweder
Mark Lacy
Eric Lake
Altaf Lal
Mary Jo Lamberti
Gordon Lan (Kuang Kuo)
Leanne Larson
Paul Lasko
Peter Lassoff
Lisa LaVange
Doreen Lechner
James Leong
Christopher Leptak
Bert Liang
Lawrence Liberti
Chih-Hwa Wallace Lin
Robert Lionberger
Richard Lippincott
Wendy Lipworth
Rebecca Little
Jordi Llinares
Murray Lumpkin
J. Jason Lundy
George Lunn
Jytte Lyngvig
Alistair MacDonald
Debra Madden
Jennifer Maguire
Elizabeth Mahon
Kent Mahoney
Lynn Mainland
Sabah Malek
Amita Malik
Marina Malikova
Penelope Manasco
Linda Marban
Thomas Marbury
Anabela Marcal
Mauricha Marcussen
Sylvia Marecki
JeanMarie Markham
Lynn Marks
Bridget Martell
Fernando Martinez
Andreas Matern
Christopher Matheus
Ambrish Mathur
Yoshihiro Matsuda
Richard Mayewski
Philomena McArthur
Neil McAuslane
Katie McCarthy
Yvonne McCracken
Libbie McKenzie
Lynn Mehler
Munish Mehra
Joan Meyer
Jon Meyer
Stephen Mikita
Gloria Miller
Stephen Miller
Brian Mittman
Shinji Miyake
Hiroshi Mizushima
Justina Molzon
Gareth Monteath
Christine Moore
Kirsten Morasco
Robert Morris
Susan Morris
Rick Morrison
Melissa Mottolo
Isabelle Moulon
Lisa Mulcahy
Jean Mulinde
Noriaki Murao
Aileen Murphy
Dianne Murphy
Ciaran Murray
Bob Muzerall
Nancy Myers
Sumimasa Nagai
Tetsuo Nagano
Takashi Nagashima
Paulami Naik
Harumasa Nakamura
Nobumasa Nakashima
Gopalan Narayanan
Kristin Neff
Lori Nesbitt
Maryanne Nicosia
Matthew Noble
Carrie Nodgaard Helland
Nicki Norris
Brian Nugent
Thomas Nyirenda
Rebecca Nyquist
Carolin Oelschlegel
Christine Oliver
Robert O'Neill
Adrian Otte
Robert Paarlberg
Eric Padron
Rebecca Padula
Shaghig Palanjian
Jonathan Palmer
Bijal Pandhi
Soo Jin Park
Cathy Parker
Mitchell Parrish
Ritesh Patel
Kirsten Paulson
Eric Peacock
Douglas Peddicord
Matthew Pepe
Maryrose Petrizzo
Kenneth Phelps
Penny Piper
Sarah Plush
Michele Pontinen
Sarah Pope Miksinski
John Potthoff
Rajiv Prasad
Johann Proeve
Thomas Provencher
Rita Purvis
George Quartey
Maria João Queiroz
Lembit Rago
Leyla Rahjou-Esfandiary
Kitty Rajagopalan
Mahesh Ramanadham
Tina Rarick
Guido Rasi
Nicole Ratliffe Sheetz
James Rawls
Kate Rawson
Jayanthi Reddy
Edward Reilly
John Reites

No Relationship or Conflicts of Interest (Nothing to Disclose), *continued*

Margaret Richards
Christine Riley-Wagenmann
Jesus Rivera
Luz Rivera
MaryAnne Rizk
Andrew Roberts
Andrew Robertson
Mitra Rocca
Tracy Rockney
Kit Roes
Janet "Lucy" Rose
Keith Ruark
Yaffa Rubinstein
Amy Rupp
Barbara Sabourin
Leonard Sacks
Patricia Saddier
Christine Sahagian
Mark Sanders
Akshay Sateesh
Daisaku Sato
Junko Sato
Donna Sattler
Alicia Savage
George Savage
Rodd Schlerf
Charles Schmidt
Benton Schoen
Kathrin Schoenborn-Sobolewski
Suzanne Sensabaugh
TJ Sharpe
Vladimir Shnaydman
Jeffrey Shuren
Donald Sickler
John Skerritt
Mary Ann Slack
Gary Slatko
Nancy Smerkanich
Lonnie Smith
Maureen Smith
Nancy Smith
William Smith
Kristen Snipes
Mike Sobczyk
Lauren Sobocinski
Ramesh Sood
Ira Spector
Paul Spreen
Gabriela St. Amant
Gary Steinman
Nicholas Steneck
Stella Stergiopoulos
Charles Stevens
Janet Stevens
Kathryn Stiede
Lisa Stockbridge
Norman Stockbridge
Pieter Stolk
Ling Su
Subra Subramanian
Teresa Suek
John Sun
Michael Swit
Vadim Tantsyura
Tomonori Tateishi
Judith Teall
Shawn Tedman
Robert Temple
Zhaoyang Teng
Sameer Thapar
Mya Thomae
Hayden Thomas
Marcus Thornton
Benjamin Thurmond
Angelika Tillmann
Ram Tiwari
Anne Tomalin
Toshiyoshi Tominaga
Francois Torche
Josephine Torrente
Andrew Townshend
Kate Trainor
John Troiani
Atsushi Tsukamoto
Adair Turner
Akio Uemura
Kathleen Uhl
Daniel Ulrey
Laszlo Urban
Dale Usner
Yoshiaki Uyama
Sivakumar Vaithiyalingam
James Valentine
Benjamin Vali
Jim Vandergriff
Chandra Vemavarapu
Thirunellai Venkateshwaran
Alisa Vespa
Lona Vincent
Joachim Vollmar
Kristin Voorhees
David Vulcano
Deborah Wade
Mark Wade
Bruce Wagman
Betsy Waldheim
Stuart Walker
Magnus Wallberg
Deborah Waltz
Sue-Jane Wang
Kimberly Washburn
Carmen Weese
Neil Weisman
Steven Weisman
Albert Wertheimer
Russell Wesdyk
Kimberly Westrich
Mark Wheeldon
Robin Whitsell
Steven Whittaker
John Whyte
Rebecca Williams
Richard Williams
Mark Willis
Stephen Wilson
Robin Winter-Sperry
Brandon Wojtowicz
Durhane Wong-Rieger
Linda Wood
Janet Woodcock
Robert Wright
Nancy Xu
Hiroshi Yamamoto
Tamar Yarkoni
Lilly Yue
Ming-kung Yeh
Lilli Zakarija
Julia Zhang
Colleen Zak
Heather Zigmund
Linda Zillman
Lisa Zimmerman
Martine Zimmermann
Jeffrey Zucker
Isabel Zwart

Following are the disclosures received by press time, May 5, 2014. Disclosure statements received after this date will be listed on the Addendum that is included in the meeting materials distributed on site.

Marijke Adams OTHER SUPPORT-Microsystems

Paul Aftring OTHER SUPPORT-Employee of Novartis, STOCK SHAREHOLDER-GlaxoSmithKline, Novartis

Lina Aljuburi OTHER SUPPORT-Employee of Merck & Co., Inc.

Nicholas Alp OTHER SUPPORT-Employee of ICON plc

Igor Altman STOCK SHAREHOLDER-Medidata Solutions

Zoran Antonijevic STOCK SHAREHOLDER-Cytel, Inc.

Jeff Antos OTHER SUPPORT-Employee of The Weinberg Group

Antoinette Azevedo OTHER SUPPORT-Speaker's Bureau for FDANews, ExpertBriefings.com, Compliance Online; Employee of E-submissionssolutions.com

Gil Bashe OTHER SUPPORT-Employee of Makovsky Health

J. Lynn Bass OTHER SUPPORT-Employee of Jazz Pharmaceuticals

Andrew Bate STOCK SHAREHOLDER-Pfizer Inc

Virginia Beakes-Read OTHER SUPPORT-Employee of Eisai

Robert Beckman CONSULTANT-Cancer Institute of New Jersey, STOCK SHAREHOLDER-Daiichi Sankyo; Johnson & Johnson

Gesine Bejeuhr OTHER SUPPORT-Employee of industry association (vfa Research-based Pharmaceutical Companies)

Karin Beloussow OTHER SUPPORT-Employee of Amgen Inc.

Alan Bennett OTHER SUPPORT-Employee of Ropes & Gray

Scott Berry OTHER SUPPORT-Employee of Berry Consultants

Stella Blackburn OTHER SUPPORT-Employee of Quintiles

Christina Bodurow OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company

Linda Bowen STOCK SHAREHOLDER-Sanofi

Bonnie Brescia STOCK SHAREHOLDER-BBK Worldwide

Christina Bucci-Rechtweg OTHER SUPPORT-Employee of Novartis, STOCK SHAREHOLDER-Novartis Pharmaceuticals Corporation

Brendan Buckley STOCK SHAREHOLDER-ICON plc

Bill Byrom OTHER SUPPORT-Employee of Perceptive Informatics

Denise Calaprice-Whitty CONSULTANT-Avoca

Bradley Carlin CONSULTANT-American Statistical Association, Merck & Co., Inc., GRANT SUPPORT-Amgen, Eli Lilly and Company, NIH, Vistakon

Lawrence Carter OTHER SUPPORT-Employee of Jazz Pharmaceuticals, STOCK SHAREHOLDER-Jazz Pharmaceuticals

Elisa Cascade OTHER SUPPORT-DrugDev.org

Thomas Casola STOCK SHAREHOLDER-Shire Specialty Pharma/Merck & Co., Inc.

Chwen-Cheng Chen STOCK SHAREHOLDER-Biogen Idec, Gilead, Pfizer Inc

Chris Chinn OTHER SUPPORT-Employee of GlaxoSmithKline, STOCK SHAREHOLDER-GlaxoSmithKline

Robert Clay CONSULTANT-Highbury Regulatory Science; Kinapse, STOCK SHAREHOLDER-AstraZeneca

David Clemow STOCK SHAREHOLDER-Eli Lilly and Company

Jemma Contreras OTHER SUPPORT-Employee of Campbell Alliance

Cheryl Coon OTHER SUPPORT-Employee of Adelphi Values

Brenda Crowe OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER- Eli Lilly and Company

Eric David OTHER SUPPORT-Organovo, Inc, STOCK SHAREHOLDER-Organovo, Inc

Robert Di Cicco OTHER SUPPORT-Employee of GlaxoSmithKline, STOCK SHAREHOLDER-GlaxoSmithKline

Douglas Faries OTHER SUPPORT-Employee of Eli Lilly and Company

Thomas Felix OTHER SUPPORT-Employee of Amgen, STOCK SHAREHOLDER-Amgen

Eva Finney OTHER SUPPORT-Employee of Merck & Co., Inc.

Stacey Fung OTHER SUPPORT-Employee of Genentech, A Member of the Roche Group

Helle-Mai Gawrylewski STOCK SHAREHOLDER-Johnson & Johnson

Stewart Geary OTHER SUPPORT-Employee of Eisai, STOCK SHAREHOLDER-Eisai Co., Ltd.

Gary Gintant OTHER SUPPORT-Employee of AbbVie

Cynthia Girman STOCK SHAREHOLDER-Merck & Co., Inc.

Vanessa Graham OTHER SUPPORT-Employee of Amgen Inc.

Alison Greene OTHER SUPPORT-Employee of Genentech, A Member of the Roche Group, STOCK SHAREHOLDER-Johnson & Johnson, Roche

William Gregory OTHER SUPPORT-Employee of Pfizer Inc, STOCK SHAREHOLDER-Pfizer Inc

Alberto Grignolo OTHER SUPPORT-Employee of PAREXEL International

Jonathan Haddad OTHER SUPPORT-Employee of GlaxoSmithKline

Ann Marie Hake OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company

Aaron Hambrick OTHER SUPPORT-Employee of AbbVie Inc., STOCK SHAREHOLDER Abbott Labs, AbbVie Inc.

Peter Harpum CONSULTANT-LEO Pharma, UCB

Yun-Yi He OTHER SUPPORT-Employee of Johnson & Johnson, STOCK SHAREHOLDER-Johnson & Johnson

Deborah Henderson OTHER SUPPORT-Employee of Merck & Co., Inc., STOCK SHAREHOLDER-Merck & Co., Inc.

Lisa Hess OTHER SUPPORT-Employee of Eli Lilly and Company

Alan Hochberg OTHER SUPPORT-Employee of F. Hoffmann La Roche, Ltd., STOCK SHAREHOLDER-F. Hoffmann-La Roche Ltd.

Peter Honig OTHER SUPPORT-Director, Celladon Corp and Orexigen, STOCK SHAREHOLDER-AstraZeneca, Merck & Co., Inc.

Disclosure Statements (as of May 5, 2014), *continued*

Florence Houn	STOCK SHAREHOLDER-AbbVie, Celgene
Jason C. Hsu	STOCK SHAREHOLDER-Taiwan Food and Drug Administration
John Humphreys	OTHER SUPPORT-Employee of IMS Health
Michael Ibara	STOCK SHAREHOLDER-Pfizer Inc.
Ekopimo Ibia	OTHER SUPPORT-Employee of Merck Sharp & Dohme Corp.
Nirdosh Jagota	STOCK SHAREHOLDER-Roche
Deepika Jalota	OTHER SUPPORT-Employee of Bayer, STOCK SHAREHOLDER-Amgen, Bayer, Johnson & Johnson, Procter & Gamble, Sanofi
Janet Jenkins-Showalter	OTHER SUPPORT-Employee of Genentech, A Member of the Roche Group, STOCK SHAREHOLDER-Genentech, A Member of the Roche Group
Silke Jörgens	OTHER SUPPORT-Employee of Aptiv Solutions
John Kamp	OTHER SUPPORT-Executive Director of CHC
Albin Karimattam	STOCK SHAREHOLDER-Spouse with Novartis
Michael Keiser	STOCK SHAREHOLDER-SeaChange Pharmaceuticals Inc
Michael Kelley	OTHER SUPPORT-Employee of Amgen Inc., STOCK SHAREHOLDER-Amgen Inc.
Mark Kryah	OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Monica Kwarcinski	OTHER SUPPORT-Employee of Purdue Pharma L.P.
Haley Laken	STOCK SHAREHOLDER-Tesaro
Courtland LaVallee	STOCK SHAREHOLDER-Elan, Pfizer, Theravance
Andrew Lawton	OTHER SUPPORT-Employee of Boehringer Ingelheim
Hanns-Georg Leimer	OTHER SUPPORT-Employee of Boehringer Ingelheim
Barbara Leishman	OTHER SUPPORT-Employee of F. Hoffmann-La Roche Ltd, STOCK SHAREHOLDER-F. Hoffmann La Roche Ltd.
Alexander Liede	OTHER SUPPORT-Employee of Amgen Inc., STOCK SHAREHOLDER-Amgen Inc.
Craig Lipset	OTHER SUPPORT-Employee of Pfizer Inc, STOCK SHAREHOLDER-Pfizer Inc
Michele Livesey	CONSULTANT-Genentech, A Member of the Roche Group
Brian Loew	OTHER SUPPORT-Spouse employee of Merck & Co., Inc.
Michael Maher	OTHER SUPPORT-Employee of Pfizer Inc, STOCK SHAREHOLDER-Pfizer Inc
Frank Malinoski	CONSULTANT-TD Consultancy, OTHER SUPPORT-Gerson Lerman Group, Guidepoint Global, STOCK SHAREHOLDER-Envisia Therapeut, Liquidia Technologies
Peter Mallow	OTHER SUPPORT-Employee of S2 Statistical Solutions
Barry Mangum	CONSULTANT-Kirin, Pfizer, Shire, SOBI, GRANT SUPPORT-NIH
Marie Manley	OTHER SUPPORT-Employee of Bristows LLP
Christopher Marrone	OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Lisa Mathis	OTHER SUPPORT-Employee of Amgen Inc, STOCK SHAREHOLDER-Amgen Inc
Brian Mayhew	OTHER SUPPORT-Employee of Novartis, STOCK SHAREHOLDER-Novartis
Ellen McErlean	GRANT SUPPORT-Eli Lilly and Company
Lindsay McNair	OTHER SUPPORT-Employee of WIRB-Copernicus Group
Ann Meeker-O'Connell	OTHER SUPPORT-Employee of Janssen, a Johnson & Johnson Pharmaceutical Company
Marilyn Metcalf	STOCK SHAREHOLDER-GlaxoSmithKline, Johnson & Johnson
Alan Minsk	OTHER SUPPORT-Employee of Arnall Golden Gregory LLP
Royce Morrison	OTHER SUPPORT-Employee of Quorum Review IRB
Mary Murray	GRANT SUPPORT-Bonnie J Addario Lung Cancer Foundation
April Naegeli	OTHER SUPPORT-Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Moheb Nasr	OTHER SUPPORT-GlaxoSmithKline, STOCK SHAREHOLDER-GlaxoSmithKline
Gerrit Nijveldt	OTHER SUPPORT-Employee of Sanofi, STOCK SHAREHOLDER-Sanofi
Frances Nolan	STOCK SHAREHOLDER-Medidata Solutions
Becky Norquist	OTHER SUPPORT-Employee of Norquist Consulting
Susan Nunchuck	STOCK SHAREHOLDER-3M, Actelion Pharmaceuticals
Ricardo Nunez	OTHER SUPPORT-Employee of ICON Clinical Research
David Ohlssen	STOCK SHAREHOLDER-Novartis
Sally Okun	STOCK SHAREHOLDER-PatientsLikeMe
Pradip Paul	STOCK SHAREHOLDER-Vertex Pharmaceuticals
Carl Peck	CONSULTANT-NDA Partners LLC, STOCK SHAREHOLDER-NDA Partners LLC
Julia Petses	OTHER SUPPORT-Employee of Sanofi U.S.
Timothy Phelan	STOCK SHAREHOLDER-Merck & Co., Inc.
Christine Pierre	CONSULTANT-RxTrials, STOCK SHAREHOLDER-RxTrials and SCRS
Cesare Pinto	OTHER SUPPORT-Employee of Bayer Health Care
John Poland	OTHER SUPPORT-Employee of Covance Inc., STOCK SHAREHOLDER-Covance Inc.
Richard Preston	CONSULTANT-Ferring Inc, GRANT SUPPORT-Abbvie, Celerion, Celgene, Cempra, Chias, OTHER SUPPORT-Book royalties MedMaster Inc
Karen Price	OTHER SUPPORT-Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Frances Pu	OTHER SUPPORT-Employee of Renaissance Writing Services, LLC
Kim Quaintance	OTHER SUPPORT-Employee of Eisai Inc.
Wayne Rackoff	OTHER SUPPORT-Employee of Janssen R&D
G.K. Raju	CONSULTANT-US FDA

Disclosure Statements (as of May 5, 2014), *continued*

Andrew Rankin	OTHER SUPPORT-Employee-Prescient Life Sciences/Qforma
Badri Rengarajan	OTHER SUPPORT-Employee of Evidera
John Rizzo	CONSULTANT-CTI
Carol Robertson-Plouch	OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Jim Rogers	STOCK SHAREHOLDER-Nextrials
Klaus Rose	OTHER SUPPORT-Employee of klausrose Consulting, STOCK SHAREHOLDER-Novartis, Roche
Matthew Rotelli	STOCK SHAREHOLDER-Eli Lilly and Company
Esther Sadler-Williams	OTHER SUPPORT-Employee of Catalent Pharma Solutions
Philip Sager	CONSULTANT-I Cardiac, Biomedical Systems, ICON, STOCK SHAREHOLDER-I Cardiac
Abdul Sankoh	OTHER SUPPORT-Employee of Vertex Pharmaceuticals
Alan Santos	OTHER SUPPORT-Employee of Pyramid Healthcare Solutions
Andreas Sashegyi	STOCK SHAREHOLDER-Eli Lilly and Company
Frank Sasinowski	OTHER SUPPORT-Employee of Hyman Phelps & McNamara
Rick Sax	STOCK SHAREHOLDER-Quintiles
Michael Schatz	CONSULTANT-Amgen, Boston Scientific, GRANT SUPPORT-Aerocrine, Genentech, A Member of the Roche Group, GlaxoSmithKline, OTHER SUPPORT-MedImmune, Merck & Co., Inc.
Mark Schweitzer	STOCK SHAREHOLDER-ABV, ABT, PFE
John Seeger	CONSULTANT-Optum, WHISCON
Saad Shakir	CONSULTANT-SAS sits on data safety management boards and provides consultancy to pharmaceutical companies, Amgen, Intermune, IPSEN Pharma, Shire Pharmaceuticals, OTHER SUPPORT-Employee of DSRU
Gary Shangold	CONSULTANT-Enteris, Johnson & Johnson, Therapeutics MD, STOCK SHAREHOLDER-InteguRx Therapeutics LLC
David Shoemaker	CONSULTANT-Cancer Prev & Res Inst of Texas
Leigh Shultz	OTHER SUPPORT-Employee of Merck & Co., Inc., STOCK SHAREHOLDER-Merck & Co., Inc.
C. Grant Simmons	OTHER SUPPORT-Employee of Novartis, STOCK SHAREHOLDER-Novartis
Gurparkash Singh	OTHER SUPPORT-Janssen Pharmaceuticals Inc, STOCK SHAREHOLDER-Bristol-Meyers Squibb, Johnson & Johnson, Merck and Co., Inc.
Damon Smith	OTHER SUPPORT-Employee of Altus, STOCK SHAREHOLDER-Altus Formulation
Joanne Spallone	STOCK SHAREHOLDER-Novartis
J. Michael Sprafka	STOCK SHAREHOLDER-Amgen
Paula Stafford	STOCK SHAREHOLDER-Quintiles Transnational Holdings Inc.
Annette Stemhagen	OTHER SUPPORT-Employee of United BioSource Corporation
Jeffrey Stuart	OTHER SUPPORT-Employee of Novartis, STOCK SHAREHOLDER-Enzon Pharmaceuticals, Novartis
Brandon Suehs	GRANT SUPPORT-Astellas, Novo Nordisk, Pfizer Inc, STOCK SHAREHOLDER-Humana, Inc.
Linda Sullivan	OTHER SUPPORT-Owner, Metrics Champion Consortium
Thomas Sullivan	STOCK SHAREHOLDER-Castle Biosciences
Masayo Takahashi	GRANT SUPPORT-Healios K.K., Kyorin Pharmaceutical Co., Ltd., Nidek Co., Ltd.
Susan Tansey	STOCK SHAREHOLDER-Pfizer Inc
Pamela Tenaerts	OTHER SUPPORT-Employee of Duke University
Patrick Thomas	OTHER SUPPORT-Employee of GlaxoSmithKline, STOCK SHAREHOLDER-GlaxoSmithKline
Carolynn Thomas-Jones	OTHER SUPPORT-Employee of University of Alabama at Birmingham
Gary Thompson	STOCK SHAREHOLDER-Eli Lilly and Company
Paul Tomkins	OTHER SUPPORT-Employee of Gilead Sciences, STOCK SHAREHOLDER-Gilead Sciences
Heather Turner	OTHER SUPPORT-Employee of Orexigen Therapeutics, STOCK SHAREHOLDER-Orexigen Therapeutics
Jay Turpen	STOCK SHAREHOLDER-Eli Lilly and Company
Hans van Bruggen	STOCK SHAREHOLDER-eCTDconsultancy; Qdossier
Jennifer Vande Weghe	OTHER SUPPORT-Employee of Amgen, Inc.
Jurgen Venitz	CONSULTANT-Alexion, Altria Client Services, Elusys, Euthymics, Furiex, Molecules for Health, N30, Otsuka, Purdue, OTHER SUPPORT-Member, Scientific Advisory Board for AesRx, Member, Board of Directors, Myasthenia Gravis Foundation
Rebecca Vermeulen	STOCK SHAREHOLDER-Genentech, A Member of the Roche Group
Jose Luis Viramontes	OTHER SUPPORT-Employee of PPD
Thomas Wallace	OTHER SUPPORT--Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company
Keith Wenzel	OTHER SUPPORT-Employee of PAREXEL
Mary Westrick	CONSULTANT-University of Wisconsin-Madison, OTHER SUPPORT-Employee of Quintiles
John Whitebrook	OTHER SUPPORT-Employee of Deloitte
Jeremy Whitty	GRANT SUPPORT-EUPATI, Pharmatrain (EU FP7 Projects), OTHER SUPPORT-Employee of Hibernia College
Beat Widler	OTHER SUPPORT-Employee of Widler & Schiemann AG, STOCK SHAREHOLDER-Cytos, Roche
Leslie Williams	STOCK SHAREHOLDER-ImmusanT
Brett Wilson	STOCK SHAREHOLDER-Bristol-Myers Squibb
Simon Wilson	OTHER SUPPORT-Employee of ArisGlobal
Liz Wool	STOCK SHAREHOLDER-QD-Quality and Training Soultions, Inc.

Disclosure Statements (as of May 5, 2014), *continued*

Gerald Yakatan	CONSULTANT-Avanir Pharmaceuticals, Cosmederm, RxBio, GRANT SUPPORT-NCI, NIH, STOCK SHAREHOLDER-IriSys, Inc
Michele Yelmene	OTHER SUPPORT-Employee of Pharmalink Consulting
Javier Zambrano	OTHER SUPPORT-Employee of Biogen Idec
Richard Zink	OTHER SUPPORT-Employee of SAS Institute, Inc.
Frances Zipp	CONSULTANT-Lachman Consulting, OTHER SUPPORT-Teva
David Zuckerman	OTHER SUPPORT-Owner of Metrics Champion Consortium

The following PIM planners and managers, Laura Excell, ND, NP, MS, MA, LPC, NCC; Trace Hutchison, PharmD; Samantha Mattiucci, PharmD, CCMEP; and Jan Schultz, RN, MSN, CCMEP hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.

The following DIA planners and managers, Melissa Buchanan; Susan Cantrell; Julie Ho; Barbara Lopez Kunz; Holly Stevens; Karen Tenaglia; and Ben Zaitz, hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months. The DIA planner and manager, Maureen Lamplugh, has disclosed that she is a stock shareholder of Express Scripts, Merck & Co., Inc.

The following DIA Pharmacy Committee members have disclosed the following: Alan F. Boyd, RPh, stock shareholder of CNS Vital Signs, LLC; David M. Cocchetto RPh, PhD, employee of Costco and Duke University Health System and stock shareholder of GlaxoSmithKline, Teva; Teresa P. Dowling, PharmD, stock shareholder of AstraZeneca, Merck & Co., Inc., and Vertex Pharmaceuticals and employee of Vertex Pharmaceuticals; Truus Janse-de Hoog, PharmD, MSc, no financial relationships; J. Christopher Prue, RPh, MBA, employee of Cerenis Therapeutics.

The following project management professional reviewer Thomas R. Dunson, MBA, PMP has disclosed no financial relationships.

NOTES

UNIVERSAL ACTIVITY NUMBERS

Below are the pharmacy designated Universal Activity Numbers (UANs) and type of activity that is applicable for each of the following program offerings:

MONDAY, JUNE 16

Number	Session Title	Assigned UAN	Type of Activity
102	Bringing the Patient Voice to Clinical Development	0286-0000-14-510-L04-P	Knowledge
103	Does One Size Fit All? Understanding the Impact of Cultural Differences Across the Globe	0286-0000-14-511-L04-P	Application
108	Delivering Value Through Medical Content to Health Care Providers	0286-0000-14-512-L04-P	Knowledge
109	Central Statistical Monitoring Revealed: How to Enhance Data Quality and 'De-Risk' Studies Through Enhanced Risk-Based Monitoring	0286-0000-14-513-L04-P	Knowledge
110	Data Warehousing and Integration: Current Status, Key Success Ingredients and Alternative Approaches for Maximizing the Value of Your Data	0286-0000-14-514-L04-P	Knowledge
119	The Twitter Value Proposition for Life Science Professionals	0286-0000-14-515-L04-P	Application
122	Adaptive Monitoring: One Company's Experience with Practical Implementation	0286-0000-14-516-L04-P	Knowledge
123	Engaging Patients through Digital and Social Media Communities	0286-0000-14-517-L04-P	Knowledge
131	Why Waste Time and Money? Data Standards from the Beginning: Working Together for Good Science and Good Submissions	0286-0000-14-518-L04-P	Knowledge
133	Pediatric Drug Development: Lessons Learned During FDASIA Implementation	0286-0000-14-519-L04-P	Knowledge
134	Fact or Fiction: Patient Engagement in the Drug Development Process	0286-0000-14-520-L04-P	Knowledge
138	Observational Studies of Comparative Effectiveness: How to Recognize Good Practice	0286-0000-14-521-L04-P	Knowledge
139	Assessment of Impact and Effectiveness of Risk Management and Minimization in the EU and US	0286-0000-14-522-L04-P	Knowledge
141	Strategic Quantitative Thinking: Designing a Roadmap for Innovation	0286-0000-14-523-L04-P	Knowledge
142	Narrative Medicine: How to Tap into the Inherent Power of Words and Stories in the Clinical Trial Process	0286-0000-14-524-L04-P	Application

TUESDAY, JUNE 17

Number	Session Title	Assigned UAN	Type of Activity
202	Collaboration in R&D: What's New for TransCelerate BioPharma?	0286-0000-14-525-L04-P	Knowledge
203	Monitor Training: Building Essential Skills for Implementing Risk-Based Monitoring - Data Interpretation, Quality by Design	0286-0000-14-526-L04-P	Application
207	Nanotechnology: Application to Medical Products	0286-0000-14-527-L04-P	Knowledge
208	Prescription Drug Marketing Regulatory Primer	0286-0000-14-528-L04-P	Application
209	Communicating Clinical Trial Results: Targeting the Patient Audience	0286-0000-14-529-L04-P	Knowledge
210	Electronic Source Data in Clinical Investigations (Part 1 of 2): Regulatory Considerations	0286-0000-14-530-L04-P	Knowledge
211	Clinical Outcomes Assessment and Patient Engagement Symposium	0286-0000-14-531-L04-P	Knowledge
212	Bioinformatics and Translational Medicine	0286-0000-14-532-L04-P	Knowledge
220	Using Comparative Effectiveness Research to Make Health Care Decisions: Exploring the Environment, Opportunities, and Challenges Through Real-World Examples	0286-0000-14-533-L04-P	Knowledge
222	Mitigating Missing Data in Clinical Trials: Moving Toward Global Behavioral Change Impacts Efficacy, Safety, and Quality	0286-0000-14-534-L04-P	Knowledge
227	Risk-Based Monitoring: From Concept to Practice	0286-0000-14-535-L04-P	Knowledge
228	Improving the Informed Consent Process	0286-0000-14-536-L04-P	Knowledge
229	Social Listening as a Tool to Inform Study Teams on Social Media Strategy for Recruitment and Building Patient-Centric Trials	0286-0000-14-537-L04-P	Knowledge
235	Preparing for a Successful Product Launch	0286-0000-14-538-L04-P	Knowledge
236	Update on Postmarketing Safety Reporting	0286-0000-14-539-L04-P	Knowledge
237	Improving Communication in the Informed Consent Process: The Advantages of eConsent	0286-0000-14-540-L04-P	Application
238	Electronic Source Data in Clinical Investigations (Part 2 of 2): Practical Implementation	0286-0000-14-541-L04-P	Knowledge
239	FDA Programs to Encourage Innovation: Maximizing the Opportunities and Confronting the Challenges of New Product Development	0286-0000-14-542-L04-P	Knowledge
242	Health Care's Revolutionary Printing Press? 3D Printing - Blue Sky and Regulatory Path	0286-0000-14-543-L04-P	Knowledge
247	Impact of Bayesian Methods in Drug Development with a Focus on Comparative Effectiveness Research	0286-0000-14-544-L04-P	Knowledge
248	Networking: It's Not What You Know, But Who You Know!	0286-0000-14-545-L04-P	Application

249	Industry Trends, Successes and Failures in Orphan and Rare Disease Therapeutics	0286-0000-14-546-L01-P	Knowledge
256	Optimization of and Enhancements to Interactive Response Technology to Ensure Efficient Investigational Product and Study Material Management	0286-0000-14-547-L04-P	Knowledge
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265	Embracing Change: The New Face of Clinical Data Management	0286-0000-14-550-L04-P	Knowledge
266	Enabling Participants' Access to the Electronic Clinical Trial Data: The Blue Button Project	0286-0000-14-551-L04-P	Knowledge
268	How to Make a Successful Electronic Registration and Listing Submission: NDC, Regulatory Compliance, and Technical Requirements	0286-0000-14-552-L04-P	Knowledge
270	Digital Health: Mobile Medical Apps and the Future of Health Care Delivery	0286-0000-14-553-L04-P	Knowledge
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276	How Do We Keep Kids Safe? Pediatric Safety Monitoring From Beginning to End	0286-0000-14-555-L04-P	Knowledge
278	Yes and ... Applying Improvisational Skills to Improve Innovation	0286-0000-14-556-L04-P	Application
281	Perfecting the Protocol: Designing Studies for Success	0286-0000-14-557-L04-P	Knowledge
282	Patient Registries: Designing, Implementing, and Leveraging to Accelerate Clinical Trials	0286-0000-14-558-L04-P	Knowledge
283	Development of Central Nervous System Drugs with Abuse Potential	0286-0000-14-559-L01-P	Knowledge
284	How a New Collaboration Between a Biopharmaceutical Company and a CRO Is Improving the Quality, Speed, and Efficiency of Drug Development	0286-0000-14-560-L04-P	Knowledge
287	Our First Year Under Sunshine: Impact on Medical and Scientific Communications	0286-0000-14-561-L04-P	Knowledge
289	Electronic Standardized Study Data: Regulatory Considerations	0286-0000-14-562-L04-P	Knowledge
290	Transforming Culture and Mindsets to Deliver a Higher Quality eTMF	0286-0000-14-563-L04-P	Knowledge
291	Prequalification of Medicines for Neglected Tropical Diseases	0286-0000-14-564-L01-P	Knowledge
295	Adapting GCPs to Evolving Drug Development Paradigm (Part 2 of 2)	0286-0000-14-565-L04-P	Knowledge
298	Assessing Comparative Effectiveness Research Feasibility and Interpretability A Priori	0286-0000-14-566-L04-P	Knowledge
299A	Evaluating Potential Contribution of Social Media to Postmarketing Medication Safety Surveillance	0286-0000-14-567-L04-P	Knowledge
299C	Key Subgroup Analysis Issues in Clinical Trials	0286-0000-14-568-L04-P	Knowledge
299E	Orphan Drugs and Treatment of Rare Diseases in Asia	0286-0000-14-569-L01-P	Knowledge

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309	CDISC BRIDG Implementation: A Model for System Interoperability and as a Data Base Model	0286-0000-14-570-L04-P	Knowledge
310	Clinical Trials Technology Implementation: Bringing Together Patient- and Site-Centric Approaches	0286-0000-14-571-L04-P	Knowledge
316	Balancing Manufacturing Quality Improvements and Drug Shortage	0286-0000-14-572-L04-P	Knowledge
318	Leveraging Electronic Health Record Data to Understand Clinical Nuance in Complex Real-World Populations: A Case Study	0286-0000-14-573-L04-P	Knowledge
319	Signal Detection: Challenges and Strategic Aspects	0286-0000-14-574-L04-P	Knowledge
322	Seeing Is Believing! Good Graphic Design Principles for Medical Research	0286-0000-14-575-L04-P	Knowledge
324	International Cooperation in Rare Disease Research	0286-0000-14-576-L04-P	Knowledge
326	Risk-Based Monitoring Symposium	0286-0000-14-577-L04-P	Knowledge
328	Clinical Supply Symposium	0286-0000-14-578-L04-P	Knowledge
334	Field-Based Medical Communications on a Global Scale	0286-0000-14-579-L04-P	Knowledge
336	Emerging Technologies in Regulatory Science	0286-0000-14-580-L04-P	Knowledge
338	From the Protocol to the Patient: Clinical Trial Data Disclosure	0286-0000-14-581-L04-P	Knowledge
340	Approaches to Decrease the Time Gap Between FDA Approval and the Ability to Market a DEA Scheduled Drug	0286-0000-14-582-L04-P	Knowledge
344	Public-Private Partnerships: An Innovative Strategy for Patient Registries	0286-0000-14-583-L04-P	Application
346	Expanding the Scope: Empowering the Public in Pharmacovigilance	0286-0000-14-584-L04-P	Knowledge
348	Be a Change Agent: Leveraging Communication and Training Tools to Help Promote Project and Career Transformation	0286-0000-14-585-L04-P	Knowledge
350	The Patient Point-of-View: An Unrehearsed but Revealing Conversation to Rectify Patient Enrollment	0286-0000-14-615-L04-P	Knowledge

353	Hot Topics in Patient Recruitment: Global Demographics, Underrepresented Populations, and the Science Behind Patient Communications	0286-0000-14-586-L04-P	Knowledge
354	Social Media in Patient Recruitment: How to Best Leverage the Digital Ecosystem	0286-0000-14-587-L04-P	Knowledge
359	Broadening Health Care Communications: Learnings from Health Authority Initiatives	0286-0000-14-588-L04-P	Knowledge
360	Innovative Direct-to-Patient Study Model to Capture PRO Instrument Validation Data for Submission to a Regulatory Authority	0286-0000-14-589-L04-P	Knowledge
363	Benefit-Risk Assessments of Medicines: Framework Development and Use in Marketing Applications	0286-0000-14-590-L04-P	Knowledge
369	Nesting Studies Within Patient Registries to Support Comparative Effectiveness Research	0286-0000-14-591-L04-P	Application
370	Natalizumab and Progressive Multifocal Leukoencephalopathy: A Risk Management Case Study	0286-0000-14-592-L01-P	Knowledge
371	The Role of Intelligent Signaling in Digital Disease Detection and Proactive Pharmacovigilance	0286-0000-14-593-L04-P	Knowledge
375	Optimizing Orphan Drug Development and Using Appropriate Methodology: Key Tips for Success	0286-0000-14-594-L01-P	Application
377	Filling the Gaps and Speeding Up Results: What an Educated, Sophisticated Patient Population Can Do for You	0286-0000-14-595-L04-P	Knowledge
378	Optimize Protocol Design: A Path to Efficient, Lower Cost Trial Execution	0286-0000-14-596-L04-P	Knowledge
383	Powering Up Communications: Improving the Information Exchange Between Patients and Industry	0286-0000-14-597-L04-P	Knowledge
387	Why, When, and How Should Patients Be Involved in the Benefit-Risk Assessment of Medicines?	0286-0000-14-598-L04-P	Knowledge
389	The Realities of Late Life Cycle Management for Very Old Legacy Brands	0286-0000-14-599-L04-P	Knowledge
391	Industry in the Sunshine: How the "Sunshine" Provisions of the Affordable Care Act Will Change Industry Policy and Practice	0286-0000-14-600-L04-P	Knowledge
395	Compliance, Potential Financial Implications, and Impact of New Safety Measures	0286-0000-14-601-L04-P	Knowledge
396	Product Crisis Management: Crisis, What Crisis?	0286-0000-14-602-L04-P	Knowledge
398	Pediatric Trials: Improvements through Bayesian Methods, Adaptive Designs, and Modeling/ Simulation	0286-0000-14-603-L04-P	Knowledge
399B	Regulatory Challenges for Orphan Medicines	0286-0000-14-604-L04-P	Knowledge
399C	Informed Medication Use in Pregnancy: A Collaborative Approach to Address Needs for Data, Communication, and Engagement	0286-0000-14-605-L04-P	Knowledge

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405	Qualifying a Software Vendor in a Regulated Industry	0286-0000-14-607-L04-P	Knowledge
407	FDA Drug Claims Substantiation after IMS and Caronia: Will Court Scrutiny Based on the First Amendment Lead to Change in Current Policy and Practice?	0286-0000-14-608-L04-P	Knowledge
411	Safety in Special Situations: Stem Cells, Vaccines, and Combination Products	0286-0000-14-609-L04-P	Knowledge
414	CDER Town Hall (Part 1 of 2)	0286-0000-14-610-L04-P	Knowledge
418	Risk-Based Monitoring: Where We Are and Where We Are Headed	0286-0000-14-611-L04-P	Knowledge
419	Ethnic Difference in Clinical Trial Data: A 15-Year History of an Investigation by Regulatory Agencies and Industry	0286-0000-14-612-L04-P	Knowledge
425	Innovative Patient Recruitment Solutions for Rare Disease Clinical Trials	0286-0000-14-613-L04-P	Knowledge
426	CDER Town Hall (Part 2 of 2)	0286-0000-14-614-L04-P	Knowledge

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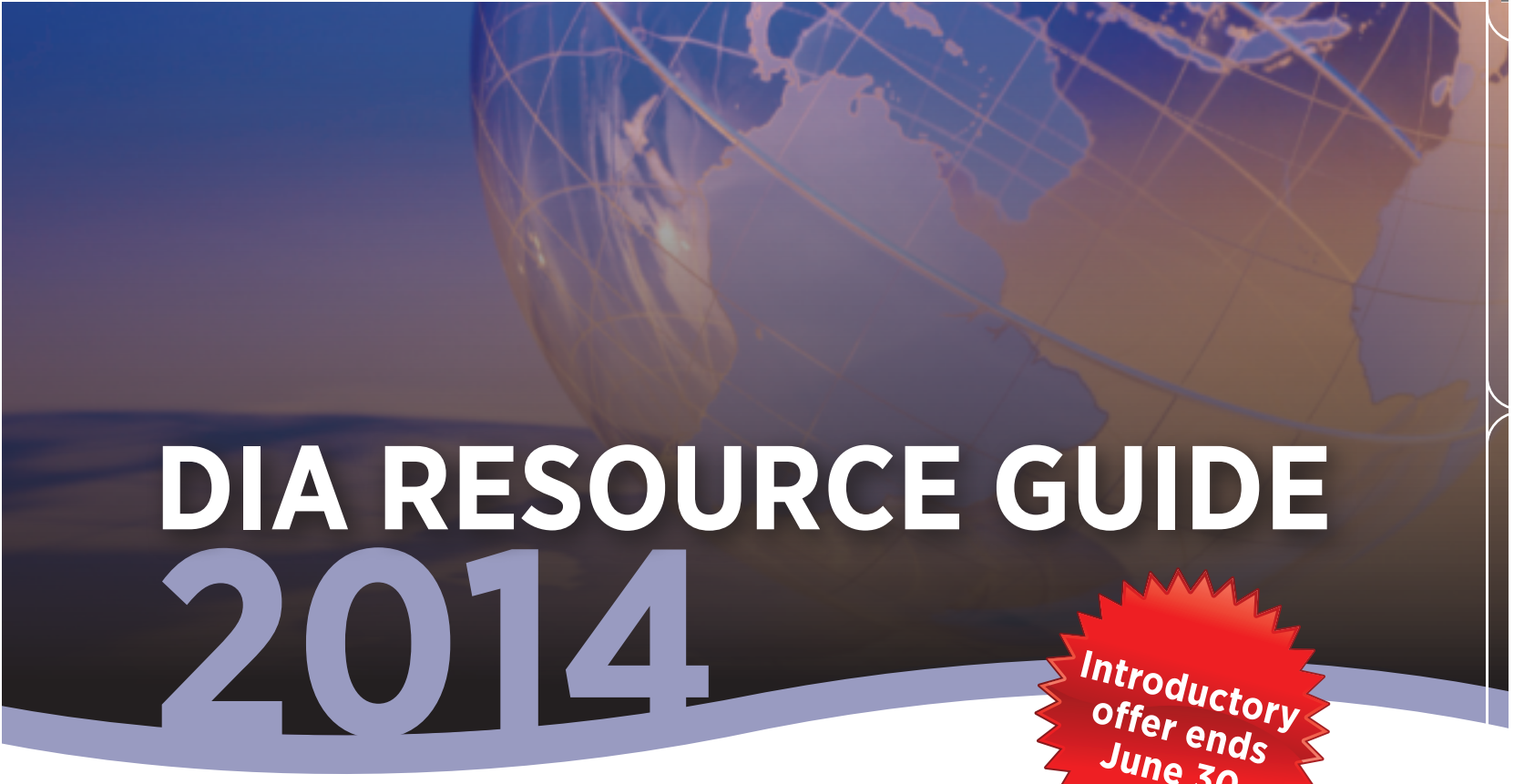

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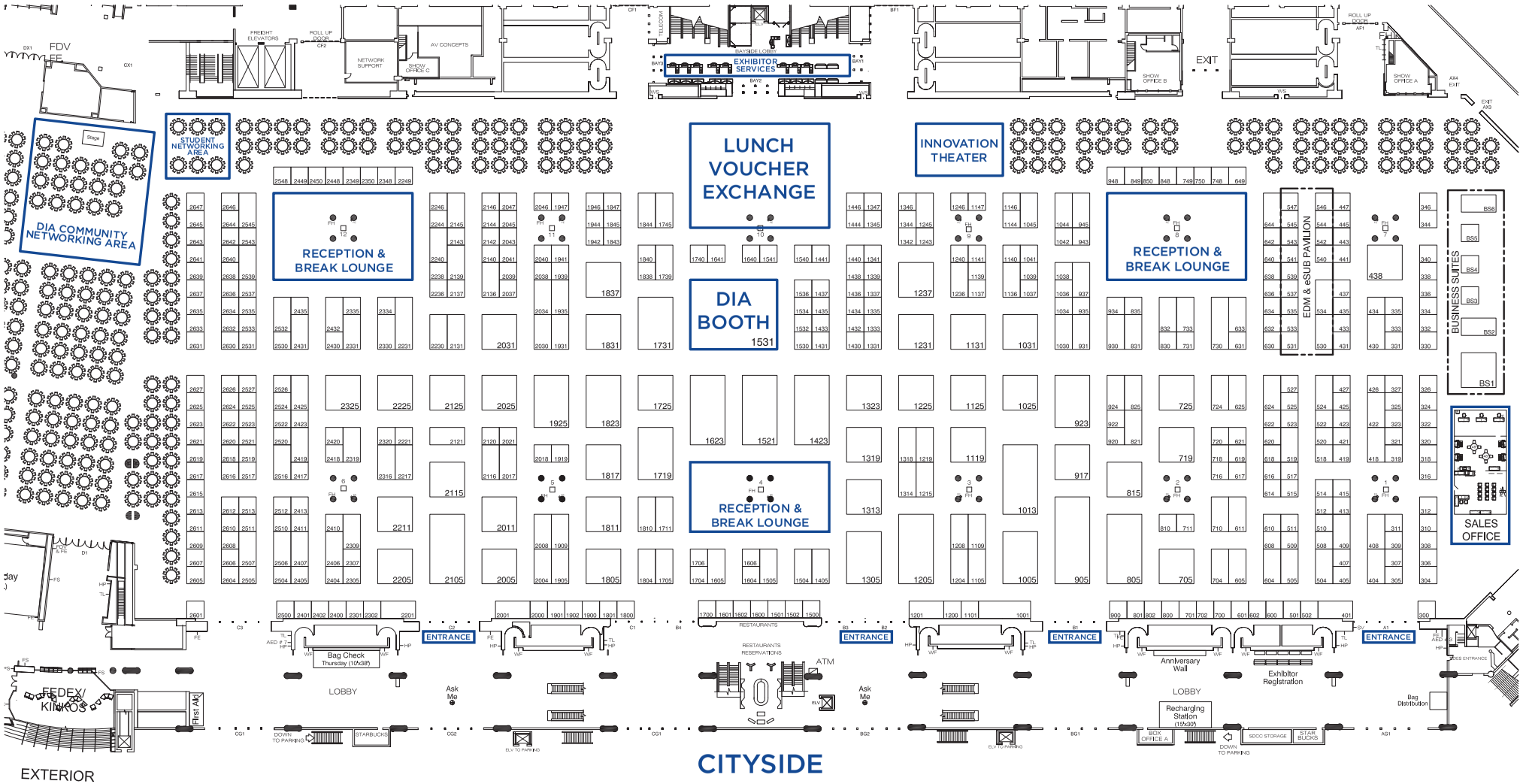

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Contact: Andrei Tsuba
Phone: +37-529-277-3027

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Phone: 240-238-4900
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Booth: 307
Contact: Sonja Riebel
Phone: +49-6196 7709-339
Email: sonja.riebel@accovion.com
Website: www.accovion.com

ACCOVION is a leading independent European full-service CRO. We provide the entire range of clinical research services to the pharmaceutical, biotechnology and medical device industries and are currently active in more than 20 countries. For more than 10 years we have been successfully conducting national and international clinical trials across all phases of clinical development. Quality, reliability and flexibility are the values that our clients can expect from Accovion.

Accurate Clinical Research
Booth: 718
Contact: Karen Obmaces
Phone: 281-481-8557
Email: kobmaces@accurateclinicalresearch.com
Website: www.accurateclinicalresearch.com

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ACM Global Central Lab
Booth: 2425
Contact: Cynthia Smith
Phone: 862-668-4092
Email: csmith@acmgloballab.com
Website: www.acmgloballab.com

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ACRP
Booth: 332
Contact: Jenna Rouse
Phone: 703-254-8109
Email: jenna@acrpnet.org
Website: www.acrpnet.org

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ActiGraph
Booth: 2046
Contact: Genevieve Murray
Phone: 850-332-7900
Email: sales@theactigraph.com
Website: www.actigraphcorp.com/

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Acurian, Inc.
Booth: 1811
Contact: Kirk McPoyle
Phone: 215-323-9000
Email: kirk.mcpoyle@acurian.com
Website: www.acurian.com

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Adicon Clinical Laboratory Inc.
Booth: 1600
Contact: Freyja Cheng
Phone: +86-215-429-8073
Website: www.adicon.com.cn

ADICON Clinical Trial Center,a leading full-service central lab for clinical trials in China, conducts activities to support new pharmaceutical developments including clinical trials and CRO (contract research organization) business. The company's comprehensive support for clinical trials contributes to realizing rapid and high quality pharmaceutical development.

Advanced Bio-Logic Solutions (ABL)
Booth: 2537
Contact: Jeff Epstein
Phone: 877-767-7550
Email: info@ablscorp.com
Website: www.ablscorp.com

ABL Solutions blends highly skilled people, processes, and best in class technology to offer interactive reporting solutions that enable life science companies to understand, examine, and interpret data across disparate sources. ABL's Workforce division delivers top talent to the industry via full time recruitment, assignment-based contract staff, and project-based services. ABL is passionate about partnering with their customers to deliver reliable, affordable, high-value solutions.

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Booth: 716
Contact: Julie Heneghan
Phone: 847-267-1176
Email: jheneghan@advancedclinical.com
Website: www.advancedclinical.com

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Aerotek
Booth: 1605
Contact: Kristen Caswell
Phone: 410-694-5160
Email: Kcaswell@aerotek.com
Website: www.aerotek.com

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Contact: Jean Cameron
Phone: 888-317-3395
Email: info@alfresco.com
Website: www.alfresco.com

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Allergan, Inc.
Booth: 719
Contact: Mary Mikels
Phone: 770-880-3570
Email: mikels_mary@allergan.com

Almac
Booth: 832
Contact: Erin Everett
Phone: 215-660-8500
Email: erin.everett@almacgroup.com
Website: www.almacgroup.com

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Booth: 2142
Contact: Sarah Park
Phone: 714-774-7777
Email: spark@act-trials.com
Website: www.act-trials.com

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Booth: 930
Contact: Suneet Walia
Phone: 609-455-1600
Email: americas@apcerpharma.com
Website: www.apcerpharma.com

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Contact: Appian
Phone: 703-442-8844
Email: info@appian.com
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Booth: 408
Contact: Anne Young
Phone: 732-596-0276
Email: ayoung@advanstar.com
Website: www.appliedclinicaltrialsonline.com

APPLIED CLINICAL TRIALS is a global peer reviewed journal that addresses the process of managing clinical trials at the intersection where pharmaceutical product developers meet the strictly regulated medical researchers who test their drugs. Applied Clinical Trials' audience is over 140,000 clinical trial professionals worldwide.

Aptiv Solutions
Booth: 1711
Contact: Lisa King
Phone: 703-483-6400
Email: info@aptivsolutions.com
Website: www.aptivsolutions.com

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Booth: 1013
Business Suite: BS3
Contact: David Liff
Phone: 203-588-3000
Email: info@arisglobal.com
Website: www.arisglobal.com

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Arizona State University
Booth: 320
Contact: Jessica Wells
Phone: 602-496-1948
Email: jessicawells@asu.edu
Website: nursingandhealth.asu.edu/DIA

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Artcraft Health Education
Booth: 433
Contact: Brian Schaechter
Phone: 908-782-4921 Ext. 4205
Email: Bschaechter@artcrafthealthed.com
Website: www.artcrafthealthed.com

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Asia CRO Alliance
Booth: 605
Contact: Sung Ho Cho
Phone: +82-220-149-500
Email: info@asiacroalliance.com
Website: www.asiacroalliance.com

The Asia CRO Alliance aims to provide clinical trials support to small and medium-sized pharma, biotech, medical device companies as well as multinational CROs. This innovative partnership was created to meet the demand for more options for conducting Asian clinical trials. Through its strong presence in Asia, the Asia CRO Alliance believes that it can help serve the demand by providing flexibility in its services and local expertise while working closely with sponsors and multinational CROs.

Asociacion Mexicana para la Investigacion Clinica, A.C. (AMIC)
Booth: 1147
Contact: Rodrigo Garcia Garagarza
Phone: +52-771-714-4377
Website: amic.com.mx

Aspire IRB
Booth: 2144
Contact: John Bancroft
Phone: 619-469-0108

AssurX Inc.
Booth: 646

August Research
Booth: 509
Contact: Liz Leff
Phone: +35-929-714-593
Email: lleff@augustresearch.com
Website: www.augustresearch.com

August Research is an American-owned niche CRO working exclusively in Central and Eastern Europe. August Research has operations in Bulgaria, Croatia, Czech Republic, Poland, Romania, Serbia and Slovakia, with office-based clinical staff. With more than 12 years of clinical trials experience in the region, the August Research team combines deep local expertise and American-style customer service.

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Booth: 2633
Contact: Adriana Hernandez
Phone: 408-701-1480
Email: adriana.hernandez@author-it.com
Website: www.author-it.com

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Axiom Real-Time Metrics Inc.
Booth: 1817
Contact: Andrew Schachter
Phone: 416-818-9800
Email: andrews@axiommetrics.com
Website: www.axiommetrics.com

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Axis Clinical Trials
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Contact: Lydie Hazan
Phone: 310-289-8242
Website: www.axistoday.com

Axis Clinical Trials specializes in Phase 1-3 Clinical Trials with Inpatient and K/PD capacities. Our expertise includes Asthma, CV, Dermatology, Endocrinology, GI, Hepatology, Metabolic, Nutritional, Pediatrics, OA, RA, Women's Health. Our centers of excellence are located in Los Angeles, Las Vegas, Miami and New York We are known as "rescue sites" Known to exceed enrollment goals with impeccable data integrity- Always on deadline. Watch us on ABC nationwide! as we represent ABC on a new series!

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Booth: 622
Contact: Kenneth Kim
Phone: 516-719-1052
Email: kkim@barcusa.com
Website: www.barclab.com

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Contact: Pippa Wilson
Phone: +44-129-377-6644
Email: pwilson@barringtonjames.com
Website: www.barringtonjames.com

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Contact: Founding Principals: Joan F. Bachenheimer and Bonnie A. Brescia
Phone: 617-630-4477
Email: info@bbkworldwide.com
Website: www.bbkworldwide.com

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Booth: 531
Contact: Christopher Kavlick
Phone: 913-451-3955
Email: info@beckloff.com
Website: www.cardinal.com/us/en/beckloff

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BioClinica
Booth: 1725
Contact: Stephen Boccardo
Phone: 888-392-7456
Email: sales@bioclinica.com
Website: www.bioclinica.com

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Biocom
Booth: 2632
Contact: Kira Jenkins
Phone: 858-455-0300 Ext. 117
Email: kjenkins@biocom.org
Website: www.biocom.org

Biocom is one of the largest regional life science associations in the world, representing more than 600 member companies in Southern California. The association focuses on initiatives that position the region's life science industry competitively on the world stage, and on the development and delivery of innovative products that improve health and quality of life. For more information on Biocom, please visit www.biocom.org.

Biomedical Systems
Booth: 1225
Contact: Kristy Galkowski
Phone: 314-576-6800
Email: kgalkowski@biomedsys.com
Website: www.biomedsys.com/

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BioPharm Insight
Booth: 2450
Contact: Holly Burke
Phone: 781-619-0131
Email: hburke@infinata.com
Website: www.biopharminsight.com

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BioPhase Solutions
Booth: 2511
Contact: James Whittington
Phone: 858-552-2000
Email: james@biophaseinc.com
Website: www.biophaseinc.com

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BioPoint
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Contact: Kevin Pike
Phone: 781-218-3790
Email: info@biopointinc.com
Website: www.biopointinc.com

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bioRASI
Booth: 2625
Contact: Steve Trattner
Phone: 786-888-1682

bioskin GmbH
Booth: 2230
Contact: Betsy Hughes-Formella, PhD
Phone: +49-406-068-970
Email: info@bioskinCRO.com
Website: www.bioskinCRO.com

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Blinded Diagnostics
Booth: 2047
Contact: Paul Savuto
Phone: 201-291-2822
Email: paul.savuto@blindeddiagnostics.com
Website: www.blindeddiagnostics.com

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Blue Chip Patient Recruitment
Booth: 2513
Contact: Ken Shore
Phone: 847-682-0287
Email: kshore@bluechipww.com
Website: www.bcpatientrecruitment.com

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Blue Sky Broadcast
Booth: 621
Contact: Jim Bohlen
Phone: 877-925-8375
Email: jbohlen@blueskybroadcast.com
Website: www.blueskybroadcast.com

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Contact: Stephane Deleger
Phone: 415-963-1773
Email: info@bracketglobal.com
Website: www.bracketglobal.com

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Booth: 501
Contact: David Dettore
Phone: 305-374-2500
Website: www.brandinstitute.com

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Contact: Carmela Houston-Henry
Phone: 516-470-6979
Email: choustonhen@brany.com
Website: www.brany.com

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Contact: Dave Hanaman
Phone: 866-327-6234
Email: sales@c3i-inc.com
Website: www.c3i-inc.com

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Booth: 1200
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Phone: 267-332-0051
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Phone: 312-297-6745
Email: clinicaltrials@cahg.com
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Camargo Pharmaceutical Services
Booth: 505
Contact: Jenna Heithoff
Phone: 513-561-3329
Email: jenna@scorrmarketing.com
Website: www.camargopharma.com/

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Cambridge Healthtech Institute
Booth: 323
Contact: Bethany Gray
Phone: 781-972-5400
Email: chi@healthtech.com
Website: www.healthtech.com/

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Canfield Scientific, Inc.
Booth: 319
Contact: Jenna Haslam
Phone: 973-276-0336
Email: info@canfieldsci.com
Website: www.canfieldsci.com/

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Cardio Analytics Ltd.
Booth: 1331
Contact: Kerri Mellor
Phone: +44-175-220-1144
Email: info@cardioanalytics.com
Website: www.cardioanalytics.com

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Cardiocore
Booth: 2211
Contact: Sara Daily
Phone: 301-214-7600
Email: sara.daily@cardiocore.com
Website: www.cardiocore.com

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Cardiovascular Imaging Technologies
Booth: 527
Contact: Staci Courter, MA, CCRP
Phone: 816-531-2842
Email: scourter@cvit.com
Website: www.cvit.com

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Contact: Lisa Gerrizzo
Phone: 732-537-6282
Email: info@catalent.com
Website: www.catalent.com

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Contact: Andrea Vadakin
Phone: 512-363-5826
Email: info@cdisc.org
Website: www.cdisc.org

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Celerion
Booth: 625
Contact: Farzana Azam
Phone: 402-476-2811
Email: info@celerion.com
Website: www.celerion.com

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Booth: 2325
Contact: Rebecca Galloway
Phone: 919-998-3372
Email: corp.communication@cenduit.com
Website: www.cenduit.com

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Center for Information and Study on Clinical Research Participation (CISCRP)
Booth: 1144
Contact: Ellyn Getz
Phone: 617-725-2750
Email: info@ciscrp.org
Website: www.ciscrp.org

The Center for Information and Study on Clinical Research Participation (CISCRP) is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. CISCRP is committed to engaging and building closer relationships among members of the public, clinical research volunteers, and clinical research professionals.

CenterWatch
Booth: 614
Contact: Amy Fontaine
Phone: 617-948-5172
Email: amy.fontaine@centerwatch.com
Website: www.centerwatch.com

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Chesapeake IRB
Booth: 2406
Contact: Lauri Carlile
Phone: 410-884-2900
Email: info@irbinfo.com
Website: www.chesapeakeirb.com

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Contact: Simon Venhuizen
Phone: 604-688-0366
Email: info@chexxinc.com
Website: www.chexxinc.com

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Booth: 2225
Contact: Spencer Jane Brunson
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Email: spencer.brunson@chiltern.com
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Cincinnati Children's Clinical Trial Services
Booth: 520
Contact: Sheri Selk
Phone: 513-803-0328
Email: sheri.selk@cchmc.org
Website: www.cincinnatichildrens.org/clinical-trials-office

Successful pediatric trials begin with well-designed protocols and strategic planning. Cincinnati Children's Clinical Trial Services can partner with you on your pediatric study plans from concept to final study report. We have expertise in PK/PD modeling, pharmacometrics, study design optimization, pediatric and adult protocol development, and full data coordinating center capabilities: biostatistics, data management, epidemiology, regulatory affairs, monitoring and pharmacovigilence.

Cincinnati Children's Research Foundation
Booth: 518
Contact: Mark Schuller
Phone: 513-636-0314
Email: mark.schuller@cchmc.org
Website: www.cincinnatichildrens.org/clinical-trials-office

Cincinnati Children's is a pediatric academic medical center and clinical research test site conducting Phase I-IV (all major therapeutic areas) and select adult Phase I-IV studies. AAHRPP accredited, it has more than 2250 active IRB approved protocols annually, more than 1100 investigators, 300 GCP trained study coordinators and 83 years of pediatric research experience. Contact our full-service Office for Clinical and Translational Research to place and conduct your next research study.

Citeline Inc.
Booth: 2000
Contact: Irene Fitzgerald
Phone: 646-957-8919
Email: irene.fitzgerald@citeline.com
Website: www.citeline.com

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CITI Program - University of Miami
Booth: 632
Contact: David Burnham
Phone: 305-243-7970
Email: citisales@med.miami.edu
Website: www.citiprogram.org

The Collaborative Institutional Training Initiative (CITI Program) at the University of Miami offers customizable, web-based training in Animal Care and Use, Biosafety and Biosecurity, Conflicts of Interest, Export Control, Good Clinical Practice, Human Subjects Research, Information Privacy and Security, and Responsible Conduct of Research. Visit www.citiprogram.org to learn more.

Clariness
Booth: 649
Contact: Carrie Swallow
Phone: 908-219-6131
Email: info@clariness.com
Website: www.clariness.com/

Clariness is a Global Patient Recruitment Service Provider offering multilingual solutions on 6 continents. Clearly focused on systems and online advertising, Clariness runs ClinLife™, the largest International patient recruitment platform—with 41 active ClinLife™ countries in 27 languages. ClinLife™, combined with our site and referral management systems and processes, have proven to be the most effective way to conduct and manage online patient recruitment campaigns and patient surveys.

ClinDatrix, Inc.
Booth: 1942
Contact: Matt Delaney
Phone: 949-428-6676
Email: matt.delaney@clindatrix.com
Website: www.clindatrix.com

ClinDatrix is committed to providing world class, full service clinical research capabilities and expertise to the biotechnology, medical device, and pharmaceutical industries. Partnering with its clients, ClinDatrix manages, monitors, collects, validates, analyzes, reports, and delivers quality global clinical data with efficiency and accuracy. The company offers pre-clinical and Phase I through Phase IV services to drug developers and pre-IDE, IDE and 501K support to device innovators.

ClinEdge, LLC
Booth: 308
Contact: Christian Burns
Phone: 857-496-0054
Email: christian@gmail.com
Website: www.clin-edge.com

ClinEdge is a full-service business development and marketing company dedicated to the success of Clinical Trials. We are dedicated to exceeding the expectations of our clients and contacts. We strive to increase the productivity, innovation and revenue of our clients through personalized services and a profound understanding of the clinical research industry.

Clinical Conductor
Booth: 421
Contact: Sergio Armani
Phone: 585-272-1960
Email: sales@bio-optronics.com
Website: www.bio-optronics.com/Products/ClinicalConductor/ClinicalConductorOverview.aspx

Clinical Conductor is the industry's first collaborative and configurable CTMS for organizations managing or executing clinical trials. Clinical Conductor is designed to provide users with the specific features and functionality they need to effectively collaborate with or among sites and other partners, deliver high-quality research and attain maximum profitability. Clinical Conductor CTMS provides organizations with the tools they need to continue to raise the bar in clinical research.

Clinical Contract Research Association (CCRA)

Booth: 1333

Contact: Sue Dilks
Email: mail@ccra.org.uk
Website: www.ccra.org.uk
Phone: +44-116-271-9727

If you are serious about the conduct of clinical trials to the highest standards and take any part in the industry (CRO or service provider in this sector) come and talk to us about membership! CCRA is the UK trade association which represents this sector and provides enhanced business opportunities and a bridge to Europe.

Clinical Ink

Booth: 624

Contact: Chris Ramm
Email: CRamm@clinicalink.com
Website: www.clinicalink.com
Phone: 336-714-7402

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Clinical Reference Laboratory

Booth: 1215

Contact: Debbie Felice
Website: www.crlcorp.com
Phone: 913-693-2550

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Clinical Research Advantage

Booth: 515

Contact: Casey Orvin
Email: caseyorvin@crastudies.com
Website: www.crastudies.com/
Phone: 480-305-5702

Clinical Research Advantage (CRA), Radiant Research, and Comprehensive Clinical Development (CCD) consists of 75 WHOLLY OWNED clinical research sites. From CRA's model of being embedded within private practice physician offices to Radiant and CCD's stand alone research centers, all three companies have provided excellent enrollment of clinical trials for the past 22+ years. Our sites have successfully conducted more than 11,000 multi-therapeutic Phase I-IV studies at our 75 sites nationwide.

Clinical SCORE

Booth: 333

Contact: Ross Weaver
Email: ross.weaver@clinical-score.com
Website: clinical-score.com
Phone: 877-334-0100

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Clinical Trials & Surveys Corp

Booth: 734

Contact: Christopher Donhauser
Email: cdonhauser@c-tasc.com
Website: www.c-tasc.com
Phone: 410-464-4182

Clinical Trials and Surveys Corp (C-TASC) is an award-winning business in Owings Mills, Maryland with a professional staff that includes: Biostatisticians, IT professionals, and CRAs. In our 25 years of existence, we have successfully completed projects for government, academic, and private entities by employing our lean/Agile business model synthesized with clinical industry best practices and standard operating procedures. We are experts in clinical trials and preparing data for FDA review.

ClinicalConnection, Inc.

Booth: 2533

Contact: Leslie Eisenberg
Email: leisenberg@clinicalconnection.com
Website: www.CinicalConnection.com
Phone: 800-887-0639 Ext. 906

Clinical Connection is the leading e-patient recruitment partner helping Sponsors/CROs harness the Internet for enrollment. With a quarter-of-a-million monthly visitors, its flagship, ClinicalConnection.com is the most visited non-government website for clinical trial searches and patient referrals. Services include customized trial listings and referral, PatientEdge™ database recruitment, online study ads, and screening recruitment websites with value-added features for clients and study sites.

clinicalRSVP

Booth: 330

Contact: Darran Boyer
Website: www.clinicalrsvp.com
Phone: 954-727-5785

ClinicalRSVP is the subject verification program supported by sites across North America that prevents research volunteers from enrolling in multiple concurrent research studies. This blinded registry allows investigators to confidentially and securely verify subject eligibility requirements prior to enrollment, resulting in improved data reliability and increased participant safety for the industry.

Clinlogix

Booth: 1041

Contact: JeanMarie Markham
Email: jmarkham@clinlogix.com
Website: www.clinlogix.com
Phone: 215-855-9054

Clinlogix is a full service global Clinical Research Service Organization providing outsourcing to the Biopharmaceutical/Medical Device Industry. Optimizing metrics-driven Project Management, Monitoring, Data Management & Investigator Site Identification Services using eClinical tools delivered by our team of experienced professionals, Clinlogix provides decreased project cycle time and cost-effective, quality data.

ClinPlus/DZS Clinical Services

Booth: 514

Contact: Bob Borysko and Greg Ambra
Email: bborysko@clinplus.com
Website: www.clinplus.com
Phone: 732-764-6969

DZS has been providing software and services supporting clinical trials to the life sciences industry since 1996. 65+ organizations currently depend on our clinical solutions for CDM, Coding, Trial Management and Statistical Reporting through ClinPlus software and our clinical services division.

ClinTec International Ltd.
Booth: 1201
Contact: Sam Baracella
Phone: 617-273-8236
Email: sbacarella@clintec.com
Website: www.clintec.com

ClinTec International is a global CRO, which was founded in 1997 by Dr Rabinder Buttar, the company's President and CEO. ClinTec has a presence in over 50 developed and emerging countries and excels in conducting clinical studies in diverse geographical locations, supported by a team of world class project managers, country managers and clinical research associates. ClinTec's 'fast, flexible and focused' approach to clinical research ensures an added advantage to the drug development process.

Clinverse, Inc.
Booth: 2432
Contact: Jeff Rogers
Phone: 919-746-7676
Email: jrogers@clinverse.com
Website: www.clinverse.com

Clinverse, Inc. architected the industry's first end-to-end technology solution that automates the financial lifecycle of global clinical trials. Powered by our secure technology platform, our solution standardizes clinical finance and manages millions of financial transactions across the globe, including clinical site payments. Used by leading BioPharma companies, our clients benefit from reduced workload, time, and costs gained through automation and unprecedented transparency and workflow.

CluePoints, Inc.
Booth: 733
Contact: Marie-Laure Dyck
Phone: 617-576-2005
Email: contact@cluepoints.com
Website: www.cluepoints.com/

CluePoints is a Central Statistical Monitoring solution that employs unique statistical algorithms to determine the quality, accuracy and integrity of clinical trial data. Aligned with guidance from the FDA and EMA, CluePoints is deployed to support traditional on-site monitoring and can be implemented as the engine to drive a risk-based monitoring strategy.

CMIC HOLDINGS Co., Ltd.
Booth: 917
Contact: Mizuho Arai
Phone: +81-35-745-7033
Email: mizuho-arai@cmic.co.jp
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CMIC - Your Strategic Partner to Lead You into the Asian Market CMIC is a one-stop gateway to the Asian market supporting pharmaceutical, biotechnology and medical device companies. Our quality services include pre-clinical and clinical research management, site management, manufacturing, sales / marketing, and consulting services which will be tailored to fit your unique specifications.

CNS Network
Booth: 304
Contact: Jessica Streit
Phone: 714-799-7799
Email: jessicastreit@cnstrial.com
Website: www.cnstrial.com

CNS has extensive experience performing Phase I-IV trials in special patient populations and Healthy Volunteers. In addition to a dedicated Phase I Clinical Pharmacology Unit in Long Beach, CA—CNS runs a licensed psychiatric unit and four outpatient locations.

Compass IRB
Booth: 1137
Contact: Will Stewart
Phone: 919-593-1357
Email: wstewart@compassirb.com
Website: www.compassirb.com

Compass IRB is a Central IRB located in Mesa, Arizona with full AAHRPP accreditation. Compass IRB is dedicated to outstanding customer service and the protection of human subjects. Compass IRB utilizes a customized online system "THE ANCHOR™ for online submissions and real time 24/7 tracking of all IRB documents.

CompleWare
Booth: 2319
Contact: Stacy Sanderson
Phone: 319-626-8888
Email: businessdevelopment@compleware.com
Website: www.compleware.com

Complete Data. Complete Trials. CompleWare. Complete trials rely on complete data. Anything less won't do. That's why CompleWare pairs comprehensive eClinical software with integrated service solutions to see your clinical trial through from concept to completion. Our solutions can be fitted to fulfill whatever your trial demands, all with a supreme level of precision. CompleWare is your all-in-one-and-done clinical trial partner.

Comprehend Clinical
Booth: 2532
Contact: Rick Morrison
Phone: 650-521-5449
Email: info@comprehend.com
Website: www.comprehend.com

Comprehend helps the life science industry gain end-to-end awareness and synchronize workflows across clinical development systems throughout the organization. Our technology provides answers to all questions in real time, regardless of where the data resides. Comprehend enables customizable collaboration and provides a single source of truth to reduce systemic risks inherent in traditional analysis methods that rely on costly and complex data warehouses.

Consent Solutions, Inc.
Booth: 517
Contact: Eric Delente, CEO
Phone: 301-788-1900
Email: info@consentsolutions.com
Website: www.consentsolutions.com

Consent Solutions Inc. is a developer of electronic systems for informed consent for clinical trials. The flagship product, SecureConsent, enables trial candidates to review consent documents that can include embedded multimedia education, as well as many other features. Handwritten digital signatures conclude the initial consenting process, which is subsequently supported through detailed tracking, a facilitated re-consent process and state-of-the-art integration with external systems.

Contact Canada
Booth: MP2
Contact: Fred Haynes
Phone: 250-708-0427
Email: fred@contactcanada.com
Website: www.contactcanada.com/guides/pharma

Published by Contact Canada, this popular directory provides information and circulation to help empower your business. Available in 3 formats: print, e-book and online database. Comprehensive and up-to-date. Year-long reference guide that delivers your business information to the desks of key industry stakeholders across North America.

Contract Pharma
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Contact: Damaris Kope
Phone: 201-825-2552
Email: dkope@rodpub.com
Website: www.contractpharma.com

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ConvergeHEALTH by Deloitte
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Contact: Tess Cunard
Phone: 617-831-4164
Email: tcunard@deloitte.com
Website: www.deloitte.com/lifesciences

ConvergeHEALTH brings powerful, demonstrated analytics platforms and data models from Recombinant by Deloitte, advanced proprietary and open source analytics, content and benchmarks through collaboration with industry leaders and deep experiences from Deloitte's Life Sciences and Health Care consulting practice to help our clients survive and thrive in the new paradigm of value-based, personalized medicine.

Conversis
Booth: 2535
Contact: Melody Aguero
Phone: +44-1869-255820
Email: melody.aguero@conversisglobal.com
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CORE
Booth: 800
Contact: Andrew Kimball
Phone: 469-854-0294
Email: andrewkimball@benchmarkresearch.net
Website: www.coresitenetwork.com

CORE (Centers for Research Excellence) is a revolutionary network of independent yet integrated research sites with broad therapeutic experience and geographic reach. Standardized recruitment, retention, quality, training and site operations combined with CORE's "One Voice" communication model offer unmatched financial efficiencies. Contact us today about making Centers for Research Excellence the CORE of your next program.

Corporate Translations
Booth: 1139
Contact: Ted Gawlicki
Phone: 860-727-6000
Email: sales@corptransinc.com
Website: www.corptransinc.com/

Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world's top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

CoSign by ARX
Booth: 2420
Contact: Rodd Schlerf
Phone: 415-839-8161
Email: rschlerf@arx.com
Website: www.arx.com

CoSign by ARX is the leading digital signature solution in the life sciences market, employed by 20,000 FDA-regulated organizations including 9 of the top 10 Pharmas and 7 of the top 10 CROs. It is the only digital signature system that supports compliance with strict industry requirements including the FDA's 21 CFR part 11 and GxP audits. CoSign can be used on any device to securely and compliantly sign documents in a variety of file types, including Word, Excel, PDF and others.

Coté Orphan Consulting, LLC
Booth: 1435

Court Square Group, Inc.
Booth: 2349
Contact: Keith Parent, CEO
Phone: 413-746-0054
Email: sales@courtsquaregroup.com
Website: www.courtsquaregroup.com

CSG is a professional consultancy specializing in the needs of FDA regulated companies, including IT planning, network, security and project management. CSG has expertise in business process optimization, auditing and quality (including validation), clinical data services, application development, and provides secure cloud based hosted and managed systems.

Covance Inc.
Booth: 2031
Contact: Sarah Wilde
Phone: 609-419-2240
Email: covance.inc@covance.com
Website: www.covance.com

As one of the world's largest and most comprehensive drug development service companies, Covance has helped pharmaceutical and biotech companies develop one-third of all prescription drugs in the marketplace today. Because of our broad experience and specialized expertise, we're in a unique position to supply insights that go above and beyond testing. Together with our clients, we create solutions that transform potential into reality.

Covigilant
Booth: 1801
Contact: Ken Nordeen
Phone: 508-864-6488
Email: kenneth.nordeen@covigilant.com
Website: www.covigilant.com

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CPRD
Booth: 447
Contact: Annie Vuong
Phone: +44-030-806-193
Email: annie.vuong@mhra.gsi.gov.uk
Website: www.cprd.com

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CRF Health
Booth: 1837
Contact: Heather Bilinski
Phone: 267-498-2349
Email: info@crfhealth.com
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CRF Health delivers electronic Clinical Outcome Assessments (eCOA) solutions for global clinical trials. Since 2000, CRF Health has initiated more than 400 clinical trials in over 70 countries and more than 150 regional languages; all while delivering the industry's highest patient compliance, data accuracy and unmatched patient and site acceptance.

CROMSOURCE
Booth: 710
Contact: Margherita Mosconi
Phone: 617-871-1128
Email: margherita.mosconi@cromsource.com
Website: www.cromsource.com

CROMSOURCE is the leading independent provider of comprehensive outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions. CROMSOURCE is unique. In an environment where delays and cost overruns are often accepted as inevitable, we GUARANTEE our trials will be delivered on time and to the contract price with zero CRO-initiated change orders. On-time, on-budget, guaranteed! Visit booth 710 to learn more...

CROS NT
Booth: 1810
Contact: Mary Wieder
Phone: 919-929-5015
Email: mary.wieder@crosnt.com
Website: www.crosnt.com

CROS NT offers a center of excellence for clinical trial data. As an international Contract Research Organisation (CRO) specialised in biometrics, we offer Biostatistics (methodology, programming and analysis), Clinical Data Management, Pharmacovigilance, Medical Writing and Training. We offer value to Sponsors of clinical trials by combining statistical and data management expertise with innovative technology solutions (ePRO, EDC, CTMS, eLearning). We are located in the U.S. and Europe.

CSSi
Booth: 1318
Contact: Charlie Speno
Phone: 443-308-5804
Email: cspeno@CSSiEnroll.com
Website: www.CSSiEnroll.com

CSSi, the leader in global patient recruitment solutions for the clinical research industry, delivers successful enrollment, on time, every time. Through its innovative enrollment planning and full-service patient recruitment solutions, CSSi is able to reduce the costs and timelines associated with recruitment of subjects for clinical studies.

CTI Clinical Trial & Consulting Services
Booth: 2316
Contact: Nick Schatzman
Phone: 513-598-9290
Website: www.ctifacts.com

CTI is an international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization, with a passion for helping life-changing therapies succeed in complex and critically ill patient populations. This focused therapeutic approach provides large and mid-size pharmaceutical and emerging biotechnology companies with clinical and disease area expertise from a unique mix of academic, medical, and industry specialists.

Cu-Tech, LLC
Booth: 2131
Contact: Kathleen Ashenfelter or Anna Majeranowski
Phone: 973-331-1620
Email: kashenfelter@cu-tech.com
Website: www.cu-tech.com/

Cu-Tech, LLC is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

Cytel Inc.
Booth: 725
Contact: Mike Weitz
Phone: 617-661-2011
Website: www.cytel.com

At Cytel, we use science and technology to change how clinical trials are designed and conducted because it improves success rates. Pioneers in adaptive designs, all 25 leading biopharmaceutical companies rely on us when planning and implementing their trials. More at cytel.com

Data Matrix
Booth: 1601
Contact: Anna Davydova
Phone: 812-449-8634
Email: adavydova@oct-clinicaltrials.com
Website: www.dm-matrix.com

Data Matrix is a full service Data Management and Statistics company with our own software platform - Matrix CDMS. Matrix CDMS is an EDC, IWRS, CTMS, and E-Diary application on one platform. The software is a fully validated and 21 CFR Part 11 compliant product. Data Matrix team provides a complete range of DM and Statistics services from CRF development to final study report preparation. Data processed by Data Matrix team has been successfully used for FDA and EMA applications.

Data Reduction Systems Corporation
Booth: 2400
Contact: Jim Peters
Phone: 908-622-9236
Email: jamesp@drscorp.com
Website: www.drscorp.com

Data Reduction Systems (DRS) Corporation is a leading provider of eTMF cloud based business solutions; offering both SaaS Technology and Professional Document Management Services. Founded in 1985, DRS has a strong history of providing solutions to the life sciences industry. The DRSeTMF offers total management of your documents. At DRS, it's all about quality review of the document, quality systems, real-time status reporting, and audit readiness of the eTMF during the course of the study.

Datapharm Australia Pty Ltd
Booth: 730
Contact: John Edington
Phone: 61-297-192-800
Email: helenallars@datapharmaustralia.com
Website: www.datapharm.com.au

Datapharm Australia, celebrating 25 years, is the most experienced, all-Australian, full service CRO having conducted 100s of studies (Phase I to IV) in over 35 therapeutic areas. Datapharm provides expertise in clinical trial design, monitoring, data management, statistical analysis and reporting, medical writing, pharmacovigilance and auditing.

DATATRAK International, Inc.
Booth: 1719
Contact: Lisa Pahl
Phone: 979-393-9025
Email: lisa.pahl@datatrak.net
Website: www.datatrak.net

DATATRAK is the leader of unified eClinical® technologies and related services for the clinical trials industry. Using the DATATRAK ONE™ multi-product, cloud-based clinical research platform, DATATRAK's Clinical and Consulting Services™ group assists clients in conducting Phase I-IV drug and device studies in multiple languages throughout the world. DATATRAK has offices located in Cleveland, Ohio; Bryan, Texas; and Cary (RTP), North Carolina. For more information, visit www.datatrak.net.

Datatrial
Booth: 1339
Contact: Julie Wright
Phone: 919-277-0050
Email: julie.wright@datatrial.com
Website: www.datatrial.com

Datatrial is an oncology-focused boutique clinical data organization that provides the reliability of a big company, but the personalized service and flexibility of a more nimble provider. We design your study with insight, innovation and expertise, backed by comprehensive bio-statistical and consulting services. With more than a decade of experience and offices in both Europe and the U.S., we bridge the huge gap between the promise of clinical outsourcing and the way you want results delivered.

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Phone: 206-204-1936
Email: petrier@datstat.com
Website: www.datstat.com

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DaVita Clinical Research
Booth: 1606
Contact: Carole Strong
Phone: 612-852-7045
Email: carole.strong@davita.com
Website: www.davitaclinicalresearch.com

For 25 years, DCR has used its extensive database and real world healthcare experience to assist client companies in the design and execution of clinical trials. From our two hospital-based Phase I clinical trial units to our extensive investigator network, we provide clinical trial support across therapeutic areas including ESRD, CKD, cardiovascular, diabetes, and pulmonary. Our capabilities span the product lifecycle and include health outcomes research, data services, and medical communications.

DIA
Booth: 1531
Contact: Courtney Ingram
Phone: 215-442-6100
Email: dia@diahome.org
Website: www.diahome.org

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for the exchange of knowledge and has the interdisciplinary experience to prepare for future developments. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients. For more information, visit www.diahome.org

DIA Patient Advocate Fellowship
Booth: 1739
Contact: Elizabeth Lincoln
Phone: 215-442-6100
Email: elizabeth.lincoln@diahome.org
Website: www.diahome.org/AnnualMeetingPatients

Patient organizations are key stakeholders in helping DIA achieve its mission and vision. Through the Patient Fellowship Program, DIA is working to ensure that the "voice of the patient" is heard globally in every facet of the life cycle management of pharmaceuticals, medical devices, and related health care products. Stop by our booth to meet with 17 patient fellows and learn more about the DIA Patient Fellowship Program.

Doctor Evidence, LLC
Booth: 2522
Contact: Mary Grace Savella
Phone: 310-451-5011 Ext. 3876

Dohmen Safety
Booth: 2221
Contact: Les Williams
Phone: 510-295-6438
Email: contact@biosoteria.com
Website: www.dohmensafety.com

Dohmen Safety is the premier medical communications, call center and pharmacovigilance service provider to pharmaceutical and medical device companies, offering global pre- and post-approval services, award-winning educational programs, and unmatched experience to maximize the benefit-risk profile of your products and protect your patients.

Dora Wirth Languages
Booth: 1436
Contact: Samuel Wirth
Phone: +44-20-7229-4552
Email: info@dwlanguages.com
Website: www.dwlanguages.com

Established in 1962, Dora Wirth Languages Ltd. (DWL) has over 50 years of excellence in global translation solutions for the life science industry. The DWL approach is built on a solid foundation of experience and in-house medical expertise, using DWL's well-practised and specially formulated procedures for translation, project management and quality control. Please see our website for our full range of services.

Dr. Ebeling & Assoc. GmbH
Booth: 611
Contact: Dr. Leonardo Ebeling
Phone: +49-40-5480070
Email: info@ebeling-assoc.com
Website: www.ebeling-assoc.com

Headquartered in Hamburg, Germany, Dr. Ebeling & Assoc. GmbH is a CSO with experience in regulatory and quality and compliance consulting as well as in project and data management, providing a wide range of services in the area of GCP and pharmacovigilance for the pharmaceutical, biotech, generic drug and medical device industry. If you need an EU-QPPV or EU Legal Representative - we have the experience to support you!

DrugDev
Booth: 1745
Contact: Kevin Williams
Phone: 888-650-1860
Email: usoffice@drugdev.org
Website: www.drugdev.org

DrugDev has the industry's largest global network of active investigators. Together, DrugDev and CFS Clinical create global, standardized processes to promote collaboration among Sponsors, CROs and Sites in finding, engaging, and paying investigators. Innovative solutions include study feasibility, site identification, site contracting, essential document management and investigator payments. The result—drug developers and investigators doing more trials.

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Booth: 2025
Contact: Jack Minster
Phone: 484-913-0210
Email: jminster@dsg-us.com
Website: www.dsg-us.com

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DSP Clinical Research
Booth: 316
Contact: Beth Sager
Phone: 973-265-1060
Website: www.dspclinical.com

DSP Clinical is an award winning specialty CRO with a focus on bringing small to mid-size pharmaceutical and biotech companies unmatched experience, aggressive strategies, operational excellence and a unique fixed cost billing model for Phase I-IV studies. DSP also works with the top five CROs in providing functional outsourcing services.

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Booth: 2417
Contact: Pam Lazor
Phone: 315-689-3407
Email: info@dfpharma.com
Website: www.dfpharma.com

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d-Wise Technologies
Booth: 2407
Contact: Keith Ward
Phone: 919-334-6095
Email: kward@d-wise.com
Website: www.d-wise.com/

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EastHORN Clinical Services in CEE, Ltd.
Booth: 1243
Contact: Iain Gordon
Phone: +44 7738 006738
Email: iain.gordon@easthorn.eu
Website: www.easthorn.com

EastHORN Clinical Services in CEE is a full-service CRO that offers high-value Phase I to IV clinical trial capabilities in Central and Eastern Europe and Germany. EastHORN is obsessed about timelines and consistently achieves the last-patient-out milestone within the guaranteed budget and schedule. EastHORN has local expertise across the region, including Poland, Czech Republic, Slovakia, Hungary, Bulgaria, Romania, Moldova, Serbia, Russia, Ukraine and Belarus.

eClinicalHealth Ltd.
Booth: 2001
Contact: Kai Langel, Co-Founder and Director
Phone: +34 637 228 747
Email: klangel@eclinicalhealth.com
Website: www.eclinicalhealth.com

eClinicalHealth is the creator of Clinpal, a leading cloud-based digital patient recruitment and engagement platform. We aim to improve clinical trial results and productivity by providing patients, sites and other key stakeholders with appropriate solutions from recruitment through the study lifecycle and beyond. For more information about Clinpal, please visit http://clinpal.com.

ECLINSO
Booth: 2431
Contact: Cathy Hlinka
Phone: 440-287-7126
Email: cathy.hlinka@eclinso.com
Website: www.eclinso.com

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EDETEK, Inc.
Booth: 2043
Contact: Marina Yu
Phone: 609-720-0888
Email: info@edetek.com
Website: www.edetek.com

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Elite Research Institute
Booth: 300
Phone: 305-620-7002

Elite Research Network, LLC
Booth: 630
Contact: Christopher Hoyle
Phone: 843-849-7382
Email: choyle@eliteresearchnetwork.com
Website: www.eliteresearchnetwork.com

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Booth: 1919
Contact: Brenda Bishop
Phone: 816-522-6340
Email: BBISHOP@EMBSTATS.COM
Website: www.EMBStats.com

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Booth: 1521
Contact: Tom Rieger
Phone: 952-221-6514
Email: tom.rieger@emc.com
Website: www.emc.com/campaign/iig-life-sciences/index.htm

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Booth: 534
Contact: Bob Dvorak
Phone: 707-344-8179
Email: Robert.Dvorak@Emerson.com
Website: www2.emersonprocess.com/en-us/brands/syncade

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endpoint
Booth: 2125
Contact: Ryan Keane
Phone: 415-531-5917
Email: rkeane@endpointclinical.com
Website: www.endpointclinical.com

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ENNOV
Booth: 2517
Contact: Kayvon Khatami
Phone: 650-619-8151
Email: kkhatami@ennov.com
Website: www.ennov.com

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Entimo AG
Booth: 1219
Contact: Dimitri Kutsenko
Phone: +49-30-520024-100
Email: dku@entimo.com
Website: www.entimo.com

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ePharmaSolutions
Booth: 1705
Contact: Lance Converse
Phone: 610-832-2100
Email: lconverse@epharmasolutions.com
Website: www.epharmasolutions.com

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EPS Corporation
Booth: 1105
Contact: Askold Kozbur
Phone: 708-657-4321
Email: akozbur@epsgr.com
Website: www.eps.co.jp/en

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ERT
Booth: 1005
Contact: Sheryl Walder
Phone: 215-972-0420
Email: eresearch@ert.com
Website: www.ert.com

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Eurofins
Booth: 2635
Contact: Brenda Guzman
Phone: 703-480-2500

Europe, Middle East & Africa/Asia Clinical Research (EMEACR)
Booth: 943
Contact: Serge Dehon
Phone: +32-047-012-0140
Email: info@emeacr.org
Website: www.emeacr.org

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European Medicines Agency
Booth: 1530
Contact: Beatrice Fayl
Phone: +44-207-418-8426
Email: beatrice.fayl@ema.europa.eu
Website: www.ema.europa.eu

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

EUROTRIALS
Booth: 2430
Contact: Cláudia Carvalho
Phone: +351 21 382 54 40
Email: claudia.carvalho@eurotrials.com
Website: www.eurotrials.com

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Booth: 619
Contact: Brian Wettlaufer
Phone: 905-752-5208
Email: brian.wettlaufer@ecrscorp.com
Website: www.ecrscorp.com

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Booth: 2116
Contact: Georgina Fradley
Phone: +44-127-970-9040
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Contact: Russell Bland
Phone: 484-804-249
Email: rbland@execupharm.com
Website: www.execupharm.com/

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ExL Pharma
Booth: 511
Contact: Michael Goldberg
Phone: 212-400-6244
Email: mgoldberg@exlpharma.com
Website: www.exlpharma.com

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Contact: Jon Douglas
Phone: 703-793-7760

Experis Clinical Practice
Booth: 610
Contact: Jim Balcom
Phone: 269-553-5130
Email: jim.balcom@experis.com
Website: www.experis.us/clinical

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Contact: Ellie Stone
Phone: 855-328-3500
Email: stone@extedo.com
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Falcon Consulting Group
Booth: 2610
Contact: Paul Ritchie
Phone: 610-363-0815
Email: ritchiep@falconnest.com
Website: www.falconnest.com

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FDA CDER
Booth: 1532
Contact: Michael Ledley
Phone: 301-796-3107
Email: michael.ledley@fda.hhs.gov
Website: www.fda.gov/

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Booth: 2302
Contact: Natalia Blagodarova
Phone: +7-812-389-22-88
Email: contactus@flexdatabases.com
Website: www.flexdatabases.com

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Foresight Group International AG
Booth: 945
Contact: John Heid
Phone: 888-992-8880
Email: dia@foresightgroup.com
Website: www.foresightgroup.com

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Contact: Louise Hopper
Phone: 781-685-4995
Email: louisehopper@formedix.com
Website: www.formedix.com

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Booth: 604
Contact: Brigid Flanagan, MS, RN, CCRC
Phone: 800-662-1237
Email: research@fmc-na.com
Website: www.fmcna.com

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Booth: 2607

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Booth: 445
Contact: Tracy Haefner
Phone: 609-409-7701
Email: jobs@galderma.com
Website: www.galderma.com

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George Washington University
Booth: 441
Contact: Christal Ramos

Global Instrumentation LLC
Booth: 2348
Contact: James DeMaso
Phone: 315-727-6659
Website: www.GlobalInstrumentation.com

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Booth: 1704
Contact: Inna Kassatkina
Phone: 949-798-1400
Email: info@globallanguages.com
Website: www.globallanguages.com

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Phone: 847-282-3280
Email: gadinamis@globalcarect.com
Website: www.globalcarect.com

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Phone: 415-671-4372
Email: mthompson@gobalto.com
Website: www.gobalto.com/

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Contact: Scott Metker, Ph.D
Phone: 443-539-8563
Email: smetker@gpstrategies.com
Website: www.gpstrategies.com

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Green Key Resources
Booth: 2143
Contact: Cheryl Chasen
Phone: 212-683-1988
Email: chasen@greenkeyllc.com
Website: www.greenkeypharma.com/

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Phone: 215-948-9251
Email: info@greenphire.com
Website: www.greenphire.com

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Guangzhou KingMed Center for Clinical Laboratory Co. Ltd.
Booth: 331
Contact: Peitian Liang
Phone: +86-183-120-6831-3

Hangzhou Tigermed Consulting Co., Ltd.
Booth: 1501
Contact: Wen Chen
Phone: +86-21-62780991
Email: bd@tigermed.net
Website: www.tigermed.net

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Booth: 1045
Contact: Leslie Hammill
Phone: 919-967-1111 Ext. 520
Website: www.healthdec.com

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Contact: Al Pacino
Phone: 512-302-3113
Website: www.HealthCarePoint.com

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Hibernia College Dublin
Booth: 1344
Contact: Jeremy Whitty
Phone: +353-1-661-0168
Email: info@hiberniacollege.net
Website: hiberniacollege.com/

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Contact: Zina Suriano
Phone: 908-273-8490
Email: zsuriano@hurleyconsulting.com
Website: www.hurleyconsulting.com

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IB Technology Solutions Inc.
Booth: 2543
Contact: Sanjay Koshatwar
Phone: 408-531-6040
Email: sanjay.koshatwar@ibtechnology.com
Website: www.ibtechnology.com/

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iCardiac Technologies
Booth: 2506
Contact: Sasha Latypova
Phone: 585-295-7610
Email: deepika.gosain@icardiac.com
Website: www.icardiac.com/

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ICON plc
Booth: 1305
Contact: Vanessa Byrne
Phone: 353 1 291 2000
Email: vanessa.byrne@iconplc.com
Website: www.iconplc.com

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IDT Australia
Booth: 2350
Contact: Mark Rowlands
Phone: +61-398-018-888
Email: mrowlands@idtaus.com.au
Website: www.idtaus.com

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Booth: 336
Contact: Violet Le
Phone: 858-673-8600 Ext. 939
Email: vle@iwsinc.com
Website: www.iwsinc.com

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Contact: Brandon Bissell
Phone: 800-777-2591
Email: connect@imperialcrs.com
Website: www.imperialcrs.com

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Booth: 1119
Contact: Michael Shaub
Phone: 484-567-6343
Email: CTOS-Sales@us.imshealth.com
Website: www.imshealth.com

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Inamed GmbH
Booth: 1604
Contact: Patrick McManus
Phone: +49-898-935-6929
Email: request@inamed-cro.com
Website: www.inamed-cro.com

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Contact: John Musante,
VP Regional Business Development
Phone: 919-876-9300
Email: info@incresearch.com
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Contact: Kevin Olson
Phone: 919-301-0106 Ext. 705
Email: info@ISRreports.com
Website: www.ISRreports.com

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Informa Business Information
Booth: 547
Contact: Ken May
Phone: 908-748-1221
Email: custcare@elsevier.com
Website: www.ElsevierBI.com

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Infotehna Inc.
Booth: 504
Contact: Eric Haase
Phone: 585-880-2590
Email: eric.haase@infotehna.com
Website: www.infotehna.com

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INNOPHARMA S.r.L.
Booth: 2136
Contact: Amy Nguyen
Phone: +39-0362-573-128
Email: a.nguyen@innopharma.it
Website: www.innopharma.it

InnoPharma is a full-service European CRO headquartered in Italy, with registered offices in Romania, Bulgaria, Czech Republic, Poland, Spain, Russia and the United Kingdom. Since 1995, InnoPharma has earned a solid reputation for providing quality and reliable clinical research services in support of Phase I-IV drug development. For more information, please visit www.innopharma.it.

Innovo Commerce LLC
Booth: 935
Contact: Hollie Van Dyke
Phone: 805-720-3075
Email: holliev@innovocommerce.com
Website: www.innovocommerce.com

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Instem
Booth: 2017
Contact: Giles Wilson
Phone: 845-838-5900
Email: giles.wilson@instem.com
Website: www.instem.com

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Integrated Clinical Systems, Inc.
Booth: 2004
Contact: Eric Herbel
Phone: 908-996-3312
Email: eherbel@i-review.com
Website: www.i-review.com

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Integrated Development Associates Co., Ltd.
Booth: 542

IntegReview IRB
Booth: 311
Contact: Rick Clemens
Phone: 512-326-3001
Email: rclemens@integreview.com
Website: www.integreview.com

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International Dermatology Research, Inc.
Booth: 631
Contact: Silvia A. Trinidad, CEO
Phone: 305-225-0400
Email: info@intldermresearch.com
Website: www.intldermresearch.com/

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Booth: 2626
Contact: Anna Metcalfe
Phone: 905-542-2900
Email: pharma.sci-reg@intertek.com
Website: www.intertek.com/pharmaceutical/consulting/

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Booth: 519
Contact: Susanne Welsch-Lehmann
Phone: +49-69-767576-225
Email: swelsch-lehmann@intralinks.com
Website: www.WherePartneringWorks.com

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Booth: 1423
Contact: Greg Skalicky
Phone: 609-951-6800
Website: www.inventivhealthclinical.com

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Investigational Cancer Therapeutics—MD Anderson
Booth: 2604
Contact: Tandy Tipps
Phone: 713-745-0317
Email: trtipps@mdanderson.org
Website: www.mdanderson.org

The Department of Investigational Cancer Therapeutics at MD Anderson Cancer Center in Houston, Texas conducts broad Phase I studies across disease boundaries and/or molecular targets. Our goal is to bring personalized cancer treatment to our patients using matched targeted therapies identified through next generation sequencing molecular profiling. We have a dedicated staff and state-of-the-art facilities for conducting complex trials and access to a large, diverse patient population.

Investigator Databank
Booth: 1745
Contact: Elisa Cascade
Phone: 610-650-1890
Email: support@investigatordatabank.org
Website: www.investigatordatabank.org

The Investigator Databank is a global collaboration between Janssen, Lilly, Merck, Pfizer and Novartis (with more companies to come) to share investigator information that each company has on file with one another. Hosted on the DrugDev platform, the Investigator Databank aims to reduce administrative burden for investigators and to increase visibility of qualified investigators to research sponsors.

IPHARMA / ChemDiv
Booth: 2615
Contact: Lorri Perkins
Phone: 408-530-8742
Email: lperkins@chemdiv.com
Website: www.ipharma.pro

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IRB Services
Booth: 1441
Contact: Simon A. Corman
Phone: 905-727-7989
Email: info@irbservices.com
Website: www.irbservices.com

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Booth: 1030
Contact: Janice Sidorick
Phone: 949-251-9800
Website: www.janix.com

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Jazz Pharmaceuticals Inc.
Booth: 425
Contact: Romy Alhadef
Phone: 215-832-3766
Email: romy.alhadef@jazzpharma.com
Website: www.jazzpharma.com

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JMAC Partners
Booth: 1840
Contact: Claudine Aquillon
Phone: 310-846-4388
Email: mfields@jmac-partners.com
Website: www.jmac-partners.com/

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Joulé Clinical Staffing Solutions
Booth: 2137
Contact: Amanda Wahl
Phone: 800-382-0382
Email: jcsinfo@jouleinc.com
Website: www.jouleclinical.com/

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Contact: Aaron Ellazar
Phone: 425-883-4200
Website: www.k2.com

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Contact: Jenny O'Neill
Phone: 443-203-1847

Kelly Scientific Resources
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Contact: Mark Lanfear
Phone: 248-244-4194
Email: mark.lanfear@kellyservices.com
Website: www.kellyservices.us/science

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Klein Hersh International
Booth: 2037
Contact: Jason Hersh
Phone: 215-830-9211 Ext. 104
Email: jhersh@kleinhersh.com
Website: www.kleinhersh.com

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KoNECT
Booth: 1534
Contact: Julie Lee
Phone: +82-236-687-609
Website: KoNECT.or.kr

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Kuantum CRO and Logistics
Booth: 848
Contact: Mehtap Asenaoktar
Phone: +90-232-328-3530
Email: mehtap.asenaoktar@kuantum-cro.com
Website: www.kuantum-cro.com/

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Booth: 2231
Contact: Dan Knabb
Phone: 206-322-4680
Email: dknabb@labconnectllc.com
Website: www.labconnectllc.com

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LabCorp Clinical Trials
Booth: 2115
Contact: Josh Goldsmith, PhD
Phone: 877-788-8861
Email: ClinTrialsSales@LabCorp.com
Website: www.labcorp.com/clinicaltrials

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Langland
Booth: 2001
Contact: Kate Spencer, Managing Partner
Phone: +44-175-383-3348
Email: kate.spencer@langland.co.uk
Website: www.langlandpatientrecruitment.com

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Contact: Sean Hoffman
Phone: 724-940-7555
Email: shoffman@vertmarkets.com
Website: www.lifescienceleader.com

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Lionbridge Life Sciences
Booth: 937
Contact: Jessica Kenney
Phone: 781-434-6000
Email: jessica.kenney@lionbridge.com
Website: www.lifesciences.lionbridge.com/

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LORENZ Life Sciences Group
Booth: 530
Contact: Yaprak Eisinger, Petra Mc Grath
Phone: 866-956-7369
Email: yeisinger@lorenz.cc
Website: www.lorenz.cc

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Contact: John Harte
Phone: 508-373-2935
Email: john.harte@makrocare.com
Website: www.makrocare.com

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Mandala International
Booth: 430
Contact: Alice Martinier
Phone: +33-4-79-36-56-70
Email: alice.martinier@mandala-intl.com
Website: www.mandala-intl.com/

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Massachusetts College of Pharmacy and Health Sciences
Booth: 1038
Contact: Brian Barilone
Phone: 617-879-5032
Website: www.mcphs.edu

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Booth: 2320
Contact: Emily O'Driscoll
Phone: 801-942-4000
Email: info@mastercontrol.com
Website: www.mastercontrol.com

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MaxisIT Inc.
Booth: 2121
Contact: Maulik Shah
Phone: 732-494-2005 Ext. 101
Email: mshah@maxisit.com
Website: www.maxisit.com

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McGuire Research Institute
Booth: 2041
Contact: Robert Dresch
Phone: 804-675-5151
Email: robert.dresch@va.gov
Website: vaww.research.va.gov

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MedDRA MSSO
Booth: 711
Contact: Char Guy
Phone: 571-313-2395
Email: mssorequest@mssotools.com
Website: www.meddramsso.com

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Booth: 334
Contact: Pauline Kearse
Phone: 877-605-2500
Email: clinicalresearch@msnhealth.com
Website: www.msnhealth.com

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Contact: Mike Davis
Phone: 513-401-1216
Email: michael.davis@cchmc.org
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Medicines Evaluation Unit
Booth: 1434
Contact: Sam Warburton
Phone: +44-161-946-4058
Email: swarburton@meu.org.uk
Website: meu.org.uk

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Contact: Craig Strauss
Phone: 212-918-1800
Website: www.mdsol.com

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Booth: 924
Contact: Dirk Nelson
Phone: 763-258-2735
Email: contact@mednetstudy.com
Website: www.mednetstudy.com

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Phone: 513-579-9911
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Website: www.medpace.com/

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Contact: William Cooney
Phone: 847-869-4700
Email: bill.cooney@medpt.com
Website: www.medpt.com

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Contact: Alexandra Allison
Phone: 415-963-3700

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Contact: Eric Lund
Phone: 281-286-2003
Email: eric@medsource.com
Website: www.medsource.com

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Contact: Jamie Edwards
Phone: 214-630-0288
Email: jedwards@medtrials.com
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Contact: Larissa Amoroso
Phone: 919-653-3425
Email: eClinical@merge.com
Website: www.merge.com/eClinical

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Contact: Alan Hutton
Phone: +44-844-844-794
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Phone: 908-393-9906
Email: kim.nitahara@metasol.com
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Contact: Jason Dugger
Phone: 972-516-4210
Email: sales@m-files.com
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Booth: 1125
Contact: Julie Smith
Phone: 703-282-0600
Email: julismit@microsoft.com
Website: www.microsoft.com/lifesciences

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Contact: Tony Compton
Phone: 630-310-5943
Email: tonyc@microsystems.com

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Contact: Dirk Beth
Phone: 602-957-2150
Email: info@mission3.com
Website: www.mission3.com

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MMG
Booth: 1505
Contact: Angelica Carter
Phone: 301-984-7191
Email: acarter@mmgct.com
Website: www.mmgct.com

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Booth: 2627
Contact: Kenneth Ying
Phone: 800-643-6483
Email: kenneth.ying@mnx.com
Website: www.mnx.com

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Phone: 610-862-0909
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Booth: 407
Contact: Oliver Pearce
Phone: 514-223-9153 Ext. 219
Email: opearce@montrium.com
Website: www.montrium.com

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Moravia
Booth: 413
Contact: Renata Keprtova
Phone: 805-262-0055
Email: info@moravia.com
Website: www.moravia.com

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Contact: Ethan Perlson
Phone: 212-643-8800
Email: ny@morningtrans.com
Website: www.morningtrans.com/

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Booth: 900
Contact: Tiffany Wisniewski
Phone: 414-354-1600
Email: tiffany.wisniewski@mortara.com
Website: www.mortara.com

Mortara Instrument is a recognized technology leader in the world of ECG. Mortara's global headquarters is located in Milwaukee, Wisconsin with operations in Australia, Germany, Italy, the Netherlands, and the United Kingdom. The complete line of ECG products includes electrocardiographs, stress exercise systems, Holter systems, data warehousing solutions, and cardiology monitoring systems. www.mortara.com.

MotherToBaby Pregnancy Studies conducted by OTIS
Booth: 701
Contact: Diana Johnson
Phone: 877-311-8972
Email: otisresearch@ucsd.edu
Website: pregnancystudies.org

MotherToBaby, a service of the non-profit Organization of Teratology Information Specialists (OTIS), is dedicated to providing evidence-based information to the general public and health professionals about medications and other exposures during pregnancy and while breastfeeding. MotherToBaby Pregnancy Studies is currently evaluating the effects to the fetus from various diseases and the safety of medications used to treat them during pregnancy. Please visit PregnancyStudies.org.

myClin
Booth: 608
Contact: James Denmark
Phone: 877-211-8297
Email: james.denmark@myclin.com
Website: www.myclin.com/

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NCGS Incorporated
Booth: 1541, 1640
Contact: Kimberly Flotta
Phone: 843-722-8330
Email: kflotta@ncgs.com
Website: www.ncgs.com

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NDA Group
Booth: 1500
Contact: John Reynolds
Phone: +44-13-728-6061-0
Email: info@ndareg.com
Website: www.ndareg.com

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NeoGenomics Laboratories
Booth: 850
Contact: David Kaminsky
Phone: 239-768-0600
Email: dkaminsky@neogenomics.com
Website: www.neogenomics.org

NeoGenomics BioPharma Services operates in a CAP accredited & CLIA certified full service oncology testing lab. NeoGenomics' service offering includes IHC, cytogenetics, FISH, flow cytometry and molecular genetics. Global centralized pathology reviews of oncology cases are made possible by our novel LIS. Our exclusive alliance with Covance Central Laboratory Services offers integrated testing services supporting oncology clinical trial & companion diagnostic strategies world-wide.

Neuroscience Trials Australia
Booth: 1343
Contact: Tina Soulis
Phone: +61-390-357-158
Email: athina.soulis@unimelb.edu.au
Website: www.neurotrialsaustralia.com

Neuroscience Trials Australia is a niche contract research organization specializing in all aspects of neuroscience clinical research and product development. We work on global or local projects. As a business within The Florey Institute of Neuroscience and Mental Health (The Florey), our staff has global management expertise in all phases of clinical research including studies sponsored by pharmaceutical and device companies, the biotechnology industry and granting bodies.

New England IRB
Booth: 810
Contact: Carolyn Newman
Phone: 617-243-3924
Email: carolyn.newman@neirb.com
Website: www.neirb.com

New England IRB (NEIRB), a national, central IRB providing ethical review of research involving human subjects for over 25 years. We review phase I - IV single and multi-site studies. NEIRB offers: • Review across North America • Free Protocol Consultation • One-week Protocol Review • 24-Hour Site Review • Full AAHRPP Accreditation • In good standing with FDA (2011 inspection) .

New Orleans Center for Clinical Research
Booth: 934
Contact: Dr. William Smith
Phone: 865-305-9100
Email: wbsmd@noccr.com
Website: www.noccr.com

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Booth: 1931
Contact: John Loucks
Phone: 610-265-9474
Email: sales@nextdocs.com
Website: www.nextdocs.com

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Booth: 1044
Contact: Michael Skinner
Phone: 925-415-8942
Email: Mskinner@nextrials.com
Website: www.nextrials.com

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NNIT
Booth: 2545
Contact: Mads Torry Lindeneg
Phone: +45-3075-1845
Email: mtld@nnit.com
Website: www.nnit.com

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Booth: 1337
Contact: Arun Mathew
Phone: +44-1908-262-808
Email: arun.mathew@nova-transnet.com
Website: www.nova-transnet.com/

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Novasyte, LLC
Booth: 1342
Contact: Tim Gleeson
Phone: 949-214-5900
Email: tgleeson@novasyte.com
Website: www.novasyte.com

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Novella Clinical
Booth: 931
Contact: Kristi Robison
Phone: 919-484-1921
Email: info@novellaclinical.com
Website: www.novellaclinical.com

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November Research Group
Booth: 419
Contact: Seth Warhaftig
Phone: 415-987-3313
Email: seth@novemberresearch.com
Website: www.novemberresearch.com

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Novotech
Booth: 1236
Contact: Julia Jones
Phone: +61-285-691-400
Email: julia.jones@novotech-cro.com
Website: www.novotech-cro.com/

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Ocasa Logistics Solutions
Booth: 1641
Contact: Melissa Delgado
Phone: 305-591-0499 Ext. 71135
Email: alejandro.serricchio@ocasa.com
Website: www.ocasa.com

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OmniComm Systems, Inc.
Booth: 2205
Contact: Beverly Hudson
Phone: 954 473 1254
Email: bhudson@omnicomm.com
Website: www.omnicomm.com

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Online Business Applications
Booth: 2008
Contact: Reed McLaughlin
Phone: 630-243-9810
Email: reed.mclaughlin@irmsonline.com
Website: www.irmsonline.com

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Booth: 1804
Contact: Tia Tep
Phone: 781-547-8410
Email: step@openclinica.com
Website: www.openclinica.com

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Booth: 831
Contact: Sheila Hetu
Phone: 401-642-9274
Email: shetu@qualitymetric.com
Website: www.optum.com/life-sciences.html

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Oracle Corporation
Booth: 805
Contact: Peggy Taylor
Phone: 408-595-3077
Email: peggy.taylor@oracle.com
Website: www.oracle.com/healthsciences

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Orlando Clinical Research Center
Booth: 2335
Contact: Thomas Marbury
Phone: 407-240-7878
Email: tmarbury@ocrc.net
Website: www.ocrc.net

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Pacific BioLabs
Booth: 434
Contact: Mimi Leong
Phone: 510-964-9000
Email: mimileong@pacificbiolabs.com
Website: www.PacificBioLabs.com

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Palm Beach CRO
Booth: 2236
Contact: Arthur Simon
Phone: 561-200-3344
Email: ASimon@PalmBeachCRO.com
Website: www.palmbeachcro.com

Palm Beach CRO is a full-service Clinical Research Organization (CRO) that provides pharmaceutical, biotechnology, medical food, medical device and consumer healthcare companies with a broad range of clinical research services in support of Phase I-III. Palm Beach CRO provides clinical services that meet the highest quality standards ensuring client timelines. Services include: site selection, protocol development, project management, monitoring, data management/bio-statistics and medical writing.

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Booth: 704
Contact: Christopher Diehl
Phone: 910-772-1599
Email: cdiehl@paragonmeetings.com
Website: www.paragonmeetings.com

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Booth: 2021
Contact: Jamie O'Keefe
Phone: 610-832-8110
Email: jokeefe@consultparagon.com
Website: www.consultparagon.com

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Contact: Heather Puffer
Phone: 781-487-9900
Email: info@parexel.com
Website: www.parexel.com

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Contact: Tim Brown
Phone: 888-479-5600
Email: LearnMore@PatientPoint.com
Website: www.PatientPoint.com

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Booth: 2045
Contact: Julie Church-Thomas/Rick Heth
Phone: 888-976-2676
Email: info@pcmtrials.com
Website: www.pcmtrials.com

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Booth: 512
Contact: Annie Hudson
Phone: 509-944-4225
Website: www.perkinelmer.com

Pharma Start
Booth: 1141
Contact: Carolyn Durham
Phone: 888-330-1726
Email: cdurham@pharma-start.com
Website: www.pharma-start.com

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Booth: 415
Contact: Yolanda Hall
Phone: 978-422-0227
Email: yh@pec-services.com
Website: www.pec-services.com

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Booth: MP1
Contact: Joel Kern
Phone: 317-816-8787

Pharmaceutical Packaging Professionals
Booth: 2624
Contact: Craig Rogers
Phone: +61-3-9673-1003
Website: www.pharmpackpro.com

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Pharmaceuticals and Medical Devices Agency (PMDA)
Booth: 1437
Contact: Tamami Fukushi
Phone: +81-335-069-456
Email: fukushi-tamami@pmda.go.jp
Website: www.pmda.go.jp

The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that reviews applications for marketing approval of pharmaceuticals and medical devices, monitors product safety, and provides financial relief to people suffering from adverse drug reactions, in collaboration with the Ministry of Health, Labour and Welfare.

PharmaCircle
Booth: 2305
Contact: Tugrul Karaarli
Phone: 760-436-1199

Pharmalink Consulting Inc.
Booth: 2516
Contact: Stephen Loughrey
Phone: 973-921-5206
Email: dia@pharmalinkconsulting.com
Website: www.pharmalinkconsulting.com

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Booth: 525
Contact: Daniel Becker
Phone: 973-808-1191
Email: daniel.becker@ubm.com
Website: www.pharmalive.com

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Booth: 2018
Contact: Annie Garvey
Phone: 608-664-9000Ext. 2238
Email: agarvey@pharmaseek.com
Website: www.pharmaseek.com

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PharmaSys, Inc.
Booth: 1034
Contact: Tracy Kahn
Phone: 919-468-2547
Email: tracy.kahn@pharma-sys.com
Website: www.pharma-sys.com

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PharmaVOICE
Booth: 1037
Contact: Marah Walsh
Phone: 215-321-8656
Email: mwalsh@pharmavoice.com
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Contact: Mark Eberhardt
Phone: 713-559-7900
Email: info@pharm-olam.com
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Booth: 2527
Contact: Kristen Boatman
Phone: 541-598-3800
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Phone: +44-1494-720420
Email: kredding@phlexglobal.com
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Booth: 1204
Contact: Sheila Rocchio
Phone: 617-973-1600
Email: info@phtcorp.com
Website: www.phtcorp.com

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Booth: 636
Contact: Sandy Carson Hessen
Phone: 813-915-1663
Website: www.pilgrimsoftware.com

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Booth: 1140
Contact: Carolyn Durham
Phone: 708-505-4350
Email: cdurham@planet-pharma.com
Website: www.planet-pharma.com

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Contact: David Cornwell
Phone: +44-166-682-6540
Email: david.cornwell@pleasetech.com
Website: www.pleasetech.com

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Contact: Guy Maestre
Phone: 610-761-7311
Email: info@popsicube.com
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Email: account.development@ppdi.com
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Contact: Tami Klerr
Phone: 610-935-0318
Email: Klerrnaivartami@praintl.com
Website: www.clearlypra.com

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Contact: Robert Loll
Phone: 716-249-5111
Email: rloll@gopraxis.com
Website: www.gopraxis.com

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Booth: 2401
Contact: Peter Vitello
Phone: 650-481-8942
Email: pvitello@prcclinical.com
Website: www.prcclinical.com

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Precept Life Sciences
Booth: 322
Contact: Aileen Ondrako
Phone: 919-457-1253
Email: aondrako@preceptlife.com
Website: www.preceptlife.com

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Precision for Medicine
Booth: 1431
Contact: Teresa Pokladowski
Phone: 617-299-3013
Email: teresa.pokladowski@precisionformedicine.com
Website: www.precisionformedicine.com

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Booth: 2011
Contact: Sean Russell
Phone: 215-282-5500
Email: infopremier@premier-research.com
Website: www.premier-research.com

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Pretium Pty Ltd.
Booth: 702
Contact: Ms Joyce Lloyd
Phone: +61 2 8088 1500
Email: joyce.lloyd@pretium.com.au
Website: www.pretium.com.au

PRL Central Laboratory Services
Booth: 431
Contact: Dan Robson
Phone: 913-339-0375
Email: dan.robson@prlnet.com
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Contact: Russell Holmes
Phone: 855-776-5324
Website: www.projecis.com

Projecis is a cloud-based platform that enables project stakeholders—sponsors, sites, CROs—to connect teams, organize data, and share information for better trial outcomes. Users access project status, assignments, Gantt charts, files, profiles (including LinkedIn®), video updates via secure site. Team collaboration is further cultivated through the integration of Skype®, IM/chat, email, text, phone, etc. FREE trial available!

Promedica International
Booth: 948
Website: promedica-intl.com
Phone: 714-460-7363 Ext. 11

Promedica International is a privately held, full-service CRO providing clinical trial services for the medical device, biotechnology and pharmaceutical industries. Founded in 1985, Promedica International, a woman-owned corporation, is headquartered in Orange County, California. We have successfully been providing exceptional value to our clients for over 28 years.

PROSAR
Booth: 2307
Contact: Mike Bieniek
Phone: 651-917-6116
Email: mbieniek@prosarcorp.com
Website: www.prosarsafety.com

PROSAR is a global provider of pharmacovigilance and medical information services to the pharmaceutical and biopharmaceutical industries. Our 24/7 drug safety call center is staffed by pharmacists and nurses that provide adverse event intake and processing including regulatory reporting; medical information services; and product complaint services. We provide the expertise and services you need to stay in compliance and enhance patient safety.

Proswell Medical Company
Booth: 849
Contact: Kelly Huo
Phone: +86-13671286641
Email: huohuanzhi@proswell.com.cn
Website: www.proswell.com.cn

Proswell found in 2004, is a local CRO company with the capability to provide full service for both domestic and global customers. Service Scope includes Regulatory Affairs, Clinical Trials, Medical Affairs, Data Management, Statistical Analysis, Pharmacovigilance, CRC and Subject Recruitment. Proswell is the first company earned the Quality Management System Certificate in CRO industry, issued by China Quality Certification Center (CQC).

ProTrials Research, Inc.
Booth: 1504
Contact: Wendy Powers
Phone: 650-864-9195
Email: wpowers@protrials.com
Website: www.protrials.com

As a clinical research organization serving the pharmaceutical, biotechnology and device industries for more than 17 years, ProTrials professionals provide one of the industry's highest average years of experience. We offer a suite of services focused on clinical operations experience: • Experience in a broad range of therapeutic areas • Phase I-IV clinical trials • Highly-skilled project management services • Operational experience in North America and throughout Europe

PSKW
Booth: 2500
Contact: Larry Buzbee
Phone: 973-769-4233
Email: larry@centricitygroup.com
Website: www.pskw.com

PSKW's core business is creating co-pay assistance programs that are extremely popular with physicians and patients. In addition, we have leveraged our relationships with banking partners, our payment processor, and our card program manager to create an efficient payment platform for all segments of the life sciences marketplace. This platform allows us to offer our ATM, debit, and Visa debit engines to firms in market research, patient reimbursement, loyalty programming, and clinical research.

Q2 Business Intelligence
Booth: 318
Contact: Gary Huang
Phone: 908-392-2820
Website: www.q2bi.com

Q2 (Q-square Business Intelligence) is a global Clinical Research Organization, with over 16 years pharmaceutical research and development experience, providing a broad range of services. Our principle is "Quality Work for Quality World". Janus Clinical Research Institute (Janus) is a Q2 based company in China. Janus possesses the capacity with extraordinary talented people for any large or small projects in clinical research.

QlikTech Inc.
Booth: 401
Contact: Kerry Marker
Phone: 610-994-5804

QPS, LLC
Booth: 2505
Contact: Bhavna Malhotra
Phone: 302-690-4962
Email: info@qps.com
Website: www.qps.com

Founded by Dr. Ben Chien in 1995, QPS has Bioanalysis and Preclinical testing and Clinical Research facilities at its Newark, DE headquarters, in Groningen, Netherlands and in Taipei, Taiwan. Early-phase clinical facilities are located in Springfield, MO, Taipei, Taiwan, and Groningen, Netherlands. Business development offices are maintained in the US, Europe, and Asia.

Quality and Compliance Consulting, Inc.
Booth: 2418
Contact: Jason Bertram
Phone: 424-208-3340
Email: qc2@qc2.com
Website: www.qc2.com

QC2 provides worldwide audit and consulting services, including: GCP, GLP, and cGMP Audits; Bioanalytical Laboratory Audits; Clinical Pathology Laboratory Audits; Sponsor, CRO, and Vendor Audits; Computerized System Validation Audits; Standard Operating Procedures Review and Preparation; GCP, GLP, QA, and SOP Training; and Consulting.

Quality Associates, Inc.
Booth: 1036
Contact: Paul Swidersky
Phone: 410-884-9100
Email: pswidersky@qualityassociatesinc.com
Website: www.qualityassociatesinc.com

Quality Associates, Inc. was established in 1986 as an independent third party QA consulting company initially specializing in GCPs and GLPs. Capabilities include all aspects of GCP and GLP QA work; e.g., site/CRO qualifications; study and data audits; database and master file audits; bio-analytical audits; training; computer system validation audits, etc. QAI has a staff of 15 auditors, all with various scientific experience. QAI also maintains a GLP compliant archive (vaulted).

Quanticate, Inc.
Booth: 1039
Contact: Shawn Strait
Phone: 919-287-5830
Email: Shawn.Strait@Quanticate.com
Website: www.quanticate.com

Quanticate strives to help our clients maximize the value of their clinical data. Quanticate offers an extensive suite of Biometric Solutions that standardize the collection, analysis, and reporting of clinical trial data. As the largest fully dedicated clinical biometrics company we utilize top industry talent and leading technology to ensure our customers bring their drugs to market more quickly than ever before.

QuantifiCare
Booth: 324
Contact: Marie Bernaert
Phone: 510-759-0382
Email: info.usa@quantificare.com
Website: www.quantificare.com

QuantifiCare is a worldwide imaging CRO providing clinical trials services to the pharmaceutical/cosmetic industry and innovative products for specialists.

Queensland Clinical Trials Network
Booth: 1540
Contact: Mario Pennisi
Phone: 61 7 3331 3955
Email: mario.pennisi@qctn.com.au
Website: www.qctn.com.au

Working with Life Sciences Queensland Ltd (LSQ), QCTN is the primary point of contact for domestic and international organisations seeking to undertake preclinical and clinical research in Australia. QCTN's aim is to promote and raise the visibility of the Australian biopharmaceutical industry and life sciences service providers at a national and international level and to support them in building their capabilities and marketing activities.

Quest Diagnostics Clinical Trials
Booth: 2410
Contact: Terry Burke
Phone: 800-209-9816
Email: terry.d.burke@questdiagnostics.com
Website: www.questdiagnostics.com/home/companies/clinical-trials.html

Quest Diagnostics Clinical Trials provides laboratory solutions through unsurpassed global central laboratory and biomarker services, diagnostics & esoteric testing, anatomic pathology and research & development innovation, combined with one of the world's largest clinical laboratory, a single global database, and unparalleled scientific and logistics expertise.

Quintiles
Booth: 905
Contact: Sandra Woodlief
Phone: 866-267-4479
Email: global.marketing@quintiles.com
Website: www.quintiles.com

Quintiles is the world's largest provider of biopharmaceutical development & commercial outsourcing services with a network of 27,000+ employees conducting business in nearly 100 countries. We have helped develop or commercialize all of the top-50, best-selling drugs on the market. Quintiles applies the breadth & depth of our service offerings with extensive therapeutic, scientific & analytics expertise to help customers navigate an increasingly complex healthcare environment. www.quintiles.com

QUMAS
Booth: 2145
Contact: Warren Perry
Phone: 973-805-8600
Email: info@qumas.com
Website: www.qumas.com

QUMAS, an Accelrys company (NASDAQ: ACCL), is the leader in Compliance and Quality Management Solutions for Life Sciences, with 270+ global customer deployments & domain expertise in regulatory compliance since 1994. QUMAS provides software solutions for Electronic Document Management (SOPs, QA Docs.), Electronic Process Management (CAPA, Deviation, Change Control, Audit), eCTD & Submission Management.

Quorum Review IRB
Booth: 2030
Contact: Business Development
Phone: 206-448-4082
Email: busdev@quorumreview.com
Website: www.quorumreview.com

Quorum Review is an independent ethics review board that is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Our primary focus is to safeguard the rights and well-being of research participants. We provide sponsors, CROs, institutions, and sites with reliable, responsive service that ensures efficient study start-up and management.

Randstad Pharma
Booth: 2330
Contact: Kimberlee Hodges
Phone: 877-335-8210
Email: RPH-webmaster@randstadusa.com
Website: www.randstadpharma.com

Randstad Pharma matches professionals with career opportunities at the world's leading biopharma and life science companies for more than 20 years. Our candidates are matched at organizations that will fully utilize their expertise while advancing the candidates skills and career aspirations. Our staffing services encompass specific areas of Clinical Research & Development, including Clinical Operations, Pharmacovigilance, Medical Writing, Clinical IT, Biometrics, Regulatory Affairs and more.

Real Staffing Group
Booth: 618

Reed Technology
Booth: 2435
Contact: Mark Bayer
Phone: 215-441-6408
Email: mbayer@reedtech.com
Website: www.ReedTech.com

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Regxia Inc.
Booth: 1944
Contact: Cameron McGregor
Phone: 416-620-5236 Ext. 231
Email: mcgregor@regxia.com
Website: www.regxia.com

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Remedy Informatics
Booth: 508
Contact: Alejandra Dahl
Phone: 801-733-3300
Website: remedyinformatics.com

Remedy Informatics is a clinical intelligence company that enables academic medical centers, biopharmaceutical companies, and biomedical research organizations to collect, harmonize, and analyze data across disciplines, detect patterns in clinical data, and accelerate disease and therapeutic research to bring safe, effective, increasingly personalized treatments to market faster and more efficiently.

Research Across America
Booth: 2334
Contact: Gaye Corbin
Phone: 610-779-7061
Email: gcorbin@raasites.com
Website: www.researchacrossamerica.com

Research Across America is an Independent Site Network-ISN (Non-SMO) that conducts Phase I through Phase IV and Post marketing trials utilizing their many regional multi-specialty sites. Our site locations include Dallas, El Paso and Plano TX, New York, NY and Reading, PA. The physicians affiliated with Research Across America have conducted over 1850 clinical trials since 1992. Our sites are under one corporate umbrella but have the flexibility of negotiating their own contracts and budgets.

Research Presentation Strategies Inc.
Booth: 418
Contact: Robert Befus
Phone: 800-948-9222
Email: info@r-pstrat.com
Website: www.r-pstrat.com

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ResearchDx
Booth: 801
Contact: Dina Scaglione
Phone: 949-910-941
Website: www.researchdx.com

ReSolution Latin America
Booth: 2246
Contact: Eric Johansson, Ph.D.
Phone: +54-114-773-2401
Email: eric.johansson@resolutioncrs.com
Website: www.resolutioncrs.com/

ReSolution Latin America is a CRO/clinical consultancy company completely focused on clinical development in Latin America and we specialize in providing clinical research solutions for development companies that are interested in Latin America for their clinical development programs. We provide the opportunity to work with a credible regional niche CRO provider that is able to successfully deliver clinical research conducted in Latin America to international quality standards and expectations.

Rho, Inc.
Booth: 427
Contact: Joan Parks
Phone: 919-408-8000
Email: joan_parks@rhoworld.com
Website: www.rhoworld.com

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RJR Consulting, Inc.
Booth: 1901
Contact: Jennifer Soronen
Phone: 614-304-0105
Email: jennifersoronen@rjr-consulting.com
Website: www.rjr-consulting.com

RJR Consulting, Inc. specializes in providing regulatory consulting services within the life sciences industry. We have affiliates positioned in strategic locations around the globe to help provide consulting services to companies of all sizes. Our focus on client service and timely delivery has helped us build a worldwide reputation for effective, efficient consulting.

RPM Alliance
Booth: 535
Contact: Ritvik Mehta
Phone: 619-821-8190

RWS Group - Medical Translation Division
Booth: 2617

Rx Supply Solutions
Booth: 325
Contact: Tom Gottschalk
Phone: 919-676-0709
Email: tomgottschalk@rxsamplesolutions.com
Website: www.rxsupplysolutions.com

Rx Supply Solutions is the innovator of the Clinical Study Pharmacy Card™, which utilizes the retail pharmacy network to deliver medicine and supplies to subjects participating in clinical studies. The Clinical Study Pharmacy Card™ provides an extremely safe and efficient method of dispensing medicines and supplies to study subjects that saves administrative effort and time as well as reduces the amount of capital expense required for the purchase and distribution of study medicine and supplies.

Rx Trials Inc.
Booth: 2413
Contact: Anne-Marie Baughn, RN MSN
Phone: 410-465-2455 Ext. 103
Email: anne-marie.baughn@rxtrialsinc.com
Website: www.rxtrialsic.com

RxTrials is an elite Integrated Site Network (ISN) and consulting/training firm focused on helping bring new treatments to patients. Our multi-therapeutic network is comprised of private physician practices, while our consulting and training divisions provide guidance to sites, sponsors, and CROs to ensure efficient and high-quality study delivery. Our commitment today is the same as it has been since 1994; to set the standard for quality in study conduct and research site management services.

RxLogix Corporation
Booth: 724
Contact: Shalini Modi
Phone: 949-362-1247
Email: shalini.modi@rxlogix.com
Website: www.rxlogix.com

RxLogix is the foremost provider of business and technology solutions and services for Drug Safety and Pharmacovigilance. Our experienced team of experts offer consulting and strategic software solutions. We bring best practices across all areas of drug safety. RxLogix Solutions have been developed by the leading experts on the Oracle Argus Safety suite and Drug Safety.

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Booth: 1838
Contact: Lisa LaMont
Phone: 805-410-7239
Email: lisa.lamont@sagepub.com
Website: www.sagepub.com

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Booth: 540
Contact: Phil Turner
Phone: 44-12-442-8828-1
Website: www.samarindrms.com

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SanaClis
Booth: 642
Contact: Adriana Kuzmisinova
Phone: +31-631-780-668
Email: adriana.kuzmisinova@exquisitealliance.com
Website: www.sanaclis.eu

SanaClis is full service CRO in Central & Eastern Europe (EU and non-EU countries), ISO-certified, operating since 2000 (clinical monitoring, regulatory, site contracting & payments, DM & statistics, medical writing, pharmacovigilance). Besides, own warehouses and customs brokerage in Ukraine and Russia with online access for sponsor ensure optimal IMP logistics.

SAS Institute Inc.
Booth: 1323
Contact: Janet Forbes
Phone: 919-677-8000
Email: tradeshows@sas.com
Website: www.sas.com/dia14

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Scarritt Group, Inc.
Booth: 2039
Contact: Kim Hruby
Phone: 303-972-8153
Email: kim.hruby@scarritt.com
Website: www.scarrittgroup.com

Scarritt Group is a global meeting planning company specializing in the execution of clinical meetings specific to the drug development process. Our business is designed to meet the unique needs of pharmaceutical companies and CROs regardless of size or meeting locale. With a collective 200 years of experience in hotel and logistics management, Scarritt Group's relationships allow us to provide our clients with an exceptional meeting experience at the most competitive price.

Schlafender Hase GmbH
Booth: 2034
Contact: Marlena Loncina
Phone: +49-69-2444810
Email: info@sh-p.de
Website: www.text-verification.com

The Text Verification Tool (TVT) developed by Schlafender Hase GmbH is the global standard solution in computer-driven proofreading. It helps global pharmaceutical leaders save time, money, improve quality, avoid embarrassment and legal costs that can result from avoidable mistakes. Designed to support all standard file types, including SPL.

Schulman Associates IRB
Booth: 1909
Contact: Kristina Vohland
Phone: 513-761-4100
Email: businessdevelopment@sairb.com
Website: www.sairb.com

Since 1983 Schulman has provided human subject protection services for sponsors, CROs, institutions and research sites. Schulman is AAHRPP accredited and has an unparalleled clean audit history with FDA. Our comprehensive suite of IRB review services includes dedicated review capabilities for all phases of research in the US and Canada. We are committed to providing high quality, rigorous IRB reviews via streamlined processes, customized technology solutions and responsive customer service.

SCI-C
Booth: 544
Contact: Yeon-Tae Kim
Phone: +82-222-280-464

SDL
Booth: 435
Contact: Jessica Connolly
Phone: 720-304-4943
Email: jconnolly@sdl.com
Website: www.sdl.com

SDL (LSE: SDL) allows companies to optimize their customers' experience across the entire buyer journey. Through its web content management, analytics, social intelligence, campaign management and translation services, SDL helps organizations leverage data-driven insights to understand what their customers want, orchestrate relevant content and communications, and deliver engaging and contextual experiences across languages, cultures, channels and devices.

Seoul National University Hospital Clinical Trials Center
Booth: 522
Contact: Howard Lee
Phone: +82-236-687-602
Website: en.ctc.snuh.org/

The Global Center of Excellence in Early Clinical Trials at Seoul National University Hospital (GREATS) is one of the two centers chosen by the Korean government in November 2012. GREATS is led by Prof. Yung-Jue Bang, a world-renowned medical oncologist, who has advised many global pharmas and CROs. Oncology and clinical pharmacology are the two leading programs. Also, GREATS has many world-class investigators in cardiovascular diseases, endocrinology, gastroenterology, and rheumatology.

Sharp Clinical Services
Booth: 634
Contact: John Phillips
Phone: 800-310-4445
Email: info@sharpclinical.com
Website: www.sharpservices.com

Sharp Clinical Services IVRS/IWRS provides a sophisticated method of optimizing & managing clinical trials through dynamic resupply algorithms, data integration with eCRF, labs & real-time study data access. Our Management Team provides guidance and advice on packaging design and distribution as well as randomization scheme and visit schedule. We optimize your clinical trial experience with the foresight to include all study requirements before "GO LIVE" reducing out of scope and change control.

Sidus Biodata
Booth: 437
Contact: Lisa Ackerson
Phone: 410-897-1050
Email: lackerson@sidusdata.com
Website: www.sidusbiodata.com

Sidus BioData provides secure, compliant data hosting solutions for the Life Sciences/Medical Device and Health IT industries. Sidus BioData is committed to the highest level of quality in the management, security, integrity and availability of regulated data. In addition, Sidus' culture of compliance ensures all regulatory goals are met with our premium service offerings.

Small Planet Events
Booth: 2539
Contact: Stacey Powles
Phone: 800-479-1637
Email: stacey.powles@smallplanetevents.com
Website: www.smallplanetevents.com

Small Planet organises and delivers events worldwide for the pharmaceutical industry. We manage logistics, create programs, train speakers, provide facilitation and deliver web training portals. We aim to help you optimise the valuable opportunities created by face to face contact and the post-meeting legacy, by delivering interesting & memorable events, and we contribute to enhanced relationships with customers and with site staff.

SOA Software, Inc.
Booth: 644
Contact: Lisa Blank
Phone: 310-570-4100
Email: info@soa.com
Website: www.soa.com/

SOA Software is a leading provider of API Security and Management products that help businesses plan, build, run and share APIs, through comprehensive cloud and on-premise solutions that encompass API lifecycle, security, management and developer engagement. SOA Software's Semantic Manager™ is a comprehensive metadata and standards management solution that BioPharma companies use to effectively meet regulatory and standards compliance requirements, while improving overall business efficiency.

Society for Clinical Research Sites—SCRS
Booth: 1900
Contact: Christine Pierre
Phone: 410-696-5080
Email: christine.pierre@myscrs.org
Website: www.myscrs.org

The Society for Clinical Research Sites (SRCS) was founded in 2012 in response to the growing need for a trade organization to represent the global voice and community of research sites within the clinical research enterprise. The goals of the Society include providing sites with resources, mentorship, and new ideas through a membership organization dedicated only to research sites.

Sonic Clinical Trials
Booth: 1347
Contact: Paullette Azar-Tannous
Phone: +61-298-556-006
Email: pazar@sonicclinicaltrials.com
Website: www.sonicclinicaltrials.com.au

Sonic Clinical Trials is a wholly owned subsidiary of Sonic Healthcare Limited, one of the world's largest medical diagnostic companies. Sonic Clinical Trials is a dedicated central laboratory supporting all phases of clinical trials and ensuring the highest regulatory compliance. Services Offered: Central Laboratory Services include: Laboratory Testing, Protocol Management, Data Management, Sample Management and Blood Collection Services.

Southern Star Research
Booth: 1446
Contact: David Lloyd
Phone: +61-2-9011-6266
Email: info@southernstarresearch.com
Website: www.SouthernStarResearch.com

Southern Star Research is a leading Australian CRO, dedicated to providing an exceptional quality of personalised service. Expertise covers Ph I-IV trials in Pharmaceutical, Medical Device & Biotechnology projects. Services include; Project Management, Monitoring, In-house staff placement, Patient Recruitment, Local safety reporting, Medical Monitoring & local study sponsorship. Staff are located across Australia & New Zealand, with a focus on providing high quality & cost effective services.

Sparta Systems
Booth: 2419
Contact: Colleen Nugent
Phone: 609-807-5100
Email: info@spartasystems.com
Website: www.spartasystems.com

Sparta Systems Inc. quality management solutions enable organizations to safely and efficiently deliver products and services to market. Its TrackWise® Enterprise Quality Management Software, trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the enterprise.

Spaulding Clinical Research
Booth: 338
Contact: Tyler Borst
Phone: 414-828-9298
Email: tyler.borst@spauldingclinical.com
Website: www.spauldingclinical.com

Spaulding Clinical Research, LLC provides Clinical Pharmacology, Cardiac Safety Core Lab clinical research services, and ECG device manufacturer. Spaulding Clinical operates a paperless, 155-bed clinical pharmacology unit with 96-beds of telemetry in West Bend, Wisconsin

Spectra Clinical Research
Booth: 2238
Contact: Charles Keyes
Phone: 800-517-7157
Email: charles.keyes@fmc-na.com
Website: www.spectraclinicalresearch.com

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SPRI Clinical Trials - Global
Booth: 602
Contact: Jamie Wajid
Phone: 646-442-4590

Springer
Booth: 2608

SQN
Booth: 1335
Contact: Alison Mann
Phone: +44-013-796-4444-9

SRI International
Booth: 1042
Contact: Cindy Arias
Phone: 650-859-3000
Email: biosciences@sri.com
Website: www.sri.com/biosciences

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Statistics & Data Corporation (SDC)
Booth: 2201
Contact: Jim Townsend
Phone: 480-632-5468
Email: jtownsend@sdcclinical.com
Website: www.sdcclinical.com

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Stefanini
Booth: 2040
Contact: Michelle Cummings
Phone: 248-263-3440
Website: www.stefanini.com

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Sterling IRB
Booth: 2612
Contact: Kathye Richards
Phone: 770-690-9491
Email: kathye.richards@sterlingirb.com
Website: www.sterlingirb.com

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Stiris Research Inc.
Booth: 2301
Contact: Shari Burgess
Phone: 519-652-5327
Email: sburgess@stirisresearch.com
Website: www.stirisresearch.com

Stiris Research Inc. is an entrepreneurial Clinical Trial Management CRO, providing both integrated team support and full-service management of Phase I-IV clinical trials for the pharmaceutical and biotechnology industries. Stiris was formed as a result of listening to all of the stakeholders engaged in clinical trials, identifying their unmet needs and developing a unique, value-based approach to address those needs. This remains Stiris' approach and the key to success.

Streck, Inc.
Booth: 510
Contact: Kevin Billings
Phone: 800-843-0912
Email: kbillings@streck.com
Website: www.streck.com

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Contact: Jack Yeager
Phone: 215-504-7000
Email: solutions@sylogent.com
Website: www.sylogent.com

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Symbio, LLC
Booth: 1240
Contact: Betsey Zbyszynski
Phone: 619-955-8926
Email: bzbyszynski@symbioresearch.com
Website: www.symbioresearch.com

Symbio is a full-service CRO. Since 2002, we have been successfully managing Phase II-IV clinical trials. By partnering with our Sponsors, we are involved with strategic planning throughout the entire product development cycle. Therapeutic areas include dermatology, ophthalmology, women's health and internal medicine.

Symphony Clinical Research
Booth: 922
Contact: Nicki Norris
Phone: 847-215-1358
Email: nnorris@symphonyclinicalresearch.com
Website: www.symphonyclincalresearch.com

Symphony Clinical Research, formerly known as Clinical Resource Network, LLC, takes clinical study visits to the patients in their homes. By making trial participation convenient, study sponsors benefit from accelerated recruitment, enhanced retention, improved compliance, increased site productivity and increased patient and site satisfaction.

Synchrogenix
Booth: 422
Contact: Lauren Sobocinski
Phone: 302-892-4800
Website: www.synchrogenix.com

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Synergy Research Centers
Booth: 306
Contact: Woody Woodaman
Phone: 619-778-7694

Synowledge
Booth: 616
Contact: Han Broekmeijer
Phone: 203-504-2561
Email: han.broekmeijer@synowledge.com
Website: www.synowledge.com

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Booth: 1731
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Phone: 760-268-8028
Email: trisha.vonderreith@synteracthcr.com
Website: www.synteracthcr.com

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Contact: Warren Pearlson
Phone: 212-681-2100
Email: wpearlson@targethealth.com
Website: www.targethealth.com

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Contact: Eva L. Petersen
Phone: +45-40-55-2300
Email: elp@tarius.com
Website: www.tarius.com

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Contact: Mark Sekula
Phone: 732-590-2702
Email: mark.sekula@tcs.com
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Contact: Jane Helmick
Phone: 301-897-1724
Email: jhelmick@tech-res.com
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Booth: 710
Contact: Silvio Severini
Phone: 360-562-9106
Email: info@techorizon.com
Website: techorizon.com/

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Booth: 1101
Contact: Douglas Andreas Valverde
Phone: +55-113-033-9740
Email: douglasvalverde@techtrials.com.br
Website: www.techtrials.com.br

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Booth: 1031
Contact: Linda Comp
Phone: 267-942-3301
Email: linda.comp@telerx.com
Website: www.telerx.com

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TFDA / Center for Drug Evaluation, Taiwan
Booth: 1536
Contact: Allen Wang
Phone: +886-2-81706000
Email: ckwang519@cde.org.tw
Website: www.cde.org.tw

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Contact: Yi Yi Liu
Phone: 212-366-4455
Email: yiyi@thatsnice.com
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Contact: David Iannucci
Phone: 919-863-4110
Email: diannucci@crnspg.com
Website: www.spgcrn.com/

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Contact: Sarah Middleton
Phone: +44-156-573-3772

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Phone: 512-789-7788
Email: lance@tprausa.com
Website: www.patientrecruiting.com/

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the Uppsala Monitoring Centre
Booth: 1208
Contact: Mats Persson
Phone: +46-186-560-60
Email: sales@umc-products.com
Website: www.umc-products.com

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Booth: 2519
Contact: Jeff Antos
Phone: 202-280-0815
Email: jeff.antos@weinberggroup.com
Website: www.weinberggroup.com

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Booth: 1245
Business Suite: BS6
Contact: Sara Davis
Phone: 214-704-0344
Email: sara.davis@theoremclinical.com
Website: www.theoremclinical.com/

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Phone: 626-357-5900 Ext. 254
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Booth: 2244
Contact: Bruce Blake
Phone: 800-681-4385
Email: bblake@therapath.com
Website: www.Therapath.com

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Contact: Bruce Gould
Phone: 952-852-5557
Email: bgould@threewire.com
Website: www.threewire.com

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Booth: 2631
Contact: Reid Tripp
Phone: 201-587-0500
Email: rtripp@tklresearch.com
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Booth: 1438
Contact: Natalie Hann
Phone: +44-120-961-2650
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Contact: Ryan Simper
Phone: 919-361-9200
Email: rsimper@transperfect.com
Website: www.transperfect.com

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Booth: 2510
Contact: Cameron Snider
Phone: 617-952-4072
Email: info@trialnetworks.com
Website: www.trialnetworks.com

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Contact: Greg Brigham
Phone: 845-481-9172
Email: greg.brigham@trievr.com
Website: trievr.com

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Trifecta
Booth: 1131
Contact: Deborah Novick
Phone: 310-385-8642
Email: sales@trifectaclinical.com
Website: www.trifectaclinical.com

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Phone: 215-591-2880
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Phone: 703-964-2149

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Contact: Sharon Pearce
Phone: 909-952-8854
Email: sharon.pearce@apollidon.com
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Booth: 750
Contact: Christopher Miciek
Phone: 215-596-8597
Email: c.miciek@usciences.edu
Website: www.usciences.edu

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University of Utah Clinical Research Services
Booth: 305
Contact: Jaci Skidmore
Phone: 801-213-4043
Email: jaci.skidmore@hsc.utah.edu
Website: medicine.utah.edu/pediatrics/cro

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Phone: 763-315-2000
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Contact: Carolyn Benslimane
Phone: 866-445-2465
Email: info@us.valesta.com
Website: www.valesta.com/

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Contact: Neil Parthasarathy
Phone: 484-224-2971
Email Address: info@valuehealthsol.com
Web Address: www.valuehealthsol.com

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Contact: Brittany Machion
Phone: 925-452-6500
Email: brittany.machion@veeva.com
Website: www.veeva.com

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Verified Clinical Trials
Booth: 1246

Contact: Mitchell Efros
Phone: 516-998-7499
Email: DrEfros@verifiedclinicaltrials.com
Website: www.verifiedclinicaltrials.com

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Contact: JoAnn Vormschlag
Phone: 617-901-0408
Email: info@veristat.com
Website: www.veristat.com/

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Contact: Meyoshi Harris
Phone: 240-568-1814
Email: meyoshi.harris1@verizonwireless.com
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Phone: 816-347-0113
Email: dawn.denny@ViracorIBT.com
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VirtualScopics
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Contact: Rosemary Shull
Phone: 585-249-6231
Email: Rosemary_Shull@virtualscopics.com
Website: www.virtualscopics.com

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Contact: John Buchholz
Phone: 913-720-3212
Email: john.buchholz@vitalograph.com
Website: www.vitalograph.com

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Phone: 760-470-2011
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Contact: Christopher Theo
Phone: 714-553-8176
Email: Christopher.Theo@wcct.com
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Contact: Cara Deieso
Phone: 609-945-0109
Email: cdeieso@wcgclinical.com
Website: www.wcgclinical.com

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Phone: 516-354-2600
Email: tredmond@worldcourier.com
Website: www.worldcourier.com

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Contact: Enrico de Leon, Jr., BS
Phone: 610-964-2000
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Contact: Paul Geary
Phone: 866-494-2002
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Contact: Richard Vachal
Phone: 732-805-3434
Email: rvachal@xtrials.com
Website: www.xtrials.com

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Contact: Ryan Forbes
Phone: 856-266-4546
Email: rforbes@y-prime.com
Website: www.y-prime.com

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Contact: Julie Beal
Phone: +44-1235-854033
Email: info@zigzag.eu.com
Website: www.zigzag.eu.com/

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Booth: 2647

Contact: Hamish Miller
Phone: 315-294-9458
Website: www.zinc-ahead.com

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GLOSSARY OF TERMS

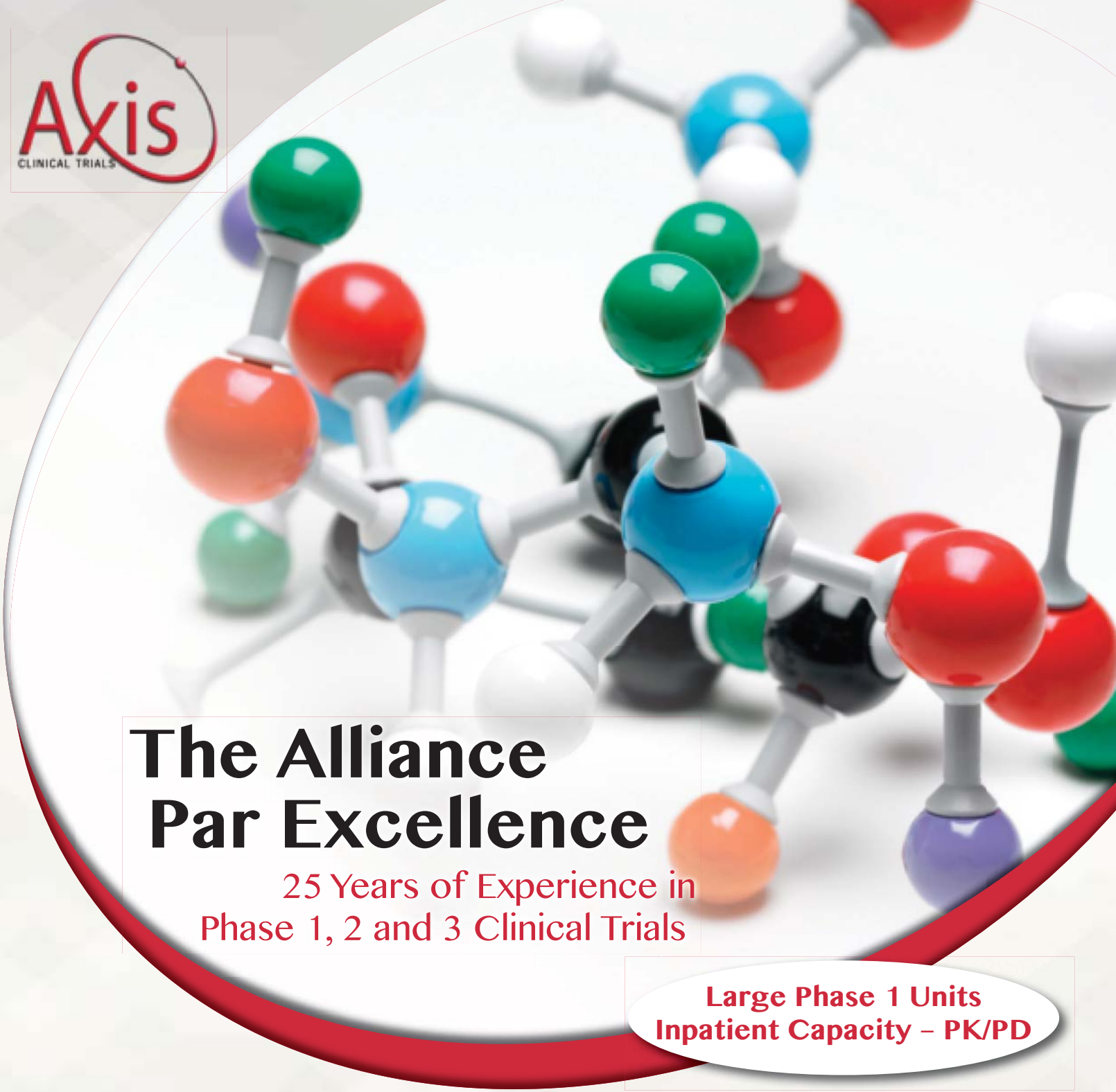
3500A	FDA form for mandatory reporting of adverse events
ADE	adverse drug event
ADR	adverse drug report or adverse drug reaction
AE	adverse event
AHRQ	Agency for Healthcare Quality and Research
ANDA	abbreviated new drug application
ANSI	American National Standards Institute
API	active pharmaceutical ingredient
BA/BE	bioavailability/bioequivalence
BB IND	biological investigational new drug
BCE	beneficial clinical event
BDPA	Bureau of Drug Policy and Administration (China)
BDS	Bureau of Drug Surveillance (Canada)
BISTIC	Biomedical Information Science and Technology Initiative Consortium (NIH)
BLA	biologics license application
BPA	Bureau of Pharmaceutical Assessment (Canada)
CCFDIE	China Center for Food and Drug International Exchange
CDASH	Clinical Data Acquisition Standards Harmonization
CDDI	Collaboration for Drug Development Improvement
CDISC	Clinical Data Interchange Standards Consortium
CDM	clinical data management
CFDA	China Food and Drug Administration
CEN	Comite Europeen de Normalisation (European Committee for Standardization)
CFR	Code of Federal Regulations
cGMP	current good manufacturing practice
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare and Medicaid Services
CPMP	Committee for Proprietary Medicinal Products (EMEA)
CRA	clinical research associate
CRADA	cooperative research and development agreement
CRF	case report form
CRIX	Clinical Research Information Exchange (FDA and NCI)
CRO	contract research organization
CSA	clinical study agreement
CSDD	Center for the Study of Drug Development (Tufts University)
CSM	Committee on Safety of Medicines (UK)
CSR	clinical study report
CTA	clinical trial application
CTD	common technical document
CTMS	Clinical Trial Management System
CTTI	Clinical Trials Transformation Initiative
DSMB	Data Safety Monitoring Board
DTC	direct-to-consumer
DTP	direct-to-patient
DUR	drug utilization review
EAB	Ethics Advisory Board
eCTD	electronic common technical document
EDMS	Electronic Document Management System
EDQM	European Directorate for the Quality of Medicines
eIND	electronic investigational new drug application
EHR	Electronic Health Records
EMA (EMEA)	European Medicines Agency (formerly European Medicines Evaluation Agency)
EMR	Electronic Medical records
ERB	Ethics Review Board
ERS	electronic regulatory submission
eSubs	electronic submissions
FDASIA	Food and Drug Administration Safety and Innovation Act
FIH	first-in-human (clinical trials)
FPE	First Patient Enrolled
FPI	First Patient In
FU	Farmacopea Ufficiale (Italian Pharmacopoeia)
GAAP	Greater Access to Affordable Pharmaceuticals Act of 2003
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GRP	good review practice
GSP	Good Statistics Practice
GXP	Good (any type) Practice
HPB	Health Protection Board (Canada)
IC	informed consent
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICSR	Individual Case Safety Reports
IDE	investigational device exemption
IND	investigational new drug
IRB	Investigational Review Board
IRS	Incident Reporting System
ISO	International Organization for Standardization
LOAEL	Lowest Observed Adverse Effect Level
LPE	Last Person Enrolled
LPI	Last person In
LPLV	Last Patient Last Visit
MCA	Medicines Control Agency (part of MHRA)
MedDRA	Medical Dictionary for Regulatory Activities
MEDLARS	Medical Literature Analysis and Retrieval System (NLM)
MedSuN	Medical Product Safety Network
MHLW	Ministry of Health, Labor and Welfare (Japan)
MPA	Medical Products Agency (Sweden)
NAF	notice of adverse findings
NAI	no action indicated
NAS	new active substance
NC	nonclinical (phase, studies)
NCE	new chemical entity
NME	new molecular entity
NCS	not clinically significant
NDA	new drug application
NDE	new drug evaluation
NDS	New Drug Submission (Canada)
OAI	official action indicated
ODM	operational data model (CDISC)
PAB	Pharmaceutical Affairs Bureau (Japan)
PAHO	Pan American Health Organization (WHO)
PD	pharmacodynamics
PDR	Physician's Desk Reference
PDUFA	Prescription Drug User Fee Act
PI	principal investigator
PIP	Pediatric Investigational Plan
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PPI	patient package insert
QL	quality of life

RMS	regulatory management system
RR	relative risk
SAE	serious adverse event
SDM	Submission Data Model (CDISC)
SDO	Standards Development Organization
SDS	Submission Data Standards (CDISC)
SEER	Surveillance, Epidemiology, and End Results (Registry of NCI)
SMART	Submission Management and Review Tracking
SME	significant medical event - or - subject matter expert
SMO	site management organization
sNDA	supplemental new drug application
SNOMED-RT	Systematized Nomenclature of Medicine Reference Terminology
SUD	sudden unexpected death
SUD	single-use device
TBP	therapeutic biologic product
TE	therapeutic equivalence
TIND	treatment investigational new drug
TMO	trial management organization
USP	U.S. Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VAI	voluntary action indicated
WHO-ART	World Health Organisation Adverse Reaction Terminology

The following are divisions and offices within the US Food and Drug Administration, FDA

CBER	Center for Biologics Evaluation and Research, FDA
OCD	Office of the Center Director
OM	Office of Management
OCBQ	Office of Compliance and Biologics Quality
OBRR	Office of Blood Research and Review
OVRR	Office of Vaccines Research and Review
OCOD	Office of Communication, Outreach and Development
OBE	Office of Biostatistics and Epidemiology
OCTGT	Office of Cellular, Tissue and Gene Therapies
CDER	Center for Drug Evaluation and Research Organization, FDA
OCD	Office of the Center Director
ORP	Office of Regulatory Policy
OM	Office of Management
OC	Office of Communications
OC	Office of Compliance
OUDLC	Office of Unapproved Drugs and Labeling Compliance
OSI	Office of Scientific Investigations
OMPQ	Office of Manufacturing and Product Quality
ODSIR	Office of Drug Security, Integrity, and Recalls
OMP	Office of Medical Policy
OPDP	Office of Prescription Drug Promotion
OMPI	Office of Medical Policy Initiatives
OTS	Office of Translational Sciences
OB	Office of Biostatistics
OCP	Office of Clinical Pharmacology
OCS	Office of Computational Science
OEP	Office of Executive Programs
OCTEC	Office of Counter-Terrorism and Emergency Coordination
OSP	Office of Strategic Programs
OPSA	Office of Program and Strategic Analysis
OBI	Office of Business Informatics
OSE	Office of Surveillance and Epidemiology
OMEPRM	Office of Medication Error and Prevention and Risk Management
OPE	Office of Pharmacovigilance and Epidemiology
OND	Office of New Drugs
ODE I	Office of Drug Evaluation I
ODE II	Office of Drug Evaluation II
ODE III	Office of Drug Evaluation III
ODE IV	Office of Drug Evaluation IV
OAP	Office of Antimicrobial Products
OHOP	Office of Hematology Oncology Products
OPS	Office of Pharmaceutical Science
OGD	Office of Generic Drugs
ONDQA	Office of New Drug Quality Assessment
OTR	Office of Testing and Research
OBP	Office of Biotechnology Products
CDRH	Center for Devices and Radiological Health, FDA
OCD	Office of the Center Director
OMO	Office of Management Operations
ODE	Office of Device Evaluation
OC	Office of Compliance
OSEL	Office of Science and Engineering Laboratories
OCERP	Office of Communication, Education, and Radiation Programs
OSB	Office of Surveillance and Biometrics
OIVDDES	Office of In Vitro Diagnostic Device Evaluation and Safety
OC	Office of the Commissioner, FDA
OCM	Office of Crisis Management
OPP	Office of Policy and Planning
OEA	Office of External Affairs
OL	Office of Legislation
OWH	Office of Women's Health
OMH	Office of Minority Health
OCS	Office of the Chief Scientist
OSI	Office of Scientific Integrity
OCET	Office of Counter-Terrorism and Emerging Threats
ORSI	Office of Regulatory Science and Innovation
OSPD	Office of Scientific Professional Development
OGROP	Office of Global Regulatory Operations and Policy, FDA
OIP	Office of International Programs
OMPT	Office of Medical Products and Tobacco, FDA
OSMP	Office of Special Medical Programs
OCP	Office of Combination Products
OOPD	Office of Orphan Products Development
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs, FDA
ORM	Office of Resource Management
OCQPM	Office of Communications and Quality Program Management
OCI	Office of Criminal Investigations
OE	Office of Enforcement
ORO	Office of Operations
ORS	Office of Regulatory Science
OMPTO	Office of Medical Products and Tobacco Operations

Axis
CLINICAL TRIALS



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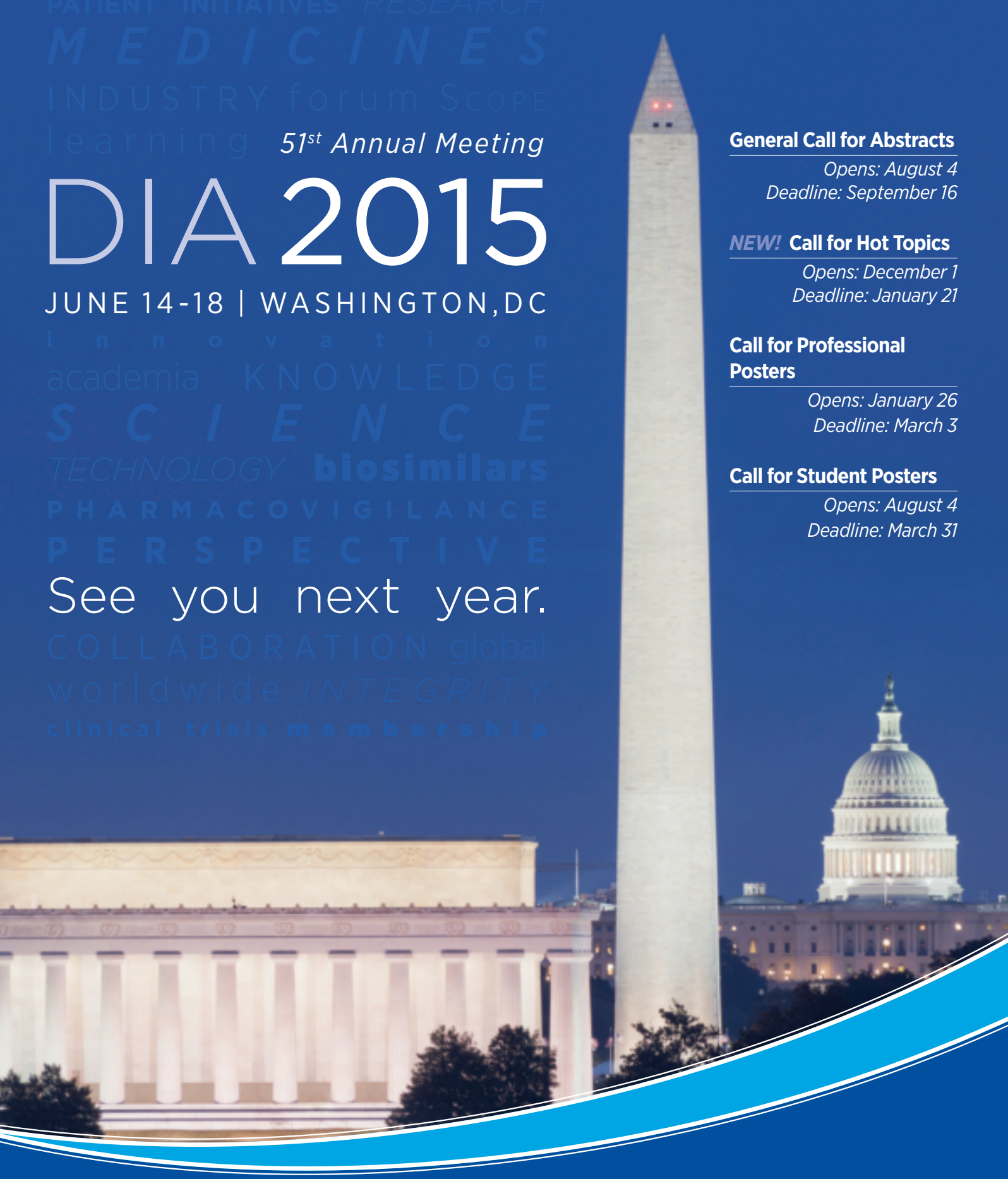

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